Post-hoc Analysen zum ersten Datenschnitt vom 14.07.2019 für den Anhang 4-G

Table 14-4.1.501. Cox Regression of Overall Survival
<Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
All randomized subjects		154	36 (23.4)	NE [NE, NE)	312	59 (18.9)	NE [NE, NE)		0.745 (0.491, 1.131)	0.1672
Age - at baseline (years)	<= 75	136	33 (24.3)	NE [NE, NE)	287	53 (18.5)	NE [NE, NE)	0.3410	0.729 (0.472, 1.126)	0.1529
	> 75	18	3 (16.7)	NE [NE, NE)	25	6 (24.0)	NE [18.8, NE)		1.415 (0.351, 5.707)	0.6236

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified or unstratified log-rank test as specified.

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Output: t14-04-001-501-eff-cox-os.rtf (Date Generated: 25MAY2020:20:22) Source Data: adam.adsl, adam.adbase, adam.adttepfs

Table 14-4.1.501. Cox Regression of Overall Survival
<Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Sex	Male	91	20 (22.0)	NE [NE, NE)	177	34 (19.2)	NE [NE, NE)	0.6321	0.859 (0.495, 1.493)	0.5907
	Female	63	16 (25.4)	NE [18.6, NE)	135	25 (18.5)	NE [NE, NE)		0.699 (0.373, 1.309)	0.2607
Race	White	123	29 (23.6)	NE [NE, NE)	243	53 (21.8)	NE [NE, NE)	0.8104	0.911 (0.579, 1.433)	0.6867
	Asian	20	4 (20.0)	NE [NE, NE)	46	6 (13.0)	NE [NE, NE)		0.596 (0.168, 2.114)	0.4184
	Other or Unknown	11	3 (27.3)	NE [6.6, NE)	23	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0113

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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<Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Region	North America	12	1 (8.3)	NE [18.6, NE)	21	1 (4.8)	NE [NE, NE)	0.8151	0.436 (0.027, 7.157)	0.5505
	Europe	103	26 (25.2)	NE [NE, NE)	207	45 (21.7)	NE [NE, NE)		0.841 (0.519, 1.363)	0.4807
	Asia Pacific	39	9 (23.1)	NE [NE, NE)	84	13 (15.5)	NE [NE, NE)		0.635 (0.272, 1.487)	0.2918
Baseline ECOG PS	0-1	147	33 (22.4)	NE [NE, NE)	295	55 (18.6)	NE [NE, NE)	0.3348	0.810 (0.526, 1.247)	0.3375
	2	7	3 (42.9)	7.0 [0.5, NE)	15	4 (26.7)	NE [1.3, NE)		0.517 (0.115, 2.333)	0.3825

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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<Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	137	36 (26.3)	NE [NE, NE)	289	57 (19.7)	NE [NE, NE)	0.9815	0.720 (0.474, 1.093)	0.1218
	No	17	0 (0.0)	NE [NE, NE)	23	2 (8.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.2529
Refractory to Bortezomib or Ixazomib	Yes	55	17 (30.9)	NE [17.0, NE)	100	27 (27.0)	NE [NE, NE)	0.8619	0.835 (0.455, 1.532)	0.5598
	No	99	19 (19.2)	NE [NE, NE)	212	32 (15.1)	NE [NE, NE)		0.767 (0.435, 1.354)	0.3585

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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<Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	15 (20.3)	NE [NE, NE)	123	27 (22.0)	NE [NE, NE)	0.1862	1.093 (0.581, 2.054)	0.7829
	No	80	21 (26.3)	NE [NE, NE)	189	32 (16.9)	NE [NE, NE)		0.607 (0.350, 1.054)	0.0734
Refractory to Lenalidomide	Yes	55	13 (23.6)	NE [18.6, NE)	99	20 (20.2)	NE [NE, NE)	0.8330	0.859 (0.427, 1.728)	0.6702
	No	99	23 (23.2)	NE [NE, NE)	213	39 (18.3)	NE [NE, NE)		0.756 (0.452, 1.266)	0.2869

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		Kd (N = 154)			KdD (N = 312)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	24 (21.8)	NE [NE, NE)	206	43 (20.9)	NE [NE, NE)	0.2273	0.926 (0.562, 1.525)	0.7620
	No	44	12 (27.3)	NE [NE, NE)	106	16 (15.1)	NE [NE, NE)		0.530 (0.251, 1.121)	0.0914
Refractory to IMiD	Yes	65	19 (29.2)	NE [18.6, NE)	130	29 (22.3)	NE [NE, NE)	0.7501	0.742 (0.416, 1.324)	0.3113
	No	89	17 (19.1)	NE [NE, NE)	182	30 (16.5)	NE [NE, NE)		0.833 (0.460, 1.511)	0.5477

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<Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	127	19 (15.0)	NE [NE, NE)	252	42 (16.7)	NE [NE, NE)	0.0061	1.113 (0.647, 1.914)	0.6991
	3	27	17 (63.0)	11.3 [4.9, NE)	60	17 (28.3)	NE [NE, NE)		0.351 (0.178, 0.693)	0.0016
Prior proteasome inhibitor exposure per IXRS	Yes	139	35 (25.2)	NE [NE, NE)	279	56 (20.1)	NE [NE, NE)	0.5769	0.760 (0.498, 1.160)	0.2026
	No	15	1 (6.7)	NE [NE, NE)	33	3 (9.1)	NE [NE, NE)		1.406 (0.146, 13.538)	0.7668

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<Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	67	14 (20.9)	NE [NE, NE)	133	17 (12.8)	NE [NE, NE)	0.2715	0.567 (0.280, 1.151)	0.1115
	>= 2	87	22 (25.3)	NE [NE, NE)	179	42 (23.5)	NE [NE, NE)		0.922 (0.550, 1.545)	0.7582

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Table 14-4.1.502. Cox Regression of Progression-free Survival as Determined by Independent Review Committee <Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
All randomized subjects		154	68 (44.2)	15.8 [12.1, NE)	312	110 (35.3)	NE [NE, NE)		0.630 (0.464, 0.854)	0.0028
Age - at baseline (years)	<= 75	136	63 (46.3)	15.3 [11.1, NE)	287	99 (34.5)	NE [NE, NE)	0.1198	0.606 (0.442, 0.832)	0.0018
	> 75	18	5 (27.8)	NE [7.4, NE)	25	11 (44.0)	18.5 [7.4, NE)		1.459 (0.504, 4.223)	0.4814

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		Kd (N = 154)			KdD (N = 312)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Sex	Male	91	39 (42.9)	17.5 [12.5, NE)	177	57 (32.2)	NE [NE, NE)	0.7914	0.636 (0.423, 0.956)	0.0285
	Female	63	29 (46.0)	14.6 [9.3, NE)	135	53 (39.3)	NE [16.8, NE)		0.686 (0.436, 1.079)	0.1020
Race	White	123	58 (47.2)	15.2 [11.1, NE)	243	94 (38.7)	NE [18.5, NE)	0.8483	0.685 (0.494, 0.952)	0.0234
	Asian	20	6 (30.0)	NE [8.4, NE)	46	11 (23.9)	NE [NE, NE)		0.686 (0.253, 1.857)	0.4484
	Other or Unknown	11	4 (36.4)	NE [1.0, NE)	23	5 (21.7)	NE [16.0, NE)		0.482 (0.129, 1.802)	0.2677

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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		Kd (N = 154)			KdD (N = 312)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Region	North America	12	8 (66.7)	12.1 [3.3, 15.7)	21	1 (4.8)	NE [NE, NE)	0.0111	0.041 (0.005, 0.339)	<.0001
	Europe	103	44 (42.7)	15.8 [11.1, NE)	207	88 (42.5)	NE [15.5, NE)		0.857 (0.596, 1.231)	0.4037
	Asia Pacific	39	16 (41.0)	17.6 [10.8, NE)	84	21 (25.0)	NE [NE, NE)		0.486 (0.253, 0.934)	0.0267
Baseline ECOG PS	0-1	147	64 (43.5)	16.6 [12.5, NE)	295	105 (35.6)	NE [NE, NE)	0.0266	0.689 (0.505, 0.941)	0.0184
	2	7	4 (57.1)	3.3 [0.5, 9.3)	15	5 (33.3)	NE [1.2, NE)		0.311 (0.081, 1.190)	0.0725

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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		Kd (N = 154)			KdD (N = 312)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	137	63 (46.0)	15.3 [11.1, NE)	289	105 (36.3)	NE [NE, NE)	0.9922	0.643 (0.470, 0.879)	0.0054
	No	17	5 (29.4)	NE [11.1, NE)	23	5 (21.7)	NE [NE, NE)		0.622 (0.180, 2.156)	0.4503
Refractory to Bortezomib or Ixazomib	Yes	55	26 (47.3)	14.9 [6.5, NE)	100	48 (48.0)	14.2 [9.2, NE)	0.1970	0.871 (0.540, 1.405)	0.5754
	No	99	42 (42.4)	17.5 [12.3, NE)	212	62 (29.2)	NE [NE, NE)		0.561 (0.379, 0.831)	0.0035

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		Kd (N = 154)			KdD (N = 312)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	40 (54.1)	12.1 [8.4, 15.3)	123	44 (35.8)	NE [18.5, NE)	0.0990	0.521 (0.339, 0.802)	0.0026
	No	80	28 (35.0)	NE [15.8, NE)	189	66 (34.9)	NE [NE, NE)		0.868 (0.558, 1.351)	0.5334
Refractory to Lenalidomide	Yes	55	32 (58.2)	11.1 [7.4, 14.9)	99	34 (34.3)	NE [18.5, NE)	0.0380	0.453 (0.279, 0.737)	0.0011
	No	99	36 (36.4)	NE [15.7, NE)	213	76 (35.7)	NE [NE, NE)		0.852 (0.573, 1.267)	0.4308

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[b] 2-sided p-values were calculated using the stratified or unstratified log-rank test as specified.

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Output: t14-04-001-502-eff-cox-pfs-irc.rtf (Date Generated: 25MAY2020:20:22) Source Data: adam.adsl, adam.adbase, adam.adttepfs

Table 14-4.1.502. Cox Regression of Progression-free Survival as Determined by Independent Review Committee <Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	54 (49.1)	14.9 [10.8, NE)	206	76 (36.9)	NE [NE, NE)	0.3851	0.622 (0.439, 0.883)	0.0074
	No	44	14 (31.8)	NE [14.6, NE)	106	34 (32.1)	NE [NE, NE)		0.849 (0.455, 1.584)	0.6071
Refractory to IMiD	Yes	65	38 (58.5)	11.1 [7.4, 14.9)	130	44 (33.8)	NE [NE, NE)	0.0120	0.448 (0.290, 0.694)	0.0002
	No	89	30 (33.7)	NE [15.8, NE)	182	66 (36.3)	NE [NE, NE)		0.941 (0.611, 1.449)	0.7844

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified or unstratified log-rank test as specified.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-eff-cox-itt.sas
Output: t14-04-001-502-eff-cox-pfs-irc.rtf (Date Generated: 25MAY2020:20:22) Source Data: adam.adsl, adam.adbase, adam.adttepfs

Table 14-4.1.502. Cox Regression of Progression-free Survival as Determined by Independent Review Committee <Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	127	55 (43.3)	17.5 [13.2, NE)	252	78 (31.0)	NE [NE, NE)	0.7650	0.610 (0.431, 0.862)	0.0047
	3	27	13 (48.1)	7.6 [3.3, NE)	60	32 (53.3)	13.1 [8.8, NE)		0.710 (0.371, 1.359)	0.3019
Prior proteasome inhibitor exposure per IXRS	Yes	139	64 (46.0)	15.3 [11.1, NE)	279	101 (36.2)	NE [NE, NE)	0.5424	0.644 (0.470, 0.881)	0.0056
	No	15	4 (26.7)	NE [8.4, NE)	33	9 (27.3)	NE [15.8, NE)		0.928 (0.286, 3.015)	0.9014

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified or unstratified log-rank test as specified.

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Output: t14-04-001-502-eff-cox-pfs-irc.rtf (Date Generated: 25MAY2020:20:22) Source Data: adam.adsl, adam.adbase, adam.adttepfs

Table 14-4.1.502. Cox Regression of Progression-free Survival as Determined by Independent Review Committee <Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	67	23 (34.3)	NE [11.1, NE)	133	39 (29.3)	NE [NE, NE)	0.7193	0.701 (0.418, 1.174)	0.1761
	>= 2	87	45 (51.7)	14.9 [9.3, 17.5)	179	71 (39.7)	NE [17.0, NE)		0.633 (0.435, 0.920)	0.0159

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified or unstratified log-rank test as specified.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-eff-cox-itt.sas
Output: t14-04-001-502-eff-cox-pfs-irc.rtf (Date Generated: 25MAY2020:20:22) Source Data: adam.adsl, adam.adbase, adam.adttepfs

Table 14-4.1.503. Cox Regression of Time to Next Treatment
<Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
All randomized subjects		154	70 (45.5)	17.3 [13.5, NE)	312	74 (23.7)	NE [NE, NE)		0.412 (0.296, 0.574)	<.0001
Age - at baseline (years)	<= 75	136	65 (47.8)	17.1 [12.2, NE)	287	67 (23.3)	NE [NE, NE)	0.1667	0.395 (0.281, 0.557)	<.0001
	> 75	18	5 (27.8)	NE [11.1, NE)	25	7 (28.0)	22.2 [12.3, NE)		0.782 (0.235, 2.611)	0.6892

Time to next treatment is defined as the time (in months) from randomization to the initiation of subsequent non-protocol anti-cancer treatment for multiple myeloma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified or unstratified log-rank test as specified.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-eff-cox-itt.sas
Output: t14-04-001-503-eff-cox-tnt.rtf (Date Generated: 25MAY2020:20:22) Source Data: adam.adsl, adam.adbase, adam.adtteef

Table 14-4.1.503. Cox Regression of Time to Next Treatment
<Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Sex	Male	91	37 (40.7)	18.3 [12.2, NE)	177	40 (22.6)	NE [NE, NE)	0.6066	0.462 (0.295, 0.724)	0.0005
	Female	63	33 (52.4)	14.9 [10.0, NE)	135	34 (25.2)	NE [22.2, NE)		0.388 (0.240, 0.627)	<.0001
Race	White	123	57 (46.3)	17.1 [12.2, NE)	243	59 (24.3)	NE [22.2, NE)	0.8012	0.434 (0.301, 0.626)	<.0001
	Asian	20	8 (40.0)	NE [8.1, NE)	46	11 (23.9)	NE [NE, NE)		0.503 (0.202, 1.252)	0.1320
	Other or Unknown	11	5 (45.5)	17.3 [1.7, NE)	23	4 (17.4)	NE [NE, NE)		0.287 (0.077, 1.071)	0.0477

Time to next treatment is defined as the time (in months) from randomization to the initiation of subsequent non-protocol anti-cancer treatment for multiple myeloma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified or unstratified log-rank test as specified.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-eff-cox-itt.sas
Output: t14-04-001-503-eff-cox-tnt.rtf (Date Generated: 25MAY2020:20:22) Source Data: adam.adsl, adam.adbase, adam.adtteef

Table 14-4.1.503. Cox Regression of Time to Next Treatment
<Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Region	North America	12	9 (75.0)	11.5 [4.5, 17.3)	21	0 (0.0)	NE [NE, NE)	0.5756	<.001 (<.001, NE)	<.0001
	Europe	103	43 (41.7)	NE [13.4, NE)	207	56 (27.1)	NE [NE, NE)		0.559 (0.375, 0.832)	0.0037
	Asia Pacific	39	18 (46.2)	18.1 [10.1, NE)	84	18 (21.4)	NE [22.2, NE)		0.357 (0.183, 0.693)	0.0015
Baseline ECOG PS	0-1	147	68 (46.3)	17.3 [13.5, NE)	295	72 (24.4)	NE [22.2, NE)	0.4886	0.438 (0.314, 0.611)	<.0001
	2	7	2 (28.6)	NE [1.4, NE)	15	2 (13.3)	NE [10.0, NE)		0.293 (0.040, 2.137)	0.1993

Time to next treatment is defined as the time (in months) from randomization to the initiation of subsequent non-protocol anti-cancer treatment for multiple myeloma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified or unstratified log-rank test as specified.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-eff-cox-itt.sas
Output: t14-04-001-503-eff-cox-tnt.rtf (Date Generated: 25MAY2020:20:22) Source Data: adam.adsl, adam.adbase, adam.adtteef

Table 14-4.1.503. Cox Regression of Time to Next Treatment
<Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	137	65 (47.4)	17.1 [12.1, NE)	289	71 (24.6)	NE [22.2, NE)	0.8133	0.422 (0.301, 0.591)	<.0001
	No	17	5 (29.4)	NE [10.1, NE)	23	3 (13.0)	NE [18.7, NE)		0.382 (0.091, 1.599)	0.1711
Refractory to Bortezomib or Ixazomib	Yes	55	28 (50.9)	13.5 [9.3, NE)	100	33 (33.0)	NE [15.7, NE)	0.2328	0.559 (0.337, 0.926)	0.0219
	No	99	42 (42.4)	18.1 [14.9, NE)	212	41 (19.3)	NE [22.2, NE)		0.363 (0.235, 0.561)	<.0001

Time to next treatment is defined as the time (in months) from randomization to the initiation of subsequent non-protocol anti-cancer treatment for multiple myeloma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified or unstratified log-rank test as specified.

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Output: t14-04-001-503-eff-cox-tnt.rtf (Date Generated: 25MAY2020:20:22) Source Data: adam.adsl, adam.adbase, adam.adtteef

Table 14-4.1.503. Cox Regression of Time to Next Treatment
<Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	39 (52.7)	14.9 [10.0, NE)	123	28 (22.8)	NE [22.2, NE)	0.1983	0.348 (0.214, 0.567)	<.0001
	No	80	31 (38.8)	18.3 [13.4, NE)	189	46 (24.3)	NE [NE, NE)		0.532 (0.337, 0.840)	0.0059
Refractory to Lenalidomide	Yes	55	28 (50.9)	14.1 [9.2, NE)	99	20 (20.2)	NE [22.2, NE)	0.1322	0.308 (0.173, 0.549)	<.0001
	No	99	42 (42.4)	18.1 [14.9, NE)	213	54 (25.4)	NE [NE, NE)		0.510 (0.341, 0.764)	0.0009

Time to next treatment is defined as the time (in months) from randomization to the initiation of subsequent non-protocol anti-cancer treatment for multiple myeloma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified or unstratified log-rank test as specified.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-eff-cox-itt.sas
Output: t14-04-001-503-eff-cox-tnt.rtf (Date Generated: 25MAY2020:20:22) Source Data: adam.adsl, adam.adbase, adam.adtteef

Table 14-4.1.503. Cox Regression of Time to Next Treatment
<Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	54 (49.1)	16.2 [12.1, NE)	206	55 (26.7)	NE [22.2, NE)	0.8086	0.448 (0.307, 0.653)	<.0001
	No	44	16 (36.4)	NE [11.1, NE)	106	19 (17.9)	NE [NE, NE)		0.407 (0.209, 0.791)	0.0062
Refractory to IMiD	Yes	65	36 (55.4)	12.1 [9.3, 17.8)	130	32 (24.6)	NE [22.2, NE)	0.1688	0.343 (0.212, 0.553)	<.0001
	No	89	34 (38.2)	18.3 [17.1, NE)	182	42 (23.1)	NE [NE, NE)		0.524 (0.333, 0.823)	0.0044

Time to next treatment is defined as the time (in months) from randomization to the initiation of subsequent non-protocol anti-cancer treatment for multiple myeloma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified or unstratified log-rank test as specified.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-eff-cox-itt.sas
Output: t14-04-001-503-eff-cox-tnt.rtf (Date Generated: 25MAY2020:20:22) Source Data: adam.adsl, adam.adbase, adam.adtteef

Table 14-4.1.503. Cox Regression of Time to Next Treatment
<Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	127	57 (44.9)	18.1 [14.1, NE)	252	56 (22.2)	NE [NE, NE)	0.8315	0.420 (0.290, 0.608)	<.0001
	3	27	13 (48.1)	9.6 [3.5, NE)	60	18 (30.0)	NE [15.3, NE)		0.383 (0.186, 0.786)	0.0066
Prior proteasome inhibitor exposure per IXRS	Yes	139	64 (46.0)	17.3 [13.5, NE)	279	68 (24.4)	NE [22.2, NE)	0.8650	0.431 (0.306, 0.607)	<.0001
	No	15	6 (40.0)	NE [3.8, NE)	33	6 (18.2)	NE [18.7, NE)		0.408 (0.132, 1.267)	0.1089

Time to next treatment is defined as the time (in months) from randomization to the initiation of subsequent non-protocol anti-cancer treatment for multiple myeloma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified or unstratified log-rank test as specified.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-eff-cox-itt.sas
Output: t14-04-001-503-eff-cox-tnt.rtf (Date Generated: 25MAY2020:20:22) Source Data: adam.adsl, adam.adbase, adam.adtteef

Table 14-4.1.503. Cox Regression of Time to Next Treatment
<Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	67	27 (40.3)	18.3 [12.2, NE)	133	31 (23.3)	NE [NE, NE)	0.6855	0.469 (0.280, 0.786)	0.0033
	>= 2	87	43 (49.4)	16.2 [10.4, NE)	179	43 (24.0)	NE [22.2, NE)		0.404 (0.264, 0.617)	<.0001

Time to next treatment is defined as the time (in months) from randomization to the initiation of subsequent non-protocol anti-cancer treatment for multiple myeloma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified or unstratified log-rank test as specified.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-eff-cox-itt.sas
Output: t14-04-001-503-eff-cox-tnt.rtf (Date Generated: 25MAY2020:20:22) Source Data: adam.adsl, adam.adbase, adam.adtteef

Table 14-4.2.501. Logistic Regression of Overall Response Rate as Determined by Independent Review Committee <Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
All randomized subjects		154	115 (74.7)	(67.0, 81.3)	312	263 (84.3)	(79.8, 88.1)		0.096 (0.017, 0.176)	1.925 (1.184, 3.129)	1.135 (1.025, 1.257)	0.0080
Age – at baseline (years)	<= 75	136	101 (74.3)	(66.1, 81.4)	287	242 (84.3)	(79.6, 88.3)	0.7930	0.101 (0.016, 0.185)	1.864 (1.131, 3.070)	1.135 (1.016, 1.268)	0.0167
	> 75	18	14 (77.8)	(52.4, 93.6)	25	21 (84.0)	(63.9, 95.5)		0.062 (-0.178, 0.302)	1.500 (0.321, 7.012)	1.080 (0.800, 1.458)	0.7010

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'All randomized subjects', and the Fisher's exact test for subgroups.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-eff-logr-irc.sas
Output: t14-04-002-501-eff-logr-orr-irc.rtf (Date Generated: 25MAY2020:22:33) Source Data: adam.adsl, adam.adef, adam.adbase

Table 14-4.2.501. Logistic Regression of Overall Response Rate as Determined by Independent Review Committee <Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Sex	Male	91	70 (76.9)	(66.9, 85.1)	177	151 (85.3)	(79.2, 90.2)	0.8189	0.084 (-0.017, 0.185)	1.742 (0.918, 3.308)	1.109 (0.976, 1.261)	0.0927
	Female	63	45 (71.4)	(58.7, 82.1)	135	112 (83.0)	(75.5, 88.9)		0.115 (-0.013, 0.244)	1.948 (0.960, 3.951)	1.161 (0.976, 1.382)	0.0890

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'All randomized subjects', and the Fisher's exact test for subgroups.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-eff-logr-irc.sas
Output: t14-04-002-501-eff-logr-orr-irc.rtf (Date Generated: 25MAY2020:22:33) Source Data: adam.adsl, adam.adef, adam.adbase

Table 14-4.2.501. Logistic Regression of Overall Response Rate as Determined by Independent Review Committee <Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Race	White	123	92 (74.8)	(66.2, 82.2)	243	198 (81.5)	(76.0, 86.2)	0.1651	0.067 (-0.024, 0.158)	1.483 (0.881, 2.494)	1.089 (0.967, 1.227)	0.1721
	Asian	20	15 (75.0)	(50.9, 91.3)	46	43 (93.5)	(82.1, 98.6)		0.185 (-0.018, 0.388)	4.778 (1.017, 22.450)	1.246 (0.957, 1.623)	0.0486
	Other or Unknown	11	8 (72.7)	(39.0, 94.0)	23	22 (95.7)	(78.1, 99.9)		0.229 (-0.047, 0.505)	8.250 (0.746, 91.259)	1.315 (0.906, 1.908)	0.0889

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'All randomized subjects', and the Fisher's exact test for subgroups.

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Table 14-4.2.501. Logistic Regression of Overall Response Rate as Determined by Independent Review Committee <Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Region	North America	12	7 (58.3)	(27.7, 84.8)	21	19 (90.5)	(69.6, 98.8)	0.2020	0.321 (0.016, 0.627)	6.786 (1.062, 43.360)	1.551 (0.943, 2.552)	0.0709
	Europe	103	79 (76.7)	(67.3, 84.5)	207	170 (82.1)	(76.2, 87.1)		0.054 (-0.043, 0.151)	1.396 (0.782, 2.490)	1.071 (0.946, 1.212)	0.2891
	Asia Pacific	39	29 (74.4)	(57.9, 87.0)	84	74 (88.1)	(79.2, 94.1)		0.137 (-0.016, 0.291)	2.552 (0.961, 6.772)	1.185 (0.970, 1.448)	0.0681

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'All randomized subjects', and the Fisher's exact test for subgroups.

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Table 14-4.2.501. Logistic Regression of Overall Response Rate as Determined by Independent Review Committee <Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Baseline ECOG PS	0-1	147	114 (77.6)	(69.9, 84.0)	295	255 (86.4)	(82.0, 90.1)	0.3937	0.089 (0.011, 0.167)	1.845 (1.107, 3.076)	1.115 (1.011, 1.229)	0.0209
	2	7	1 (14.3)	(0.4, 57.9)	15	7 (46.7)	(21.3, 73.4)		0.324 (-0.038, 0.686)	5.250 (0.502, 54.911)	3.267 (0.492, 21.699)	0.1932

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'All randomized subjects', and the Fisher's exact test for subgroups.

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Table 14-4.2.501. Logistic Regression of Overall Response Rate as Determined by Independent Review Committee <Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	137	101 (73.7)	(65.5, 80.9)	289	241 (83.4)	(78.6, 87.5)	0.4310	0.097 (0.011, 0.182)	1.790 (1.096, 2.923)	1.131 (1.011, 1.266)	0.0262
	No	17	14 (82.4)	(56.6, 96.2)	23	22 (95.7)	(78.1, 99.9)		0.133 (-0.066, 0.332)	4.714 (0.445, 49.943)	1.161 (0.917, 1.472)	0.2941

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'All randomized subjects', and the Fisher's exact test for subgroups.

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Table 14-4.2.501. Logistic Regression of Overall Response Rate as Determined by Independent Review Committee <Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Refractory to Bortezomib or Ixazomib	Yes	55	38 (69.1)	(55.2, 80.9)	100	79 (79.0)	(69.7, 86.5)	0.8251	0.099 (-0.047, 0.245)	1.683 (0.797, 3.554)	1.143 (0.933, 1.402)	0.1781
	No	99	77 (77.8)	(68.3, 85.5)	212	184 (86.8)	(81.5, 91.0)		0.090 (-0.004, 0.184)	1.878 (1.012, 3.485)	1.116 (0.992, 1.255)	0.0482

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'All randomized subjects', and the Fisher's exact test for subgroups.

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Table 14-4.2.501. Logistic Regression of Overall Response Rate as Determined by Independent Review Committee <Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	55 (74.3)	(62.8, 83.8)	123	97 (78.9)	(70.6, 85.7)	0.1986	0.045 (-0.078, 0.168)	1.289 (0.654, 2.538)	1.061 (0.902, 1.248)	0.4868
	No	80	60 (75.0)	(64.1, 84.0)	189	166 (87.8)	(82.3, 92.1)		0.128 (0.023, 0.234)	2.406 (1.233, 4.692)	1.171 (1.021, 1.343)	0.0111

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'All randomized subjects', and the Fisher's exact test for subgroups.

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Table 14-4.2.501. Logistic Regression of Overall Response Rate as Determined by Independent Review Committee <Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Refractory to Lenalidomide	Yes	55	40 (72.7)	(59.0, 83.9)	99	79 (79.8)	(70.5, 87.2)	0.5277	0.071 (-0.071, 0.213)	1.481 (0.686, 3.199)	1.097 (0.908, 1.327)	0.3233
	No	99	75 (75.8)	(66.1, 83.8)	213	184 (86.4)	(81.0, 90.7)		0.106 (0.010, 0.202)	2.030 (1.110, 3.714)	1.140 (1.008, 1.290)	0.0237

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'All randomized subjects', and the Fisher's exact test for subgroups.

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Table 14-4.2.501. Logistic Regression of Overall Response Rate as Determined by Independent Review Committee <Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	81 (73.6)	(64.4, 81.6)	206	173 (84.0)	(78.2, 88.7)	0.8134	0.103 (0.007, 0.200)	1.877 (1.067, 3.300)	1.140 (1.005, 1.295)	0.0368
	No	44	34 (77.3)	(62.2, 88.5)	106	90 (84.9)	(76.6, 91.1)		0.076 (-0.065, 0.218)	1.654 (0.684, 4.001)	1.099 (0.918, 1.314)	0.3429

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'All randomized subjects', and the Fisher's exact test for subgroups.

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Table 14-4.2.501. Logistic Regression of Overall Response Rate as Determined by Independent Review Committee <Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Refractory to IMiD	Yes	65	47 (72.3)	(59.8, 82.7)	130	106 (81.5)	(73.8, 87.8)	0.7786	0.092 (-0.035, 0.220)	1.691 (0.839, 3.410)	1.128 (0.950, 1.338)	0.1445
	No	89	68 (76.4)	(66.2, 84.8)	182	157 (86.3)	(80.4, 90.9)		0.099 (-0.003, 0.200)	1.939 (1.016, 3.701)	1.129 (0.992, 1.285)	0.0572

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'All randomized subjects', and the Fisher's exact test for subgroups.

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Table 14-4.2.501. Logistic Regression of Overall Response Rate as Determined by Independent Review Committee <Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	127	101 (79.5)	(71.5, 86.2)	252	219 (86.9)	(82.1, 90.8)	0.4751	0.074 (-0.008, 0.155)	1.708 (0.971, 3.007)	1.093 (0.988, 1.208)	0.0718
	3	27	14 (51.9)	(31.9, 71.3)	60	44 (73.3)	(60.3, 83.9)		0.215 (-0.004, 0.434)	2.554 (0.990, 6.585)	1.414 (0.954, 2.098)	0.0839

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'All randomized subjects', and the Fisher's exact test for subgroups.

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Table 14-4.2.501. Logistic Regression of Overall Response Rate as Determined by Independent Review Committee <Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Prior proteasome inhibitor exposure per IXRS	Yes	139	102 (73.4)	(65.2, 80.5)	279	233 (83.5)	(78.6, 87.7)	0.8594	0.101 (0.016, 0.187)	1.837 (1.124, 3.003)	1.138 (1.017, 1.274)	0.0188
	No	15	13 (86.7)	(59.5, 98.3)	33	30 (90.9)	(75.7, 98.1)		0.042 (-0.156, 0.240)	1.538 (0.229, 10.326)	1.049 (0.837, 1.315)	0.6415

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'All randomized subjects', and the Fisher's exact test for subgroups.

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Table 14-4.2.501. Logistic Regression of Overall Response Rate as Determined by Independent Review Committee <Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	67	51 (76.1)	(64.1, 85.7)	133	120 (90.2)	(83.9, 94.7)	0.1664	0.141 (0.027, 0.255)	2.896 (1.299, 6.457)	1.185 (1.025, 1.371)	0.0104
	>= 2	87	64 (73.6)	(63.0, 82.4)	179	143 (79.9)	(73.3, 85.5)		0.063 (-0.046, 0.173)	1.428 (0.783, 2.602)	1.086 (0.939, 1.256)	0.2720

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'All randomized subjects', and the Fisher's exact test for subgroups.

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Table 14-4.2.502. Logistic Regression of Minimal Residual Disease Negative Complete Response as Determined by Independent Review Committee
<Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
All randomized subjects		154	2 (1.3)	(0.2, 4.6)	312	39 (12.5)	(9.0, 16.7)		0.112 (0.071, 0.153)	11.329 (2.703, 47.476)	9.816 (2.402, 40.110)	<.0001
Age – at baseline (years)	<= 75	136	1 (0.7)	(0.0, 4.0)	287	37 (12.9)	(9.2, 17.3)	0.1962	0.122 (0.080, 0.163)	19.980 (2.711, 147.231)	17.533 (2.431, 126.451)	<.0001
	> 75	18	1 (5.6)	(0.1, 27.3)	25	2 (8.0)	(1.0, 26.0)		0.024 (-0.126, 0.174)	1.478 (0.124, 17.669)	1.440 (0.141, 14.693)	1.0000

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from an exact logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'All randomized subjects', and the Fisher's exact test for subgroups.

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Table 14-4.2.502. Logistic Regression of Minimal Residual Disease Negative Complete Response as Determined by Independent Review Committee
<Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Sex	Male	91	2 (2.2)	(0.3, 7.7)	177	24 (13.6)	(8.9, 19.5)	0.5392	0.114 (0.055, 0.172)	6.980 (1.611, 30.237)	6.169 (1.491, 25.528)	0.0020
	Female	63	0 (0.0)	(0.0, 5.7)	135	15 (11.1)	(6.4, 17.7)		0.111 (0.058, 0.164)	NE (NE, NE)	NE (NE, NE)	0.0032

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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[a] The p-value (2-sided) for interaction was from an exact logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-4.2.502. Logistic Regression of Minimal Residual Disease Negative Complete Response as Determined by Independent Review Committee
<Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Race	White	123	1 (0.8)	(0.0, 4.4)	243	28 (11.5)	(7.8, 16.2)	0.4860	0.107 (0.064, 0.150)	15.888 (2.135, 118.224)	14.173 (1.951, 102.941)	0.0001
	Asian	20	1 (5.0)	(0.1, 24.9)	46	9 (19.6)	(9.4, 33.9)		0.146 (-0.004, 0.295)	4.622 (0.544, 39.232)	3.913 (0.531, 28.861)	0.2607
	Other or Unknown	11	0 (0.0)	(0.0, 28.5)	23	2 (8.7)	(1.1, 28.0)		0.087 (-0.028, 0.202)	NE (NE, NE)	NE (NE, NE)	1.0000

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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<Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Region	North America	12	0 (0.0)	(0.0, 26.5)	21	2 (9.5)	(1.2, 30.4)	1.0000	0.095 (-0.030, 0.221)	NE (NE, NE)	NE (NE, NE)	0.5227
	Europe	103	1 (1.0)	(0.0, 5.3)	207	24 (11.6)	(7.6, 16.8)		0.106 (0.059, 0.154)	13.377 (1.783, 100.336)	11.942 (1.638, 87.046)	0.0006
	Asia Pacific	39	1 (2.6)	(0.1, 13.5)	84	13 (15.5)	(8.5, 25.0)		0.129 (0.037, 0.221)	6.958 (0.876, 55.236)	6.036 (0.818, 44.517)	0.0368

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from an exact logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'All randomized subjects', and the Fisher's exact test for subgroups.

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<Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Baseline ECOG PS	0-1	147	2 (1.4)	(0.2, 4.8)	295	39 (13.2)	(9.6, 17.6)	1.0000	0.119 (0.076, 0.162)	11.045 (2.629, 46.409)	9.717 (2.379, 39.687)	<.0001
	2	7	0 (0.0)	(0.0, 41.0)	15	0 (0.0)	(0.0, 21.8)		NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from an exact logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'All randomized subjects', and the Fisher's exact test for subgroups.

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<Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	137	2 (1.5)	(0.2, 5.2)	289	34 (11.8)	(8.3, 16.1)	1.0000	0.103 (0.061, 0.145)	9.000 (2.130, 38.034)	8.059 (1.965, 33.059)	0.0001
	No	17	0 (0.0)	(0.0, 19.5)	23	5 (21.7)	(7.5, 43.7)		0.217 (0.049, 0.386)	NE (NE, NE)	NE (NE, NE)	0.0605

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from an exact logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'All randomized subjects', and the Fisher's exact test for subgroups.

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<Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Refractory to Bortezomib or Ixazomib	Yes	55	1 (1.8)	(0.0, 9.7)	100	7 (7.0)	(2.9, 13.9)	0.3776	0.052 (-0.009, 0.113)	4.065 (0.487, 33.928)	3.850 (0.486, 30.489)	0.2609
	No	99	1 (1.0)	(0.0, 5.5)	212	32 (15.1)	(10.6, 20.6)		0.141 (0.089, 0.193)	17.422 (2.345, 129.444)	14.943 (2.071, 107.799)	<.0001

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from an exact logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'All randomized subjects', and the Fisher's exact test for subgroups.

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		Kd (N = 154)			KdD (N = 312)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	(0.0, 4.9)	123	14 (11.4)	(6.4, 18.4)	0.4969	0.114 (0.058, 0.170)	NE (NE, NE)	NE (NE, NE)	0.0012
	No	80	2 (2.5)	(0.3, 8.7)	189	25 (13.2)	(8.7, 18.9)		0.107 (0.048, 0.166)	5.945 (1.373, 25.735)	5.291 (1.284, 21.810)	0.0067

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from an exact logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'All randomized subjects', and the Fisher's exact test for subgroups.

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Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Refractory to Lenalidomide	Yes	55	0 (0.0)	(0.0, 6.5)	99	13 (13.1)	(7.2, 21.4)	0.5256	0.131 (0.065, 0.198)	NE (NE, NE)	NE (NE, NE)	0.0044
	No	99	2 (2.0)	(0.2, 7.1)	213	26 (12.2)	(8.1, 17.4)		0.102 (0.050, 0.154)	6.743 (1.568, 29.007)	6.042 (1.463, 24.956)	0.0024

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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		Kd (N = 154)			KdD (N = 312)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	0 (0.0)	(0.0, 3.3)	206	24 (11.7)	(7.6, 16.8)	0.1259	0.117 (0.073, 0.160)	NE (NE, NE)	NE (NE, NE)	<.0001
	No	44	2 (4.5)	(0.6, 15.5)	106	15 (14.2)	(8.1, 22.3)		0.096 (0.006, 0.187)	3.462 (0.757, 15.827)	3.113 (0.743, 13.047)	0.1543

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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[b] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'All randomized subjects', and the Fisher's exact test for subgroups.

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Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Refractory to IMiD	Yes	65	0 (0.0)	(0.0, 5.5)	130	16 (12.3)	(7.2, 19.2)	0.5070	0.123 (0.067, 0.180)	NE (NE, NE)	NE (NE, NE)	0.0016
	No	89	2 (2.2)	(0.3, 7.9)	182	23 (12.6)	(8.2, 18.4)		0.104 (0.047, 0.161)	6.292 (1.449, 27.322)	5.624 (1.356, 23.324)	0.0061

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	127	2 (1.6)	(0.2, 5.6)	252	38 (15.1)	(10.9, 20.1)	1.0000	0.135 (0.086, 0.184)	11.098 (2.632, 46.791)	9.575 (2.348, 39.057)	<.0001
	3	27	0 (0.0)	(0.0, 12.8)	60	1 (1.7)	(0.0, 8.9)		0.017 (-0.016, 0.049)	NE (NE, NE)	NE (NE, NE)	1.0000

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Prior proteasome inhibitor exposure per IXRS	Yes	139	2 (1.4)	(0.2, 5.1)	279	32 (11.5)	(8.0, 15.8)	1.0000	0.100 (0.058, 0.143)	8.874 (2.095, 37.597)	7.971 (1.938, 32.781)	0.0002
	No	15	0 (0.0)	(0.0, 21.8)	33	7 (21.2)	(9.0, 38.9)		0.212 (0.073, 0.352)	NE (NE, NE)	NE (NE, NE)	0.0819

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-4.2.502. Logistic Regression of Minimal Residual Disease Negative Complete Response as Determined by Independent Review Committee
<Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	67	1 (1.5)	(0.0, 8.0)	133	22 (16.5)	(10.7, 24.0)	1.0000	0.150 (0.081, 0.220)	13.081 (1.723, 99.306)	11.083 (1.527, 80.461)	0.0008
	>= 2	87	1 (1.1)	(0.0, 6.2)	179	17 (9.5)	(5.6, 14.8)		0.083 (0.035, 0.132)	9.025 (1.181, 68.967)	8.263 (1.118, 61.080)	0.0087

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from an exact logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'All randomized subjects', and the Fisher's exact test for subgroups.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-eff-logr-irc.sas
Output: t14-04-002-502-eff-logr-mrd-irc.rtf (Date Generated: 25MAY2020:22:33) Source Data: adam.adsl, adam.adpf, adam.adbase

Table 14-6.1.501. Cox Regression of Adverse Events
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	147 (96.1)	0.5 [0.3, 0.5)	308	306 (99.4)	0.3 [0.2, 0.3)		1.404 (1.153, 1.711)	0.0011
Age - at baseline (years)	<= 75	135	129 (95.6)	0.5 [0.3, 0.5)	283	282 (99.6)	0.3 [0.2, 0.3)	0.2575	1.450 (1.176, 1.787)	0.0007
	> 75	18	18 (100.0)	0.4 [0.1, 1.4)	25	24 (96.0)	0.3 [0.1, 1.0)		0.944 (0.505, 1.766)	0.8243

Includes subjects with at least one adverse event. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-sub.sas
Output: t14-06-001-501-ae-cox.rtf (Date Generated: 25MAY2020:20:18) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.501. Cox Regression of Adverse Events
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Sex	Male	91	88 (96.7)	0.5 [0.4, 1.0)	174	174 (100.0)	0.3 [0.2, 0.4)	0.2501	1.571 (1.213, 2.035)	0.0007
	Female	62	59 (95.2)	0.3 [0.2, 0.5)	134	132 (98.5)	0.2 [0.1, 0.3)		1.217 (0.895, 1.655)	0.2927
Race	White	122	116 (95.1)	0.5 [0.4, 0.7)	240	238 (99.2)	0.3 [0.3, 0.4)	0.4530	1.366 (1.094, 1.707)	0.0076
	Asian	20	20 (100.0)	0.2 [0.1, 0.4)	46	46 (100.0)	0.1 [0.0, 0.1)		2.377 (1.345, 4.201)	0.0023
	Other or Unknown	11	11 (100.0)	0.3 [0.0, 1.2)	22	22 (100.0)	0.1 [0.0, 0.4)		1.653 (0.747, 3.660)	0.2206

Includes subjects with at least one adverse event. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-sub.sas
Output: t14-06-001-501-ae-cox.rtf (Date Generated: 25MAY2020:20:18) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.501. Cox Regression of Adverse Events
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Region	North America	12	12 (100.0)	0.2 [0.1, 0.4)	21	21 (100.0)	0.0 [0.0, 0.1)	0.2723	2.323 (1.102, 4.899)	0.0325
	Europe	102	96 (94.1)	0.5 [0.4, 0.9)	203	201 (99.0)	0.4 [0.3, 0.5)		1.341 (1.050, 1.712)	0.0206
	Asia Pacific	39	39 (100.0)	0.3 [0.1, 0.5)	84	84 (100.0)	0.1 [0.0, 0.1)		1.819 (1.232, 2.685)	0.0031
Baseline ECOG PS	0-1	146	141 (96.6)	0.5 [0.3, 0.5)	294	292 (99.3)	0.3 [0.2, 0.3)	0.8232	1.409 (1.151, 1.723)	0.0013
	2	7	6 (85.7)	0.2 [0.0, 0.5)	13	13 (100.0)	0.1 [0.0, 0.7)		1.111 (0.414, 2.978)	0.8758

Includes subjects with at least one adverse event. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-sub.sas
Output: t14-06-001-501-ae-cox.rtf (Date Generated: 25MAY2020:20:18) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.501. Cox Regression of Adverse Events
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	132 (97.1)	0.4 [0.3, 0.5)	285	283 (99.3)	0.3 [0.2, 0.3)	0.3526	1.350 (1.097, 1.661)	0.0063
	No	17	15 (88.2)	0.5 [0.2, 1.4)	23	23 (100.0)	0.1 [0.0, 0.7)		1.532 (0.796, 2.948)	0.2423
Refractory to Bortezomib or Ixazomib	Yes	55	53 (96.4)	0.5 [0.3, 1.3)	99	99 (100.0)	0.3 [0.2, 0.4)	0.4727	1.518 (1.083, 2.129)	0.0159
	No	98	94 (95.9)	0.4 [0.3, 0.5)	209	207 (99.0)	0.2 [0.1, 0.3)		1.311 (1.027, 1.674)	0.0411

Includes subjects with at least one adverse event. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-sub.sas
Output: t14-06-001-501-ae-cox.rtf (Date Generated: 25MAY2020:20:18) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.501. Cox Regression of Adverse Events
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	70 (94.6)	0.3 [0.2, 0.5)	122	122 (100.0)	0.2 [0.1, 0.3)	0.2973	1.586 (1.178, 2.136)	0.0029
	No	79	77 (97.5)	0.5 [0.4, 0.7)	186	184 (98.9)	0.3 [0.3, 0.4)		1.322 (1.013, 1.727)	0.0511
Refractory to Lenalidomide	Yes	55	53 (96.4)	0.3 [0.2, 0.5)	98	98 (100.0)	0.2 [0.1, 0.3)	0.8814	1.355 (0.966, 1.901)	0.0945
	No	98	94 (95.9)	0.5 [0.3, 0.7)	210	208 (99.0)	0.3 [0.2, 0.3)		1.423 (1.114, 1.818)	0.0062

Includes subjects with at least one adverse event. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-sub.sas
Output: t14-06-001-501-ae-cox.rtf (Date Generated: 25MAY2020:20:18) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.501. Cox Regression of Adverse Events
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	105 (95.5)	0.3 [0.3, 0.5)	205	205 (100.0)	0.2 [0.1, 0.3)	0.8123	1.444 (1.139, 1.829)	0.0033
	No	43	42 (97.7)	0.7 [0.5, 1.5)	103	101 (98.1)	0.3 [0.2, 0.5)		1.405 (0.978, 2.018)	0.0727
Refractory to IMiD	Yes	65	62 (95.4)	0.3 [0.2, 0.5)	129	129 (100.0)	0.2 [0.1, 0.3)	0.9390	1.383 (1.019, 1.877)	0.0443
	No	88	85 (96.6)	0.5 [0.4, 0.7)	179	177 (98.9)	0.3 [0.2, 0.4)		1.416 (1.092, 1.835)	0.0113

Includes subjects with at least one adverse event. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-sub.sas
Output: t14-06-001-501-ae-cox.rtf (Date Generated: 25MAY2020:20:18) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.501. Cox Regression of Adverse Events
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	120 (95.2)	0.5 [0.3, 0.7)	250	248 (99.2)	0.3 [0.1, 0.3)	0.1901	1.477 (1.187, 1.839)	0.0008
	3	27	27 (100.0)	0.3 [0.0, 0.5)	58	58 (100.0)	0.3 [0.2, 0.3)		1.074 (0.677, 1.702)	0.7431
Prior proteasome inhibitor exposure per IXRS	Yes	138	133 (96.4)	0.5 [0.3, 0.5)	276	275 (99.6)	0.3 [0.2, 0.3)	0.8250	1.414 (1.149, 1.741)	0.0015
	No	15	14 (93.3)	0.5 [0.1, 1.0)	32	31 (96.9)	0.2 [0.0, 0.8)		1.175 (0.623, 2.214)	0.6789

Includes subjects with at least one adverse event. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-sub.sas
Output: t14-06-001-501-ae-cox.rtf (Date Generated: 25MAY2020:20:18) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.501. Cox Regression of Adverse Events
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	63 (95.5)	0.5 [0.4, 0.7)	131	129 (98.5)	0.3 [0.2, 0.4)	0.9674	1.391 (1.028, 1.882)	0.0419
	>= 2	87	84 (96.6)	0.3 [0.3, 0.5)	177	177 (100.0)	0.3 [0.1, 0.3)		1.403 (1.080, 1.823)	0.0130

Includes subjects with at least one adverse event. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-sub.sas
Output: t14-06-001-501-ae-cox.rtf (Date Generated: 25MAY2020:20:18) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.502. Cox Regression of Grade ≥3 Adverse Events
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	113 (73.9)	2.6 [1.9, 3.5)	308	253 (82.1)	1.7 [1.1, 2.4)		1.200 (0.961, 1.498)	0.1087
Age - at baseline (years)	<= 75	135	97 (71.9)	2.8 [1.9, 4.1)	283	232 (82.0)	1.6 [1.0, 2.3)	0.2660	1.260 (0.994, 1.598)	0.0559
	> 75	18	16 (88.9)	1.7 [0.5, 3.9)	25	21 (84.0)	3.1 [0.7, 4.2)		0.820 (0.427, 1.574)	0.5382

Includes subjects with at least one CTCAE Grade ≥3 adverse event. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-sub.sas
Output: t14-06-001-502-ae-cox-grd345.rtf (Date Generated: 25MAY2020:20:18) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.502. Cox Regression of Grade ≥3 Adverse Events
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Sex	Male	91	67 (73.6)	2.8 [1.9, 4.1)	174	142 (81.6)	1.5 [1.0, 2.8)	0.9272	1.211 (0.905, 1.621)	0.1990
	Female	62	46 (74.2)	2.3 [0.5, 4.4)	134	111 (82.8)	2.1 [0.8, 3.0)		1.187 (0.841, 1.674)	0.3273
Race	White	122	88 (72.1)	2.9 [2.1, 5.0)	240	188 (78.3)	2.4 [1.4, 4.0)	0.4843	1.130 (0.877, 1.456)	0.3465
	Asian	20	18 (90.0)	0.5 [0.2, 2.6)	46	44 (95.7)	0.5 [0.2, 0.6)		1.400 (0.807, 2.430)	0.2287
	Other or Unknown	11	7 (63.6)	4.1 [0.7, NE)	22	21 (95.5)	2.5 [0.7, 7.0)		1.823 (0.770, 4.315)	0.1668

Includes subjects with at least one CTCAE Grade ≥3 adverse event. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-sub.sas
Output: t14-06-001-502-ae-cox-grd345.rtf (Date Generated: 25MAY2020:20:18) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.502. Cox Regression of Grade ≥3 Adverse Events
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Region	North America	12	10 (83.3)	3.6 [0.4, 11.5)	21	18 (85.7)	0.7 [0.5, 6.3)	0.9259	1.253 (0.567, 2.766)	0.5875
	Europe	102	69 (67.6)	3.2 [2.2, 7.0)	203	159 (78.3)	2.8 [1.6, 4.2)		1.222 (0.921, 1.621)	0.1636
	Asia Pacific	39	34 (87.2)	1.4 [0.7, 2.1)	84	76 (90.5)	0.7 [0.5, 1.4)		1.125 (0.749, 1.688)	0.5828
Baseline ECOG PS	0-1	146	108 (74.0)	2.6 [1.9, 3.7)	294	242 (82.3)	1.7 [1.2, 2.5)	0.3390	1.225 (0.977, 1.537)	0.0796
	2	7	5 (71.4)	0.5 [0.2, NE)	13	11 (84.6)	0.7 [0.3, 4.0)		0.853 (0.289, 2.521)	0.7890

Includes subjects with at least one CTCAE Grade ≥3 adverse event. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-sub.sas
Output: t14-06-001-502-ae-cox-grd345.rtf (Date Generated: 25MAY2020:20:18) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.502. Cox Regression of Grade ≥3 Adverse Events
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	99 (72.8)	2.6 [1.9, 4.1)	285	233 (81.8)	1.7 [1.0, 2.5)	0.8163	1.215 (0.961, 1.538)	0.1038
	No	17	14 (82.4)	2.2 [1.0, 3.9)	23	20 (87.0)	1.7 [0.5, 6.5)		1.073 (0.540, 2.132)	0.8418
Refractory to Bortezomib or Ixazomib	Yes	55	41 (74.5)	2.6 [1.2, 4.0)	99	80 (80.8)	2.2 [0.6, 3.8)	0.4496	1.063 (0.729, 1.551)	0.7664
	No	98	72 (73.5)	2.4 [1.5, 4.4)	209	173 (82.8)	1.6 [1.0, 2.4)		1.277 (0.970, 1.681)	0.0805

Includes subjects with at least one CTCAE Grade ≥3 adverse event. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Output: t14-06-001-502-ae-cox-grd345.rtf (Date Generated: 25MAY2020:20:18) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.502. Cox Regression of Grade ≥3 Adverse Events
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	54 (73.0)	2.4 [1.5, 4.4)	122	104 (85.2)	0.9 [0.5, 1.5)	0.2047	1.428 (1.027, 1.985)	0.0344
	No	79	59 (74.7)	2.6 [1.2, 4.1)	186	149 (80.1)	2.7 [1.6, 4.0)		1.070 (0.791, 1.446)	0.6619
Refractory to Lenalidomide	Yes	55	41 (74.5)	2.4 [1.4, 4.4)	98	81 (82.7)	1.1 [0.6, 2.3)	0.8857	1.178 (0.808, 1.718)	0.4021
	No	98	72 (73.5)	2.6 [1.4, 4.1)	210	172 (81.9)	2.1 [1.2, 3.1)		1.216 (0.923, 1.601)	0.1623

Includes subjects with at least one CTCAE Grade ≥3 adverse event. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.502. Cox Regression of Grade ≥3 Adverse Events
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	82 (74.5)	2.1 [1.4, 3.2)	205	173 (84.4)	1.2 [0.7, 1.7)	0.5650	1.281 (0.985, 1.667)	0.0665
	No	43	31 (72.1)	3.9 [1.9, 12.0)	103	80 (77.7)	4.0 [2.1, 5.1)		1.087 (0.717, 1.646)	0.6931
Refractory to IMiD	Yes	65	49 (75.4)	2.1 [1.4, 3.5)	129	107 (82.9)	1.3 [0.6, 2.3)	0.7306	1.149 (0.819, 1.613)	0.4281
	No	88	64 (72.7)	2.9 [1.9, 5.1)	179	146 (81.6)	2.1 [1.1, 3.2)		1.236 (0.922, 1.659)	0.1559

Includes subjects with at least one CTCAE Grade ≥3 adverse event. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.502. Cox Regression of Grade ≥3 Adverse Events
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	90 (71.4)	2.9 [2.1, 4.0)	250	201 (80.4)	2.3 [1.4, 3.2)	0.8659	1.205 (0.940, 1.546)	0.1420
	3	27	23 (85.2)	0.5 [0.3, 5.0)	58	52 (89.7)	0.5 [0.4, 0.7)		1.115 (0.682, 1.824)	0.6607
Prior proteasome inhibitor exposure per IXRS	Yes	138	100 (72.5)	2.4 [1.6, 4.0)	276	227 (82.2)	1.5 [1.0, 2.3)	0.4263	1.239 (0.980, 1.568)	0.0736
	No	15	13 (86.7)	2.6 [1.3, 3.9)	32	26 (81.3)	3.8 [0.7, 8.7)		0.871 (0.445, 1.703)	0.6727

Includes subjects with at least one CTCAE Grade ≥3 adverse event. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.502. Cox Regression of Grade ≥3 Adverse Events
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	49 (74.2)	2.9 [1.8, 5.8)	131	108 (82.4)	2.5 [1.1, 4.1)	0.9222	1.186 (0.846, 1.662)	0.3212
	>= 2	87	64 (73.6)	2.3 [1.4, 3.5)	177	145 (81.9)	1.3 [0.8, 2.3)		1.218 (0.907, 1.634)	0.1947

Includes subjects with at least one CTCAE Grade ≥3 adverse event. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.503. Cox Regression of Serious Adverse Events
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	70 (45.8)	13.2 [7.6, NE)	308	173 (56.2)	10.3 [8.2, 13.5)		1.152 (0.872, 1.521)	0.3165
Age - at baseline (years)	<= 75	135	61 (45.2)	13.2 [8.3, NE)	283	158 (55.8)	10.3 [8.5, 13.7)	0.7927	1.169 (0.870, 1.572)	0.2983
	> 75	18	9 (50.0)	7.0 [2.1, NE)	25	15 (60.0)	7.6 [3.0, NE)		0.998 (0.435, 2.291)	0.9992

Includes subjects with at least one serious adverse event. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.503. Cox Regression of Serious Adverse Events
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Sex	Male	91	41 (45.1)	13.2 [5.8, NE)	174	99 (56.9)	11.2 [7.0, 14.7)	0.7543	1.194 (0.829, 1.719)	0.3394
	Female	62	29 (46.8)	16.2 [2.7, NE)	134	74 (55.2)	9.8 [6.4, 18.5)		1.095 (0.712, 1.683)	0.6764
Race	White	122	57 (46.7)	12.0 [7.0, NE)	240	135 (56.3)	10.5 [7.6, 14.7)	0.7462	1.127 (0.826, 1.537)	0.4478
	Asian	20	8 (40.0)	NE [2.4, NE)	46	27 (58.7)	9.5 [3.8, NE)		1.477 (0.671, 3.252)	0.3310
	Other or Unknown	11	5 (45.5)	NE [0.9, NE)	22	11 (50.0)	17.4 [1.2, NE)		0.983 (0.340, 2.846)	0.9730

Includes subjects with at least one serious adverse event. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.503. Cox Regression of Serious Adverse Events
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Region	North America	12	4 (33.3)	16.2 [2.5, NE)	21	13 (61.9)	14.7 [4.1, NE)	0.7707	1.456 (0.466, 4.546)	0.5150
	Europe	102	45 (44.1)	NE [7.0, NE)	203	109 (53.7)	11.4 [8.7, 18.5)		1.142 (0.807, 1.618)	0.4497
	Asia Pacific	39	21 (53.8)	8.3 [3.0, NE)	84	51 (60.7)	7.9 [3.2, 12.7)		1.081 (0.650, 1.798)	0.7643
Baseline ECOG PS	0-1	146	67 (45.9)	13.2 [7.6, NE)	294	166 (56.5)	10.3 [8.2, 13.5)	0.4413	1.175 (0.885, 1.562)	0.2625
	2	7	3 (42.9)	NE [0.0, NE)	13	7 (53.8)	6.2 [0.3, NE)		0.932 (0.235, 3.699)	0.9138

Includes subjects with at least one serious adverse event. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.503. Cox Regression of Serious Adverse Events
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	61 (44.9)	13.2 [7.6, NE)	285	160 (56.1)	10.4 [7.9, 13.7)	0.7408	1.173 (0.873, 1.575)	0.2885
	No	17	9 (52.9)	9.0 [2.1, NE)	23	13 (56.5)	9.7 [2.3, NE)		1.006 (0.428, 2.366)	0.9920
Refractory to Bortezomib or Ixazomib	Yes	55	24 (43.6)	11.6 [5.1, NE)	99	57 (57.6)	10.4 [4.6, 16.7)	0.6463	1.257 (0.779, 2.030)	0.3485
	No	98	46 (46.9)	16.2 [5.8, NE)	209	116 (55.5)	10.3 [8.2, 16.7)		1.103 (0.784, 1.553)	0.5675

Includes subjects with at least one serious adverse event. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.503. Cox Regression of Serious Adverse Events
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	34 (45.9)	11.6 [3.5, NE)	122	71 (58.2)	9.5 [6.2, 16.8)	0.9765	1.163 (0.772, 1.752)	0.4684
	No	79	36 (45.6)	13.2 [7.3, NE)	186	102 (54.8)	10.9 [8.7, 16.7)		1.156 (0.790, 1.691)	0.4546
Refractory to Lenalidomide	Yes	55	26 (47.3)	11.6 [3.5, NE)	98	53 (54.1)	11.2 [6.8, NE)	0.3566	0.955 (0.596, 1.532)	0.8537
	No	98	44 (44.9)	NE [7.3, NE)	210	120 (57.1)	9.7 [7.0, 13.5)		1.260 (0.892, 1.781)	0.1876

Includes subjects with at least one serious adverse event. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.503. Cox Regression of Serious Adverse Events
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	51 (46.4)	13.2 [5.8, NE)	205	120 (58.5)	9.5 [6.3, 11.4)	0.7838	1.199 (0.864, 1.665)	0.2750
	No	43	19 (44.2)	NE [5.1, NE)	103	53 (51.5)	16.7 [9.5, NE)		1.076 (0.636, 1.819)	0.7860
Refractory to IMiD	Yes	65	32 (49.2)	11.4 [3.5, NE)	129	74 (57.4)	9.8 [6.4, 14.7)	0.4357	1.000 (0.660, 1.516)	0.9997
	No	88	38 (43.2)	NE [5.8, NE)	179	99 (55.3)	10.3 [7.0, 16.7)		1.268 (0.872, 1.844)	0.2111

Includes subjects with at least one serious adverse event. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Output: t14-06-001-503-sae-cox.rtf (Date Generated: 25MAY2020:20:18) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.503. Cox Regression of Serious Adverse Events
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	52 (41.3)	NE [11.4, NE)	250	129 (51.6)	12.7 [9.5, 18.5)	0.4979	1.180 (0.855, 1.629)	0.3117
	3	27	18 (66.7)	1.6 [0.5, 7.0)	58	44 (75.9)	3.5 [1.0, 9.5)		1.003 (0.578, 1.739)	0.9891
Prior proteasome inhibitor exposure per IXRS	Yes	138	61 (44.2)	16.2 [8.3, NE)	276	156 (56.5)	10.4 [7.9, 13.7)	0.3804	1.199 (0.891, 1.613)	0.2282
	No	15	9 (60.0)	5.3 [2.0, NE)	32	17 (53.1)	9.7 [2.9, NE)		0.800 (0.355, 1.801)	0.5883

Includes subjects with at least one serious adverse event. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-sub.sas
Output: t14-06-001-503-sae-cox.rtf (Date Generated: 25MAY2020:20:18) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.503. Cox Regression of Serious Adverse Events
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	31 (47.0)	12.5 [5.1, NE)	131	74 (56.5)	9.8 [7.4, 18.5)	0.9067	1.128 (0.741, 1.717)	0.5704
	>= 2	87	39 (44.8)	13.2 [7.0, NE)	177	99 (55.9)	10.9 [6.3, 16.7)		1.169 (0.806, 1.694)	0.4096

Includes subjects with at least one serious adverse event. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-sub.sas
Output: t14-06-001-503-sae-cox.rtf (Date Generated: 25MAY2020:20:18) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.510. Cox Regression of Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	147 (96.1)	0.5 [0.3, 0.5)	308	306 (99.4)	0.3 [0.2, 0.3)		1.404 (1.153, 1.711)	0.0011
Age - at baseline (years)	<= 75	135	129 (95.6)	0.5 [0.3, 0.5)	283	282 (99.6)	0.3 [0.2, 0.3)	0.2575	1.450 (1.176, 1.787)	0.0007
	> 75	18	18 (100.0)	0.4 [0.1, 1.4)	25	24 (96.0)	0.3 [0.1, 1.0)		0.944 (0.505, 1.766)	0.8243

Includes subjects with at least one adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-sub.sas
Output: t14-06-001-510-ae-cox-excl-dpe.rtf (Date Generated: 25MAY2020:20:18) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.510. Cox Regression of Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Sex	Male	91	88 (96.7)	0.5 [0.4, 1.0)	174	174 (100.0)	0.3 [0.2, 0.4)	0.2501	1.571 (1.213, 2.035)	0.0007
	Female	62	59 (95.2)	0.3 [0.2, 0.5)	134	132 (98.5)	0.2 [0.1, 0.3)		1.217 (0.895, 1.655)	0.2927
Race	White	122	116 (95.1)	0.5 [0.4, 0.7)	240	238 (99.2)	0.3 [0.3, 0.4)	0.4530	1.366 (1.094, 1.707)	0.0076

Includes subjects with at least one adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	Asian	20	20 (100.0)	0.2 [0.1, 0.4)	46	46 (100.0)	0.1 [0.0, 0.1)		2.377 (1.345, 4.201)	0.0023
	Other or Unknown	11	11 (100.0)	0.3 [0.0, 1.2)	22	22 (100.0)	0.1 [0.0, 0.4)		1.653 (0.747, 3.660)	0.2206
Region	North America	12	12 (100.0)	0.2 [0.1, 0.4)	21	21 (100.0)	0.0 [0.0, 0.1)	0.2723	2.323 (1.102, 4.899)	0.0325

Includes subjects with at least one adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Region	Europe	102	96 (94.1)	0.5 [0.4, 0.9)	203	201 (99.0)	0.4 [0.3, 0.5)		1.341 (1.050, 1.712)	0.0206
	Asia Pacific	39	39 (100.0)	0.3 [0.1, 0.5)	84	84 (100.0)	0.1 [0.0, 0.1)		1.819 (1.232, 2.685)	0.0031
Baseline ECOG PS	0-1	146	141 (96.6)	0.5 [0.3, 0.5)	294	292 (99.3)	0.3 [0.2, 0.3)	0.8232	1.409 (1.151, 1.723)	0.0013

Includes subjects with at least one adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Baseline ECOG PS	2	7	6 (85.7)	0.2 [0.0, 0.5)	13	13 (100.0)	0.1 [0.0, 0.7)		1.111 (0.414, 2.978)	0.8758
Prior Bortezomib or Ixazomib exposure	Yes	136	132 (97.1)	0.4 [0.3, 0.5)	285	283 (99.3)	0.3 [0.2, 0.3)	0.3526	1.350 (1.097, 1.661)	0.0063
	No	17	15 (88.2)	0.5 [0.2, 1.4)	23	23 (100.0)	0.1 [0.0, 0.7)		1.532 (0.796, 2.948)	0.2423

Includes subjects with at least one adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Refractory to Bortezomib or Ixazomib	Yes	55	53 (96.4)	0.5 [0.3, 1.3)	99	99 (100.0)	0.3 [0.2, 0.4)	0.4727	1.518 (1.083, 2.129)	0.0159
	No	98	94 (95.9)	0.4 [0.3, 0.5)	209	207 (99.0)	0.2 [0.1, 0.3)		1.311 (1.027, 1.674)	0.0411
Prior Lenalidomide exposure	Yes	74	70 (94.6)	0.3 [0.2, 0.5)	122	122 (100.0)	0.2 [0.1, 0.3)	0.2973	1.586 (1.178, 2.136)	0.0029

Includes subjects with at least one adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	No	79	77 (97.5)	0.5 [0.4, 0.7)	186	184 (98.9)	0.3 [0.3, 0.4)		1.322 (1.013, 1.727)	0.0511
Refractory to Lenalidomide	Yes	55	53 (96.4)	0.3 [0.2, 0.5)	98	98 (100.0)	0.2 [0.1, 0.3)	0.8814	1.355 (0.966, 1.901)	0.0945
	No	98	94 (95.9)	0.5 [0.3, 0.7)	210	208 (99.0)	0.3 [0.2, 0.3)		1.423 (1.114, 1.818)	0.0062

Includes subjects with at least one adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	105 (95.5)	0.3 [0.3, 0.5)	205	205 (100.0)	0.2 [0.1, 0.3)	0.8123	1.444 (1.139, 1.829)	0.0033
	No	43	42 (97.7)	0.7 [0.5, 1.5)	103	101 (98.1)	0.3 [0.2, 0.5)		1.405 (0.978, 2.018)	0.0727
Refractory to IMiD	Yes	65	62 (95.4)	0.3 [0.2, 0.5)	129	129 (100.0)	0.2 [0.1, 0.3)	0.9390	1.383 (1.019, 1.877)	0.0443

Includes subjects with at least one adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
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Table 14-6.1.510. Cox Regression of Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Refractory to IMiD	No	88	85 (96.6)	0.5 [0.4, 0.7)	179	177 (98.9)	0.3 [0.2, 0.4)		1.416 (1.092, 1.835)	0.0113
ISS stage per IXRS	1 or 2	126	120 (95.2)	0.5 [0.3, 0.7)	250	248 (99.2)	0.3 [0.1, 0.3)	0.1901	1.477 (1.187, 1.839)	0.0008
	3	27	27 (100.0)	0.3 [0.0, 0.5)	58	58 (100.0)	0.3 [0.2, 0.3)		1.074 (0.677, 1.702)	0.7431

Includes subjects with at least one adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.510. Cox Regression of Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior proteasome inhibitor exposure per IXRS	Yes	138	133 (96.4)	0.5 [0.3, 0.5)	276	275 (99.6)	0.3 [0.2, 0.3)	0.8250	1.414 (1.149, 1.741)	0.0015
	No	15	14 (93.3)	0.5 [0.1, 1.0)	32	31 (96.9)	0.2 [0.0, 0.8)		1.175 (0.623, 2.214)	0.6789
Number of prior lines of therapy per IXRS	1	66	63 (95.5)	0.5 [0.4, 0.7)	131	129 (98.5)	0.3 [0.2, 0.4)	0.9674	1.391 (1.028, 1.882)	0.0419

Includes subjects with at least one adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	>= 2	87	84 (96.6)	0.3 [0.3, 0.5)	177	177 (100.0)	0.3 [0.1, 0.3)		1.403 (1.080, 1.823)	0.0130

Includes subjects with at least one adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-sub.sas
Output: t14-06-001-510-ae-cox-excl-dpe.rtf (Date Generated: 25MAY2020:20:18) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	113 (73.9)	2.6 [1.9, 3.5)	308	252 (81.8)	1.7 [1.1, 2.5)		1.193 (0.956, 1.490)	0.1197
Age - at baseline (years)	<= 75	135	97 (71.9)	2.8 [1.9, 4.1)	283	231 (81.6)	1.6 [1.0, 2.4)	0.2727	1.253 (0.989, 1.589)	0.0625
	> 75	18	16 (88.9)	1.7 [0.5, 3.9)	25	21 (84.0)	3.1 [0.7, 4.2)		0.820 (0.427, 1.574)	0.5382

Includes subjects with at least one CTCAE Grade ≥3 adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Output: t14-06-001-511-ae-cox-grd345-excl-dpe.rtf (Date Generated: 25MAY2020:20:18) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Sex	Male	91	67 (73.6)	2.8 [1.9, 4.1)	174	142 (81.6)	1.5 [1.0, 2.8)	0.8917	1.211 (0.905, 1.621)	0.1990
	Female	62	46 (74.2)	2.3 [0.5, 4.4)	134	110 (82.1)	2.1 [0.8, 3.1)		1.173 (0.831, 1.656)	0.3620
Race	White	122	88 (72.1)	2.9 [2.1, 5.0)	240	187 (77.9)	2.5 [1.4, 4.0)	0.4729	1.123 (0.871, 1.447)	0.3736

Includes subjects with at least one CTCAE Grade ≥3 adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	Asian	20	18 (90.0)	0.5 [0.2, 2.6)	46	44 (95.7)	0.5 [0.2, 0.6)		1.400 (0.807, 2.430)	0.2287
	Other or Unknown	11	7 (63.6)	4.1 [0.7, NE)	22	21 (95.5)	2.5 [0.7, 7.0)		1.823 (0.770, 4.315)	0.1668
Region	North America	12	10 (83.3)	3.6 [0.4, 11.5)	21	18 (85.7)	0.7 [0.5, 6.3)	0.9091	1.253 (0.567, 2.766)	0.5875

Includes subjects with at least one CTCAE Grade ≥3 adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Region	Europe	102	69 (67.6)	3.2 [2.2, 7.0)	203	159 (78.3)	2.8 [1.6, 4.2)		1.220 (0.920, 1.619)	0.1656
	Asia Pacific	39	34 (87.2)	1.4 [0.7, 2.1)	84	75 (89.3)	0.7 [0.5, 1.4)		1.108 (0.737, 1.664)	0.6356
Baseline ECOG PS	0-1	146	108 (74.0)	2.6 [1.9, 3.7)	294	241 (82.0)	1.7 [1.2, 2.5)	0.3446	1.218 (0.971, 1.529)	0.0884

Includes subjects with at least one CTCAE Grade ≥3 adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Baseline ECOG PS	2	7	5 (71.4)	0.5 [0.2, NE)	13	11 (84.6)	0.7 [0.3, 4.0)		0.853 (0.289, 2.521)	0.7890
Prior Bortezomib or Ixazomib exposure	Yes	136	99 (72.8)	2.6 [1.9, 4.1)	285	232 (81.4)	1.7 [1.0, 2.5)	0.8253	1.208 (0.955, 1.529)	0.1147
	No	17	14 (82.4)	2.2 [1.0, 3.9)	23	20 (87.0)	1.7 [0.5, 6.5)		1.073 (0.540, 2.132)	0.8418

Includes subjects with at least one CTCAE Grade ≥3 adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Refractory to Bortezomib or Ixazomib	Yes	55	41 (74.5)	2.6 [1.2, 4.0)	99	79 (79.8)	2.2 [0.6, 3.9)	0.4145	1.047 (0.717, 1.528)	0.8301
	No	98	72 (73.5)	2.4 [1.5, 4.4)	209	173 (82.8)	1.6 [1.0, 2.4)		1.276 (0.969, 1.679)	0.0817
Prior Lenalidomide exposure	Yes	74	54 (73.0)	2.4 [1.5, 4.4)	122	104 (85.2)	0.9 [0.5, 1.5)	0.1915	1.428 (1.027, 1.985)	0.0344

Includes subjects with at least one CTCAE Grade ≥3 adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	No	79	59 (74.7)	2.6 [1.2, 4.1)	186	148 (79.6)	2.8 [1.6, 4.1)		1.059 (0.783, 1.432)	0.7124
Refractory to Lenalidomide	Yes	55	41 (74.5)	2.4 [1.4, 4.4)	98	81 (82.7)	1.1 [0.6, 2.3)	0.9162	1.178 (0.808, 1.718)	0.4021
	No	98	72 (73.5)	2.6 [1.4, 4.1)	210	171 (81.4)	2.1 [1.2, 3.2)		1.205 (0.915, 1.587)	0.1830

Includes subjects with at least one CTCAE Grade ≥3 adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	82 (74.5)	2.1 [1.4, 3.2)	205	172 (83.9)	1.2 [0.7, 1.7)	0.5796	1.272 (0.978, 1.656)	0.0749
	No	43	31 (72.1)	3.9 [1.9, 12.0)	103	80 (77.7)	4.0 [2.1, 5.1)		1.083 (0.715, 1.640)	0.7066
Refractory to IMiD	Yes	65	49 (75.4)	2.1 [1.4, 3.5)	129	106 (82.2)	1.3 [0.6, 2.4)	0.7055	1.137 (0.810, 1.597)	0.4659

Includes subjects with at least one CTCAE Grade ≥3 adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Refractory to IMiD	No	88	64 (72.7)	2.9 [1.9, 5.1)	179	146 (81.6)	2.1 [1.1, 3.2)		1.233 (0.919, 1.654)	0.1617
ISS stage per IXRS	1 or 2	126	90 (71.4)	2.9 [2.1, 4.0)	250	200 (80.0)	2.3 [1.4, 3.3)	0.8720	1.198 (0.934, 1.537)	0.1555
	3	27	23 (85.2)	0.5 [0.3, 5.0)	58	52 (89.7)	0.5 [0.4, 0.7)		1.102 (0.673, 1.805)	0.6962

Includes subjects with at least one CTCAE Grade ≥3 adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior proteasome inhibitor exposure per IXRS	Yes	138	100 (72.5)	2.4 [1.6, 4.0)	276	226 (81.9)	1.5 [1.0, 2.4)	0.4314	1.232 (0.974, 1.560)	0.0818
	No	15	13 (86.7)	2.6 [1.3, 3.9)	32	26 (81.3)	3.8 [0.7, 8.7)		0.871 (0.445, 1.703)	0.6727
Number of prior lines of therapy per IXRS	1	66	49 (74.2)	2.9 [1.8, 5.8)	131	108 (82.4)	2.5 [1.1, 4.1)	0.9425	1.182 (0.843, 1.657)	0.3306

Includes subjects with at least one CTCAE Grade ≥3 adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	>= 2	87	64 (73.6)	2.3 [1.4, 3.5)	177	144 (81.4)	1.3 [0.8, 2.3)		1.208 (0.899, 1.622)	0.2148

Includes subjects with at least one CTCAE Grade ≥3 adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	69 (45.1)	13.2 [7.6, NE)	308	171 (55.5)	10.4 [8.5, 13.7)		1.152 (0.871, 1.525)	0.3185
Age - at baseline (years)	<= 75	135	60 (44.4)	13.2 [9.0, NE)	283	156 (55.1)	10.5 [8.7, 14.7)	0.7876	1.171 (0.869, 1.577)	0.2981
	> 75	18	9 (50.0)	7.0 [2.1, NE)	25	15 (60.0)	7.6 [3.0, NE)		0.998 (0.435, 2.291)	0.9992

Includes subjects with at least one serious adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-sub.sas
Output: t14-06-001-512-sae-cox-excl-dpe.rtf (Date Generated: 25MAY2020:20:18) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.512. Cox Regression of Serious Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Sex	Male	91	40 (44.0)	13.2 [7.0, NE)	174	98 (56.3)	11.2 [7.0, 14.8)	0.6843	1.207 (0.835, 1.745)	0.3149
	Female	62	29 (46.8)	16.2 [2.7, NE)	134	73 (54.5)	9.8 [7.0, 18.5)		1.079 (0.702, 1.660)	0.7258
Race	White	122	56 (45.9)	12.5 [7.0, NE)	240	134 (55.8)	10.5 [8.1, 14.8)	0.7974	1.137 (0.832, 1.554)	0.4182

Includes subjects with at least one serious adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-sub.sas
Output: t14-06-001-512-sae-cox-excl-dpe.rtf (Date Generated: 25MAY2020:20:18) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.512. Cox Regression of Serious Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	Asian	20	8 (40.0)	NE [2.4, NE)	46	26 (56.5)	9.7 [3.9, NE)		1.416 (0.641, 3.128)	0.3893
	Other or Unknown	11	5 (45.5)	NE [0.9, NE)	22	11 (50.0)	17.4 [1.2, NE)		0.983 (0.340, 2.846)	0.9730
Region	North America	12	4 (33.3)	16.2 [2.5, NE)	21	13 (61.9)	14.7 [4.1, NE)	0.7266	1.456 (0.466, 4.546)	0.5150

Includes subjects with at least one serious adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-sub.sas
Output: t14-06-001-512-sae-cox-excl-dpe.rtf (Date Generated: 25MAY2020:20:18) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.512. Cox Regression of Serious Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Region	Europe	102	44 (43.1)	NE [7.0, NE)	203	109 (53.7)	11.4 [8.7, 18.5)		1.168 (0.823, 1.658)	0.3827
	Asia Pacific	39	21 (53.8)	8.3 [3.0, NE)	84	49 (58.3)	8.7 [3.8, 12.7)		1.031 (0.618, 1.720)	0.9071
Baseline ECOG PS	0-1	146	66 (45.2)	13.2 [8.3, NE)	294	164 (55.8)	10.4 [8.5, 13.7)	0.4355	1.176 (0.884, 1.566)	0.2644

Includes subjects with at least one serious adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-sub.sas
Output: t14-06-001-512-sae-cox-excl-dpe.rtf (Date Generated: 25MAY2020:20:18) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.512. Cox Regression of Serious Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Baseline ECOG PS	2	7	3 (42.9)	NE [0.0, NE)	13	7 (53.8)	6.2 [0.3, NE)		0.932 (0.235, 3.699)	0.9138
Prior Bortezomib or Ixazomib exposure	Yes	136	60 (44.1)	16.2 [8.3, NE)	285	158 (55.4)	10.5 [8.1, 14.7)	0.7342	1.174 (0.872, 1.582)	0.2876
	No	17	9 (52.9)	9.0 [2.1, NE)	23	13 (56.5)	9.7 [2.3, NE)		1.006 (0.428, 2.366)	0.9920

Includes subjects with at least one serious adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-sub.sas
Output: t14-06-001-512-sae-cox-excl-dpe.rtf (Date Generated: 25MAY2020:20:18) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.512. Cox Regression of Serious Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Refractory to Bortezomib or Ixazomib	Yes	55	23 (41.8)	13.2 [5.3, NE)	99	56 (56.6)	11.2 [4.6, 16.7)	0.5759	1.282 (0.787, 2.087)	0.3180
	No	98	46 (46.9)	16.2 [5.8, NE)	209	115 (55.0)	10.3 [8.2, 16.8)		1.092 (0.775, 1.538)	0.6087
Prior Lenalidomide exposure	Yes	74	33 (44.6)	16.2 [5.3, NE)	122	70 (57.4)	9.8 [6.3, 16.8)	0.9575	1.176 (0.776, 1.780)	0.4431

Includes subjects with at least one serious adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-sub.sas
Output: t14-06-001-512-sae-cox-excl-dpe.rtf (Date Generated: 25MAY2020:20:18) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.512. Cox Regression of Serious Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	No	79	36 (45.6)	13.2 [7.3, NE)	186	101 (54.3)	10.9 [8.7, 16.7)		1.144 (0.781, 1.674)	0.4896
Refractory to Lenalidomide	Yes	55	25 (45.5)	11.6 [3.5, NE)	98	52 (53.1)	11.4 [7.6, NE)	0.4088	0.967 (0.599, 1.563)	0.8949
	No	98	44 (44.9)	NE [7.3, NE)	210	119 (56.7)	9.7 [7.0, 13.5)		1.249 (0.883, 1.765)	0.2066

Includes subjects with at least one serious adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-sub.sas
Output: t14-06-001-512-sae-cox-excl-dpe.rtf (Date Generated: 25MAY2020:20:18) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.512. Cox Regression of Serious Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	50 (45.5)	13.2 [5.8, NE)	205	118 (57.6)	9.5 [6.4, 12.2)	0.7812	1.199 (0.861, 1.669)	0.2809
	No	43	19 (44.2)	NE [5.1, NE)	103	53 (51.5)	16.7 [9.5, NE)		1.076 (0.636, 1.819)	0.7860
Refractory to IMiD	Yes	65	31 (47.7)	11.4 [3.5, NE)	129	72 (55.8)	10.4 [6.5, 16.8)	0.4417	0.997 (0.653, 1.521)	0.9895

Includes subjects with at least one serious adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-sub.sas
Output: t14-06-001-512-sae-cox-excl-dpe.rtf (Date Generated: 25MAY2020:20:18) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.512. Cox Regression of Serious Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Refractory to IMiD	No	88	38 (43.2)	NE [5.8, NE)	179	99 (55.3)	10.3 [7.0, 16.7)		1.268 (0.872, 1.844)	0.2111
ISS stage per IXRS	1 or 2	126	52 (41.3)	NE [11.4, NE)	250	127 (50.8)	12.7 [9.7, NE)	0.6596	1.159 (0.839, 1.601)	0.3695
	3	27	17 (63.0)	1.6 [0.5, 7.0)	58	44 (75.9)	3.5 [1.0, 9.5)		1.059 (0.603, 1.858)	0.8388

Includes subjects with at least one serious adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-sub.sas
Output: t14-06-001-512-sae-cox-excl-dpe.rtf (Date Generated: 25MAY2020:20:18) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.512. Cox Regression of Serious Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior proteasome inhibitor exposure per IXRS	Yes	138	60 (43.5)	16.2 [8.3, NE)	276	154 (55.8)	10.5 [8.1, 14.7)	0.3769	1.200 (0.890, 1.618)	0.2290
	No	15	9 (60.0)	5.3 [2.0, NE)	32	17 (53.1)	9.7 [2.9, NE)		0.800 (0.355, 1.801)	0.5883
Number of prior lines of therapy per IXRS	1	66	31 (47.0)	12.5 [5.1, NE)	131	74 (56.5)	9.8 [7.4, 18.5)	0.8985	1.128 (0.741, 1.717)	0.5704

Includes subjects with at least one serious adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-sub.sas
Output: t14-06-001-512-sae-cox-excl-dpe.rtf (Date Generated: 25MAY2020:20:18) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.512. Cox Regression of Serious Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	>= 2	87	38 (43.7)	13.2 [7.6, NE)	177	97 (54.8)	11.3 [6.5, 16.8)		1.170 (0.803, 1.703)	0.4132

Includes subjects with at least one serious adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-sub.sas
Output: t14-06-001-512-sae-cox-excl-dpe.rtf (Date Generated: 25MAY2020:20:18) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Acute renal failure (SMQ) - Narrow										
Total subjects		153	12 (7.8)	NE [NE, NE)	308	18 (5.8)	NE [NE, NE)		0.683 (0.329, 1.419)	0.3038

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-504-ae-cox-eoi-cfz.rtf (Date Generated: 25MAY2020:20:48) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	12 (8.9)	NE [NE, NE)	283	15 (5.3)	NE [NE, NE)	0.9889	0.541 (0.253, 1.157)	0.1074
	> 75	18	0 (0.0)	NE [NE, NE)	25	3 (12.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.1450
Sex	Male	91	10 (11.0)	NE [NE, NE)	174	10 (5.7)	NE [NE, NE)	0.1511	0.463 (0.192, 1.115)	0.0786
	Female	62	2 (3.2)	NE [NE, NE)	134	8 (6.0)	NE [NE, NE)		1.784 (0.379, 8.404)	0.4581

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-504-ae-cox-eoi-cfz.rtf (Date Generated: 25MAY2020:20:48) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	7 (5.7)	NE [NE, NE)	240	15 (6.3)	NE [NE, NE)	0.2341	1.018 (0.415, 2.500)	0.9691
	Asian	20	3 (15.0)	NE [11.5, NE)	46	2 (4.3)	NE [NE, NE)		0.259 (0.043, 1.556)	0.1118
	Other or Unknown	11	2 (18.2)	NE [0.5, NE)	22	1 (4.5)	NE [NE, NE)		0.197 (0.018, 2.186)	0.1414
Region	North America	12	0 (0.0)	NE [NE, NE)	21	1 (4.8)	NE [NE, NE)	0.3049	>999.999 (<.001, NE)	0.4497

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	7 (6.9)	NE [NE, NE)	203	14 (6.9)	NE [NE, NE)		0.926 (0.374, 2.297)	0.8694
	Asia Pacific	39	5 (12.8)	NE [NE, NE)	84	3 (3.6)	NE [NE, NE)		0.256 (0.061, 1.076)	0.0449
Baseline ECOG PS	0-1	146	12 (8.2)	NE [NE, NE)	294	16 (5.4)	NE [NE, NE)	0.9869	0.613 (0.290, 1.298)	0.1968
	2	7	0 (0.0)	NE [NE, NE)	13	2 (15.4)	NE [1.6, NE)		>999.999 (<.001, NE)	0.3507

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	10 (7.4)	NE [NE, NE)	285	15 (5.3)	NE [NE, NE)	0.7132	0.667 (0.299, 1.487)	0.3189
	No	17	2 (11.8)	NE [9.5, NE)	23	3 (13.0)	NE [NE, NE)		0.879 (0.145, 5.319)	0.8880
Refractory to Bortezomib or Ixazomib	Yes	55	4 (7.3)	NE [NE, NE)	99	6 (6.1)	NE [NE, NE)	0.8010	0.780 (0.220, 2.766)	0.6998
	No	98	8 (8.2)	NE [NE, NE)	209	12 (5.7)	NE [NE, NE)		0.628 (0.256, 1.540)	0.3053

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	6 (8.1)	NE [NE, NE)	122	9 (7.4)	NE [NE, NE)	0.6588	0.838 (0.297, 2.359)	0.7364
	No	79	6 (7.6)	NE [NE, NE)	186	9 (4.8)	NE [NE, NE)		0.589 (0.209, 1.656)	0.3104
Refractory to Lenalidomide	Yes	55	5 (9.1)	NE [NE, NE)	98	7 (7.1)	NE [NE, NE)	0.9786	0.685 (0.217, 2.169)	0.5179
	No	98	7 (7.1)	NE [NE, NE)	210	11 (5.2)	NE [NE, NE)		0.687 (0.266, 1.772)	0.4342

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	10 (9.1)	NE [NE, NE)	205	14 (6.8)	NE [NE, NE)	0.8908	0.688 (0.305, 1.550)	0.3637
	No	43	2 (4.7)	NE [NE, NE)	103	4 (3.9)	NE [NE, NE)		0.778 (0.142, 4.256)	0.7712
Refractory to IMiD	Yes	65	8 (12.3)	NE [NE, NE)	129	9 (7.0)	NE [NE, NE)	0.3557	0.502 (0.193, 1.307)	0.1504
	No	88	4 (4.5)	NE [NE, NE)	179	9 (5.0)	NE [NE, NE)		1.033 (0.318, 3.358)	0.9559

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	9 (7.1)	NE [NE, NE)	250	11 (4.4)	NE [NE, NE)	0.6420	0.568 (0.235, 1.372)	0.2028
	3	27	3 (11.1)	NE [NE, NE)	58	7 (12.1)	NE [NE, NE)		0.917 (0.236, 3.559)	0.9000
Prior proteasome inhibitor exposure per IXRS	Yes	138	10 (7.2)	NE [NE, NE)	276	15 (5.4)	NE [NE, NE)	0.8745	0.703 (0.316, 1.567)	0.3863
	No	15	2 (13.3)	NE [9.5, NE)	32	3 (9.4)	NE [NE, NE)		0.552 (0.092, 3.331)	0.5113

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	4 (6.1)	NE [NE, NE)	131	4 (3.1)	NE [NE, NE)	0.5028	0.426 (0.106, 1.712)	0.2154
	>= 2	87	8 (9.2)	NE [NE, NE)	177	14 (7.9)	NE [NE, NE)		0.812 (0.340, 1.937)	0.6382

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Cardiac arrhythmias (SMQ) - Narrow										
Total subjects		153	9 (5.9)	NE [NE, NE)	308	22 (7.1)	NE [NE, NE)		1.094 (0.503, 2.380)	0.8204

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	7 (5.2)	NE [NE, NE)	283	18 (6.4)	NE [NE, NE)	0.8411	1.099 (0.458, 2.636)	0.8322
	> 75	18	2 (11.1)	NE [NE, NE)	25	4 (16.0)	NE [NE, NE)		1.327 (0.243, 7.257)	0.7430
Sex	Male	91	6 (6.6)	NE [NE, NE)	174	14 (8.0)	NE [NE, NE)	0.9926	1.127 (0.433, 2.938)	0.8063
	Female	62	3 (4.8)	NE [NE, NE)	134	8 (6.0)	NE [NE, NE)		1.122 (0.297, 4.232)	0.8654

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	8 (6.6)	NE [NE, NE)	240	18 (7.5)	NE [NE, NE)	0.9941	1.026 (0.445, 2.363)	0.9526
	Asian	20	1 (5.0)	NE [NE, NE)	46	3 (6.5)	NE [NE, NE)		1.264 (0.131, 12.171)	0.8392
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	1 (4.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.4795
Region	North America	12	1 (8.3)	NE [NE, NE)	21	4 (19.0)	NE [NE, NE)	0.8621	1.933 (0.212, 17.584)	0.5464

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	6 (5.9)	NE [NE, NE)	203	13 (6.4)	NE [NE, NE)		0.992 (0.377, 2.613)	0.9874
	Asia Pacific	39	2 (5.1)	NE [NE, NE)	84	5 (6.0)	NE [NE, NE)		1.102 (0.213, 5.684)	0.9080
Baseline ECOG PS	0-1	146	9 (6.2)	NE [NE, NE)	294	20 (6.8)	NE [NE, NE)	0.9878	1.030 (0.469, 2.264)	0.9407
	2	7	0 (0.0)	NE [NE, NE)	13	2 (15.4)	18.9 [18.9, NE)		>999.999 (<.001, NE)	0.6015

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	8 (5.9)	NE [NE, NE)	285	22 (7.7)	NE [NE, NE)	0.9867	1.185 (0.527, 2.665)	0.6812
	No	17	1 (5.9)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.2207
Refractory to Bortezomib or Ixazomib	Yes	55	6 (10.9)	NE [NE, NE)	99	6 (6.1)	NE [NE, NE)	0.0809	0.528 (0.170, 1.639)	0.2611
	No	98	3 (3.1)	NE [NE, NE)	209	16 (7.7)	NE [NE, NE)		2.165 (0.629, 7.453)	0.2092

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-504-ae-cox-eoi-cfz.rtf (Date Generated: 25MAY2020:20:48) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	5 (6.8)	NE [NE, NE)	122	10 (8.2)	NE [NE, NE)	0.9131	1.068 (0.364, 3.140)	0.9039
	No	79	4 (5.1)	NE [NE, NE)	186	12 (6.5)	NE [NE, NE)		1.173 (0.378, 3.639)	0.7817
Refractory to Lenalidomide	Yes	55	4 (7.3)	NE [NE, NE)	98	7 (7.1)	NE [NE, NE)	0.6141	0.862 (0.251, 2.957)	0.8131
	No	98	5 (5.1)	NE [NE, NE)	210	15 (7.1)	NE [NE, NE)		1.274 (0.463, 3.509)	0.6379

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	6 (5.5)	NE [NE, NE)	205	14 (6.8)	NE [NE, NE)	0.9281	1.122 (0.430, 2.929)	0.8137
	No	43	3 (7.0)	NE [NE, NE)	103	8 (7.8)	NE [NE, NE)		1.014 (0.269, 3.828)	0.9831
Refractory to IMiD	Yes	65	5 (7.7)	NE [NE, NE)	129	9 (7.0)	NE [NE, NE)	0.4360	0.810 (0.271, 2.425)	0.7060
	No	88	4 (4.5)	NE [NE, NE)	179	13 (7.3)	NE [NE, NE)		1.449 (0.472, 4.450)	0.5134

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	7 (5.6)	NE [NE, NE)	250	16 (6.4)	NE [NE, NE)	0.9645	1.086 (0.446, 2.641)	0.8563
	3	27	2 (7.4)	NE [NE, NE)	58	6 (10.3)	NE [18.9, NE)		0.983 (0.198, 4.892)	0.9837
Prior proteasome inhibitor exposure per IXRS	Yes	138	8 (5.8)	NE [NE, NE)	276	22 (8.0)	NE [NE, NE)	0.9898	1.247 (0.554, 2.804)	0.5929
	No	15	1 (6.7)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0986

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	2 (3.0)	NE [NE, NE)	131	12 (9.2)	NE [NE, NE)	0.1039	2.643 (0.591, 11.828)	0.1860
	>= 2	87	7 (8.0)	NE [NE, NE)	177	10 (5.6)	NE [NE, NE)		0.627 (0.238, 1.655)	0.3414

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Cardiac failure (SMQ) - Narrow										
Total subjects		153	16 (10.5)	NE [NE, NE)	308	23 (7.5)	NE [NE, NE)		0.606 (0.319, 1.148)	0.1208

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	9 (6.7)	NE [NE, NE)	283	18 (6.4)	NE [NE, NE)	0.3886	0.781 (0.350, 1.742)	0.5452
	> 75	18	7 (38.9)	NE [3.2, NE)	25	5 (20.0)	NE [NE, NE)		0.479 (0.152, 1.512)	0.1964
Sex	Male	91	11 (12.1)	NE [NE, NE)	174	13 (7.5)	NE [NE, NE)	0.5078	0.515 (0.230, 1.156)	0.1013
	Female	62	5 (8.1)	NE [NE, NE)	134	10 (7.5)	NE [NE, NE)		0.809 (0.276, 2.368)	0.6983

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	13 (10.7)	NE [NE, NE)	240	20 (8.3)	NE [NE, NE)	0.8200	0.663 (0.329, 1.336)	0.2474
	Asian	20	3 (15.0)	NE [NE, NE)	46	3 (6.5)	NE [NE, NE)		0.393 (0.079, 1.961)	0.2380
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	1 (8.3)	NE [11.5, NE)	21	2 (9.5)	NE [NE, NE)	0.7154	0.926 (0.083, 10.274)	0.9497

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	10 (9.8)	NE [NE, NE)	203	16 (7.9)	NE [NE, NE)		0.687 (0.312, 1.516)	0.3509
	Asia Pacific	39	5 (12.8)	NE [NE, NE)	84	5 (6.0)	NE [NE, NE)		0.400 (0.115, 1.386)	0.1347
Baseline ECOG PS	0-1	146	16 (11.0)	NE [NE, NE)	294	21 (7.1)	NE [NE, NE)	0.9881	0.564 (0.294, 1.083)	0.0815
	2	7	0 (0.0)	NE [NE, NE)	13	2 (15.4)	NE [7.0, NE)		>999.999 (<.001, NE)	0.5186

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	13 (9.6)	NE [NE, NE)	285	20 (7.0)	NE [NE, NE)	0.9943	0.615 (0.305, 1.239)	0.1697
	No	17	3 (17.6)	NE [7.3, NE)	23	3 (13.0)	NE [NE, NE)		0.663 (0.133, 3.305)	0.6133
Refractory to Bortezomib or Ixazomib	Yes	55	5 (9.1)	NE [NE, NE)	99	6 (6.1)	NE [NE, NE)	0.9519	0.577 (0.175, 1.902)	0.3601
	No	98	11 (11.2)	NE [NE, NE)	209	17 (8.1)	NE [NE, NE)		0.611 (0.286, 1.306)	0.1993

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	8 (10.8)	NE [NE, NE)	122	8 (6.6)	NE [NE, NE)	0.6221	0.528 (0.198, 1.409)	0.1951
	No	79	8 (10.1)	NE [NE, NE)	186	15 (8.1)	NE [NE, NE)		0.678 (0.287, 1.602)	0.3725
Refractory to Lenalidomide	Yes	55	5 (9.1)	NE [NE, NE)	98	5 (5.1)	NE [NE, NE)	0.5733	0.500 (0.144, 1.730)	0.2642
	No	98	11 (11.2)	NE [NE, NE)	210	18 (8.6)	NE [NE, NE)		0.661 (0.312, 1.402)	0.2778

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	10 (9.1)	NE [NE, NE)	205	13 (6.3)	NE [NE, NE)	0.9866	0.611 (0.268, 1.395)	0.2379
	No	43	6 (14.0)	NE [NE, NE)	103	10 (9.7)	NE [NE, NE)		0.587 (0.213, 1.620)	0.2983
Refractory to IMiD	Yes	65	5 (7.7)	NE [NE, NE)	129	7 (5.4)	NE [NE, NE)	0.8839	0.619 (0.196, 1.955)	0.4099
	No	88	11 (12.5)	NE [NE, NE)	179	16 (8.9)	NE [NE, NE)		0.620 (0.287, 1.338)	0.2192

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	12 (9.5)	NE [NE, NE)	250	20 (8.0)	NE [NE, NE)	0.1816	0.734 (0.358, 1.504)	0.3966
	3	27	4 (14.8)	NE [NE, NE)	58	3 (5.2)	NE [NE, NE)		0.252 (0.056, 1.139)	0.0536
Prior proteasome inhibitor exposure per IXRS	Yes	138	13 (9.4)	NE [NE, NE)	276	19 (6.9)	NE [NE, NE)	0.8329	0.609 (0.300, 1.237)	0.1662
	No	15	3 (20.0)	NE [3.5, NE)	32	4 (12.5)	NE [NE, NE)		0.551 (0.123, 2.473)	0.4303

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-504-ae-cox-eoi-cfz.rtf (Date Generated: 25MAY2020:20:48) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	9 (13.6)	NE [NE, NE)	131	8 (6.1)	NE [NE, NE)	0.1942	0.367 (0.141, 0.955)	0.0324
	>= 2	87	7 (8.0)	NE [NE, NE)	177	15 (8.5)	NE [NE, NE)		0.900 (0.366, 2.213)	0.8198

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Cardiomyopathy (SMQ) - Narrow										
Total subjects		153	4 (2.6)	NE [NE, NE)	308	4 (1.3)	NE [NE, NE)		0.402 (0.100, 1.611)	0.1831

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	2 (1.5)	NE [NE, NE)	283	4 (1.4)	NE [NE, NE)	0.9922	0.762 (0.139, 4.172)	0.7534
	> 75	18	2 (11.1)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0550
Sex	Male	91	3 (3.3)	NE [NE, NE)	174	4 (2.3)	NE [NE, NE)	0.9944	0.554 (0.124, 2.487)	0.4348
	Female	62	1 (1.6)	NE [NE, NE)	134	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.1080

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	4 (3.3)	NE [NE, NE)	240	2 (0.8)	NE [NE, NE)	1.0000	0.210 (0.038, 1.148)	0.0468
	Asian	20	0 (0.0)	NE [NE, NE)	46	1 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.6115
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	1 (4.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.5465
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	0.9942	NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	2 (2.0)	NE [NE, NE)	203	2 (1.0)	NE [NE, NE)		0.443 (0.062, 3.145)	0.4026
	Asia Pacific	39	2 (5.1)	NE [NE, NE)	84	2 (2.4)	NE [NE, NE)		0.328 (0.046, 2.336)	0.2414
Baseline ECOG PS	0-1	146	4 (2.7)	NE [NE, NE)	294	4 (1.4)	NE [NE, NE)	0.9999	0.416 (0.104, 1.664)	0.2002
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	3 (2.2)	NE [NE, NE)	285	3 (1.1)	NE [NE, NE)	0.8624	0.392 (0.079, 1.949)	0.2354
	No	17	1 (5.9)	NE [NE, NE)	23	1 (4.3)	NE [NE, NE)		0.504 (0.031, 8.101)	0.6220
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	1 (1.0)	NE [NE, NE)	0.9923	>999.999 (<.001, NE)	0.4715
	No	98	4 (4.1)	NE [NE, NE)	209	3 (1.4)	NE [NE, NE)		0.276 (0.062, 1.237)	0.0719

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	2 (2.7)	NE [NE, NE)	122	2 (1.6)	NE [NE, NE)	0.8627	0.475 (0.067, 3.380)	0.4467
	No	79	2 (2.5)	NE [NE, NE)	186	2 (1.1)	NE [NE, NE)		0.363 (0.051, 2.583)	0.2911
Refractory to Lenalidomide	Yes	55	2 (3.6)	NE [NE, NE)	98	1 (1.0)	NE [NE, NE)	0.4925	0.238 (0.022, 2.628)	0.2027
	No	98	2 (2.0)	NE [NE, NE)	210	3 (1.4)	NE [NE, NE)		0.583 (0.097, 3.495)	0.5505

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	2 (1.8)	NE [NE, NE)	205	4 (2.0)	NE [NE, NE)	0.9918	0.863 (0.158, 4.714)	0.8644
	No	43	2 (4.7)	NE [NE, NE)	103	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0186
Refractory to IMiD	Yes	65	2 (3.1)	NE [NE, NE)	129	1 (0.8)	NE [NE, NE)	0.4268	0.210 (0.019, 2.316)	0.1592
	No	88	2 (2.3)	NE [NE, NE)	179	3 (1.7)	NE [NE, NE)		0.619 (0.103, 3.709)	0.5964

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	4 (3.2)	NE [NE, NE)	250	3 (1.2)	NE [NE, NE)	0.9948	0.317 (0.071, 1.419)	0.1128
	3	27	0 (0.0)	NE [NE, NE)	58	1 (1.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.5590
Prior proteasome inhibitor exposure per IXRS	Yes	138	3 (2.2)	NE [NE, NE)	276	2 (0.7)	NE [NE, NE)	0.5493	0.267 (0.045, 1.606)	0.1217
	No	15	1 (6.7)	NE [3.5, NE)	32	2 (6.3)	NE [NE, NE)		0.684 (0.062, 7.541)	0.7550

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	1 (1.5)	NE [NE, NE)	131	2 (1.5)	NE [NE, NE)	0.4722	0.819 (0.074, 9.081)	0.8706
	>= 2	87	3 (3.4)	NE [NE, NE)	177	2 (1.1)	NE [NE, NE)		0.264 (0.044, 1.584)	0.1173

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Dyspnoeas (HLT)										
Total subjects		153	37 (24.2)	NE [NE, NE)	308	69 (22.4)	NE [NE, NE)		0.844 (0.565, 1.259)	0.4027

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	30 (22.2)	NE [NE, NE)	283	65 (23.0)	NE [NE, NE)	0.1114	0.953 (0.618, 1.470)	0.8270
	> 75	18	7 (38.9)	NE [2.3, NE)	25	4 (16.0)	NE [NE, NE)		0.313 (0.091, 1.075)	0.0515
Sex	Male	91	24 (26.4)	NE [NE, NE)	174	38 (21.8)	NE [NE, NE)	0.5246	0.762 (0.456, 1.272)	0.2948
	Female	62	13 (21.0)	NE [NE, NE)	134	31 (23.1)	NE [NE, NE)		1.006 (0.526, 1.924)	0.9834

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	29 (23.8)	NE [NE, NE)	240	52 (21.7)	NE [NE, NE)	0.9707	0.826 (0.524, 1.302)	0.4069
	Asian	20	4 (20.0)	NE [11.0, NE)	46	9 (19.6)	NE [NE, NE)		0.904 (0.278, 2.938)	0.8718
	Other or Unknown	11	4 (36.4)	14.3 [0.9, NE)	22	8 (36.4)	NE [1.8, NE)		0.926 (0.278, 3.082)	0.9005
Region	North America	12	6 (50.0)	10.8 [0.5, NE)	21	12 (57.1)	7.9 [1.8, NE)	0.6196	1.032 (0.387, 2.757)	0.9601

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-504-ae-cox-eoi-cfz.rtf (Date Generated: 25MAY2020:20:48) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	16 (15.7)	NE [NE, NE)	203	33 (16.3)	NE [NE, NE)		0.954 (0.525, 1.736)	0.8769
	Asia Pacific	39	15 (38.5)	NE [6.4, NE)	84	24 (28.6)	NE [NE, NE)		0.654 (0.343, 1.249)	0.1948
Baseline ECOG PS	0-1	146	35 (24.0)	NE [NE, NE)	294	65 (22.1)	NE [NE, NE)	0.4235	0.858 (0.569, 1.295)	0.4643
	2	7	2 (28.6)	NE [0.0, NE)	13	3 (23.1)	NE [1.3, NE)		0.442 (0.062, 3.153)	0.4205

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	35 (25.7)	NE [NE, NE)	285	64 (22.5)	NE [NE, NE)	0.3905	0.797 (0.528, 1.204)	0.2790
	No	17	2 (11.8)	NE [5.1, NE)	23	5 (21.7)	NE [13.8, NE)		1.448 (0.280, 7.493)	0.6573
Refractory to Bortezomib or Ixazomib	Yes	55	6 (10.9)	NE [NE, NE)	99	17 (17.2)	NE [NE, NE)	0.1450	1.459 (0.575, 3.703)	0.4232
	No	98	31 (31.6)	NE [15.8, NE)	209	52 (24.9)	NE [NE, NE)		0.699 (0.447, 1.091)	0.1116

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	17 (23.0)	NE [NE, NE)	122	29 (23.8)	NE [NE, NE)	0.6147	0.951 (0.522, 1.733)	0.8707
	No	79	20 (25.3)	NE [NE, NE)	186	40 (21.5)	NE [NE, NE)		0.773 (0.452, 1.324)	0.3461
Refractory to Lenalidomide	Yes	55	12 (21.8)	NE [14.3, NE)	98	23 (23.5)	NE [NE, NE)	0.6847	0.935 (0.464, 1.884)	0.8502
	No	98	25 (25.5)	NE [NE, NE)	210	46 (21.9)	NE [NE, NE)		0.797 (0.490, 1.298)	0.3597

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	27 (24.5)	NE [NE, NE)	205	53 (25.9)	NE [NE, NE)	0.3653	0.951 (0.598, 1.512)	0.8308
	No	43	10 (23.3)	NE [NE, NE)	103	16 (15.5)	NE [NE, NE)		0.635 (0.287, 1.401)	0.2550
Refractory to IMiD	Yes	65	14 (21.5)	NE [14.3, NE)	129	34 (26.4)	NE [NE, NE)	0.2575	1.090 (0.584, 2.034)	0.7866
	No	88	23 (26.1)	NE [NE, NE)	179	35 (19.6)	NE [NE, NE)		0.691 (0.408, 1.170)	0.1657

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CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	33 (26.2)	NE [NE, NE)	250	59 (23.6)	NE [NE, NE)	0.9031	0.842 (0.549, 1.290)	0.4254
	3	27	4 (14.8)	NE [NE, NE)	58	10 (17.2)	NE [NE, NE)		0.910 (0.283, 2.920)	0.8774
Prior proteasome inhibitor exposure per IXRS	Yes	138	35 (25.4)	NE [NE, NE)	276	60 (21.7)	NE [NE, NE)	0.2274	0.777 (0.512, 1.179)	0.2333
	No	15	2 (13.3)	NE [3.3, NE)	32	9 (28.1)	NE [13.8, NE)		1.989 (0.429, 9.218)	0.3729

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	16 (24.2)	NE [NE, NE)	131	34 (26.0)	NE [NE, NE)	0.4919	0.984 (0.542, 1.784)	0.9554
	>= 2	87	21 (24.1)	NE [NE, NE)	177	35 (19.8)	NE [NE, NE)		0.742 (0.431, 1.276)	0.2788

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Embolic and thrombotic events, venous (SMQ) - Narrow										
Total subjects		153	17 (11.1)	NE [NE, NE)	308	19 (6.2)	NE [NE, NE)		0.442 (0.229, 0.852)	0.0123

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	16 (11.9)	NE [NE, NE)	283	16 (5.7)	NE [NE, NE)	0.2129	0.382 (0.191, 0.766)	0.0049
	> 75	18	1 (5.6)	NE [NE, NE)	25	3 (12.0)	NE [NE, NE)		1.830 (0.190, 17.630)	0.5956
Sex	Male	91	10 (11.0)	NE [NE, NE)	174	13 (7.5)	NE [NE, NE)	0.4070	0.568 (0.249, 1.298)	0.1747
	Female	62	7 (11.3)	NE [NE, NE)	134	6 (4.5)	NE [NE, NE)		0.309 (0.104, 0.924)	0.0262

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	16 (13.1)	NE [NE, NE)	240	17 (7.1)	NE [NE, NE)	0.9999	0.429 (0.216, 0.851)	0.0127
	Asian	20	1 (5.0)	NE [NE, NE)	46	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.1117
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	2 (9.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.4038
Region	North America	12	2 (16.7)	NE [3.8, NE)	21	1 (4.8)	NE [19.6, NE)	0.6379	<.001 (<.001, NE)	0.0469

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	10 (9.8)	NE [NE, NE)	203	13 (6.4)	NE [NE, NE)		0.532 (0.233, 1.215)	0.1280
	Asia Pacific	39	5 (12.8)	NE [NE, NE)	84	5 (6.0)	NE [NE, NE)		0.371 (0.107, 1.290)	0.1047
Baseline ECOG PS	0-1	146	17 (11.6)	NE [NE, NE)	294	18 (6.1)	NE [NE, NE)	0.9901	0.431 (0.222, 0.838)	0.0107
	2	7	0 (0.0)	NE [NE, NE)	13	1 (7.7)	NE [6.2, NE)		>999.999 (<.001, NE)	0.7389

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	15 (11.0)	NE [NE, NE)	285	18 (6.3)	NE [NE, NE)	0.6329	0.461 (0.232, 0.918)	0.0240
	No	17	2 (11.8)	NE [NE, NE)	23	1 (4.3)	NE [NE, NE)		0.241 (0.021, 2.765)	0.2177
Refractory to Bortezomib or Ixazomib	Yes	55	5 (9.1)	NE [NE, NE)	99	2 (2.0)	NE [NE, NE)	0.2504	0.177 (0.034, 0.915)	0.0198
	No	98	12 (12.2)	NE [NE, NE)	209	17 (8.1)	NE [NE, NE)		0.531 (0.253, 1.115)	0.0896

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Output: t14-06-001-504-ae-cox-eoi-cfz.rtf (Date Generated: 25MAY2020:20:48) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	6 (8.1)	NE [NE, NE)	122	7 (5.7)	NE [NE, NE)	0.5929	0.520 (0.173, 1.561)	0.2357
	No	79	11 (13.9)	NE [NE, NE)	186	12 (6.5)	NE [NE, NE)		0.391 (0.172, 0.888)	0.0200
Refractory to Lenalidomide	Yes	55	4 (7.3)	NE [NE, NE)	98	5 (5.1)	NE [NE, NE)	0.7906	0.469 (0.121, 1.816)	0.2627
	No	98	13 (13.3)	NE [NE, NE)	210	14 (6.7)	NE [NE, NE)		0.423 (0.199, 0.901)	0.0215

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	11 (10.0)	NE [NE, NE)	205	12 (5.9)	NE [NE, NE)	0.8723	0.447 (0.196, 1.019)	0.0493
	No	43	6 (14.0)	NE [NE, NE)	103	7 (6.8)	NE [NE, NE)		0.413 (0.138, 1.234)	0.1023
Refractory to IMiD	Yes	65	5 (7.7)	NE [NE, NE)	129	7 (5.4)	NE [NE, NE)	0.7138	0.476 (0.148, 1.537)	0.2047
	No	88	12 (13.6)	NE [NE, NE)	179	12 (6.7)	NE [NE, NE)		0.418 (0.188, 0.932)	0.0277

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	15 (11.9)	NE [NE, NE)	250	17 (6.8)	NE [NE, NE)	0.6542	0.478 (0.238, 0.960)	0.0341
	3	27	2 (7.4)	NE [NE, NE)	58	2 (3.4)	NE [NE, NE)		0.231 (0.032, 1.674)	0.1148
Prior proteasome inhibitor exposure per IXRS	Yes	138	15 (10.9)	NE [NE, NE)	276	18 (6.5)	NE [NE, NE)	0.3643	0.482 (0.243, 0.960)	0.0339
	No	15	2 (13.3)	NE [3.9, NE)	32	1 (3.1)	NE [NE, NE)		0.177 (0.016, 1.970)	0.1127

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	10 (15.2)	NE [NE, NE)	131	9 (6.9)	NE [NE, NE)	0.5015	0.364 (0.147, 0.899)	0.0225
	>= 2	87	7 (8.0)	NE [NE, NE)	177	10 (5.6)	NE [NE, NE)		0.565 (0.215, 1.486)	0.2410

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Haematopoietic erythropenia (SMQ) - Broad										
Total subjects		153	50 (32.7)	NE [17.5, NE)	308	102 (33.1)	NE [NE, NE)		1.005 (0.717, 1.411)	0.9819

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	42 (31.1)	NE [17.5, NE)	283	93 (32.9)	NE [NE, NE)	0.4533	1.066 (0.740, 1.534)	0.7401
	> 75	18	8 (44.4)	11.9 [1.2, NE)	25	9 (36.0)	NE [2.8, NE)		0.699 (0.269, 1.814)	0.4628
Sex	Male	91	30 (33.0)	NE [17.3, NE)	174	49 (28.2)	NE [NE, NE)	0.1980	0.812 (0.515, 1.279)	0.3641
	Female	62	20 (32.3)	NE [10.2, NE)	134	53 (39.6)	NE [16.6, NE)		1.288 (0.770, 2.154)	0.3378

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	39 (32.0)	NE [17.5, NE)	240	74 (30.8)	NE [NE, NE)	0.3041	0.961 (0.652, 1.417)	0.8344
	Asian	20	7 (35.0)	NE [2.3, NE)	46	23 (50.0)	15.3 [1.7, NE)		1.586 (0.680, 3.701)	0.2804
	Other or Unknown	11	4 (36.4)	NE [0.8, NE)	22	5 (22.7)	NE [NE, NE)		0.444 (0.118, 1.666)	0.2165
Region	North America	12	6 (50.0)	8.3 [1.4, NE)	21	7 (33.3)	NE [3.7, NE)	0.5702	0.562 (0.188, 1.676)	0.2945

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	30 (29.4)	NE [17.5, NE)	203	61 (30.0)	NE [NE, NE)		1.016 (0.656, 1.573)	0.9554
	Asia Pacific	39	14 (35.9)	NE [11.9, NE)	84	34 (40.5)	NE [9.3, NE)		1.163 (0.624, 2.169)	0.6351
Baseline ECOG PS	0-1	146	47 (32.2)	NE [17.5, NE)	294	97 (33.0)	NE [NE, NE)	0.3305	1.035 (0.731, 1.467)	0.8499
	2	7	3 (42.9)	NE [0.3, NE)	13	5 (38.5)	NE [0.5, NE)		0.617 (0.136, 2.793)	0.5274

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	42 (30.9)	NE [NE, NE)	285	98 (34.4)	NE [NE, NE)	0.0523	1.118 (0.779, 1.605)	0.5496
	No	17	8 (47.1)	17.3 [1.4, NE)	23	4 (17.4)	NE [NE, NE)		0.319 (0.096, 1.066)	0.0505
Refractory to Bortezomib or Ixazomib	Yes	55	18 (32.7)	NE [11.6, NE)	99	37 (37.4)	NE [16.6, NE)	0.4409	1.204 (0.685, 2.115)	0.5233
	No	98	32 (32.7)	NE [17.3, NE)	209	65 (31.1)	NE [NE, NE)		0.915 (0.599, 1.397)	0.6753

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	31 (41.9)	NE [4.6, NE)	122	54 (44.3)	NE [6.7, NE)	0.9823	1.072 (0.689, 1.669)	0.7644
	No	79	19 (24.1)	NE [17.5, NE)	186	48 (25.8)	NE [NE, NE)		1.068 (0.627, 1.817)	0.8124
Refractory to Lenalidomide	Yes	55	22 (40.0)	NE [3.7, NE)	98	43 (43.9)	NE [3.9, NE)	0.6467	1.119 (0.668, 1.873)	0.6750
	No	98	28 (28.6)	NE [17.5, NE)	210	59 (28.1)	NE [NE, NE)		0.967 (0.616, 1.516)	0.8822

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	38 (34.5)	NE [17.3, NE)	205	75 (36.6)	NE [NE, NE)	0.6762	1.073 (0.726, 1.586)	0.7297
	No	43	12 (27.9)	NE [17.5, NE)	103	27 (26.2)	NE [NE, NE)		0.907 (0.459, 1.791)	0.7719
Refractory to IMiD	Yes	65	24 (36.9)	NE [4.7, NE)	129	53 (41.1)	NE [11.5, NE)	0.4641	1.150 (0.709, 1.865)	0.5759
	No	88	26 (29.5)	NE [17.5, NE)	179	49 (27.4)	NE [NE, NE)		0.895 (0.556, 1.441)	0.6472

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	37 (29.4)	NE [17.5, NE)	250	79 (31.6)	NE [NE, NE)	0.1182	1.111 (0.751, 1.642)	0.6002
	3	27	13 (48.1)	2.1 [0.7, NE)	58	23 (39.7)	NE [4.2, NE)		0.654 (0.330, 1.293)	0.2128
Prior proteasome inhibitor exposure per IXRS	Yes	138	43 (31.2)	NE [NE, NE)	276	97 (35.1)	NE [NE, NE)	0.0257	1.139 (0.795, 1.632)	0.4818
	No	15	7 (46.7)	17.3 [1.4, NE)	32	5 (15.6)	NE [NE, NE)		0.292 (0.092, 0.924)	0.0260

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-504-ae-cox-eoi-cfz.rtf (Date Generated: 25MAY2020:20:48) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	18 (27.3)	NE [17.3, NE)	131	41 (31.3)	NE [NE, NE)	0.4791	1.179 (0.677, 2.052)	0.5628
	>= 2	87	32 (36.8)	NE [10.2, NE)	177	61 (34.5)	NE [NE, NE)		0.911 (0.593, 1.398)	0.6633

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Haematopoietic leukopenia (SMQ) - Narrow										
Total subjects		153	26 (17.0)	NE [NE, NE)	308	71 (23.1)	NE [NE, NE)		1.314 (0.838, 2.061)	0.2333

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	20 (14.8)	NE [NE, NE)	283	65 (23.0)	NE [NE, NE)	0.1811	1.524 (0.923, 2.518)	0.0973
	> 75	18	6 (33.3)	NE [6.5, NE)	25	6 (24.0)	NE [16.6, NE)		0.583 (0.184, 1.845)	0.3490
Sex	Male	91	15 (16.5)	NE [NE, NE)	174	36 (20.7)	NE [NE, NE)	0.6200	1.178 (0.644, 2.156)	0.5936
	Female	62	11 (17.7)	NE [NE, NE)	134	35 (26.1)	NE [NE, NE)		1.489 (0.756, 2.934)	0.2484

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	15 (12.3)	NE [NE, NE)	240	43 (17.9)	NE [NE, NE)	0.8918	1.394 (0.774, 2.512)	0.2664
	Asian	20	10 (50.0)	6.9 [0.3, NE)	46	25 (54.3)	6.4 [0.5, NE)		1.101 (0.529, 2.296)	0.8082
	Other or Unknown	11	1 (9.1)	NE [12.1, NE)	22	3 (13.6)	NE [16.8, NE)		1.386 (0.144, 13.329)	0.7767
Region	North America	12	0 (0.0)	NE [NE, NE)	21	1 (4.8)	NE [NE, NE)	0.9181	>999.999 (<.001, NE)	0.4497

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	14 (13.7)	NE [NE, NE)	203	40 (19.7)	NE [NE, NE)		1.365 (0.742, 2.510)	0.3150
	Asia Pacific	39	12 (30.8)	NE [6.9, NE)	84	30 (35.7)	NE [NE, NE)		1.167 (0.597, 2.282)	0.6555
Baseline ECOG PS	0-1	146	25 (17.1)	NE [NE, NE)	294	66 (22.4)	NE [NE, NE)	0.6829	1.279 (0.807, 2.029)	0.2946
	2	7	1 (14.3)	NE [0.3, NE)	13	5 (38.5)	NE [1.0, NE)		2.199 (0.256, 18.876)	0.4648

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	23 (16.9)	NE [NE, NE)	285	67 (23.5)	NE [NE, NE)	0.6094	1.350 (0.840, 2.170)	0.2137
	No	17	3 (17.6)	NE [NE, NE)	23	4 (17.4)	NE [NE, NE)		0.844 (0.187, 3.813)	0.8257
Refractory to Bortezomib or Ixazomib	Yes	55	10 (18.2)	NE [NE, NE)	99	25 (25.3)	NE [NE, NE)	0.9655	1.330 (0.638, 2.770)	0.4470
	No	98	16 (16.3)	NE [NE, NE)	209	46 (22.0)	NE [NE, NE)		1.330 (0.752, 2.352)	0.3252

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	12 (16.2)	NE [NE, NE)	122	36 (29.5)	NE [NE, NE)	0.1878	1.857 (0.965, 3.572)	0.0596
	No	79	14 (17.7)	NE [NE, NE)	186	35 (18.8)	NE [NE, NE)		0.993 (0.534, 1.847)	0.9821
Refractory to Lenalidomide	Yes	55	10 (18.2)	NE [NE, NE)	98	28 (28.6)	NE [NE, NE)	0.6321	1.552 (0.752, 3.201)	0.2299
	No	98	16 (16.3)	NE [NE, NE)	210	43 (20.5)	NE [NE, NE)		1.217 (0.685, 2.162)	0.5020

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	18 (16.4)	NE [NE, NE)	205	50 (24.4)	NE [NE, NE)	0.5369	1.457 (0.850, 2.500)	0.1692
	No	43	8 (18.6)	NE [NE, NE)	103	21 (20.4)	NE [NE, NE)		1.037 (0.458, 2.346)	0.9340
Refractory to IMiD	Yes	65	12 (18.5)	NE [NE, NE)	129	34 (26.4)	NE [NE, NE)	0.8776	1.390 (0.719, 2.688)	0.3257
	No	88	14 (15.9)	NE [NE, NE)	179	37 (20.7)	NE [NE, NE)		1.266 (0.684, 2.344)	0.4525

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	23 (18.3)	NE [NE, NE)	250	57 (22.8)	NE [NE, NE)	0.5191	1.228 (0.756, 1.995)	0.4072
	3	27	3 (11.1)	NE [NE, NE)	58	14 (24.1)	NE [NE, NE)		1.905 (0.546, 6.644)	0.3028
Prior proteasome inhibitor exposure per IXRS	Yes	138	24 (17.4)	NE [NE, NE)	276	66 (23.9)	NE [NE, NE)	0.8542	1.330 (0.833, 2.124)	0.2309
	No	15	2 (13.3)	NE [NE, NE)	32	5 (15.6)	NE [NE, NE)		1.083 (0.208, 5.629)	0.9285

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	11 (16.7)	NE [NE, NE)	131	29 (22.1)	NE [NE, NE)	0.9018	1.281 (0.639, 2.566)	0.4858
	>= 2	87	15 (17.2)	NE [NE, NE)	177	42 (23.7)	NE [NE, NE)		1.336 (0.740, 2.412)	0.3364

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Haematopoietic thrombocytopenia (SMQ) - Narrow										
Total subjects		153	46 (30.1)	NE [NE, NE)	308	115 (37.3)	NE [NE, NE)		1.325 (0.941, 1.865)	0.1090

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	41 (30.4)	NE [NE, NE)	283	109 (38.5)	NE [NE, NE)	0.5166	1.356 (0.947, 1.943)	0.0975
	> 75	18	5 (27.8)	NE [6.2, NE)	25	6 (24.0)	NE [NE, NE)		0.870 (0.265, 2.855)	0.8189
Sex	Male	91	28 (30.8)	NE [NE, NE)	174	64 (36.8)	NE [NE, NE)	0.8768	1.302 (0.835, 2.032)	0.2515
	Female	62	18 (29.0)	NE [14.3, NE)	134	51 (38.1)	NE [19.5, NE)		1.352 (0.789, 2.315)	0.2708

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	29 (23.8)	NE [NE, NE)	240	81 (33.8)	NE [NE, NE)	0.2947	1.556 (1.018, 2.379)	0.0400
	Asian	20	12 (60.0)	9.5 [0.4, NE)	46	27 (58.7)	1.9 [0.5, NE)		1.057 (0.535, 2.090)	0.8853
	Other or Unknown	11	5 (45.5)	15.2 [0.5, NE)	22	7 (31.8)	NE [1.4, NE)		0.621 (0.196, 1.962)	0.4025
Region	North America	12	4 (33.3)	NE [1.2, NE)	21	11 (52.4)	0.7 [0.5, NE)	0.6181	2.071 (0.657, 6.533)	0.2205

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	26 (25.5)	NE [NE, NE)	203	68 (33.5)	NE [19.5, NE)		1.375 (0.875, 2.161)	0.1670
	Asia Pacific	39	16 (41.0)	NE [1.5, NE)	84	36 (42.9)	NE [3.0, NE)		1.118 (0.620, 2.015)	0.7254
Baseline ECOG PS	0-1	146	44 (30.1)	NE [NE, NE)	294	107 (36.4)	NE [NE, NE)	0.5202	1.302 (0.916, 1.850)	0.1428
	2	7	2 (28.6)	NE [0.2, NE)	13	8 (61.5)	11.3 [0.4, NE)		1.901 (0.383, 9.450)	0.4270

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	42 (30.9)	NE [NE, NE)	285	113 (39.6)	NE [19.5, NE)	0.1238	1.379 (0.967, 1.966)	0.0757
	No	17	4 (23.5)	NE [9.5, NE)	23	2 (8.7)	NE [NE, NE)		0.300 (0.054, 1.656)	0.1435
Refractory to Bortezomib or Ixazomib	Yes	55	20 (36.4)	NE [10.9, NE)	99	36 (36.4)	NE [NE, NE)	0.3068	1.059 (0.613, 1.831)	0.8452
	No	98	26 (26.5)	NE [NE, NE)	209	79 (37.8)	NE [NE, NE)		1.536 (0.986, 2.394)	0.0565

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	26 (35.1)	NE [15.2, NE)	122	59 (48.4)	19.5 [0.8, NE)	0.5505	1.523 (0.959, 2.417)	0.0760
	No	79	20 (25.3)	NE [NE, NE)	186	56 (30.1)	NE [NE, NE)		1.264 (0.758, 2.106)	0.3706
Refractory to Lenalidomide	Yes	55	19 (34.5)	NE [9.5, NE)	98	45 (45.9)	NE [0.8, NE)	0.6582	1.467 (0.858, 2.511)	0.1628
	No	98	27 (27.6)	NE [NE, NE)	210	70 (33.3)	NE [NE, NE)		1.276 (0.818, 1.990)	0.2837

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	35 (31.8)	NE [NE, NE)	205	81 (39.5)	NE [19.5, NE)	0.9318	1.323 (0.890, 1.969)	0.1706
	No	43	11 (25.6)	NE [NE, NE)	103	34 (33.0)	NE [NE, NE)		1.397 (0.707, 2.758)	0.3369
Refractory to IMiD	Yes	65	23 (35.4)	NE [9.5, NE)	129	55 (42.6)	NE [2.2, NE)	0.9228	1.303 (0.800, 2.121)	0.2917
	No	88	23 (26.1)	NE [NE, NE)	179	60 (33.5)	NE [NE, NE)		1.359 (0.840, 2.199)	0.2114

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	33 (26.2)	NE [NE, NE)	250	84 (33.6)	NE [NE, NE)	0.5871	1.382 (0.923, 2.067)	0.1163
	3	27	13 (48.1)	1.4 [0.5, NE)	58	31 (53.4)	2.2 [0.5, NE)		1.136 (0.594, 2.174)	0.7078
Prior proteasome inhibitor exposure per IXRS	Yes	138	42 (30.4)	NE [NE, NE)	276	110 (39.9)	NE [19.5, NE)	0.2173	1.413 (0.990, 2.017)	0.0567
	No	15	4 (26.7)	NE [9.5, NE)	32	5 (15.6)	NE [NE, NE)		0.517 (0.137, 1.948)	0.3214

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	15 (22.7)	NE [NE, NE)	131	46 (35.1)	NE [NE, NE)	0.2876	1.694 (0.945, 3.035)	0.0741
	>= 2	87	31 (35.6)	NE [13.3, NE)	177	69 (39.0)	NE [19.5, NE)		1.144 (0.748, 1.749)	0.5433

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Haemorrhage terms (excl laboratory terms) (SMQ) - Narrow										
Total subjects		153	18 (11.8)	NE [NE, NE)	308	44 (14.3)	NE [NE, NE)		1.068 (0.616, 1.850)	0.8154

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	14 (10.4)	NE [NE, NE)	283	38 (13.4)	NE [NE, NE)	0.7913	1.156 (0.625, 2.135)	0.6442
	> 75	18	4 (22.2)	NE [7.8, NE)	25	6 (24.0)	NE [11.7, NE)		0.867 (0.241, 3.118)	0.8265
Sex	Male	91	5 (5.5)	NE [NE, NE)	174	23 (13.2)	NE [NE, NE)	0.0499	2.145 (0.814, 5.651)	0.1137
	Female	62	13 (21.0)	NE [NE, NE)	134	21 (15.7)	NE [NE, NE)		0.643 (0.322, 1.287)	0.2091

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	12 (9.8)	NE [NE, NE)	240	35 (14.6)	NE [NE, NE)	0.1356	1.325 (0.687, 2.555)	0.3997
	Asian	20	3 (15.0)	NE [NE, NE)	46	8 (17.4)	NE [NE, NE)		1.054 (0.279, 3.985)	0.9385
	Other or Unknown	11	3 (27.3)	NE [7.2, NE)	22	1 (4.5)	NE [NE, NE)		0.113 (0.012, 1.100)	0.0240
Region	North America	12	4 (33.3)	14.7 [6.9, 14.7)	21	7 (33.3)	NE [11.7, NE)	0.8432	0.658 (0.187, 2.320)	0.5127

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	8 (7.8)	NE [NE, NE)	203	21 (10.3)	NE [NE, NE)		1.164 (0.515, 2.631)	0.7149
	Asia Pacific	39	6 (15.4)	NE [NE, NE)	84	16 (19.0)	NE [NE, NE)		1.134 (0.443, 2.902)	0.7936
Baseline ECOG PS	0-1	146	18 (12.3)	NE [NE, NE)	294	41 (13.9)	NE [NE, NE)	0.9844	1.015 (0.583, 1.769)	0.9575
	2	7	0 (0.0)	NE [NE, NE)	13	3 (23.1)	NE [8.2, NE)		>999.999 (<.001, NE)	0.4631

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	16 (11.8)	NE [NE, NE)	285	39 (13.7)	NE [NE, NE)	0.5403	1.009 (0.563, 1.809)	0.9752
	No	17	2 (11.8)	NE [NE, NE)	23	5 (21.7)	NE [15.1, NE)		1.813 (0.349, 9.410)	0.4724
Refractory to Bortezomib or Ixazomib	Yes	55	3 (5.5)	NE [NE, NE)	99	17 (17.2)	NE [NE, NE)	0.0426	3.116 (0.913, 10.639)	0.0558
	No	98	15 (15.3)	NE [NE, NE)	209	27 (12.9)	NE [NE, NE)		0.699 (0.371, 1.316)	0.2650

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-504-ae-cox-eoi-cfz.rtf (Date Generated: 25MAY2020:20:48) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	12 (16.2)	NE [NE, NE)	122	16 (13.1)	NE [NE, NE)	0.0872	0.682 (0.322, 1.447)	0.3158
	No	79	6 (7.6)	NE [NE, NE)	186	28 (15.1)	NE [NE, NE)		1.823 (0.754, 4.406)	0.1757
Refractory to Lenalidomide	Yes	55	8 (14.5)	NE [NE, NE)	98	15 (15.3)	NE [NE, NE)	0.4719	0.852 (0.358, 2.023)	0.7158
	No	98	10 (10.2)	NE [NE, NE)	210	29 (13.8)	NE [NE, NE)		1.251 (0.609, 2.568)	0.5414

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	15 (13.6)	NE [NE, NE)	205	28 (13.7)	NE [NE, NE)	0.2292	0.886 (0.473, 1.662)	0.7057
	No	43	3 (7.0)	NE [NE, NE)	103	16 (15.5)	NE [NE, NE)		1.982 (0.577, 6.809)	0.2679
Refractory to IMiD	Yes	65	8 (12.3)	NE [NE, NE)	129	18 (14.0)	NE [NE, NE)	0.6798	0.936 (0.405, 2.164)	0.8771
	No	88	10 (11.4)	NE [NE, NE)	179	26 (14.5)	NE [NE, NE)		1.172 (0.565, 2.432)	0.6690

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	17 (13.5)	NE [NE, NE)	250	34 (13.6)	NE [NE, NE)	0.2083	0.900 (0.502, 1.614)	0.7237
	3	27	1 (3.7)	NE [NE, NE)	58	10 (17.2)	NE [NE, NE)		3.450 (0.439, 27.081)	0.2100
Prior proteasome inhibitor exposure per IXRS	Yes	138	16 (11.6)	NE [NE, NE)	276	39 (14.1)	NE [NE, NE)	0.9884	1.062 (0.593, 1.903)	0.8397
	No	15	2 (13.3)	NE [NE, NE)	32	5 (15.6)	NE [NE, NE)		1.126 (0.218, 5.817)	0.8869

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	8 (12.1)	NE [NE, NE)	131	19 (14.5)	NE [NE, NE)	0.9539	1.035 (0.452, 2.369)	0.9337
	>= 2	87	10 (11.5)	NE [NE, NE)	177	25 (14.1)	NE [NE, NE)		1.110 (0.532, 2.314)	0.7812

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Hepatic failure, fibrosis and cirrhosis and other liver damage-related conditions (SMQ) - Narrow										
Total subjects		153	6 (3.9)	NE [NE, NE)	308	6 (1.9)	NE [NE, NE)		0.459 (0.148, 1.423)	0.1666

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	5 (3.7)	NE [NE, NE)	283	5 (1.8)	NE [NE, NE)	0.7878	0.434 (0.126, 1.501)	0.1748
	> 75	18	1 (5.6)	NE [NE, NE)	25	1 (4.0)	NE [NE, NE)		0.735 (0.046, 11.750)	0.8269
Sex	Male	91	6 (6.6)	NE [NE, NE)	174	2 (1.1)	NE [NE, NE)	0.9927	0.163 (0.033, 0.806)	0.0110
	Female	62	0 (0.0)	NE [NE, NE)	134	4 (3.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.1928

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	3 (2.5)	NE [NE, NE)	240	4 (1.7)	NE [NE, NE)	0.9367	0.604 (0.135, 2.703)	0.5054
	Asian	20	2 (10.0)	NE [NE, NE)	46	2 (4.3)	NE [NE, NE)		0.421 (0.059, 2.991)	0.3728
	Other or Unknown	11	1 (9.1)	NE [2.1, NE)	22	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0973
Region	North America	12	1 (8.3)	NE [6.0, NE)	21	0 (0.0)	NE [NE, NE)	0.9590	<.001 (<.001, NE)	0.1573

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	3 (2.9)	NE [NE, NE)	203	4 (2.0)	NE [NE, NE)		0.597 (0.133, 2.671)	0.4951
	Asia Pacific	39	2 (5.1)	NE [NE, NE)	84	2 (2.4)	NE [NE, NE)		0.460 (0.065, 3.266)	0.4260
Baseline ECOG PS	0-1	146	6 (4.1)	NE [NE, NE)	294	5 (1.7)	NE [NE, NE)	0.9917	0.390 (0.119, 1.278)	0.1067
	2	7	0 (0.0)	NE [NE, NE)	13	1 (7.7)	NE [5.5, NE)		>999.999 (<.001, NE)	0.7518

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CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	5 (3.7)	NE [NE, NE)	285	6 (2.1)	NE [NE, NE)	0.9922	0.530 (0.161, 1.737)	0.2862
	No	17	1 (5.9)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.2448
Refractory to Bortezomib or Ixazomib	Yes	55	3 (5.5)	NE [NE, NE)	99	3 (3.0)	NE [NE, NE)	0.8477	0.550 (0.111, 2.724)	0.4569
	No	98	3 (3.1)	NE [NE, NE)	209	3 (1.4)	NE [NE, NE)		0.428 (0.086, 2.123)	0.2844

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	4 (5.4)	NE [NE, NE)	122	3 (2.5)	NE [NE, NE)	0.7666	0.420 (0.094, 1.881)	0.2421
	No	79	2 (2.5)	NE [NE, NE)	186	3 (1.6)	NE [NE, NE)		0.588 (0.098, 3.523)	0.5566
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	2 (2.0)	NE [NE, NE)	0.9932	>999.999 (<.001, NE)	0.3232
	No	98	6 (6.1)	NE [NE, NE)	210	4 (1.9)	NE [NE, NE)		0.290 (0.082, 1.028)	0.0411

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	5 (4.5)	NE [NE, NE)	205	5 (2.4)	NE [NE, NE)	0.8835	0.499 (0.144, 1.727)	0.2631
	No	43	1 (2.3)	NE [NE, NE)	103	1 (1.0)	NE [NE, NE)		0.399 (0.025, 6.385)	0.5012
Refractory to IMiD	Yes	65	1 (1.5)	NE [NE, NE)	129	4 (3.1)	NE [NE, NE)	0.0935	1.895 (0.211, 16.990)	0.5614
	No	88	5 (5.7)	NE [NE, NE)	179	2 (1.1)	NE [NE, NE)		0.180 (0.035, 0.929)	0.0210

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	3 (2.4)	NE [NE, NE)	250	6 (2.4)	NE [NE, NE)	0.9899	0.947 (0.237, 3.790)	0.9400
	3	27	3 (11.1)	NE [NE, NE)	58	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0088
Prior proteasome inhibitor exposure per IXRS	Yes	138	5 (3.6)	NE [NE, NE)	276	6 (2.2)	NE [NE, NE)	0.9909	0.557 (0.170, 1.827)	0.3277
	No	15	1 (6.7)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.1441

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
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[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Output: t14-06-001-504-ae-cox-eoi-cfz.rtf (Date Generated: 25MAY2020:20:48) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	2 (3.0)	NE [NE, NE)	131	1 (0.8)	NE [NE, NE)	0.5365	0.238 (0.022, 2.627)	0.2025
	>= 2	87	4 (4.6)	NE [NE, NE)	177	5 (2.8)	NE [NE, NE)		0.560 (0.150, 2.091)	0.3824

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-504-ae-cox-eoi-cfz.rtf (Date Generated: 25MAY2020:20:48) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Hepatitis B reactivation (AMQ)										
Total subjects		153	0 (0.0)	NE [NE, NE)	308	1 (0.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.5141

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-504-ae-cox-eoi-cfz.rtf (Date Generated: 25MAY2020:20:48) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	0 (0.0)	NE [NE, NE)	283	1 (0.4)	NE [NE, NE)	0.9995	>999.999 (<.001, NE)	0.5193
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	0 (0.0)	NE [NE, NE)	0.9993	NE (NE, NE)	NE
	Female	62	0 (0.0)	NE [NE, NE)	134	1 (0.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.5344

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	0 (0.0)	NE [NE, NE)	240	1 (0.4)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.5042
	Asian	20	0 (0.0)	NE [NE, NE)	46	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	1 (0.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.5089
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Baseline ECOG PS	0-1	146	0 (0.0)	NE [NE, NE)	294	0 (0.0)	NE [NE, NE)	NE	NE (NE, NE)	NE
	2	7	0 (0.0)	NE [NE, NE)	13	1 (7.7)	NE [5.8, NE)		>999.999 (<.001, NE)	0.7518

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	0 (0.0)	NE [NE, NE)	285	1 (0.4)	NE [NE, NE)	0.9995	>999.999 (<.001, NE)	0.5193
	No	17	0 (0.0)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	1 (1.0)	NE [NE, NE)	0.9993	>999.999 (<.001, NE)	0.4711
	No	98	0 (0.0)	NE [NE, NE)	209	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	0 (0.0)	NE [NE, NE)	0.9992	NE (NE, NE)	NE
	No	79	0 (0.0)	NE [NE, NE)	186	1 (0.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.5424
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	0 (0.0)	NE [NE, NE)	0.9992	NE (NE, NE)	NE
	No	98	0 (0.0)	NE [NE, NE)	210	1 (0.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.5224

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	0 (0.0)	NE [NE, NE)	205	0 (0.0)	NE [NE, NE)	0.9992	NE (NE, NE)	NE
	No	43	0 (0.0)	NE [NE, NE)	103	1 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.5426
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	0 (0.0)	NE [NE, NE)	0.9992	NE (NE, NE)	NE
	No	88	0 (0.0)	NE [NE, NE)	179	1 (0.6)	NE [NE, NE)		>999.999 (<.001, NE)	0.5113

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	0 (0.0)	NE [NE, NE)	250	1 (0.4)	NE [NE, NE)	0.9994	>999.999 (<.001, NE)	0.5040
	3	27	0 (0.0)	NE [NE, NE)	58	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Prior proteasome inhibitor exposure per IXRS	Yes	138	0 (0.0)	NE [NE, NE)	276	1 (0.4)	NE [NE, NE)	0.9995	>999.999 (<.001, NE)	0.5087
	No	15	0 (0.0)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	1 (0.8)	NE [NE, NE)	0.9993	>999.999 (<.001, NE)	0.5078
	>= 2	87	0 (0.0)	NE [NE, NE)	177	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Hypertension (SMQ) - Narrow										
Total subjects		153	44 (28.8)	NE [16.8, NE)	308	98 (31.8)	NE [NE, NE)		0.997 (0.698, 1.423)	0.9832

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	39 (28.9)	NE [16.8, NE)	283	87 (30.7)	NE [NE, NE)	0.6370	0.970 (0.665, 1.417)	0.8740
	> 75	18	5 (27.8)	NE [1.9, NE)	25	11 (44.0)	8.6 [4.2, NE)		1.257 (0.436, 3.624)	0.6713
Sex	Male	91	27 (29.7)	NE [16.7, NE)	174	56 (32.2)	NE [NE, NE)	0.9857	1.001 (0.632, 1.586)	0.9985
	Female	62	17 (27.4)	NE [14.2, NE)	134	42 (31.3)	NE [15.9, NE)		1.003 (0.571, 1.763)	0.9938

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	34 (27.9)	NE [16.7, NE)	240	67 (27.9)	NE [NE, NE)	0.6731	0.889 (0.588, 1.344)	0.5767
	Asian	20	7 (35.0)	NE [5.0, NE)	46	21 (45.7)	NE [5.1, NE)		1.320 (0.560, 3.111)	0.5244
	Other or Unknown	11	3 (27.3)	NE [1.2, NE)	22	10 (45.5)	15.9 [9.0, NE)		1.416 (0.387, 5.175)	0.6052
Region	North America	12	5 (41.7)	11.5 [0.3, NE)	21	8 (38.1)	NE [8.1, NE)	0.4303	0.673 (0.213, 2.125)	0.4969

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-504-ae-cox-eoi-cfz.rtf (Date Generated: 25MAY2020:20:48) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	27 (26.5)	NE [16.7, NE)	203	53 (26.1)	NE [NE, NE)		0.855 (0.538, 1.360)	0.5083
	Asia Pacific	39	12 (30.8)	NE [9.8, NE)	84	37 (44.0)	NE [8.6, NE)		1.416 (0.738, 2.717)	0.2922
Baseline ECOG PS	0-1	146	43 (29.5)	NE [16.8, NE)	294	96 (32.7)	NE [NE, NE)	0.4816	1.028 (0.717, 1.473)	0.8822
	2	7	1 (14.3)	NE [3.1, NE)	13	2 (15.4)	NE [8.9, NE)		0.402 (0.024, 6.621)	0.5101

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	36 (26.5)	NE [16.8, NE)	285	89 (31.2)	NE [NE, NE)	0.3677	1.082 (0.734, 1.594)	0.6927
	No	17	8 (47.1)	9.8 [1.3, NE)	23	9 (39.1)	NE [10.6, NE)		0.637 (0.244, 1.664)	0.3568
Refractory to Bortezomib or Ixazomib	Yes	55	11 (20.0)	NE [NE, NE)	99	23 (23.2)	NE [NE, NE)	0.8536	1.067 (0.519, 2.193)	0.8605
	No	98	33 (33.7)	NE [14.2, NE)	209	75 (35.9)	NE [NE, NE)		0.965 (0.641, 1.454)	0.8663

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	17 (23.0)	NE [16.8, NE)	122	36 (29.5)	NE [NE, NE)	0.3572	1.205 (0.676, 2.146)	0.5277
	No	79	27 (34.2)	NE [11.5, NE)	186	62 (33.3)	NE [NE, NE)		0.850 (0.541, 1.337)	0.4829
Refractory to Lenalidomide	Yes	55	15 (27.3)	17.3 [11.1, NE)	98	29 (29.6)	NE [NE, NE)	0.8954	0.949 (0.508, 1.775)	0.8695
	No	98	29 (29.6)	NE [16.7, NE)	210	69 (32.9)	NE [NE, NE)		1.012 (0.656, 1.563)	0.9552

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	30 (27.3)	NE [16.8, NE)	205	66 (32.2)	NE [NE, NE)	0.3925	1.110 (0.721, 1.710)	0.6349
	No	43	14 (32.6)	NE [7.6, NE)	103	32 (31.1)	NE [NE, NE)		0.783 (0.417, 1.472)	0.4497
Refractory to IMiD	Yes	65	16 (24.6)	17.3 [16.8, NE)	129	37 (28.7)	NE [NE, NE)	0.8244	1.051 (0.584, 1.893)	0.8683
	No	88	28 (31.8)	NE [12.3, NE)	179	61 (34.1)	NE [NE, NE)		0.961 (0.614, 1.504)	0.8630

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	37 (29.4)	NE [16.8, NE)	250	84 (33.6)	NE [NE, NE)	0.3250	1.069 (0.726, 1.574)	0.7382
	3	27	7 (25.9)	NE [7.6, NE)	58	14 (24.1)	NE [NE, NE)		0.696 (0.278, 1.740)	0.4360
Prior proteasome inhibitor exposure per IXRS	Yes	138	36 (26.1)	NE [16.8, NE)	276	88 (31.9)	NE [NE, NE)	0.0659	1.132 (0.768, 1.669)	0.5325
	No	15	8 (53.3)	9.8 [0.5, NE)	32	10 (31.3)	NE [11.0, NE)		0.435 (0.170, 1.109)	0.0743

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	21 (31.8)	NE [12.3, NE)	131	50 (38.2)	NE [14.8, NE)	0.5627	1.104 (0.663, 1.838)	0.7065
	>= 2	87	23 (26.4)	NE [16.8, NE)	177	48 (27.1)	NE [NE, NE)		0.915 (0.556, 1.506)	0.7255

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Infusion reaction (AMQ) - Narrow (event on same date of any Carfilzomib dosing)										
Total subjects		153	43 (28.1)	NE [17.3, NE)	308	126 (40.9)	NE [14.3, NE)		1.508 (1.066, 2.132)	0.0226

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	39 (28.9)	NE [17.3, NE)	283	114 (40.3)	NE [15.2, NE)	0.4560	1.445 (1.004, 2.080)	0.0535
	> 75	18	4 (22.2)	NE [5.6, NE)	25	12 (48.0)	14.3 [3.8, NE)		2.173 (0.700, 6.749)	0.1686
Sex	Male	91	24 (26.4)	NE [16.8, NE)	174	67 (38.5)	NE [15.0, NE)	0.9313	1.507 (0.944, 2.403)	0.0896
	Female	62	19 (30.6)	NE [17.5, NE)	134	59 (44.0)	15.9 [10.7, NE)		1.482 (0.883, 2.486)	0.1473

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	32 (26.2)	NE [17.3, NE)	240	83 (34.6)	NE [NE, NE)	0.3316	1.306 (0.868, 1.965)	0.2132
	Asian	20	9 (45.0)	14.1 [3.0, NE)	46	30 (65.2)	3.8 [0.5, 10.7)		1.829 (0.868, 3.857)	0.1167
	Other or Unknown	11	2 (18.2)	NE [0.5, NE)	22	13 (59.1)	9.0 [0.1, NE)		3.896 (0.877, 17.315)	0.0547
Region	North America	12	7 (58.3)	7.6 [0.3, NE)	21	12 (57.1)	11.1 [0.5, NE)	0.4151	0.819 (0.316, 2.122)	0.6523

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	21 (20.6)	NE [NE, NE)	203	64 (31.5)	NE [NE, NE)		1.546 (0.944, 2.532)	0.0870
	Asia Pacific	39	15 (38.5)	17.3 [10.4, 17.5)	84	50 (59.5)	8.6 [3.4, 11.3)		1.773 (0.994, 3.161)	0.0534
Baseline ECOG PS	0-1	146	41 (28.1)	NE [17.3, NE)	294	122 (41.5)	NE [13.4, NE)	0.2209	1.552 (1.089, 2.212)	0.0162
	2	7	2 (28.6)	NE [0.3, NE)	13	3 (23.1)	NE [0.1, NE)		0.836 (0.138, 5.052)	0.8296

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	37 (27.2)	NE [17.5, NE)	285	115 (40.4)	NE [15.2, NE)	0.8609	1.543 (1.065, 2.235)	0.0236
	No	17	6 (35.3)	17.3 [1.2, NE)	23	11 (47.8)	15.0 [3.4, NE)		1.329 (0.489, 3.612)	0.6090
Refractory to Bortezomib or Ixazomib	Yes	55	11 (20.0)	NE [12.3, NE)	99	31 (31.3)	NE [16.6, NE)	0.7060	1.652 (0.830, 3.289)	0.1559
	No	98	32 (32.7)	17.5 [16.8, NE)	209	95 (45.5)	16.3 [10.7, NE)		1.426 (0.955, 2.130)	0.0911

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	21 (28.4)	NE [16.8, NE)	122	47 (38.5)	NE [13.4, NE)	0.6419	1.390 (0.830, 2.329)	0.2221
	No	79	22 (27.8)	NE [14.1, NE)	186	79 (42.5)	NE [10.7, NE)		1.606 (1.001, 2.577)	0.0524
Refractory to Lenalidomide	Yes	55	19 (34.5)	17.3 [10.4, NE)	98	33 (33.7)	NE [15.9, NE)	0.0289	0.893 (0.506, 1.576)	0.6829
	No	98	24 (24.5)	NE [17.5, NE)	210	93 (44.3)	16.6 [10.6, NE)		1.982 (1.265, 3.105)	0.0027

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	33 (30.0)	NE [16.8, NE)	205	86 (42.0)	NE [11.3, NE)	0.6432	1.449 (0.969, 2.166)	0.0797
	No	43	10 (23.3)	NE [17.5, NE)	103	40 (38.8)	NE [11.1, NE)		1.769 (0.884, 3.540)	0.1041
Refractory to IMiD	Yes	65	20 (30.8)	17.3 [11.1, NE)	129	45 (34.9)	NE [15.9, NE)	0.1017	1.075 (0.633, 1.824)	0.8086
	No	88	23 (26.1)	NE [17.5, NE)	179	81 (45.3)	16.3 [10.4, NE)		1.910 (1.202, 3.036)	0.0062

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	36 (28.6)	NE [17.3, NE)	250	109 (43.6)	NE [11.1, NE)	0.2851	1.626 (1.115, 2.370)	0.0125
	3	27	7 (25.9)	NE [3.1, NE)	58	17 (29.3)	NE [NE, NE)		1.086 (0.449, 2.626)	0.8641
Prior proteasome inhibitor exposure per IXRS	Yes	138	37 (26.8)	NE [17.5, NE)	276	113 (40.9)	NE [14.3, NE)	0.3345	1.601 (1.104, 2.321)	0.0140
	No	15	6 (40.0)	17.3 [1.0, NE)	32	13 (40.6)	NE [10.2, NE)		0.972 (0.368, 2.564)	0.9241

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	18 (27.3)	NE [14.1, NE)	131	58 (44.3)	16.6 [10.2, NE)	0.4996	1.713 (1.009, 2.908)	0.0493
	>= 2	87	25 (28.7)	NE [16.8, NE)	177	68 (38.4)	NE [14.3, NE)		1.371 (0.866, 2.169)	0.1868

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Infusion reaction (AMQ) - Narrow (event on same date of first Carfilzomib dosing)										
Total subjects		153	1 (0.7)	NE [NE, NE)	308	39 (12.7)	NE [NE, NE)		20.608 (2.832, 149.984)	<.0001

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	0 (0.0)	NE [NE, NE)	283	36 (12.7)	NE [NE, NE)	0.9869	>999.999 (<.001, NE)	<.0001
	> 75	18	1 (5.6)	NE [NE, NE)	25	3 (12.0)	NE [NE, NE)		2.216 (0.230, 21.305)	0.4781
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	19 (10.9)	NE [NE, NE)	0.9853	>999.999 (<.001, NE)	0.0011
	Female	62	1 (1.6)	NE [NE, NE)	134	20 (14.9)	NE [NE, NE)		9.896 (1.329, 73.689)	0.0052

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	1 (0.8)	NE [NE, NE)	240	24 (10.0)	NE [NE, NE)	0.9999	12.775 (1.728, 94.434)	0.0011
	Asian	20	0 (0.0)	NE [NE, NE)	46	10 (21.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.0247
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	5 (22.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.0910
Region	North America	12	0 (0.0)	NE [NE, NE)	21	4 (19.0)	NE [NE, NE)	0.9998	>999.999 (<.001, NE)	0.1123

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	20 (9.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.0011
	Asia Pacific	39	1 (2.6)	NE [NE, NE)	84	15 (17.9)	NE [NE, NE)		7.528 (0.994, 56.989)	0.0195
Baseline ECOG PS	0-1	146	1 (0.7)	NE [NE, NE)	294	36 (12.2)	NE [NE, NE)	0.9908	18.970 (2.601, 138.353)	<.0001
	2	7	0 (0.0)	NE [NE, NE)	13	2 (15.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.2863

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CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	1 (0.7)	NE [NE, NE)	285	34 (11.9)	NE [NE, NE)	0.9904	17.181 (2.352, 125.510)	0.0001
	No	17	0 (0.0)	NE [NE, NE)	23	5 (21.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.0424
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	10 (10.1)	NE [NE, NE)	0.9889	>999.999 (<.001, NE)	0.0151
	No	98	1 (1.0)	NE [NE, NE)	209	29 (13.9)	NE [NE, NE)		14.528 (1.979, 106.652)	0.0004

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
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[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	14 (11.5)	NE [NE, NE)	0.9867	>999.999 (<.001, NE)	0.0026
	No	79	1 (1.3)	NE [NE, NE)	186	25 (13.4)	NE [NE, NE)		11.300 (1.531, 83.397)	0.0024
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	7 (7.1)	NE [NE, NE)	0.9896	>999.999 (<.001, NE)	0.0431
	No	98	1 (1.0)	NE [NE, NE)	210	32 (15.2)	NE [NE, NE)		16.078 (2.197, 117.661)	0.0002

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CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	0 (0.0)	NE [NE, NE)	205	29 (14.1)	NE [NE, NE)	0.9887	>999.999 (<.001, NE)	<.0001
	No	43	1 (2.3)	NE [NE, NE)	103	10 (9.7)	NE [NE, NE)		4.324 (0.553, 33.779)	0.1247
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	11 (8.5)	NE [NE, NE)	0.9885	>999.999 (<.001, NE)	0.0156
	No	88	1 (1.1)	NE [NE, NE)	179	28 (15.6)	NE [NE, NE)		14.840 (2.019, 109.075)	0.0004

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	1 (0.8)	NE [NE, NE)	250	34 (13.6)	NE [NE, NE)	0.9886	18.306 (2.506, 133.727)	<.0001
	3	27	0 (0.0)	NE [NE, NE)	58	5 (8.6)	NE [NE, NE)		>999.999 (<.001, NE)	0.1180
Prior proteasome inhibitor exposure per IXRS	Yes	138	1 (0.7)	NE [NE, NE)	276	34 (12.3)	NE [NE, NE)	0.9910	18.041 (2.470, 131.790)	<.0001
	No	15	0 (0.0)	NE [NE, NE)	32	5 (15.6)	NE [NE, NE)		>999.999 (<.001, NE)	0.1091

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	1 (1.5)	NE [NE, NE)	131	21 (16.0)	NE [NE, NE)	0.9861	11.399 (1.533, 84.749)	0.0023
	>= 2	87	0 (0.0)	NE [NE, NE)	177	18 (10.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.0021

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-504-ae-cox-eoi-cfz.rtf (Date Generated: 25MAY2020:20:48) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Interstitial lung disease (SMQ) - Narrow										
Total subjects		153	2 (1.3)	NE [NE, NE)	308	6 (1.9)	NE [NE, NE)		1.386 (0.279, 6.880)	0.6880

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	1 (0.7)	NE [NE, NE)	283	5 (1.8)	NE [NE, NE)	0.4933	2.200 (0.256, 18.869)	0.4607
	> 75	18	1 (5.6)	NE [NE, NE)	25	1 (4.0)	NE [NE, NE)		0.685 (0.043, 10.965)	0.7881
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	4 (2.3)	NE [NE, NE)	0.9920	>999.999 (<.001, NE)	0.1716
	Female	62	2 (3.2)	NE [NE, NE)	134	2 (1.5)	NE [NE, NE)		0.447 (0.063, 3.177)	0.4085

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	2 (1.6)	NE [NE, NE)	240	4 (1.7)	NE [NE, NE)	1.0000	1.001 (0.183, 5.467)	0.9988
	Asian	20	0 (0.0)	NE [NE, NE)	46	2 (4.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.4208
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	0.8825	NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	1 (1.0)	NE [NE, NE)	203	4 (2.0)	NE [NE, NE)		1.961 (0.219, 17.548)	0.5393
	Asia Pacific	39	1 (2.6)	NE [NE, NE)	84	2 (2.4)	NE [NE, NE)		0.746 (0.067, 8.331)	0.8111
Baseline ECOG PS	0-1	146	2 (1.4)	NE [NE, NE)	294	6 (2.0)	NE [NE, NE)	0.9999	1.406 (0.283, 6.976)	0.6750
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	2 (1.5)	NE [NE, NE)	285	4 (1.4)	NE [NE, NE)	0.9929	0.924 (0.169, 5.045)	0.9271
	No	17	0 (0.0)	NE [NE, NE)	23	2 (8.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.2994
Refractory to Bortezomib or Ixazomib	Yes	55	1 (1.8)	NE [NE, NE)	99	2 (2.0)	NE [NE, NE)	0.7745	1.084 (0.098, 11.953)	0.9476
	No	98	1 (1.0)	NE [NE, NE)	209	4 (1.9)	NE [NE, NE)		1.681 (0.187, 15.099)	0.6389

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	1 (1.4)	NE [NE, NE)	122	3 (2.5)	NE [NE, NE)	0.8542	1.536 (0.159, 14.866)	0.7086
	No	79	1 (1.3)	NE [NE, NE)	186	3 (1.6)	NE [NE, NE)		1.264 (0.131, 12.150)	0.8390
Refractory to Lenalidomide	Yes	55	1 (1.8)	NE [NE, NE)	98	1 (1.0)	NE [NE, NE)	0.4029	0.412 (0.025, 6.806)	0.5225
	No	98	1 (1.0)	NE [NE, NE)	210	5 (2.4)	NE [NE, NE)		2.278 (0.266, 19.502)	0.4394

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	2 (1.8)	NE [NE, NE)	205	3 (1.5)	NE [NE, NE)	0.9943	0.704 (0.117, 4.233)	0.7001
	No	43	0 (0.0)	NE [NE, NE)	103	3 (2.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.2603
Refractory to IMiD	Yes	65	2 (3.1)	NE [NE, NE)	129	1 (0.8)	NE [NE, NE)	0.9919	0.202 (0.018, 2.276)	0.1528
	No	88	0 (0.0)	NE [NE, NE)	179	5 (2.8)	NE [NE, NE)		>999.999 (<.001, NE)	0.1200

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	1 (0.8)	NE [NE, NE)	250	5 (2.0)	NE [NE, NE)	0.3062	2.355 (0.275, 20.192)	0.4207
	3	27	1 (3.7)	NE [NE, NE)	58	1 (1.7)	NE [NE, NE)		0.427 (0.027, 6.825)	0.5347
Prior proteasome inhibitor exposure per IXRS	Yes	138	2 (1.4)	NE [NE, NE)	276	5 (1.8)	NE [NE, NE)	0.9949	1.164 (0.225, 6.013)	0.8559
	No	15	0 (0.0)	NE [NE, NE)	32	1 (3.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.5271

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	3 (2.3)	NE [NE, NE)	0.9931	>999.999 (<.001, NE)	0.2532
	>= 2	87	2 (2.3)	NE [NE, NE)	177	3 (1.7)	NE [NE, NE)		0.709 (0.118, 4.242)	0.7046

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Ischaemic heart disease (SMQ) - Narrow										
Total subjects		153	5 (3.3)	NE [NE, NE)	308	13 (4.2)	NE [NE, NE)		1.089 (0.387, 3.065)	0.8716

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	4 (3.0)	NE [NE, NE)	283	12 (4.2)	NE [NE, NE)	0.5756	1.235 (0.397, 3.841)	0.7143
	> 75	18	1 (5.6)	NE [NE, NE)	25	1 (4.0)	NE [NE, NE)		0.341 (0.018, 6.511)	0.4591
Sex	Male	91	3 (3.3)	NE [NE, NE)	174	9 (5.2)	NE [NE, NE)	0.6662	1.331 (0.358, 4.944)	0.6686
	Female	62	2 (3.2)	NE [NE, NE)	134	4 (3.0)	NE [NE, NE)		0.806 (0.147, 4.415)	0.8034

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	2 (1.6)	NE [NE, NE)	240	12 (5.0)	NE [NE, NE)	0.4725	2.563 (0.572, 11.488)	0.2021
	Asian	20	2 (10.0)	NE [11.3, NE)	46	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0128
	Other or Unknown	11	1 (9.1)	NE [2.4, NE)	22	1 (4.5)	NE [NE, NE)		0.437 (0.027, 7.023)	0.5474
Region	North America	12	0 (0.0)	NE [NE, NE)	21	2 (9.5)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.2791

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-504-ae-cox-eoi-cfz.rtf (Date Generated: 25MAY2020:20:48) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	3 (2.9)	NE [NE, NE)	203	11 (5.4)	NE [NE, NE)		1.533 (0.426, 5.512)	0.5095
	Asia Pacific	39	2 (5.1)	NE [NE, NE)	84	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0213
Baseline ECOG PS	0-1	146	5 (3.4)	NE [NE, NE)	294	13 (4.4)	NE [NE, NE)	1.0000	1.118 (0.397, 3.144)	0.8328
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	5 (3.7)	NE [NE, NE)	285	12 (4.2)	NE [NE, NE)	0.9921	0.968 (0.340, 2.758)	0.9520
	No	17	0 (0.0)	NE [NE, NE)	23	1 (4.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.4583
Refractory to Bortezomib or Ixazomib	Yes	55	2 (3.6)	NE [NE, NE)	99	0 (0.0)	NE [NE, NE)	0.9876	<.001 (<.001, NE)	0.0352
	No	98	3 (3.1)	NE [NE, NE)	209	13 (6.2)	NE [NE, NE)		1.723 (0.489, 6.069)	0.3911

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	1 (1.4)	NE [NE, NE)	122	7 (5.7)	NE [NE, NE)	0.1348	3.954 (0.486, 32.159)	0.1648
	No	79	4 (5.1)	NE [NE, NE)	186	6 (3.2)	NE [NE, NE)		0.525 (0.148, 1.866)	0.3110
Refractory to Lenalidomide	Yes	55	1 (1.8)	NE [NE, NE)	98	5 (5.1)	NE [NE, NE)	0.4255	2.441 (0.284, 20.959)	0.4006
	No	98	4 (4.1)	NE [NE, NE)	210	8 (3.8)	NE [NE, NE)		0.804 (0.242, 2.677)	0.7219

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	4 (3.6)	NE [NE, NE)	205	7 (3.4)	NE [NE, NE)	0.4111	0.856 (0.250, 2.928)	0.8035
	No	43	1 (2.3)	NE [NE, NE)	103	6 (5.8)	NE [NE, NE)		2.013 (0.242, 16.775)	0.5091
Refractory to IMiD	Yes	65	2 (3.1)	NE [NE, NE)	129	6 (4.7)	NE [NE, NE)	0.8588	1.313 (0.264, 6.529)	0.7387
	No	88	3 (3.4)	NE [NE, NE)	179	7 (3.9)	NE [NE, NE)		0.982 (0.253, 3.807)	0.9790

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	4 (3.2)	NE [NE, NE)	250	9 (3.6)	NE [NE, NE)	0.8285	0.959 (0.294, 3.127)	0.9451
	3	27	1 (3.7)	NE [NE, NE)	58	4 (6.9)	NE [NE, NE)		1.365 (0.148, 12.608)	0.7829
Prior proteasome inhibitor exposure per IXRS	Yes	138	5 (3.6)	NE [NE, NE)	276	9 (3.3)	NE [NE, NE)	0.9895	0.715 (0.239, 2.146)	0.5484
	No	15	0 (0.0)	NE [NE, NE)	32	4 (12.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.1766

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	3 (4.5)	NE [NE, NE)	131	6 (4.6)	NE [NE, NE)	0.5982	0.801 (0.199, 3.220)	0.7540
	>= 2	87	2 (2.3)	NE [NE, NE)	177	7 (4.0)	NE [NE, NE)		1.521 (0.315, 7.346)	0.5991

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Liver related investigations, signs and symptoms (SMQ) - Narrow										
Total subjects		153	13 (8.5)	NE [NE, NE)	308	35 (11.4)	NE [NE, NE)		1.255 (0.663, 2.375)	0.4849

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	12 (8.9)	NE [NE, NE)	283	31 (11.0)	NE [NE, NE)	0.5118	1.180 (0.606, 2.299)	0.6269
	> 75	18	1 (5.6)	NE [NE, NE)	25	4 (16.0)	NE [19.3, NE)		1.987 (0.206, 19.119)	0.5445
Sex	Male	91	8 (8.8)	NE [NE, NE)	174	16 (9.2)	NE [NE, NE)	0.3879	0.920 (0.391, 2.165)	0.8500
	Female	62	5 (8.1)	NE [NE, NE)	134	19 (14.2)	NE [NE, NE)		1.739 (0.649, 4.658)	0.2660

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	10 (8.2)	NE [NE, NE)	240	23 (9.6)	NE [NE, NE)	0.9335	1.080 (0.513, 2.275)	0.8385
	Asian	20	3 (15.0)	NE [NE, NE)	46	10 (21.7)	NE [NE, NE)		1.495 (0.411, 5.433)	0.5411
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	2 (9.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.3807
Region	North America	12	2 (16.7)	NE [7.4, NE)	21	1 (4.8)	NE [NE, NE)	0.3824	0.270 (0.024, 2.977)	0.2511

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	6 (5.9)	NE [NE, NE)	203	19 (9.4)	NE [NE, NE)		1.526 (0.609, 3.821)	0.3625
	Asia Pacific	39	5 (12.8)	NE [17.3, NE)	84	15 (17.9)	NE [NE, NE)		1.270 (0.458, 3.520)	0.6461
Baseline ECOG PS	0-1	146	12 (8.2)	NE [NE, NE)	294	33 (11.2)	NE [NE, NE)	0.5254	1.323 (0.683, 2.564)	0.4049
	2	7	1 (14.3)	NE [0.5, NE)	13	2 (15.4)	NE [19.3, NE)		0.408 (0.025, 6.622)	0.5151

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	11 (8.1)	NE [NE, NE)	285	30 (10.5)	NE [NE, NE)	0.6460	1.219 (0.610, 2.435)	0.5742
	No	17	2 (11.8)	NE [17.3, NE)	23	5 (21.7)	NE [NE, NE)		1.751 (0.335, 9.137)	0.5048
Refractory to Bortezomib or Ixazomib	Yes	55	6 (10.9)	NE [NE, NE)	99	7 (7.1)	NE [NE, NE)	0.1238	0.580 (0.194, 1.734)	0.3240
	No	98	7 (7.1)	NE [NE, NE)	209	28 (13.4)	NE [NE, NE)		1.800 (0.785, 4.123)	0.1590

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	6 (8.1)	NE [NE, NE)	122	13 (10.7)	NE [NE, NE)	0.9674	1.264 (0.480, 3.328)	0.6347
	No	79	7 (8.9)	NE [NE, NE)	186	22 (11.8)	NE [NE, NE)		1.246 (0.531, 2.924)	0.6120
Refractory to Lenalidomide	Yes	55	5 (9.1)	NE [NE, NE)	98	10 (10.2)	NE [NE, NE)	0.6477	1.064 (0.363, 3.115)	0.9104
	No	98	8 (8.2)	NE [NE, NE)	210	25 (11.9)	NE [NE, NE)		1.381 (0.622, 3.066)	0.4255

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-504-ae-cox-eoi-cfz.rtf (Date Generated: 25MAY2020:20:48) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	9 (8.2)	NE [NE, NE)	205	24 (11.7)	NE [NE, NE)	0.7821	1.311 (0.608, 2.828)	0.4898
	No	43	4 (9.3)	NE [NE, NE)	103	11 (10.7)	NE [NE, NE)		1.112 (0.354, 3.494)	0.8543
Refractory to IMiD	Yes	65	6 (9.2)	NE [NE, NE)	129	14 (10.9)	NE [NE, NE)	0.6495	1.016 (0.387, 2.664)	0.9748
	No	88	7 (8.0)	NE [NE, NE)	179	21 (11.7)	NE [NE, NE)		1.444 (0.613, 3.397)	0.3978

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	10 (7.9)	NE [NE, NE)	250	30 (12.0)	NE [NE, NE)	0.2884	1.483 (0.725, 3.036)	0.2778
	3	27	3 (11.1)	NE [NE, NE)	58	5 (8.6)	NE [19.3, NE)		0.603 (0.143, 2.541)	0.4907
Prior proteasome inhibitor exposure per IXRS	Yes	138	11 (8.0)	NE [NE, NE)	276	30 (10.9)	NE [NE, NE)	0.8623	1.285 (0.643, 2.567)	0.4758
	No	15	2 (13.3)	NE [17.3, NE)	32	5 (15.6)	NE [NE, NE)		1.101 (0.213, 5.693)	0.9128

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	7 (10.6)	NE [NE, NE)	131	14 (10.7)	NE [NE, NE)	0.4062	0.950 (0.383, 2.359)	0.9130
	>= 2	87	6 (6.9)	NE [NE, NE)	177	21 (11.9)	NE [NE, NE)		1.578 (0.635, 3.922)	0.3207

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Myocardial infarction (SMQ) - Narrow										
Total subjects		153	1 (0.7)	NE [NE, NE)	308	4 (1.3)	NE [NE, NE)		1.398 (0.156, 12.554)	0.7637

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	1 (0.7)	NE [NE, NE)	283	3 (1.1)	NE [NE, NE)	0.9948	1.029 (0.107, 9.929)	0.9804
	> 75	18	0 (0.0)	NE [NE, NE)	25	1 (4.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.6171
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	3 (1.7)	NE [NE, NE)	0.9942	>999.999 (<.001, NE)	0.3097
	Female	62	1 (1.6)	NE [NE, NE)	134	1 (0.7)	NE [NE, NE)		0.348 (0.022, 5.602)	0.4356

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	0 (0.0)	NE [NE, NE)	240	4 (1.7)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.2366
	Asian	20	1 (5.0)	NE [11.3, NE)	46	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0593
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	4 (2.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.2348
	Asia Pacific	39	1 (2.6)	NE [NE, NE)	84	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0806
Baseline ECOG PS	0-1	146	1 (0.7)	NE [NE, NE)	294	4 (1.4)	NE [NE, NE)	1.0000	1.460 (0.163, 13.107)	0.7337
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	1 (0.7)	NE [NE, NE)	285	4 (1.4)	NE [NE, NE)	1.0000	1.360 (0.151, 12.220)	0.7829
	No	17	0 (0.0)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to Bortezomib or Ixazomib	Yes	55	1 (1.8)	NE [NE, NE)	99	0 (0.0)	NE [NE, NE)	0.9949	<.001 (<.001, NE)	0.1103
	No	98	0 (0.0)	NE [NE, NE)	209	4 (1.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.2544

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	2 (1.6)	NE [NE, NE)	0.9951	>999.999 (<.001, NE)	0.3287
	No	79	1 (1.3)	NE [NE, NE)	186	2 (1.1)	NE [NE, NE)		0.618 (0.056, 6.839)	0.6919
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	2 (2.0)	NE [NE, NE)	0.9960	>999.999 (<.001, NE)	0.3658
	No	98	1 (1.0)	NE [NE, NE)	210	2 (1.0)	NE [NE, NE)		0.684 (0.062, 7.573)	0.7557

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	1 (0.9)	NE [NE, NE)	205	2 (1.0)	NE [NE, NE)	0.9957	0.852 (0.077, 9.404)	0.8958
	No	43	0 (0.0)	NE [NE, NE)	103	2 (1.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.4532
Refractory to IMiD	Yes	65	1 (1.5)	NE [NE, NE)	129	2 (1.6)	NE [NE, NE)	0.9943	0.729 (0.066, 8.056)	0.7955
	No	88	0 (0.0)	NE [NE, NE)	179	2 (1.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.4028

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	1 (0.8)	NE [NE, NE)	250	3 (1.2)	NE [NE, NE)	0.9946	1.098 (0.113, 10.622)	0.9357
	3	27	0 (0.0)	NE [NE, NE)	58	1 (1.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.6698
Prior proteasome inhibitor exposure per IXRS	Yes	138	1 (0.7)	NE [NE, NE)	276	4 (1.4)	NE [NE, NE)	1.0000	1.394 (0.155, 12.539)	0.7660
	No	15	0 (0.0)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	3 (2.3)	NE [NE, NE)	0.9947	>999.999 (<.001, NE)	0.3212
	>= 2	87	1 (1.1)	NE [NE, NE)	177	1 (0.6)	NE [NE, NE)		0.386 (0.024, 6.171)	0.4846

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Output: t14-06-001-504-ae-cox-eoi-cfz.rtf (Date Generated: 25MAY2020:20:48) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Peripheral neuropathy (SMQ) - Narrow										
Total subjects		153	13 (8.5)	NE [NE, NE)	308	53 (17.2)	NE [NE, NE)		1.874 (1.021, 3.440)	0.0394

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	12 (8.9)	NE [NE, NE)	283	48 (17.0)	NE [NE, NE)	0.5655	1.756 (0.932, 3.309)	0.0774
	> 75	18	1 (5.6)	NE [NE, NE)	25	5 (20.0)	NE [NE, NE)		3.465 (0.405, 29.673)	0.2279
Sex	Male	91	8 (8.8)	NE [NE, NE)	174	29 (16.7)	NE [NE, NE)	0.7822	1.767 (0.807, 3.869)	0.1493
	Female	62	5 (8.1)	NE [NE, NE)	134	24 (17.9)	NE [NE, NE)		2.068 (0.789, 5.420)	0.1311

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	11 (9.0)	NE [NE, NE)	240	36 (15.0)	NE [NE, NE)	0.5554	1.521 (0.773, 2.991)	0.2210
	Asian	20	1 (5.0)	NE [NE, NE)	46	9 (19.6)	NE [NE, NE)		3.903 (0.494, 30.816)	0.1634
	Other or Unknown	11	1 (9.1)	NE [3.8, NE)	22	8 (36.4)	NE [4.6, NE)		3.465 (0.432, 27.773)	0.2131
Region	North America	12	2 (16.7)	NE [3.8, NE)	21	7 (33.3)	NE [4.6, NE)	0.3791	2.046 (0.424, 9.873)	0.3624

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	9 (8.8)	NE [NE, NE)	203	27 (13.3)	NE [NE, NE)		1.357 (0.637, 2.889)	0.4275
	Asia Pacific	39	2 (5.1)	NE [NE, NE)	84	19 (22.6)	NE [NE, NE)		4.359 (1.015, 18.720)	0.0305
Baseline ECOG PS	0-1	146	13 (8.9)	NE [NE, NE)	294	51 (17.3)	NE [NE, NE)	0.9850	1.841 (1.001, 3.386)	0.0464
	2	7	0 (0.0)	NE [NE, NE)	13	2 (15.4)	NE [2.5, NE)		>999.999 (<.001, NE)	0.3977

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	12 (8.8)	NE [NE, NE)	285	51 (17.9)	NE [NE, NE)	0.7815	1.874 (0.999, 3.517)	0.0469
	No	17	1 (5.9)	NE [NE, NE)	23	2 (8.7)	NE [NE, NE)		1.411 (0.128, 15.598)	0.7780
Refractory to Bortezomib or Ixazomib	Yes	55	4 (7.3)	NE [NE, NE)	99	12 (12.1)	NE [NE, NE)	0.7079	1.559 (0.502, 4.842)	0.4387
	No	98	9 (9.2)	NE [NE, NE)	209	41 (19.6)	NE [NE, NE)		1.969 (0.957, 4.054)	0.0609

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	5 (6.8)	NE [NE, NE)	122	19 (15.6)	NE [NE, NE)	0.7672	2.062 (0.769, 5.532)	0.1415
	No	79	8 (10.1)	NE [NE, NE)	186	34 (18.3)	NE [NE, NE)		1.710 (0.791, 3.697)	0.1681
Refractory to Lenalidomide	Yes	55	2 (3.6)	NE [NE, NE)	98	16 (16.3)	NE [NE, NE)	0.2126	4.160 (0.956, 18.110)	0.0389
	No	98	11 (11.2)	NE [NE, NE)	210	37 (17.6)	NE [NE, NE)		1.458 (0.743, 2.860)	0.2709

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	7 (6.4)	NE [NE, NE)	205	38 (18.5)	NE [NE, NE)	0.1010	2.711 (1.210, 6.075)	0.0116
	No	43	6 (14.0)	NE [NE, NE)	103	15 (14.6)	NE [NE, NE)		0.961 (0.372, 2.481)	0.9331
Refractory to IMiD	Yes	65	3 (4.6)	NE [NE, NE)	129	24 (18.6)	NE [NE, NE)	0.1547	3.677 (1.106, 12.224)	0.0227
	No	88	10 (11.4)	NE [NE, NE)	179	29 (16.2)	NE [NE, NE)		1.326 (0.646, 2.724)	0.4417

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	11 (8.7)	NE [NE, NE)	250	45 (18.0)	NE [NE, NE)	0.6666	2.007 (1.038, 3.882)	0.0348
	3	27	2 (7.4)	NE [6.3, NE)	58	8 (13.8)	NE [18.2, NE)		1.131 (0.237, 5.400)	0.8777
Prior proteasome inhibitor exposure per IXRS	Yes	138	12 (8.7)	NE [NE, NE)	276	49 (17.8)	NE [NE, NE)	0.9088	1.894 (1.007, 3.563)	0.0441
	No	15	1 (6.7)	NE [4.9, NE)	32	4 (12.5)	NE [NE, NE)		1.633 (0.182, 14.655)	0.6583

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	5 (7.6)	NE [NE, NE)	131	19 (14.5)	NE [NE, NE)	0.8783	1.739 (0.648, 4.665)	0.2666
	>= 2	87	8 (9.2)	NE [NE, NE)	177	34 (19.2)	NE [NE, NE)		1.961 (0.908, 4.239)	0.0809

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Pulmonary hypertension (SMQ) - Narrow										
Total subjects		153	4 (2.6)	NE [NE, NE)	308	6 (1.9)	NE [NE, NE)		0.602 (0.168, 2.155)	0.4306

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	3 (2.2)	NE [NE, NE)	283	6 (2.1)	NE [NE, NE)	0.9927	0.791 (0.196, 3.190)	0.7407
	> 75	18	1 (5.6)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.1573
Sex	Male	91	3 (3.3)	NE [NE, NE)	174	6 (3.4)	NE [21.2, NE)	0.9934	0.842 (0.208, 3.418)	0.8101
	Female	62	1 (1.6)	NE [NE, NE)	134	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.1048

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	4 (3.3)	NE [NE, NE)	240	5 (2.1)	NE [NE, NE)	1.0000	0.516 (0.137, 1.949)	0.3208
	Asian	20	0 (0.0)	NE [NE, NE)	46	1 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.5322
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	1 (4.8)	NE [NE, NE)	0.5096	>999.999 (<.001, NE)	0.4795

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	1 (1.0)	NE [NE, NE)	203	3 (1.5)	NE [21.2, NE)		1.248 (0.128, 12.178)	0.8484
	Asia Pacific	39	3 (7.7)	NE [NE, NE)	84	2 (2.4)	NE [NE, NE)		0.246 (0.041, 1.470)	0.0955
Baseline ECOG PS	0-1	146	4 (2.7)	NE [NE, NE)	294	6 (2.0)	NE [NE, NE)	0.9999	0.626 (0.175, 2.234)	0.4663
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-504-ae-cox-eoi-cfz.rtf (Date Generated: 25MAY2020:20:48) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	3 (2.2)	NE [NE, NE)	285	4 (1.4)	NE [NE, NE)	0.6388	0.512 (0.113, 2.324)	0.3777
	No	17	1 (5.9)	NE [NE, NE)	23	2 (8.7)	NE [NE, NE)		1.136 (0.103, 12.535)	0.9172
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	2 (2.0)	NE [21.2, NE)	0.9933	>999.999 (<.001, NE)	0.2692
	No	98	4 (4.1)	NE [NE, NE)	209	4 (1.9)	NE [NE, NE)		0.391 (0.098, 1.565)	0.1689

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	1 (1.4)	NE [NE, NE)	122	3 (2.5)	NE [NE, NE)	0.2612	1.611 (0.167, 15.502)	0.6766
	No	79	3 (3.8)	NE [NE, NE)	186	3 (1.6)	NE [21.2, NE)		0.255 (0.043, 1.526)	0.1060
Refractory to Lenalidomide	Yes	55	1 (1.8)	NE [NE, NE)	98	2 (2.0)	NE [NE, NE)	0.6867	1.010 (0.091, 11.166)	0.9933
	No	98	3 (3.1)	NE [NE, NE)	210	4 (1.9)	NE [21.2, NE)		0.474 (0.103, 2.175)	0.3264

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	2 (1.8)	NE [NE, NE)	205	4 (2.0)	NE [NE, NE)	0.4116	0.931 (0.170, 5.088)	0.9345
	No	43	2 (4.7)	NE [NE, NE)	103	2 (1.9)	NE [21.2, NE)		0.197 (0.018, 2.169)	0.1391
Refractory to IMiD	Yes	65	1 (1.5)	NE [NE, NE)	129	2 (1.6)	NE [NE, NE)	0.7774	0.902 (0.082, 9.969)	0.9329
	No	88	3 (3.4)	NE [NE, NE)	179	4 (2.2)	NE [21.2, NE)		0.506 (0.111, 2.316)	0.3718

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	4 (3.2)	NE [NE, NE)	250	5 (2.0)	NE [NE, NE)	0.9939	0.507 (0.134, 1.915)	0.3080
	3	27	0 (0.0)	NE [NE, NE)	58	1 (1.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.4951
Prior proteasome inhibitor exposure per IXRS	Yes	138	3 (2.2)	NE [NE, NE)	276	4 (1.4)	NE [NE, NE)	0.9137	0.538 (0.118, 2.443)	0.4149
	No	15	1 (6.7)	NE [5.3, NE)	32	2 (6.3)	NE [NE, NE)		0.673 (0.061, 7.429)	0.7450

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	3 (4.5)	NE [NE, NE)	131	3 (2.3)	NE [21.2, NE)	0.3733	0.285 (0.048, 1.707)	0.1427
	>= 2	87	1 (1.1)	NE [NE, NE)	177	3 (1.7)	NE [NE, NE)		1.361 (0.141, 13.102)	0.7890

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Respiratory failure (SMQ) - Narrow										
Total subjects		153	1 (0.7)	NE [NE, NE)	308	3 (1.0)	NE [NE, NE)		1.273 (0.132, 12.271)	0.8345

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	1 (0.7)	NE [NE, NE)	283	3 (1.1)	NE [NE, NE)	1.0000	1.227 (0.127, 11.835)	0.8593
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	1 (0.6)	NE [NE, NE)	0.9952	>999.999 (<.001, NE)	0.5132
	Female	62	1 (1.6)	NE [NE, NE)	134	2 (1.5)	NE [NE, NE)		0.820 (0.074, 9.069)	0.8716

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	0 (0.0)	NE [NE, NE)	240	3 (1.3)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.2358
	Asian	20	1 (5.0)	NE [12.0, NE)	46	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0635
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	3 (1.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.2437
	Asia Pacific	39	1 (2.6)	NE [NE, NE)	84	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0752
Baseline ECOG PS	0-1	146	1 (0.7)	NE [NE, NE)	294	3 (1.0)	NE [NE, NE)	1.0000	1.304 (0.135, 12.565)	0.8179
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	1 (0.7)	NE [NE, NE)	285	3 (1.1)	NE [NE, NE)	1.0000	1.234 (0.128, 11.896)	0.8555
	No	17	0 (0.0)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to Bortezomib or Ixazomib	Yes	55	1 (1.8)	NE [NE, NE)	99	0 (0.0)	NE [NE, NE)	0.9953	<.001 (<.001, NE)	0.1213
	No	98	0 (0.0)	NE [NE, NE)	209	3 (1.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.2618

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	1 (0.8)	NE [NE, NE)	0.9953	>999.999 (<.001, NE)	0.4723
	No	79	1 (1.3)	NE [NE, NE)	186	2 (1.1)	NE [NE, NE)		0.752 (0.068, 8.318)	0.8153
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	1 (1.0)	NE [NE, NE)	0.9958	>999.999 (<.001, NE)	0.5036
	No	98	1 (1.0)	NE [NE, NE)	210	2 (1.0)	NE [NE, NE)		0.822 (0.074, 9.088)	0.8727

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	1 (0.9)	NE [NE, NE)	205	1 (0.5)	NE [NE, NE)	0.9940	0.425 (0.027, 6.815)	0.5333
	No	43	0 (0.0)	NE [NE, NE)	103	2 (1.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.3632
Refractory to IMiD	Yes	65	1 (1.5)	NE [NE, NE)	129	1 (0.8)	NE [NE, NE)	0.9945	0.362 (0.023, 5.832)	0.4551
	No	88	0 (0.0)	NE [NE, NE)	179	2 (1.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.3354

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	1 (0.8)	NE [NE, NE)	250	1 (0.4)	NE [NE, NE)	0.9958	0.412 (0.026, 6.600)	0.5174
	3	27	0 (0.0)	NE [NE, NE)	58	2 (3.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.3876
Prior proteasome inhibitor exposure per IXRS	Yes	138	1 (0.7)	NE [NE, NE)	276	3 (1.1)	NE [NE, NE)	1.0000	1.294 (0.134, 12.479)	0.8231
	No	15	0 (0.0)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	1 (0.8)	NE [NE, NE)	0.9955	>999.999 (<.001, NE)	0.4829
	>= 2	87	1 (1.1)	NE [NE, NE)	177	2 (1.1)	NE [NE, NE)		0.802 (0.073, 8.854)	0.8569

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Respiratory tract infections (HLGT)										
Total subjects		153	84 (54.9)	7.6 [4.3, 11.6)	308	225 (73.1)	5.1 [3.9, 6.5)		1.324 (1.030, 1.701)	0.0280

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CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	76 (56.3)	7.6 [3.7, 11.6)	283	207 (73.1)	4.6 [3.9, 6.5)	0.5945	1.281 (0.985, 1.667)	0.0644
	> 75	18	8 (44.4)	10.2 [1.9, NE)	25	18 (72.0)	6.8 [2.1, 12.1)		1.639 (0.709, 3.792)	0.2433
Sex	Male	91	51 (56.0)	6.5 [3.4, 11.6)	174	129 (74.1)	5.3 [3.8, 8.1)	0.6472	1.256 (0.908, 1.737)	0.1704
	Female	62	33 (53.2)	8.6 [4.1, 13.2)	134	96 (71.6)	4.5 [3.5, 6.6)		1.407 (0.947, 2.090)	0.0894

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CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	66 (54.1)	8.6 [3.7, 11.6)	240	171 (71.3)	5.3 [3.9, 6.9)	0.4090	1.276 (0.960, 1.695)	0.0927
	Asian	20	11 (55.0)	7.3 [3.3, 17.3)	46	38 (82.6)	4.4 [2.0, 7.9)		2.014 (1.002, 4.048)	0.0442
	Other or Unknown	11	7 (63.6)	4.6 [1.3, 13.6)	22	16 (72.7)	4.0 [1.2, 14.9)		0.862 (0.342, 2.168)	0.7417
Region	North America	12	8 (66.7)	2.6 [0.5, NE)	21	18 (85.7)	5.4 [1.5, 11.1)	0.7611	0.951 (0.409, 2.212)	0.8939

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CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	55 (53.9)	9.7 [4.6, 12.1)	203	139 (68.5)	5.1 [3.8, 8.3)		1.291 (0.944, 1.764)	0.1089
	Asia Pacific	39	21 (53.8)	6.5 [2.7, 17.3)	84	68 (81.0)	5.1 [3.3, 6.1)		1.422 (0.870, 2.324)	0.1567
Baseline ECOG PS	0-1	146	83 (56.8)	7.6 [4.1, 11.6)	294	215 (73.1)	4.5 [3.8, 6.5)	0.6919	1.323 (1.027, 1.705)	0.0300
	2	7	1 (14.3)	NE [0.5, NE)	13	9 (69.2)	8.3 [0.7, 17.9)		1.348 (0.144, 12.643)	0.7930

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Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	76 (55.9)	7.6 [4.3, 11.6)	285	206 (72.3)	5.1 [3.9, 6.5)	0.4372	1.276 (0.981, 1.660)	0.0694
	No	17	8 (47.1)	7.3 [1.0, NE)	23	19 (82.6)	4.6 [1.6, 9.7)		1.704 (0.745, 3.900)	0.2013
Refractory to Bortezomib or Ixazomib	Yes	55	24 (43.6)	11.6 [4.3, 17.3)	99	66 (66.7)	5.7 [3.7, 8.2)	0.3640	1.570 (0.984, 2.506)	0.0564
	No	98	60 (61.2)	6.3 [2.9, 8.6)	209	159 (76.1)	4.4 [3.7, 6.6)		1.216 (0.903, 1.637)	0.1985

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CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	38 (51.4)	8.6 [4.3, 12.1)	122	85 (69.7)	5.9 [3.8, 9.2)	0.7023	1.246 (0.849, 1.829)	0.2611
	No	79	46 (58.2)	7.3 [2.8, 12.3)	186	140 (75.3)	4.6 [3.7, 6.4)		1.364 (0.977, 1.905)	0.0682
Refractory to Lenalidomide	Yes	55	30 (54.5)	7.4 [3.5, 11.6)	98	69 (70.4)	5.5 [2.2, 9.2)	0.2234	1.078 (0.698, 1.665)	0.7367
	No	98	54 (55.1)	8.1 [3.4, 12.5)	210	156 (74.3)	4.6 [3.8, 6.5)		1.475 (1.081, 2.014)	0.0138

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	58 (52.7)	7.6 [4.1, 12.1)	205	153 (74.6)	4.3 [3.4, 6.4)	0.4619	1.416 (1.046, 1.916)	0.0236
	No	43	26 (60.5)	8.1 [2.4, 12.3)	103	72 (69.9)	6.5 [4.2, 10.1)		1.149 (0.733, 1.801)	0.5491
Refractory to IMiD	Yes	65	35 (53.8)	7.4 [3.5, 11.6)	129	91 (70.5)	5.5 [3.3, 7.9)	0.2950	1.141 (0.770, 1.689)	0.5114
	No	88	49 (55.7)	8.1 [3.4, 12.5)	179	134 (74.9)	4.6 [3.8, 6.5)		1.480 (1.065, 2.056)	0.0191

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	69 (54.8)	8.6 [5.8, 12.3)	250	189 (75.6)	4.4 [3.7, 6.0)	0.0016	1.556 (1.181, 2.051)	0.0016
	3	27	15 (55.6)	2.8 [1.3, 12.1)	58	36 (62.1)	10.6 [5.3, 12.7)		0.501 (0.261, 0.959)	0.0342
Prior proteasome inhibitor exposure per IXRS	Yes	138	77 (55.8)	7.6 [4.3, 11.6)	276	200 (72.5)	5.1 [3.9, 6.5)	0.6893	1.299 (0.998, 1.689)	0.0511
	No	15	7 (46.7)	NE [0.7, NE)	32	25 (78.1)	5.5 [1.6, 11.5)		1.575 (0.677, 3.666)	0.2856

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	39 (59.1)	5.8 [2.4, 12.3)	131	98 (74.8)	4.6 [3.8, 7.9)	0.9536	1.319 (0.909, 1.915)	0.1435
	>= 2	87	45 (51.7)	9.7 [4.6, 12.1)	177	127 (71.8)	5.5 [3.5, 7.3)		1.313 (0.934, 1.846)	0.1163

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-504-ae-cox-eoi-cfz.rtf (Date Generated: 25MAY2020:20:48) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Reversible posterior leukoencephalopathy syndrome (AMQ) - Narrow										
Total subjects		153	8 (5.2)	NE [NE, NE)	308	38 (12.3)	NE [NE, NE)		2.226 (1.038, 4.773)	0.0349

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	5 (3.7)	NE [NE, NE)	283	32 (11.3)	NE [NE, NE)	0.3623	2.929 (1.141, 7.520)	0.0192
	> 75	18	3 (16.7)	NE [16.9, NE)	25	6 (24.0)	NE [11.7, NE)		1.254 (0.312, 5.036)	0.7495
Sex	Male	91	5 (5.5)	NE [NE, NE)	174	20 (11.5)	NE [NE, NE)	0.6665	1.838 (0.689, 4.903)	0.2173
	Female	62	3 (4.8)	NE [NE, NE)	134	18 (13.4)	NE [NE, NE)		2.797 (0.823, 9.500)	0.0858

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	5 (4.1)	NE [NE, NE)	240	31 (12.9)	NE [NE, NE)	0.1884	3.007 (1.169, 7.737)	0.0164
	Asian	20	1 (5.0)	NE [NE, NE)	46	5 (10.9)	NE [NE, NE)		2.168 (0.253, 18.576)	0.4691
	Other or Unknown	11	2 (18.2)	NE [1.2, NE)	22	2 (9.1)	NE [NE, NE)		0.425 (0.059, 3.047)	0.3803
Region	North America	12	2 (16.7)	NE [3.8, NE)	21	9 (42.9)	15.0 [8.5, NE)	0.9022	2.404 (0.518, 11.159)	0.2478

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	3 (2.9)	NE [NE, NE)	203	12 (5.9)	NE [NE, NE)		1.818 (0.511, 6.461)	0.3492
	Asia Pacific	39	3 (7.7)	NE [NE, NE)	84	17 (20.2)	NE [NE, NE)		2.701 (0.791, 9.222)	0.0982
Baseline ECOG PS	0-1	146	8 (5.5)	NE [NE, NE)	294	37 (12.6)	NE [NE, NE)	0.9869	2.207 (1.028, 4.742)	0.0374
	2	7	0 (0.0)	NE [NE, NE)	13	1 (7.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.6015

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	7 (5.1)	NE [NE, NE)	285	37 (13.0)	NE [NE, NE)	0.3584	2.399 (1.069, 5.383)	0.0286
	No	17	1 (5.9)	NE [NE, NE)	23	1 (4.3)	NE [NE, NE)		0.608 (0.038, 9.849)	0.7235
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	10 (10.1)	NE [NE, NE)	0.9859	>999.999 (<.001, NE)	0.0199
	No	98	8 (8.2)	NE [NE, NE)	209	28 (13.4)	NE [NE, NE)		1.526 (0.695, 3.352)	0.2888

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	4 (5.4)	NE [NE, NE)	122	18 (14.8)	NE [NE, NE)	0.7684	2.416 (0.816, 7.152)	0.1001
	No	79	4 (5.1)	NE [NE, NE)	186	20 (10.8)	NE [NE, NE)		2.079 (0.710, 6.085)	0.1719
Refractory to Lenalidomide	Yes	55	3 (5.5)	NE [16.9, NE)	98	17 (17.3)	NE [NE, NE)	0.5720	2.721 (0.794, 9.327)	0.0972
	No	98	5 (5.1)	NE [NE, NE)	210	21 (10.0)	NE [NE, NE)		1.901 (0.716, 5.042)	0.1895

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	7 (6.4)	NE [NE, NE)	205	30 (14.6)	NE [NE, NE)	0.7587	2.193 (0.963, 4.996)	0.0556
	No	43	1 (2.3)	NE [NE, NE)	103	8 (7.8)	NE [NE, NE)		3.126 (0.391, 25.019)	0.2571
Refractory to IMiD	Yes	65	3 (4.6)	NE [16.9, NE)	129	22 (17.1)	NE [NE, NE)	0.2877	3.292 (0.983, 11.025)	0.0406
	No	88	5 (5.7)	NE [NE, NE)	179	16 (8.9)	NE [NE, NE)		1.519 (0.556, 4.147)	0.4113

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	6 (4.8)	NE [NE, NE)	250	31 (12.4)	NE [NE, NE)	0.4381	2.542 (1.060, 6.095)	0.0302
	3	27	2 (7.4)	NE [7.0, NE)	58	7 (12.1)	NE [NE, NE)		1.173 (0.237, 5.810)	0.8452
Prior proteasome inhibitor exposure per IXRS	Yes	138	8 (5.8)	NE [NE, NE)	276	36 (13.0)	NE [NE, NE)	0.9890	2.126 (0.988, 4.578)	0.0485
	No	15	0 (0.0)	NE [NE, NE)	32	2 (6.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.3671

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	4 (6.1)	NE [NE, NE)	131	15 (11.5)	NE [NE, NE)	0.5894	1.778 (0.589, 5.365)	0.2996
	>= 2	87	4 (4.6)	NE [NE, NE)	177	23 (13.0)	NE [NE, NE)		2.668 (0.922, 7.721)	0.0598

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Torsade de pointes/QT prolongation (SMQ) - Narrow										
Total subjects		153	0 (0.0)	NE [NE, NE)	308	2 (0.6)	NE [NE, NE)		>999.999 (<.001, NE)	0.3617

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	0 (0.0)	NE [NE, NE)	283	2 (0.7)	NE [NE, NE)	0.9992	>999.999 (<.001, NE)	0.3717
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	2 (1.1)	NE [NE, NE)	0.9989	>999.999 (<.001, NE)	0.3545
	Female	62	0 (0.0)	NE [NE, NE)	134	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	0 (0.0)	NE [NE, NE)	240	2 (0.8)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.3553
	Asian	20	0 (0.0)	NE [NE, NE)	46	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	1 (4.8)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.6650

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	1 (0.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.4817
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Baseline ECOG PS	0-1	146	0 (0.0)	NE [NE, NE)	294	2 (0.7)	NE [NE, NE)	0.9996	>999.999 (<.001, NE)	0.3555
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-504-ae-cox-eoi-cfz.rtf (Date Generated: 25MAY2020:20:48) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	0 (0.0)	NE [NE, NE)	285	2 (0.7)	NE [NE, NE)	0.9992	>999.999 (<.001, NE)	0.3704
	No	17	0 (0.0)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	0 (0.0)	NE [NE, NE)	0.9989	NE (NE, NE)	NE
	No	98	0 (0.0)	NE [NE, NE)	209	2 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.3789

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	2 (1.6)	NE [NE, NE)	0.9992	>999.999 (<.001, NE)	0.3292
	No	79	0 (0.0)	NE [NE, NE)	186	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	2 (2.0)	NE [NE, NE)	0.9990	>999.999 (<.001, NE)	0.3561
	No	98	0 (0.0)	NE [NE, NE)	210	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	0 (0.0)	NE [NE, NE)	205	2 (1.0)	NE [NE, NE)	0.9989	>999.999 (<.001, NE)	0.3472
	No	43	0 (0.0)	NE [NE, NE)	103	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	2 (1.6)	NE [NE, NE)	0.9991	>999.999 (<.001, NE)	0.3799
	No	88	0 (0.0)	NE [NE, NE)	179	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	0 (0.0)	NE [NE, NE)	250	2 (0.8)	NE [NE, NE)	0.9991	>999.999 (<.001, NE)	0.3521
	3	27	0 (0.0)	NE [NE, NE)	58	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Prior proteasome inhibitor exposure per IXRS	Yes	138	0 (0.0)	NE [NE, NE)	276	2 (0.7)	NE [NE, NE)	0.9992	>999.999 (<.001, NE)	0.3606
	No	15	0 (0.0)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	1 (0.8)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.5710
	>= 2	87	0 (0.0)	NE [NE, NE)	177	1 (0.6)	NE [NE, NE)		>999.999 (<.001, NE)	0.4833

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Tumour lysis syndrome (SMQ) - Narrow										
Total subjects		153	1 (0.7)	NE [NE, NE)	308	3 (1.0)	NE [NE, NE)		1.501 (0.156, 14.427)	0.7231

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	1 (0.7)	NE [NE, NE)	283	3 (1.1)	NE [NE, NE)	1.0000	1.442 (0.150, 13.864)	0.7497
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	1 (1.1)	NE [NE, NE)	174	1 (0.6)	NE [NE, NE)	0.9952	0.523 (0.033, 8.364)	0.6411
	Female	62	0 (0.0)	NE [NE, NE)	134	2 (1.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.3342

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	0 (0.0)	NE [NE, NE)	240	3 (1.3)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.2146
	Asian	20	0 (0.0)	NE [NE, NE)	46	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
	Other or Unknown	11	1 (9.1)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.1573
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	1 (1.0)	NE [NE, NE)	203	3 (1.5)	NE [NE, NE)		1.524 (0.159, 14.649)	0.7130
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Baseline ECOG PS	0-1	146	1 (0.7)	NE [NE, NE)	294	3 (1.0)	NE [NE, NE)	0.9999	1.501 (0.156, 14.428)	0.7231
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	1 (0.7)	NE [NE, NE)	285	3 (1.1)	NE [NE, NE)	1.0000	1.443 (0.150, 13.868)	0.7495
	No	17	0 (0.0)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	1 (1.0)	NE [NE, NE)	0.9955	>999.999 (<.001, NE)	0.4538
	No	98	1 (1.0)	NE [NE, NE)	209	2 (1.0)	NE [NE, NE)		0.941 (0.085, 10.373)	0.9601

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	2 (1.6)	NE [NE, NE)	0.9948	>999.999 (<.001, NE)	0.2687
	No	79	1 (1.3)	NE [NE, NE)	186	1 (0.5)	NE [NE, NE)		0.424 (0.027, 6.785)	0.5320
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	2 (2.0)	NE [NE, NE)	0.9957	>999.999 (<.001, NE)	0.2869
	No	98	1 (1.0)	NE [NE, NE)	210	1 (0.5)	NE [NE, NE)		0.467 (0.029, 7.459)	0.5807

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	1 (0.9)	NE [NE, NE)	205	2 (1.0)	NE [NE, NE)	0.9960	1.082 (0.098, 11.933)	0.9487
	No	43	0 (0.0)	NE [NE, NE)	103	1 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.5162
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	2 (1.6)	NE [NE, NE)	0.9951	>999.999 (<.001, NE)	0.3135
	No	88	1 (1.1)	NE [NE, NE)	179	1 (0.6)	NE [NE, NE)		0.492 (0.031, 7.859)	0.6081

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-504-ae-cox-eoi-cfz.rtf (Date Generated: 25MAY2020:20:48) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	0 (0.0)	NE [NE, NE)	250	1 (0.4)	NE [NE, NE)	0.9956	>999.999 (<.001, NE)	0.4769
	3	27	1 (3.7)	NE [NE, NE)	58	2 (3.4)	NE [NE, NE)		0.941 (0.085, 10.381)	0.9605
Prior proteasome inhibitor exposure per IXRS	Yes	138	1 (0.7)	NE [NE, NE)	276	3 (1.1)	NE [NE, NE)	0.9999	1.512 (0.157, 14.534)	0.7182
	No	15	0 (0.0)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
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Table 14-6.1.504. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	1 (1.5)	NE [NE, NE)	131	2 (1.5)	NE [NE, NE)	0.9950	1.008 (0.091, 11.113)	0.9950
	>= 2	87	0 (0.0)	NE [NE, NE)	177	1 (0.6)	NE [NE, NE)		>999.999 (<.001, NE)	0.4808

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-504-ae-cox-eoi-cfz.rtf (Date Generated: 25MAY2020:20:48) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Acute renal failure (SMQ) - Narrow										
Total subjects		153	10 (6.5)	NE [NE, NE)	308	9 (2.9)	NE [NE, NE)		0.402 (0.163, 0.990)	0.0405

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-505-ae-cox-eoi-cfz-grd345.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	10 (7.4)	NE [NE, NE)	283	7 (2.5)	NE [NE, NE)	0.9915	0.299 (0.113, 0.786)	0.0094
	> 75	18	0 (0.0)	NE [NE, NE)	25	2 (8.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.2648
Sex	Male	91	8 (8.8)	NE [NE, NE)	174	5 (2.9)	NE [NE, NE)	0.3050	0.290 (0.094, 0.887)	0.0209
	Female	62	2 (3.2)	NE [NE, NE)	134	4 (3.0)	NE [NE, NE)		0.868 (0.159, 4.743)	0.8698

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	6 (4.9)	NE [NE, NE)	240	9 (3.8)	NE [NE, NE)	0.9999	0.710 (0.252, 1.997)	0.5142
	Asian	20	3 (15.0)	NE [11.5, NE)	46	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0036
	Other or Unknown	11	1 (9.1)	NE [1.1, NE)	22	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.1380
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	0.2019	NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	5 (4.9)	NE [NE, NE)	203	8 (3.9)	NE [NE, NE)		0.750 (0.245, 2.295)	0.6133
	Asia Pacific	39	5 (12.8)	NE [NE, NE)	84	1 (1.2)	NE [NE, NE)		0.079 (0.009, 0.679)	0.0029
Baseline ECOG PS	0-1	146	10 (6.8)	NE [NE, NE)	294	7 (2.4)	NE [NE, NE)	0.9919	0.317 (0.121, 0.834)	0.0140
	2	7	0 (0.0)	NE [NE, NE)	13	2 (15.4)	NE [3.3, NE)		>999.999 (<.001, NE)	0.4070

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	8 (5.9)	NE [NE, NE)	285	8 (2.8)	NE [NE, NE)	0.8027	0.436 (0.164, 1.164)	0.0885
	No	17	2 (11.8)	NE [9.5, NE)	23	1 (4.3)	NE [NE, NE)		0.272 (0.024, 3.031)	0.2572
Refractory to Bortezomib or Ixazomib	Yes	55	3 (5.5)	NE [NE, NE)	99	5 (5.1)	NE [NE, NE)	0.1836	0.869 (0.207, 3.640)	0.8473
	No	98	7 (7.1)	NE [NE, NE)	209	4 (1.9)	NE [NE, NE)		0.233 (0.068, 0.798)	0.0115

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	5 (6.8)	NE [NE, NE)	122	4 (3.3)	NE [NE, NE)	0.9188	0.434 (0.116, 1.618)	0.2005
	No	79	5 (6.3)	NE [NE, NE)	186	5 (2.7)	NE [NE, NE)		0.389 (0.113, 1.347)	0.1227
Refractory to Lenalidomide	Yes	55	5 (9.1)	NE [NE, NE)	98	4 (4.1)	NE [NE, NE)	0.9179	0.396 (0.106, 1.480)	0.1540
	No	98	5 (5.1)	NE [NE, NE)	210	5 (2.4)	NE [NE, NE)		0.427 (0.124, 1.478)	0.1667

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	8 (7.3)	NE [NE, NE)	205	7 (3.4)	NE [NE, NE)	0.9382	0.424 (0.154, 1.171)	0.0877
	No	43	2 (4.7)	NE [NE, NE)	103	2 (1.9)	NE [NE, NE)		0.370 (0.052, 2.641)	0.3019
Refractory to IMiD	Yes	65	7 (10.8)	NE [NE, NE)	129	5 (3.9)	NE [NE, NE)	0.5030	0.312 (0.099, 0.987)	0.0362
	No	88	3 (3.4)	NE [NE, NE)	179	4 (2.2)	NE [NE, NE)		0.604 (0.135, 2.704)	0.5070

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	8 (6.3)	NE [NE, NE)	250	4 (1.6)	NE [NE, NE)	0.2142	0.230 (0.069, 0.766)	0.0090
	3	27	2 (7.4)	NE [NE, NE)	58	5 (8.6)	NE [NE, NE)		0.930 (0.180, 4.818)	0.9312
Prior proteasome inhibitor exposure per IXRS	Yes	138	8 (5.8)	NE [NE, NE)	276	8 (2.9)	NE [NE, NE)	0.5243	0.459 (0.172, 1.225)	0.1110
	No	15	2 (13.3)	NE [9.5, NE)	32	1 (3.1)	NE [NE, NE)		0.191 (0.017, 2.117)	0.1320

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	3 (4.5)	NE [NE, NE)	131	1 (0.8)	NE [NE, NE)	0.3337	0.136 (0.014, 1.316)	0.0436
	>= 2	87	7 (8.0)	NE [NE, NE)	177	8 (4.5)	NE [NE, NE)		0.519 (0.188, 1.432)	0.1974

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Cardiac arrhythmias (SMQ) - Narrow										
Total subjects		153	4 (2.6)	NE [NE, NE)	308	9 (2.9)	NE [NE, NE)		0.979 (0.301, 3.181)	0.9713

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-505-ae-cox-eoi-cfz-grd345.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	3 (2.2)	NE [NE, NE)	283	6 (2.1)	NE [NE, NE)	0.5577	0.822 (0.205, 3.293)	0.7814
	> 75	18	1 (5.6)	NE [NE, NE)	25	3 (12.0)	NE [NE, NE)		1.838 (0.191, 17.709)	0.5930
Sex	Male	91	4 (4.4)	NE [NE, NE)	174	8 (4.6)	NE [NE, NE)	0.9932	0.933 (0.280, 3.105)	0.9101
	Female	62	0 (0.0)	NE [NE, NE)	134	1 (0.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.5344

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	4 (3.3)	NE [NE, NE)	240	8 (3.3)	NE [NE, NE)	1.0000	0.895 (0.269, 2.977)	0.8569
	Asian	20	0 (0.0)	NE [NE, NE)	46	1 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.5097
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	1 (4.8)	NE [NE, NE)	0.9423	>999.999 (<.001, NE)	0.6650

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	3 (2.9)	NE [NE, NE)	203	5 (2.5)	NE [NE, NE)		0.737 (0.176, 3.086)	0.6749
	Asia Pacific	39	1 (2.6)	NE [NE, NE)	84	3 (3.6)	NE [NE, NE)		1.283 (0.133, 12.344)	0.8286
Baseline ECOG PS	0-1	146	4 (2.7)	NE [NE, NE)	294	8 (2.7)	NE [NE, NE)	0.9936	0.891 (0.268, 2.961)	0.8499
	2	7	0 (0.0)	NE [NE, NE)	13	1 (7.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.6015

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	3 (2.2)	NE [NE, NE)	285	9 (3.2)	NE [NE, NE)	0.9911	1.262 (0.341, 4.668)	0.7264
	No	17	1 (5.9)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.2207
Refractory to Bortezomib or Ixazomib	Yes	55	2 (3.6)	NE [NE, NE)	99	3 (3.0)	NE [NE, NE)	0.7274	0.787 (0.132, 4.713)	0.7931
	No	98	2 (2.0)	NE [NE, NE)	209	6 (2.9)	NE [NE, NE)		1.183 (0.238, 5.877)	0.8370

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	2 (2.7)	NE [NE, NE)	122	4 (3.3)	NE [NE, NE)	0.9560	1.038 (0.189, 5.696)	0.9658
	No	79	2 (2.5)	NE [NE, NE)	186	5 (2.7)	NE [NE, NE)		0.942 (0.183, 4.861)	0.9435
Refractory to Lenalidomide	Yes	55	2 (3.6)	NE [NE, NE)	98	2 (2.0)	NE [NE, NE)	0.3597	0.425 (0.059, 3.053)	0.3811
	No	98	2 (2.0)	NE [NE, NE)	210	7 (3.3)	NE [NE, NE)		1.494 (0.310, 7.194)	0.6141

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	2 (1.8)	NE [NE, NE)	205	6 (2.9)	NE [NE, NE)	0.4705	1.399 (0.282, 6.943)	0.6798
	No	43	2 (4.7)	NE [NE, NE)	103	3 (2.9)	NE [NE, NE)		0.549 (0.092, 3.293)	0.5056
Refractory to IMiD	Yes	65	2 (3.1)	NE [NE, NE)	129	4 (3.1)	NE [NE, NE)	0.8080	0.792 (0.144, 4.346)	0.7877
	No	88	2 (2.3)	NE [NE, NE)	179	5 (2.8)	NE [NE, NE)		1.125 (0.218, 5.802)	0.8882

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	4 (3.2)	NE [NE, NE)	250	6 (2.4)	NE [NE, NE)	0.9926	0.679 (0.191, 2.412)	0.5475
	3	27	0 (0.0)	NE [NE, NE)	58	3 (5.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.3142
Prior proteasome inhibitor exposure per IXRS	Yes	138	3 (2.2)	NE [NE, NE)	276	9 (3.3)	NE [NE, NE)	0.9897	1.327 (0.359, 4.907)	0.6707
	No	15	1 (6.7)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0986

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	1 (1.5)	NE [NE, NE)	131	5 (3.8)	NE [NE, NE)	0.3129	2.065 (0.240, 17.729)	0.4995
	>= 2	87	3 (3.4)	NE [NE, NE)	177	4 (2.3)	NE [NE, NE)		0.589 (0.132, 2.634)	0.4837

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Cardiac failure (SMQ) - Narrow										
Total subjects		153	13 (8.5)	NE [NE, NE)	308	12 (3.9)	NE [NE, NE)		0.372 (0.169, 0.821)	0.0109

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	9 (6.7)	NE [NE, NE)	283	9 (3.2)	NE [NE, NE)	0.8901	0.372 (0.147, 0.944)	0.0304
	> 75	18	4 (22.2)	NE [12.9, NE)	25	3 (12.0)	NE [NE, NE)		0.509 (0.114, 2.276)	0.3675
Sex	Male	91	9 (9.9)	NE [NE, NE)	174	7 (4.0)	NE [NE, NE)	0.6248	0.345 (0.128, 0.929)	0.0276
	Female	62	4 (6.5)	NE [NE, NE)	134	5 (3.7)	NE [NE, NE)		0.470 (0.126, 1.760)	0.2518

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	10 (8.2)	NE [NE, NE)	240	12 (5.0)	NE [NE, NE)	0.9999	0.499 (0.214, 1.162)	0.1005
	Asian	20	3 (15.0)	NE [NE, NE)	46	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0077
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	1 (8.3)	NE [11.5, NE)	21	2 (9.5)	NE [NE, NE)	0.3843	0.926 (0.083, 10.274)	0.9497

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	7 (6.9)	NE [NE, NE)	203	8 (3.9)	NE [NE, NE)		0.483 (0.174, 1.335)	0.1521
	Asia Pacific	39	5 (12.8)	NE [NE, NE)	84	2 (2.4)	NE [NE, NE)		0.157 (0.030, 0.811)	0.0112
Baseline ECOG PS	0-1	146	13 (8.9)	NE [NE, NE)	294	10 (3.4)	NE [NE, NE)	0.9910	0.330 (0.144, 0.753)	0.0056
	2	7	0 (0.0)	NE [NE, NE)	13	2 (15.4)	NE [19.2, NE)		>999.999 (<.001, NE)	0.5186

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-505-ae-cox-eoi-cfz-grd345.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	11 (8.1)	NE [NE, NE)	285	9 (3.2)	NE [NE, NE)	0.3029	0.309 (0.127, 0.752)	0.0063
	No	17	2 (11.8)	NE [7.3, NE)	23	3 (13.0)	NE [NE, NE)		0.958 (0.159, 5.767)	0.9624
Refractory to Bortezomib or Ixazomib	Yes	55	5 (9.1)	NE [NE, NE)	99	2 (2.0)	NE [NE, NE)	0.3324	0.193 (0.037, 0.998)	0.0287
	No	98	8 (8.2)	NE [NE, NE)	209	10 (4.8)	NE [NE, NE)		0.463 (0.181, 1.185)	0.1003

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	7 (9.5)	NE [NE, NE)	122	4 (3.3)	NE [NE, NE)	0.4822	0.262 (0.075, 0.912)	0.0241
	No	79	6 (7.6)	NE [NE, NE)	186	8 (4.3)	NE [NE, NE)		0.491 (0.170, 1.418)	0.1795
Refractory to Lenalidomide	Yes	55	4 (7.3)	NE [NE, NE)	98	3 (3.1)	NE [NE, NE)	0.7813	0.352 (0.079, 1.577)	0.1536
	No	98	9 (9.2)	NE [NE, NE)	210	9 (4.3)	NE [NE, NE)		0.393 (0.155, 0.995)	0.0410

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	8 (7.3)	NE [NE, NE)	205	6 (2.9)	NE [NE, NE)	0.7309	0.314 (0.107, 0.923)	0.0265
	No	43	5 (11.6)	NE [NE, NE)	103	6 (5.8)	NE [NE, NE)		0.428 (0.130, 1.408)	0.1504
Refractory to IMiD	Yes	65	4 (6.2)	NE [NE, NE)	129	3 (2.3)	NE [NE, NE)	0.6604	0.320 (0.071, 1.430)	0.1154
	No	88	9 (10.2)	NE [NE, NE)	179	9 (5.0)	NE [NE, NE)		0.417 (0.165, 1.056)	0.0569

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	9 (7.1)	NE [NE, NE)	250	10 (4.0)	NE [NE, NE)	0.2503	0.488 (0.198, 1.202)	0.1113
	3	27	4 (14.8)	NE [NE, NE)	58	2 (3.4)	NE [19.2, NE)		0.166 (0.030, 0.923)	0.0202
Prior proteasome inhibitor exposure per IXRS	Yes	138	11 (8.0)	NE [NE, NE)	276	9 (3.3)	NE [NE, NE)	0.6155	0.324 (0.133, 0.786)	0.0088
	No	15	2 (13.3)	NE [3.5, NE)	32	3 (9.4)	NE [NE, NE)		0.624 (0.104, 3.750)	0.6027

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	8 (12.1)	NE [NE, NE)	131	5 (3.8)	NE [NE, NE)	0.3384	0.256 (0.083, 0.785)	0.0103
	>= 2	87	5 (5.7)	NE [NE, NE)	177	7 (4.0)	NE [NE, NE)		0.540 (0.169, 1.731)	0.2938

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Cardiomyopathy (SMQ) - Narrow										
Total subjects		153	1 (0.7)	NE [NE, NE)	308	1 (0.3)	NE [NE, NE)		0.403 (0.025, 6.452)	0.5060

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	0 (0.0)	NE [NE, NE)	283	1 (0.4)	NE [NE, NE)	0.9975	>999.999 (<.001, NE)	0.5516
	> 75	18	1 (5.6)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.1835
Sex	Male	91	1 (1.1)	NE [NE, NE)	174	1 (0.6)	NE [NE, NE)	0.9999	0.417 (0.026, 6.710)	0.5242
	Female	62	0 (0.0)	NE [NE, NE)	134	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	1 (0.8)	NE [NE, NE)	240	1 (0.4)	NE [NE, NE)	1.0000	0.419 (0.026, 6.715)	0.5258
	Asian	20	0 (0.0)	NE [NE, NE)	46	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
	Asia Pacific	39	1 (2.6)	NE [NE, NE)	84	1 (1.2)	NE [NE, NE)		0.368 (0.023, 5.901)	0.4621
Baseline ECOG PS	0-1	146	1 (0.7)	NE [NE, NE)	294	1 (0.3)	NE [NE, NE)	0.9999	0.416 (0.026, 6.669)	0.5226
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	0 (0.0)	NE [NE, NE)	285	0 (0.0)	NE [NE, NE)	0.9999	NE (NE, NE)	NE
	No	17	1 (5.9)	NE [NE, NE)	23	1 (4.3)	NE [NE, NE)		0.504 (0.031, 8.101)	0.6220
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	0 (0.0)	NE [NE, NE)	0.9999	NE (NE, NE)	NE
	No	98	1 (1.0)	NE [NE, NE)	209	1 (0.5)	NE [NE, NE)		0.382 (0.024, 6.115)	0.4800

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	1 (1.4)	NE [NE, NE)	122	0 (0.0)	NE [NE, NE)	0.9972	<.001 (<.001, NE)	0.1573
	No	79	0 (0.0)	NE [NE, NE)	186	1 (0.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.5622
Refractory to Lenalidomide	Yes	55	1 (1.8)	NE [NE, NE)	98	0 (0.0)	NE [NE, NE)	0.9974	<.001 (<.001, NE)	0.1504
	No	98	0 (0.0)	NE [NE, NE)	210	1 (0.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.5412

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	1 (0.9)	NE [NE, NE)	205	1 (0.5)	NE [NE, NE)	0.9999	0.425 (0.027, 6.797)	0.5326
	No	43	0 (0.0)	NE [NE, NE)	103	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to IMiD	Yes	65	1 (1.5)	NE [NE, NE)	129	0 (0.0)	NE [NE, NE)	0.9963	<.001 (<.001, NE)	0.1250
	No	88	0 (0.0)	NE [NE, NE)	179	1 (0.6)	NE [NE, NE)		>999.999 (<.001, NE)	0.5271

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-505-ae-cox-eoi-cfz-grd345.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	1 (0.8)	NE [NE, NE)	250	1 (0.4)	NE [NE, NE)	0.9999	0.435 (0.027, 6.966)	0.5451
	3	27	0 (0.0)	NE [NE, NE)	58	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Prior proteasome inhibitor exposure per IXRS	Yes	138	0 (0.0)	NE [NE, NE)	276	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE
	No	15	1 (6.7)	NE [3.5, NE)	32	1 (3.1)	NE [NE, NE)		0.333 (0.021, 5.329)	0.4142

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	0 (0.0)	NE [NE, NE)	0.9999	NE (NE, NE)	NE
	>= 2	87	1 (1.1)	NE [NE, NE)	177	1 (0.6)	NE [NE, NE)		0.397 (0.025, 6.356)	0.4984

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Dyspnoeas (HLT)										
Total subjects		153	4 (2.6)	NE [NE, NE)	308	12 (3.9)	NE [NE, NE)		1.387 (0.447, 4.302)	0.5700

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	4 (3.0)	NE [NE, NE)	283	12 (4.2)	NE [NE, NE)	0.9999	1.340 (0.432, 4.158)	0.6114
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	2 (2.2)	NE [NE, NE)	174	8 (4.6)	NE [NE, NE)	0.4679	2.037 (0.432, 9.594)	0.3584
	Female	62	2 (3.2)	NE [NE, NE)	134	4 (3.0)	NE [NE, NE)		0.850 (0.155, 4.650)	0.8514

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	3 (2.5)	NE [NE, NE)	240	10 (4.2)	NE [NE, NE)	0.9999	1.587 (0.436, 5.769)	0.4792
	Asian	20	1 (5.0)	NE [NE, NE)	46	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.1294
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	2 (9.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.3324
Region	North America	12	0 (0.0)	NE [NE, NE)	21	1 (4.8)	NE [NE, NE)	0.9686	>999.999 (<.001, NE)	0.4497

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	2 (2.0)	NE [NE, NE)	203	6 (3.0)	NE [NE, NE)		1.404 (0.283, 6.966)	0.6762
	Asia Pacific	39	2 (5.1)	NE [NE, NE)	84	5 (6.0)	NE [NE, NE)		1.048 (0.203, 5.409)	0.9552
Baseline ECOG PS	0-1	146	3 (2.1)	NE [NE, NE)	294	10 (3.4)	NE [NE, NE)	0.5748	1.535 (0.422, 5.579)	0.5119
	2	7	1 (14.3)	NE [0.3, NE)	13	2 (15.4)	NE [1.3, NE)		1.080 (0.098, 11.920)	0.9500

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	4 (2.9)	NE [NE, NE)	285	12 (4.2)	NE [NE, NE)	0.9999	1.334 (0.430, 4.140)	0.6165
	No	17	0 (0.0)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to Bortezomib or Ixazomib	Yes	55	1 (1.8)	NE [NE, NE)	99	2 (2.0)	NE [NE, NE)	0.8196	1.064 (0.096, 11.742)	0.9596
	No	98	3 (3.1)	NE [NE, NE)	209	10 (4.8)	NE [NE, NE)		1.438 (0.395, 5.232)	0.5789

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	1 (1.4)	NE [NE, NE)	122	7 (5.7)	NE [NE, NE)	0.1661	3.943 (0.484, 32.095)	0.1660
	No	79	3 (3.8)	NE [NE, NE)	186	5 (2.7)	NE [NE, NE)		0.661 (0.158, 2.767)	0.5682
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	5 (5.1)	NE [NE, NE)	0.9911	>999.999 (<.001, NE)	0.1127
	No	98	4 (4.1)	NE [NE, NE)	210	7 (3.3)	NE [NE, NE)		0.767 (0.224, 2.622)	0.6717

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	3 (2.7)	NE [NE, NE)	205	12 (5.9)	NE [NE, NE)	0.9882	1.997 (0.563, 7.083)	0.2747
	No	43	1 (2.3)	NE [NE, NE)	103	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.1186
Refractory to IMiD	Yes	65	1 (1.5)	NE [NE, NE)	129	7 (5.4)	NE [NE, NE)	0.2672	3.198 (0.393, 26.059)	0.2509
	No	88	3 (3.4)	NE [NE, NE)	179	5 (2.8)	NE [NE, NE)		0.777 (0.186, 3.253)	0.7290

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	3 (2.4)	NE [NE, NE)	250	10 (4.0)	NE [NE, NE)	0.5929	1.592 (0.438, 5.788)	0.4759
	3	27	1 (3.7)	NE [NE, NE)	58	2 (3.4)	NE [NE, NE)		0.851 (0.076, 9.475)	0.8952
Prior proteasome inhibitor exposure per IXRS	Yes	138	4 (2.9)	NE [NE, NE)	276	11 (4.0)	NE [NE, NE)	0.9932	1.280 (0.407, 4.022)	0.6720
	No	15	0 (0.0)	NE [NE, NE)	32	1 (3.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.4867

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	2 (3.0)	NE [NE, NE)	131	6 (4.6)	NE [NE, NE)	0.9876	1.358 (0.274, 6.742)	0.7067
	>= 2	87	2 (2.3)	NE [NE, NE)	177	6 (3.4)	NE [NE, NE)		1.423 (0.287, 7.053)	0.6640

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Embolic and thrombotic events, venous (SMQ) - Narrow										
Total subjects		153	10 (6.5)	NE [NE, NE)	308	6 (1.9)	NE [NE, NE)		0.232 (0.084, 0.640)	0.0021

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	9 (6.7)	NE [NE, NE)	283	5 (1.8)	NE [NE, NE)	0.5313	0.209 (0.070, 0.626)	0.0021
	> 75	18	1 (5.6)	NE [NE, NE)	25	1 (4.0)	NE [NE, NE)		0.522 (0.033, 8.355)	0.6402
Sex	Male	91	5 (5.5)	NE [18.6, NE)	174	5 (2.9)	NE [NE, NE)	0.1667	0.393 (0.113, 1.372)	0.1298
	Female	62	5 (8.1)	NE [NE, NE)	134	1 (0.7)	NE [NE, NE)		0.075 (0.009, 0.643)	0.0021

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-505-ae-cox-eoi-cfz-grd345.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	10 (8.2)	NE [NE, NE)	240	5 (2.1)	NE [NE, NE)	1.0000	0.197 (0.067, 0.579)	0.0010
	Asian	20	0 (0.0)	NE [NE, NE)	46	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	1 (4.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.5741
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	0.8139	NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	7 (6.9)	NE [NE, NE)	203	5 (2.5)	NE [NE, NE)		0.281 (0.089, 0.888)	0.0209
	Asia Pacific	39	3 (7.7)	NE [18.6, NE)	84	1 (1.2)	NE [NE, NE)		0.103 (0.010, 1.027)	0.0193
Baseline ECOG PS	0-1	146	10 (6.8)	NE [NE, NE)	294	6 (2.0)	NE [NE, NE)	0.9997	0.240 (0.087, 0.663)	0.0028
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	8 (5.9)	NE [NE, NE)	285	5 (1.8)	NE [NE, NE)	0.8882	0.246 (0.080, 0.751)	0.0077
	No	17	2 (11.8)	NE [18.6, NE)	23	1 (4.3)	NE [NE, NE)		0.267 (0.024, 3.022)	0.2538
Refractory to Bortezomib or Ixazomib	Yes	55	2 (3.6)	NE [NE, NE)	99	1 (1.0)	NE [NE, NE)	0.9886	0.232 (0.021, 2.571)	0.1943
	No	98	8 (8.2)	NE [NE, NE)	209	5 (2.4)	NE [NE, NE)		0.226 (0.074, 0.695)	0.0046

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	2 (2.7)	NE [NE, NE)	122	1 (0.8)	NE [NE, NE)	0.9585	0.236 (0.021, 2.625)	0.2015
	No	79	8 (10.1)	NE [18.6, NE)	186	5 (2.7)	NE [NE, NE)		0.210 (0.068, 0.645)	0.0027
Refractory to Lenalidomide	Yes	55	2 (3.6)	NE [NE, NE)	98	1 (1.0)	NE [NE, NE)	0.8934	0.208 (0.018, 2.342)	0.1618
	No	98	8 (8.2)	NE [18.6, NE)	210	5 (2.4)	NE [NE, NE)		0.236 (0.077, 0.724)	0.0060

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	5 (4.5)	NE [NE, NE)	205	3 (1.5)	NE [NE, NE)	0.8041	0.244 (0.058, 1.030)	0.0378
	No	43	5 (11.6)	NE [NE, NE)	103	3 (2.9)	NE [NE, NE)		0.197 (0.047, 0.827)	0.0136
Refractory to IMiD	Yes	65	3 (4.6)	NE [NE, NE)	129	1 (0.8)	NE [NE, NE)	0.5025	0.126 (0.013, 1.226)	0.0349
	No	88	7 (8.0)	NE [18.6, NE)	179	5 (2.8)	NE [NE, NE)		0.284 (0.090, 0.900)	0.0226

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	9 (7.1)	NE [NE, NE)	250	5 (2.0)	NE [NE, NE)	0.9248	0.230 (0.077, 0.690)	0.0043
	3	27	1 (3.7)	NE [NE, NE)	58	1 (1.7)	NE [NE, NE)		0.261 (0.016, 4.223)	0.3090
Prior proteasome inhibitor exposure per IXRS	Yes	138	8 (5.8)	NE [NE, NE)	276	5 (1.8)	NE [NE, NE)	0.7959	0.254 (0.083, 0.779)	0.0097
	No	15	2 (13.3)	18.6 [3.9, NE)	32	1 (3.1)	NE [NE, NE)		0.176 (0.016, 1.950)	0.1100

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	7 (10.6)	NE [18.6, NE)	131	3 (2.3)	NE [NE, NE)	0.4537	0.172 (0.044, 0.669)	0.0041
	>= 2	87	3 (3.4)	NE [NE, NE)	177	3 (1.7)	NE [NE, NE)		0.391 (0.079, 1.943)	0.2341

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Haematopoietic erythropenia (SMQ) - Broad										
Total subjects		153	22 (14.4)	NE [NE, NE)	308	52 (16.9)	NE [NE, NE)		1.147 (0.696, 1.888)	0.5906

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	20 (14.8)	NE [NE, NE)	283	49 (17.3)	NE [NE, NE)	0.9046	1.145 (0.680, 1.926)	0.6106
	> 75	18	2 (11.1)	NE [NE, NE)	25	3 (12.0)	NE [NE, NE)		1.038 (0.173, 6.213)	0.9673
Sex	Male	91	15 (16.5)	NE [NE, NE)	174	22 (12.6)	NE [NE, NE)	0.0604	0.727 (0.377, 1.403)	0.3403
	Female	62	7 (11.3)	NE [NE, NE)	134	30 (22.4)	NE [NE, NE)		2.009 (0.882, 4.573)	0.0899

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	17 (13.9)	NE [NE, NE)	240	35 (14.6)	NE [NE, NE)	0.6712	1.024 (0.573, 1.829)	0.9367
	Asian	20	4 (20.0)	NE [11.8, NE)	46	15 (32.6)	NE [15.3, NE)		1.655 (0.548, 4.993)	0.3655
	Other or Unknown	11	1 (9.1)	NE [0.8, NE)	22	2 (9.1)	NE [NE, NE)		0.763 (0.069, 8.455)	0.8251
Region	North America	12	1 (8.3)	NE [NE, NE)	21	2 (9.5)	NE [NE, NE)	0.5647	1.006 (0.091, 11.171)	0.9959

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	11 (10.8)	NE [NE, NE)	203	32 (15.8)	NE [NE, NE)		1.445 (0.728, 2.868)	0.2890
	Asia Pacific	39	10 (25.6)	NE [17.3, NE)	84	18 (21.4)	NE [NE, NE)		0.789 (0.363, 1.713)	0.5473
Baseline ECOG PS	0-1	146	20 (13.7)	NE [NE, NE)	294	50 (17.0)	NE [NE, NE)	0.1637	1.236 (0.735, 2.076)	0.4232
	2	7	2 (28.6)	NE [0.3, NE)	13	2 (15.4)	NE [2.1, NE)		0.333 (0.045, 2.447)	0.2578

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	19 (14.0)	NE [NE, NE)	285	50 (17.5)	NE [NE, NE)	0.3180	1.235 (0.728, 2.095)	0.4316
	No	17	3 (17.6)	NE [11.8, NE)	23	2 (8.7)	NE [NE, NE)		0.376 (0.061, 2.322)	0.2750
Refractory to Bortezomib or Ixazomib	Yes	55	8 (14.5)	NE [NE, NE)	99	23 (23.2)	NE [NE, NE)	0.2914	1.624 (0.726, 3.630)	0.2315
	No	98	14 (14.3)	NE [NE, NE)	209	29 (13.9)	NE [NE, NE)		0.916 (0.484, 1.735)	0.7868

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	13 (17.6)	NE [NE, NE)	122	26 (21.3)	NE [NE, NE)	0.9937	1.207 (0.620, 2.350)	0.5804
	No	79	9 (11.4)	NE [NE, NE)	186	26 (14.0)	NE [NE, NE)		1.189 (0.557, 2.537)	0.6553
Refractory to Lenalidomide	Yes	55	10 (18.2)	NE [NE, NE)	98	23 (23.5)	NE [NE, NE)	0.7707	1.281 (0.609, 2.695)	0.5122
	No	98	12 (12.2)	NE [NE, NE)	210	29 (13.8)	NE [NE, NE)		1.095 (0.558, 2.146)	0.7921

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	18 (16.4)	NE [NE, NE)	205	38 (18.5)	NE [NE, NE)	0.7180	1.119 (0.638, 1.962)	0.6951
	No	43	4 (9.3)	NE [NE, NE)	103	14 (13.6)	NE [NE, NE)		1.411 (0.464, 4.286)	0.5429
Refractory to IMiD	Yes	65	12 (18.5)	NE [NE, NE)	129	27 (20.9)	NE [NE, NE)	0.8878	1.134 (0.574, 2.241)	0.7179
	No	88	10 (11.4)	NE [NE, NE)	179	25 (14.0)	NE [NE, NE)		1.193 (0.573, 2.484)	0.6380

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	12 (9.5)	NE [NE, NE)	250	38 (15.2)	NE [NE, NE)	0.0243	1.603 (0.838, 3.070)	0.1501
	3	27	10 (37.0)	NE [0.9, NE)	58	14 (24.1)	NE [NE, NE)		0.534 (0.237, 1.203)	0.1240
Prior proteasome inhibitor exposure per IXRS	Yes	138	19 (13.8)	NE [NE, NE)	276	48 (17.4)	NE [NE, NE)	0.3691	1.247 (0.733, 2.122)	0.4134
	No	15	3 (20.0)	NE [11.8, NE)	32	4 (12.5)	NE [NE, NE)		0.575 (0.128, 2.577)	0.4639

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	6 (9.1)	NE [NE, NE)	131	18 (13.7)	NE [NE, NE)	0.5060	1.450 (0.575, 3.657)	0.4284
	>= 2	87	16 (18.4)	NE [NE, NE)	177	34 (19.2)	NE [NE, NE)		1.029 (0.568, 1.865)	0.9238

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Haematopoietic leukopenia (SMQ) - Narrow										
Total subjects		153	18 (11.8)	NE [NE, NE)	308	47 (15.3)	NE [NE, NE)		1.245 (0.723, 2.146)	0.4297

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	14 (10.4)	NE [NE, NE)	283	45 (15.9)	NE [NE, NE)	0.1031	1.485 (0.814, 2.707)	0.1944
	> 75	18	4 (22.2)	NE [12.1, NE)	25	2 (8.0)	NE [NE, NE)		0.338 (0.062, 1.853)	0.1851
Sex	Male	91	9 (9.9)	NE [NE, NE)	174	26 (14.9)	NE [NE, NE)	0.5901	1.448 (0.678, 3.094)	0.3360
	Female	62	9 (14.5)	NE [NE, NE)	134	21 (15.7)	NE [NE, NE)		1.050 (0.481, 2.295)	0.9036

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	8 (6.6)	NE [NE, NE)	240	19 (7.9)	NE [NE, NE)	0.9708	1.121 (0.490, 2.566)	0.7880
	Asian	20	9 (45.0)	NE [0.4, NE)	46	25 (54.3)	6.4 [0.6, NE)		1.278 (0.596, 2.741)	0.5334
	Other or Unknown	11	1 (9.1)	NE [12.1, NE)	22	3 (13.6)	NE [16.8, NE)		1.386 (0.144, 13.329)	0.7767
Region	North America	12	0 (0.0)	NE [NE, NE)	21	1 (4.8)	NE [NE, NE)	0.9723	>999.999 (<.001, NE)	0.4497

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	7 (6.9)	NE [NE, NE)	203	19 (9.4)	NE [NE, NE)		1.261 (0.529, 3.003)	0.6006
	Asia Pacific	39	11 (28.2)	NE [NE, NE)	84	27 (32.1)	NE [NE, NE)		1.149 (0.570, 2.320)	0.7027
Baseline ECOG PS	0-1	146	17 (11.6)	NE [NE, NE)	294	44 (15.0)	NE [NE, NE)	0.9249	1.244 (0.710, 2.179)	0.4454
	2	7	1 (14.3)	NE [0.3, NE)	13	3 (23.1)	NE [1.0, NE)		1.216 (0.126, 11.773)	0.8799

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	16 (11.8)	NE [NE, NE)	285	44 (15.4)	NE [NE, NE)	0.8205	1.262 (0.711, 2.238)	0.4269
	No	17	2 (11.8)	NE [NE, NE)	23	3 (13.0)	NE [NE, NE)		1.018 (0.169, 6.132)	0.9849
Refractory to Bortezomib or Ixazomib	Yes	55	7 (12.7)	NE [NE, NE)	99	16 (16.2)	NE [NE, NE)	0.9073	1.207 (0.496, 2.934)	0.6771
	No	98	11 (11.2)	NE [NE, NE)	209	31 (14.8)	NE [NE, NE)		1.290 (0.647, 2.569)	0.4697

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	7 (9.5)	NE [NE, NE)	122	27 (22.1)	NE [NE, NE)	0.0367	2.371 (1.032, 5.450)	0.0361
	No	79	11 (13.9)	NE [NE, NE)	186	20 (10.8)	NE [NE, NE)		0.711 (0.340, 1.485)	0.3616
Refractory to Lenalidomide	Yes	55	5 (9.1)	NE [NE, NE)	98	20 (20.4)	NE [NE, NE)	0.1574	2.173 (0.814, 5.804)	0.1122
	No	98	13 (13.3)	NE [NE, NE)	210	27 (12.9)	NE [NE, NE)		0.927 (0.478, 1.798)	0.8220

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	13 (11.8)	NE [NE, NE)	205	36 (17.6)	NE [NE, NE)	0.4316	1.442 (0.764, 2.722)	0.2569
	No	43	5 (11.6)	NE [NE, NE)	103	11 (10.7)	NE [NE, NE)		0.876 (0.304, 2.525)	0.8046
Refractory to IMiD	Yes	65	7 (10.8)	NE [NE, NE)	129	24 (18.6)	NE [NE, NE)	0.3574	1.674 (0.720, 3.893)	0.2266
	No	88	11 (12.5)	NE [NE, NE)	179	23 (12.8)	NE [NE, NE)		0.984 (0.479, 2.020)	0.9653

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-505-ae-cox-eoi-cfz-grd345.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	15 (11.9)	NE [NE, NE)	250	39 (15.6)	NE [NE, NE)	0.7735	1.294 (0.713, 2.349)	0.3969
	3	27	3 (11.1)	NE [NE, NE)	58	8 (13.8)	NE [NE, NE)		1.017 (0.268, 3.854)	0.9806
Prior proteasome inhibitor exposure per IXRS	Yes	138	17 (12.3)	NE [NE, NE)	276	43 (15.6)	NE [NE, NE)	0.7157	1.209 (0.689, 2.122)	0.5094
	No	15	1 (6.7)	NE [NE, NE)	32	4 (12.5)	NE [NE, NE)		1.876 (0.209, 16.829)	0.5703

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	9 (13.6)	NE [NE, NE)	131	17 (13.0)	NE [NE, NE)	0.2837	0.884 (0.394, 1.987)	0.7653
	>= 2	87	9 (10.3)	NE [NE, NE)	177	30 (16.9)	NE [NE, NE)		1.620 (0.769, 3.416)	0.2002

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Haematopoietic thrombocytopenia (SMQ) - Narrow										
Total subjects		153	25 (16.3)	NE [NE, NE)	308	76 (24.7)	NE [NE, NE)		1.582 (1.006, 2.486)	0.0457

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	22 (16.3)	NE [NE, NE)	283	71 (25.1)	NE [NE, NE)	0.7222	1.624 (1.006, 2.620)	0.0454
	> 75	18	3 (16.7)	NE [10.9, NE)	25	5 (20.0)	NE [NE, NE)		1.178 (0.281, 4.930)	0.8227
Sex	Male	91	15 (16.5)	NE [NE, NE)	174	42 (24.1)	NE [NE, NE)	0.8903	1.538 (0.852, 2.774)	0.1535
	Female	62	10 (16.1)	NE [NE, NE)	134	34 (25.4)	NE [NE, NE)		1.635 (0.808, 3.310)	0.1669

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	16 (13.1)	NE [NE, NE)	240	48 (20.0)	NE [NE, NE)	0.3915	1.618 (0.919, 2.850)	0.0934
	Asian	20	6 (30.0)	NE [2.1, NE)	46	24 (52.2)	9.4 [0.6, NE)		2.014 (0.823, 4.932)	0.1177
	Other or Unknown	11	3 (27.3)	NE [0.8, NE)	22	4 (18.2)	NE [NE, NE)		0.558 (0.124, 2.503)	0.4400
Region	North America	12	3 (25.0)	NE [1.2, NE)	21	6 (28.6)	NE [0.7, NE)	0.7239	1.221 (0.305, 4.889)	0.7891

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	14 (13.7)	NE [NE, NE)	203	39 (19.2)	NE [NE, NE)		1.434 (0.778, 2.641)	0.2479
	Asia Pacific	39	8 (20.5)	NE [NE, NE)	84	31 (36.9)	NE [NE, NE)		1.999 (0.918, 4.350)	0.0757
Baseline ECOG PS	0-1	146	23 (15.8)	NE [NE, NE)	294	72 (24.5)	NE [NE, NE)	0.5105	1.641 (1.026, 2.625)	0.0372
	2	7	2 (28.6)	NE [0.4, NE)	13	4 (30.8)	NE [0.4, NE)		1.149 (0.210, 6.290)	0.8597

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	24 (17.6)	NE [NE, NE)	285	74 (26.0)	NE [NE, NE)	0.9503	1.549 (0.978, 2.456)	0.0614
	No	17	1 (5.9)	NE [9.5, NE)	23	2 (8.7)	NE [NE, NE)		1.304 (0.118, 14.456)	0.8285
Refractory to Bortezomib or Ixazomib	Yes	55	13 (23.6)	NE [NE, NE)	99	29 (29.3)	NE [NE, NE)	0.4442	1.331 (0.691, 2.561)	0.3998
	No	98	12 (12.2)	NE [NE, NE)	209	47 (22.5)	NE [NE, NE)		1.901 (1.008, 3.585)	0.0435

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	16 (21.6)	NE [NE, NE)	122	39 (32.0)	NE [NE, NE)	0.8331	1.606 (0.897, 2.875)	0.1119
	No	79	9 (11.4)	NE [NE, NE)	186	37 (19.9)	NE [NE, NE)		1.797 (0.867, 3.724)	0.1097
Refractory to Lenalidomide	Yes	55	11 (20.0)	NE [NE, NE)	98	33 (33.7)	NE [NE, NE)	0.5782	1.869 (0.944, 3.701)	0.0698
	No	98	14 (14.3)	NE [NE, NE)	210	43 (20.5)	NE [NE, NE)		1.460 (0.799, 2.669)	0.2168

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	18 (16.4)	NE [NE, NE)	205	56 (27.3)	NE [NE, NE)	0.4463	1.792 (1.053, 3.048)	0.0299
	No	43	7 (16.3)	NE [NE, NE)	103	20 (19.4)	NE [NE, NE)		1.188 (0.502, 2.811)	0.6968
Refractory to IMiD	Yes	65	13 (20.0)	NE [NE, NE)	129	41 (31.8)	NE [NE, NE)	0.6809	1.749 (0.937, 3.265)	0.0769
	No	88	12 (13.6)	NE [NE, NE)	179	35 (19.6)	NE [NE, NE)		1.448 (0.752, 2.791)	0.2655

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	17 (13.5)	NE [NE, NE)	250	56 (22.4)	NE [NE, NE)	0.3515	1.754 (1.019, 3.019)	0.0401
	3	27	8 (29.6)	NE [1.2, NE)	58	20 (34.5)	NE [NE, NE)		1.163 (0.512, 2.642)	0.7317
Prior proteasome inhibitor exposure per IXRS	Yes	138	23 (16.7)	NE [NE, NE)	276	71 (25.7)	NE [NE, NE)	0.7296	1.629 (1.018, 2.607)	0.0407
	No	15	2 (13.3)	NE [9.5, NE)	32	5 (15.6)	NE [NE, NE)		1.114 (0.215, 5.760)	0.8975

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	8 (12.1)	NE [NE, NE)	131	28 (21.4)	NE [NE, NE)	0.6807	1.795 (0.818, 3.940)	0.1388
	>= 2	87	17 (19.5)	NE [NE, NE)	177	48 (27.1)	NE [NE, NE)		1.501 (0.863, 2.610)	0.1511

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Haemorrhage terms (excl laboratory terms) (SMQ) - Narrow										
Total subjects		153	4 (2.6)	NE [NE, NE)	308	6 (1.9)	NE [NE, NE)		0.687 (0.194, 2.438)	0.5590

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	3 (2.2)	NE [NE, NE)	283	6 (2.1)	NE [NE, NE)	0.9925	0.883 (0.221, 3.538)	0.8609
	> 75	18	1 (5.6)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.2305
Sex	Male	91	1 (1.1)	NE [NE, NE)	174	3 (1.7)	NE [NE, NE)	0.3745	1.517 (0.158, 14.588)	0.7163
	Female	62	3 (4.8)	NE [NE, NE)	134	3 (2.2)	NE [NE, NE)		0.408 (0.082, 2.026)	0.2570

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	4 (3.3)	NE [NE, NE)	240	4 (1.7)	NE [NE, NE)	0.9999	0.463 (0.115, 1.854)	0.2647
	Asian	20	0 (0.0)	NE [NE, NE)	46	1 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.5097
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	1 (4.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.4795
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	4 (3.9)	NE [NE, NE)	203	4 (2.0)	NE [NE, NE)		0.453 (0.113, 1.811)	0.2501
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	2 (2.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.3338
Baseline ECOG PS	0-1	146	4 (2.7)	NE [NE, NE)	294	5 (1.7)	NE [NE, NE)	0.9931	0.575 (0.154, 2.145)	0.4045
	2	7	0 (0.0)	NE [NE, NE)	13	1 (7.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.4631

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	2 (1.5)	NE [NE, NE)	285	5 (1.8)	NE [NE, NE)	0.4192	1.136 (0.220, 5.856)	0.8792
	No	17	2 (11.8)	NE [NE, NE)	23	1 (4.3)	NE [NE, NE)		0.310 (0.028, 3.483)	0.3166
Refractory to Bortezomib or Ixazomib	Yes	55	1 (1.8)	NE [NE, NE)	99	4 (4.0)	NE [NE, NE)	0.1642	2.136 (0.239, 19.116)	0.4872
	No	98	3 (3.1)	NE [NE, NE)	209	2 (1.0)	NE [NE, NE)		0.277 (0.046, 1.666)	0.1338

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	3 (4.1)	NE [NE, NE)	122	3 (2.5)	NE [NE, NE)	0.5782	0.551 (0.111, 2.734)	0.4596
	No	79	1 (1.3)	NE [NE, NE)	186	3 (1.6)	NE [NE, NE)		1.200 (0.125, 11.569)	0.8743
Refractory to Lenalidomide	Yes	55	1 (1.8)	NE [NE, NE)	98	3 (3.1)	NE [NE, NE)	0.3796	1.553 (0.161, 14.950)	0.7005
	No	98	3 (3.1)	NE [NE, NE)	210	3 (1.4)	NE [NE, NE)		0.440 (0.089, 2.183)	0.3016

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	3 (2.7)	NE [NE, NE)	205	4 (2.0)	NE [NE, NE)	0.8988	0.665 (0.149, 2.973)	0.5907
	No	43	1 (2.3)	NE [NE, NE)	103	2 (1.9)	NE [NE, NE)		0.757 (0.068, 8.398)	0.8204
Refractory to IMiD	Yes	65	1 (1.5)	NE [NE, NE)	129	3 (2.3)	NE [NE, NE)	0.4467	1.372 (0.142, 13.208)	0.7835
	No	88	3 (3.4)	NE [NE, NE)	179	3 (1.7)	NE [NE, NE)		0.465 (0.094, 2.305)	0.3365

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	3 (2.4)	NE [NE, NE)	250	4 (1.6)	NE [NE, NE)	0.9141	0.629 (0.141, 2.817)	0.5412
	3	27	1 (3.7)	NE [NE, NE)	58	2 (3.4)	NE [NE, NE)		0.742 (0.067, 8.231)	0.8070
Prior proteasome inhibitor exposure per IXRS	Yes	138	2 (1.4)	NE [NE, NE)	276	5 (1.8)	NE [NE, NE)	0.2433	1.194 (0.232, 6.157)	0.8320
	No	15	2 (13.3)	NE [NE, NE)	32	1 (3.1)	NE [NE, NE)		0.199 (0.018, 2.200)	0.1432

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	2 (3.0)	NE [NE, NE)	131	3 (2.3)	NE [NE, NE)	0.9896	0.684 (0.114, 4.116)	0.6766
	>= 2	87	2 (2.3)	NE [NE, NE)	177	3 (1.7)	NE [NE, NE)		0.681 (0.114, 4.082)	0.6727

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Hepatic failure, fibrosis and cirrhosis and other liver damage-related conditions (SMQ) - Narrow										
Total subjects		153	1 (0.7)	NE [NE, NE)	308	3 (1.0)	NE [NE, NE)		1.373 (0.143, 13.213)	0.7827

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	1 (0.7)	NE [NE, NE)	283	3 (1.1)	NE [NE, NE)	1.0000	1.332 (0.138, 12.813)	0.8033
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	1 (1.1)	NE [NE, NE)	174	0 (0.0)	NE [NE, NE)	0.9959	<.001 (<.001, NE)	0.1377
	Female	62	0 (0.0)	NE [NE, NE)	134	3 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.2533

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
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[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	1 (0.8)	NE [NE, NE)	240	2 (0.8)	NE [NE, NE)	1.0000	0.929 (0.084, 10.252)	0.9521
	Asian	20	0 (0.0)	NE [NE, NE)	46	1 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.5097
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	1 (8.3)	NE [6.0, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	<.001 (<.001, NE)	0.1573

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	2 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.3384
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	1 (1.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.4930
Baseline ECOG PS	0-1	146	1 (0.7)	NE [NE, NE)	294	2 (0.7)	NE [NE, NE)	0.9949	0.947 (0.086, 10.446)	0.9643
	2	7	0 (0.0)	NE [NE, NE)	13	1 (7.7)	NE [5.5, NE)		>999.999 (<.001, NE)	0.7518

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Output: t14-06-001-505-ae-cox-eoi-cfz-grd345.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	1 (0.7)	NE [NE, NE)	285	3 (1.1)	NE [NE, NE)	1.0000	1.326 (0.138, 12.751)	0.8066
	No	17	0 (0.0)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to Bortezomib or Ixazomib	Yes	55	1 (1.8)	NE [NE, NE)	99	2 (2.0)	NE [NE, NE)	0.9954	1.060 (0.096, 11.697)	0.9618
	No	98	0 (0.0)	NE [NE, NE)	209	1 (0.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.4938

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	1 (1.4)	NE [NE, NE)	122	1 (0.8)	NE [NE, NE)	0.9947	0.545 (0.034, 8.726)	0.6633
	No	79	0 (0.0)	NE [NE, NE)	186	2 (1.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.3724
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE
	No	98	1 (1.0)	NE [NE, NE)	210	3 (1.4)	NE [NE, NE)		1.308 (0.136, 12.581)	0.8155

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	1 (0.9)	NE [NE, NE)	205	2 (1.0)	NE [NE, NE)	0.9960	1.004 (0.091, 11.081)	0.9976
	No	43	0 (0.0)	NE [NE, NE)	103	1 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.5365
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	2 (1.6)	NE [NE, NE)	0.9953	>999.999 (<.001, NE)	0.3183
	No	88	1 (1.1)	NE [NE, NE)	179	1 (0.6)	NE [NE, NE)		0.436 (0.027, 6.973)	0.5459

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	1 (0.8)	NE [NE, NE)	250	3 (1.2)	NE [NE, NE)	0.9999	1.437 (0.149, 13.827)	0.7520
	3	27	0 (0.0)	NE [NE, NE)	58	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Prior proteasome inhibitor exposure per IXRS	Yes	138	1 (0.7)	NE [NE, NE)	276	3 (1.1)	NE [NE, NE)	1.0000	1.395 (0.145, 13.423)	0.7719
	No	15	0 (0.0)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	1 (0.8)	NE [NE, NE)	0.9953	>999.999 (<.001, NE)	0.5054
	>= 2	87	1 (1.1)	NE [NE, NE)	177	2 (1.1)	NE [NE, NE)		0.926 (0.084, 10.222)	0.9497

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Hypertension (SMQ) - Narrow										
Total subjects		153	21 (13.7)	NE [NE, NE)	308	55 (17.9)	NE [NE, NE)		1.168 (0.706, 1.933)	0.5437

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	17 (12.6)	NE [NE, NE)	283	46 (16.3)	NE [NE, NE)	0.9262	1.182 (0.677, 2.063)	0.5560
	> 75	18	4 (22.2)	NE [2.4, NE)	25	9 (36.0)	NE [5.6, NE)		1.129 (0.343, 3.708)	0.8419
Sex	Male	91	14 (15.4)	NE [NE, NE)	174	31 (17.8)	NE [NE, NE)	0.5054	1.025 (0.544, 1.929)	0.9390
	Female	62	7 (11.3)	NE [NE, NE)	134	24 (17.9)	NE [NE, NE)		1.477 (0.636, 3.429)	0.3590

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	14 (11.5)	NE [NE, NE)	240	37 (15.4)	NE [NE, NE)	0.4774	1.217 (0.657, 2.252)	0.5319
	Asian	20	5 (25.0)	NE [7.5, NE)	46	9 (19.6)	NE [NE, NE)		0.682 (0.227, 2.045)	0.4904
	Other or Unknown	11	2 (18.2)	NE [1.9, NE)	22	9 (40.9)	NE [9.3, NE)		2.120 (0.457, 9.833)	0.3259
Region	North America	12	2 (16.7)	NE [11.5, NE)	21	7 (33.3)	NE [8.1, NE)	0.5990	1.937 (0.398, 9.437)	0.4047

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	9 (8.8)	NE [NE, NE)	203	26 (12.8)	NE [NE, NE)		1.303 (0.610, 2.781)	0.4923
	Asia Pacific	39	10 (25.6)	NE [17.3, NE)	84	22 (26.2)	NE [NE, NE)		0.899 (0.425, 1.902)	0.7803
Baseline ECOG PS	0-1	146	20 (13.7)	NE [NE, NE)	294	54 (18.4)	NE [NE, NE)	0.2114	1.236 (0.740, 2.065)	0.4171
	2	7	1 (14.3)	NE [3.1, NE)	13	1 (7.7)	NE [NE, NE)		0.402 (0.024, 6.621)	0.5101

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	16 (11.8)	NE [NE, NE)	285	50 (17.5)	NE [NE, NE)	0.2667	1.354 (0.771, 2.378)	0.2898
	No	17	5 (29.4)	17.3 [6.9, NE)	23	5 (21.7)	NE [15.9, NE)		0.600 (0.172, 2.092)	0.4177
Refractory to Bortezomib or Ixazomib	Yes	55	7 (12.7)	NE [NE, NE)	99	11 (11.1)	NE [NE, NE)	0.3030	0.757 (0.293, 1.956)	0.5639
	No	98	14 (14.3)	NE [NE, NE)	209	44 (21.1)	NE [NE, NE)		1.359 (0.745, 2.482)	0.3150

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	7 (9.5)	NE [NE, NE)	122	25 (20.5)	NE [NE, NE)	0.0903	1.978 (0.855, 4.577)	0.1042
	No	79	14 (17.7)	NE [NE, NE)	186	30 (16.1)	NE [NE, NE)		0.815 (0.432, 1.538)	0.5278
Refractory to Lenalidomide	Yes	55	7 (12.7)	NE [17.3, NE)	98	20 (20.4)	NE [NE, NE)	0.5955	1.380 (0.582, 3.274)	0.4627
	No	98	14 (14.3)	NE [NE, NE)	210	35 (16.7)	NE [NE, NE)		1.068 (0.575, 1.986)	0.8333

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	16 (14.5)	NE [NE, NE)	205	39 (19.0)	NE [NE, NE)	0.9715	1.180 (0.659, 2.114)	0.5753
	No	43	5 (11.6)	NE [NE, NE)	103	16 (15.5)	NE [NE, NE)		1.221 (0.447, 3.336)	0.6968
Refractory to IMiD	Yes	65	8 (12.3)	NE [17.3, NE)	129	25 (19.4)	NE [NE, NE)	0.5613	1.387 (0.624, 3.081)	0.4198
	No	88	13 (14.8)	NE [NE, NE)	179	30 (16.8)	NE [NE, NE)		1.031 (0.537, 1.977)	0.9261

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-505-ae-cox-eoi-cfz-grd345.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	16 (12.7)	NE [NE, NE)	250	47 (18.8)	NE [NE, NE)	0.1209	1.387 (0.786, 2.447)	0.2564
	3	27	5 (18.5)	NE [14.2, NE)	58	8 (13.8)	NE [NE, NE)		0.518 (0.168, 1.600)	0.2450
Prior proteasome inhibitor exposure per IXRS	Yes	138	16 (11.6)	NE [NE, NE)	276	50 (18.1)	NE [NE, NE)	0.0550	1.434 (0.816, 2.519)	0.2068
	No	15	5 (33.3)	17.3 [6.9, NE)	32	5 (15.6)	NE [NE, NE)		0.373 (0.108, 1.293)	0.1058

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	10 (15.2)	NE [NE, NE)	131	25 (19.1)	NE [NE, NE)	0.9096	1.137 (0.546, 2.369)	0.7318
	>= 2	87	11 (12.6)	NE [NE, NE)	177	30 (16.9)	NE [NE, NE)		1.206 (0.604, 2.409)	0.5947

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Infusion reaction (AMQ) - Narrow (event on same date of any Carfilzomib dosing)										
Total subjects		153	8 (5.2)	NE [NE, NE)	308	38 (12.3)	NE [NE, NE)		2.166 (1.010, 4.645)	0.0420

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	6 (4.4)	NE [NE, NE)	283	30 (10.6)	NE [NE, NE)	0.8479	2.197 (0.914, 5.284)	0.0715
	> 75	18	2 (11.1)	NE [NE, NE)	25	8 (32.0)	NE [8.6, NE)		2.600 (0.552, 12.254)	0.2082
Sex	Male	91	5 (5.5)	NE [NE, NE)	174	23 (13.2)	NE [NE, NE)	0.9596	2.209 (0.839, 5.819)	0.0999
	Female	62	3 (4.8)	NE [NE, NE)	134	15 (11.2)	NE [NE, NE)		2.162 (0.626, 7.474)	0.2114

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	7 (5.7)	NE [NE, NE)	240	26 (10.8)	NE [NE, NE)	0.9551	1.715 (0.744, 3.956)	0.2003
	Asian	20	1 (5.0)	NE [NE, NE)	46	6 (13.0)	NE [NE, NE)		2.563 (0.308, 21.297)	0.3668
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	6 (27.3)	NE [12.2, NE)		>999.999 (<.001, NE)	0.0895
Region	North America	12	0 (0.0)	NE [NE, NE)	21	6 (28.6)	NE [8.1, NE)	0.9189	>999.999 (<.001, NE)	0.0659

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	4 (3.9)	NE [NE, NE)	203	18 (8.9)	NE [NE, NE)		2.024 (0.685, 5.985)	0.1932
	Asia Pacific	39	4 (10.3)	NE [17.3, NE)	84	14 (16.7)	NE [NE, NE)		1.519 (0.500, 4.621)	0.4567
Baseline ECOG PS	0-1	146	7 (4.8)	NE [NE, NE)	294	36 (12.2)	NE [NE, NE)	0.2307	2.391 (1.063, 5.375)	0.0296
	2	7	1 (14.3)	NE [3.1, NE)	13	2 (15.4)	NE [6.0, NE)		0.402 (0.024, 6.621)	0.5101

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	6 (4.4)	NE [NE, NE)	285	34 (11.9)	NE [NE, NE)	0.5214	2.501 (1.050, 5.961)	0.0321
	No	17	2 (11.8)	NE [17.3, NE)	23	4 (17.4)	NE [NE, NE)		1.225 (0.222, 6.751)	0.8155
Refractory to Bortezomib or Ixazomib	Yes	55	3 (5.5)	NE [NE, NE)	99	8 (8.1)	NE [NE, NE)	0.4394	1.307 (0.346, 4.936)	0.6925
	No	98	5 (5.1)	NE [NE, NE)	209	30 (14.4)	NE [NE, NE)		2.620 (1.016, 6.756)	0.0384

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	3 (4.1)	NE [NE, NE)	122	15 (12.3)	NE [NE, NE)	0.6094	2.662 (0.769, 9.217)	0.1086
	No	79	5 (6.3)	NE [NE, NE)	186	23 (12.4)	NE [NE, NE)		1.848 (0.702, 4.862)	0.2063
Refractory to Lenalidomide	Yes	55	3 (5.5)	NE [17.3, NE)	98	11 (11.2)	NE [NE, NE)	0.7218	1.644 (0.456, 5.927)	0.4442
	No	98	5 (5.1)	NE [NE, NE)	210	27 (12.9)	NE [NE, NE)		2.418 (0.931, 6.281)	0.0611

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	6 (5.5)	NE [NE, NE)	205	24 (11.7)	NE [NE, NE)	0.7037	1.944 (0.794, 4.761)	0.1391
	No	43	2 (4.7)	NE [NE, NE)	103	14 (13.6)	NE [NE, NE)		2.802 (0.637, 12.336)	0.1542
Refractory to IMiD	Yes	65	3 (4.6)	NE [17.3, NE)	129	16 (12.4)	NE [NE, NE)	0.8446	2.257 (0.655, 7.778)	0.1853
	No	88	5 (5.7)	NE [NE, NE)	179	22 (12.3)	NE [NE, NE)		2.065 (0.782, 5.454)	0.1347

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	6 (4.8)	NE [NE, NE)	250	31 (12.4)	NE [NE, NE)	0.4436	2.487 (1.037, 5.964)	0.0346
	3	27	2 (7.4)	NE [NE, NE)	58	7 (12.1)	NE [NE, NE)		1.105 (0.227, 5.375)	0.9019
Prior proteasome inhibitor exposure per IXRS	Yes	138	6 (4.3)	NE [NE, NE)	276	35 (12.7)	NE [NE, NE)	0.1408	2.726 (1.146, 6.484)	0.0180
	No	15	2 (13.3)	NE [17.3, NE)	32	3 (9.4)	NE [NE, NE)		0.631 (0.105, 3.792)	0.6115

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	3 (4.5)	NE [NE, NE)	131	15 (11.5)	NE [NE, NE)	0.9180	2.301 (0.665, 7.954)	0.1752
	>= 2	87	5 (5.7)	NE [NE, NE)	177	23 (13.0)	NE [NE, NE)		2.095 (0.796, 5.517)	0.1258

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Infusion reaction (AMQ) - Narrow (event on same date of first Carfilzomib dosing)										
Total subjects		153	1 (0.7)	NE [NE, NE)	308	5 (1.6)	NE [NE, NE)		2.494 (0.291, 21.346)	0.3875

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	0 (0.0)	NE [NE, NE)	283	4 (1.4)	NE [NE, NE)	0.9948	>999.999 (<.001, NE)	0.1656
	> 75	18	1 (5.6)	NE [NE, NE)	25	1 (4.0)	NE [NE, NE)		0.717 (0.045, 11.465)	0.8133
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	3 (1.7)	NE [NE, NE)	0.9930	>999.999 (<.001, NE)	0.2086
	Female	62	1 (1.6)	NE [NE, NE)	134	2 (1.5)	NE [NE, NE)		0.925 (0.084, 10.201)	0.9492

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	1 (0.8)	NE [NE, NE)	240	2 (0.8)	NE [NE, NE)	1.0000	1.017 (0.092, 11.212)	0.9892
	Asian	20	0 (0.0)	NE [NE, NE)	46	2 (4.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.3473
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	1 (4.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.4795
Region	North America	12	0 (0.0)	NE [NE, NE)	21	1 (4.8)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.4497

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	2 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.3153
	Asia Pacific	39	1 (2.6)	NE [NE, NE)	84	2 (2.4)	NE [NE, NE)		0.928 (0.084, 10.234)	0.9513
Baseline ECOG PS	0-1	146	1 (0.7)	NE [NE, NE)	294	5 (1.7)	NE [NE, NE)	0.9998	2.494 (0.291, 21.343)	0.3876
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	1 (0.7)	NE [NE, NE)	285	4 (1.4)	NE [NE, NE)	0.9936	1.914 (0.214, 17.124)	0.5544
	No	17	0 (0.0)	NE [NE, NE)	23	1 (4.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.3899
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	0 (0.0)	NE [NE, NE)	0.9999	NE (NE, NE)	NE
	No	98	1 (1.0)	NE [NE, NE)	209	5 (2.4)	NE [NE, NE)		2.358 (0.275, 20.183)	0.4190

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	3 (2.5)	NE [NE, NE)	0.9938	>999.999 (<.001, NE)	0.1751
	No	79	1 (1.3)	NE [NE, NE)	186	2 (1.1)	NE [NE, NE)		0.849 (0.077, 9.362)	0.8935
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	0 (0.0)	NE [NE, NE)	0.9999	NE (NE, NE)	NE
	No	98	1 (1.0)	NE [NE, NE)	210	5 (2.4)	NE [NE, NE)		2.347 (0.274, 20.086)	0.4218

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	0 (0.0)	NE [NE, NE)	205	4 (2.0)	NE [NE, NE)	0.9950	>999.999 (<.001, NE)	0.1410
	No	43	1 (2.3)	NE [NE, NE)	103	1 (1.0)	NE [NE, NE)		0.416 (0.026, 6.653)	0.5224
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	1 (0.8)	NE [NE, NE)	0.9949	>999.999 (<.001, NE)	0.4778
	No	88	1 (1.1)	NE [NE, NE)	179	4 (2.2)	NE [NE, NE)		1.975 (0.221, 17.672)	0.5345

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	1 (0.8)	NE [NE, NE)	250	4 (1.6)	NE [NE, NE)	0.9943	2.023 (0.226, 18.096)	0.5199
	3	27	0 (0.0)	NE [NE, NE)	58	1 (1.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.4951
Prior proteasome inhibitor exposure per IXRS	Yes	138	1 (0.7)	NE [NE, NE)	276	5 (1.8)	NE [NE, NE)	0.9999	2.511 (0.293, 21.496)	0.3836
	No	15	0 (0.0)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	1 (1.5)	NE [NE, NE)	131	3 (2.3)	NE [NE, NE)	0.9938	1.516 (0.158, 14.568)	0.7166
	>= 2	87	0 (0.0)	NE [NE, NE)	177	2 (1.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.3205

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Interstitial lung disease (SMQ) - Narrow										
Total subjects		153	0 (0.0)	NE [NE, NE)	308	5 (1.6)	NE [NE, NE)		>999.999 (<.001, NE)	0.1219

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	0 (0.0)	NE [NE, NE)	283	4 (1.4)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.1739
	> 75	18	0 (0.0)	NE [NE, NE)	25	1 (4.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.4193
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	3 (1.7)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.2157
	Female	62	0 (0.0)	NE [NE, NE)	134	2 (1.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.3454

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	0 (0.0)	NE [NE, NE)	240	4 (1.7)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.1568
	Asian	20	0 (0.0)	NE [NE, NE)	46	1 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.5271
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	4 (2.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.1619
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	1 (1.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.5171
Baseline ECOG PS	0-1	146	0 (0.0)	NE [NE, NE)	294	5 (1.7)	NE [NE, NE)	0.9993	>999.999 (<.001, NE)	0.1195
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	0 (0.0)	NE [NE, NE)	285	4 (1.4)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.1747
	No	17	0 (0.0)	NE [NE, NE)	23	1 (4.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.3980
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	2 (2.0)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.2953
	No	98	0 (0.0)	NE [NE, NE)	209	3 (1.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.2482

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-505-ae-cox-eoi-cfz-grd345.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	2 (1.6)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.2971
	No	79	0 (0.0)	NE [NE, NE)	186	3 (1.6)	NE [NE, NE)		>999.999 (<.001, NE)	0.2611
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	0 (0.0)	NE [NE, NE)	0.9982	NE (NE, NE)	NE
	No	98	0 (0.0)	NE [NE, NE)	210	5 (2.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.1303

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	0 (0.0)	NE [NE, NE)	205	2 (1.0)	NE [NE, NE)	0.9998	>999.999 (<.001, NE)	0.3262
	No	43	0 (0.0)	NE [NE, NE)	103	3 (2.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.2603
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	0 (0.0)	NE [NE, NE)	0.9982	NE (NE, NE)	NE
	No	88	0 (0.0)	NE [NE, NE)	179	5 (2.8)	NE [NE, NE)		>999.999 (<.001, NE)	0.1200

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	0 (0.0)	NE [NE, NE)	250	4 (1.6)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.1606
	3	27	0 (0.0)	NE [NE, NE)	58	1 (1.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.5040
Prior proteasome inhibitor exposure per IXRS	Yes	138	0 (0.0)	NE [NE, NE)	276	4 (1.4)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.1633
	No	15	0 (0.0)	NE [NE, NE)	32	1 (3.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.5271

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	2 (1.5)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.3222
	>= 2	87	0 (0.0)	NE [NE, NE)	177	3 (1.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.2364

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Ischaemic heart disease (SMQ) - Narrow										
Total subjects		153	4 (2.6)	NE [NE, NE)	308	9 (2.9)	NE [NE, NE)		0.911 (0.280, 2.971)	0.8777

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	3 (2.2)	NE [NE, NE)	283	8 (2.8)	NE [NE, NE)	0.6370	1.059 (0.280, 4.005)	0.9327
	> 75	18	1 (5.6)	NE [NE, NE)	25	1 (4.0)	NE [NE, NE)		0.341 (0.018, 6.511)	0.4591
Sex	Male	91	2 (2.2)	NE [NE, NE)	174	6 (3.4)	NE [NE, NE)	0.5422	1.297 (0.260, 6.472)	0.7504
	Female	62	2 (3.2)	NE [NE, NE)	134	3 (2.2)	NE [NE, NE)		0.585 (0.097, 3.515)	0.5532

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	2 (1.6)	NE [NE, NE)	240	9 (3.8)	NE [NE, NE)	0.9999	1.884 (0.405, 8.751)	0.4115
	Asian	20	1 (5.0)	NE [11.3, NE)	46	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0593
	Other or Unknown	11	1 (9.1)	NE [2.4, NE)	22	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0973
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	3 (2.9)	NE [NE, NE)	203	9 (4.4)	NE [NE, NE)		1.247 (0.336, 4.622)	0.7409
	Asia Pacific	39	1 (2.6)	NE [NE, NE)	84	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0806
Baseline ECOG PS	0-1	146	4 (2.7)	NE [NE, NE)	294	9 (3.1)	NE [NE, NE)	1.0000	0.939 (0.288, 3.059)	0.9171
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	4 (2.9)	NE [NE, NE)	285	8 (2.8)	NE [NE, NE)	0.9932	0.780 (0.234, 2.603)	0.6859
	No	17	0 (0.0)	NE [NE, NE)	23	1 (4.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.4583
Refractory to Bortezomib or Ixazomib	Yes	55	2 (3.6)	NE [NE, NE)	99	0 (0.0)	NE [NE, NE)	0.9893	<.001 (<.001, NE)	0.0352
	No	98	2 (2.0)	NE [NE, NE)	209	9 (4.3)	NE [NE, NE)		1.736 (0.374, 8.065)	0.4761

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	1 (1.4)	NE [NE, NE)	122	4 (3.3)	NE [NE, NE)	0.3861	2.089 (0.233, 18.740)	0.5008
	No	79	3 (3.8)	NE [NE, NE)	186	5 (2.7)	NE [NE, NE)		0.588 (0.140, 2.468)	0.4634
Refractory to Lenalidomide	Yes	55	1 (1.8)	NE [NE, NE)	98	3 (3.1)	NE [NE, NE)	0.7419	1.312 (0.136, 12.653)	0.8136
	No	98	3 (3.1)	NE [NE, NE)	210	6 (2.9)	NE [NE, NE)		0.798 (0.199, 3.200)	0.7495

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	3 (2.7)	NE [NE, NE)	205	4 (2.0)	NE [NE, NE)	0.4042	0.620 (0.138, 2.776)	0.5278
	No	43	1 (2.3)	NE [NE, NE)	103	5 (4.9)	NE [NE, NE)		1.684 (0.196, 14.473)	0.6311
Refractory to IMiD	Yes	65	2 (3.1)	NE [NE, NE)	129	4 (3.1)	NE [NE, NE)	0.7879	0.810 (0.148, 4.446)	0.8084
	No	88	2 (2.3)	NE [NE, NE)	179	5 (2.8)	NE [NE, NE)		1.036 (0.200, 5.358)	0.9659

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	3 (2.4)	NE [NE, NE)	250	5 (2.0)	NE [NE, NE)	0.7033	0.668 (0.159, 2.809)	0.5799
	3	27	1 (3.7)	NE [NE, NE)	58	4 (6.9)	NE [NE, NE)		1.365 (0.148, 12.608)	0.7829
Prior proteasome inhibitor exposure per IXRS	Yes	138	4 (2.9)	NE [NE, NE)	276	7 (2.5)	NE [NE, NE)	0.9935	0.691 (0.201, 2.374)	0.5554
	No	15	0 (0.0)	NE [NE, NE)	32	2 (6.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.3671

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	2 (3.0)	NE [NE, NE)	131	6 (4.6)	NE [NE, NE)	0.5549	1.197 (0.240, 5.960)	0.8259
	>= 2	87	2 (2.3)	NE [NE, NE)	177	3 (1.7)	NE [NE, NE)		0.635 (0.106, 3.812)	0.6169

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Liver related investigations, signs and symptoms (SMQ) - Narrow										
Total subjects		153	3 (2.0)	NE [NE, NE)	308	14 (4.5)	NE [NE, NE)		2.155 (0.617, 7.524)	0.2178

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	3 (2.2)	NE [NE, NE)	283	12 (4.2)	NE [NE, NE)	0.9923	1.865 (0.526, 6.610)	0.3270
	> 75	18	0 (0.0)	NE [NE, NE)	25	2 (8.0)	NE [19.3, NE)		>999.999 (<.001, NE)	0.4193
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	3 (1.7)	NE [NE, NE)	0.9910	>999.999 (<.001, NE)	0.2896
	Female	62	3 (4.8)	NE [NE, NE)	134	11 (8.2)	NE [NE, NE)		1.643 (0.458, 5.894)	0.4415

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	1 (0.8)	NE [NE, NE)	240	9 (3.8)	NE [NE, NE)	0.4752	4.253 (0.536, 33.713)	0.1357
	Asian	20	2 (10.0)	NE [NE, NE)	46	4 (8.7)	NE [NE, NE)		0.860 (0.157, 4.696)	0.8613
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	1 (4.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.5839
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	8 (3.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.0481
	Asia Pacific	39	3 (7.7)	NE [NE, NE)	84	6 (7.1)	NE [NE, NE)		0.805 (0.196, 3.304)	0.7632
Baseline ECOG PS	0-1	146	2 (1.4)	NE [NE, NE)	294	13 (4.4)	NE [NE, NE)	0.1603	3.176 (0.717, 14.077)	0.1080
	2	7	1 (14.3)	NE [0.5, NE)	13	1 (7.7)	NE [19.3, NE)		<.001 (<.001, NE)	0.1573

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	2 (1.5)	NE [NE, NE)	285	11 (3.9)	NE [NE, NE)	0.9364	2.376 (0.524, 10.771)	0.2472
	No	17	1 (5.9)	NE [NE, NE)	23	3 (13.0)	NE [NE, NE)		2.324 (0.242, 22.344)	0.4558
Refractory to Bortezomib or Ixazomib	Yes	55	1 (1.8)	NE [NE, NE)	99	2 (2.0)	NE [NE, NE)	0.5308	0.898 (0.079, 10.186)	0.9310
	No	98	2 (2.0)	NE [NE, NE)	209	12 (5.7)	NE [NE, NE)		2.716 (0.608, 12.139)	0.1731

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	1 (1.4)	NE [NE, NE)	122	4 (3.3)	NE [NE, NE)	0.9339	2.417 (0.270, 21.638)	0.4150
	No	79	2 (2.5)	NE [NE, NE)	186	10 (5.4)	NE [NE, NE)		1.953 (0.425, 8.960)	0.3806
Refractory to Lenalidomide	Yes	55	1 (1.8)	NE [NE, NE)	98	3 (3.1)	NE [NE, NE)	0.7339	1.650 (0.172, 15.876)	0.6610
	No	98	2 (2.0)	NE [NE, NE)	210	11 (5.2)	NE [NE, NE)		2.397 (0.530, 10.844)	0.2417

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	2 (1.8)	NE [NE, NE)	205	10 (4.9)	NE [NE, NE)	0.7569	2.407 (0.523, 11.070)	0.2445
	No	43	1 (2.3)	NE [NE, NE)	103	4 (3.9)	NE [NE, NE)		1.688 (0.189, 15.099)	0.6359
Refractory to IMiD	Yes	65	1 (1.5)	NE [NE, NE)	129	5 (3.9)	NE [NE, NE)	0.9509	1.960 (0.222, 17.296)	0.5372
	No	88	2 (2.3)	NE [NE, NE)	179	9 (5.0)	NE [NE, NE)		2.206 (0.477, 10.209)	0.2993

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	2 (1.6)	NE [NE, NE)	250	12 (4.8)	NE [NE, NE)	0.3729	3.011 (0.674, 13.455)	0.1293
	3	27	1 (3.7)	NE [NE, NE)	58	2 (3.4)	NE [19.3, NE)		0.650 (0.058, 7.258)	0.7243
Prior proteasome inhibitor exposure per IXRS	Yes	138	2 (1.4)	NE [NE, NE)	276	11 (4.0)	NE [NE, NE)	0.6083	2.511 (0.554, 11.374)	0.2161
	No	15	1 (6.7)	NE [NE, NE)	32	3 (9.4)	NE [NE, NE)		1.393 (0.145, 13.406)	0.7776

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	2 (3.0)	NE [NE, NE)	131	4 (3.1)	NE [NE, NE)	0.2433	1.002 (0.184, 5.472)	0.9980
	>= 2	87	1 (1.1)	NE [NE, NE)	177	10 (5.6)	NE [NE, NE)		4.385 (0.558, 34.463)	0.1246

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Myocardial infarction (SMQ) - Narrow										
Total subjects		153	1 (0.7)	NE [NE, NE)	308	4 (1.3)	NE [NE, NE)		1.398 (0.156, 12.554)	0.7637

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	1 (0.7)	NE [NE, NE)	283	3 (1.1)	NE [NE, NE)	0.9948	1.029 (0.107, 9.929)	0.9804
	> 75	18	0 (0.0)	NE [NE, NE)	25	1 (4.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.6171
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	3 (1.7)	NE [NE, NE)	0.9942	>999.999 (<.001, NE)	0.3097
	Female	62	1 (1.6)	NE [NE, NE)	134	1 (0.7)	NE [NE, NE)		0.348 (0.022, 5.602)	0.4356

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-505-ae-cox-eoi-cfz-grd345.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	0 (0.0)	NE [NE, NE)	240	4 (1.7)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.2366
	Asian	20	1 (5.0)	NE [11.3, NE)	46	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0593
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	4 (2.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.2348
	Asia Pacific	39	1 (2.6)	NE [NE, NE)	84	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0806
Baseline ECOG PS	0-1	146	1 (0.7)	NE [NE, NE)	294	4 (1.4)	NE [NE, NE)	1.0000	1.460 (0.163, 13.107)	0.7337
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	1 (0.7)	NE [NE, NE)	285	4 (1.4)	NE [NE, NE)	1.0000	1.360 (0.151, 12.220)	0.7829
	No	17	0 (0.0)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to Bortezomib or Ixazomib	Yes	55	1 (1.8)	NE [NE, NE)	99	0 (0.0)	NE [NE, NE)	0.9949	<.001 (<.001, NE)	0.1103
	No	98	0 (0.0)	NE [NE, NE)	209	4 (1.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.2544

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	2 (1.6)	NE [NE, NE)	0.9951	>999.999 (<.001, NE)	0.3287
	No	79	1 (1.3)	NE [NE, NE)	186	2 (1.1)	NE [NE, NE)		0.618 (0.056, 6.839)	0.6919
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	2 (2.0)	NE [NE, NE)	0.9960	>999.999 (<.001, NE)	0.3658
	No	98	1 (1.0)	NE [NE, NE)	210	2 (1.0)	NE [NE, NE)		0.684 (0.062, 7.573)	0.7557

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	1 (0.9)	NE [NE, NE)	205	2 (1.0)	NE [NE, NE)	0.9957	0.852 (0.077, 9.404)	0.8958
	No	43	0 (0.0)	NE [NE, NE)	103	2 (1.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.4532
Refractory to IMiD	Yes	65	1 (1.5)	NE [NE, NE)	129	2 (1.6)	NE [NE, NE)	0.9943	0.729 (0.066, 8.056)	0.7955
	No	88	0 (0.0)	NE [NE, NE)	179	2 (1.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.4028

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	1 (0.8)	NE [NE, NE)	250	3 (1.2)	NE [NE, NE)	0.9946	1.098 (0.113, 10.622)	0.9357
	3	27	0 (0.0)	NE [NE, NE)	58	1 (1.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.6698
Prior proteasome inhibitor exposure per IXRS	Yes	138	1 (0.7)	NE [NE, NE)	276	4 (1.4)	NE [NE, NE)	1.0000	1.394 (0.155, 12.539)	0.7660
	No	15	0 (0.0)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	3 (2.3)	NE [NE, NE)	0.9947	>999.999 (<.001, NE)	0.3212
	>= 2	87	1 (1.1)	NE [NE, NE)	177	1 (0.6)	NE [NE, NE)		0.386 (0.024, 6.171)	0.4846

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Peripheral neuropathy (SMQ) - Narrow										
Total subjects		153	0 (0.0)	NE [NE, NE)	308	3 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.2657

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	0 (0.0)	NE [NE, NE)	283	3 (1.1)	NE [NE, NE)	0.9991	>999.999 (<.001, NE)	0.2712
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	1 (0.6)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.5028
	Female	62	0 (0.0)	NE [NE, NE)	134	2 (1.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.3807

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	0 (0.0)	NE [NE, NE)	240	3 (1.3)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.2570
	Asian	20	0 (0.0)	NE [NE, NE)	46	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	3 (1.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.2606
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Baseline ECOG PS	0-1	146	0 (0.0)	NE [NE, NE)	294	3 (1.0)	NE [NE, NE)	0.9997	>999.999 (<.001, NE)	0.2562
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	0 (0.0)	NE [NE, NE)	285	3 (1.1)	NE [NE, NE)	0.9991	>999.999 (<.001, NE)	0.2717
	No	17	0 (0.0)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	1 (1.0)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.4821
	No	98	0 (0.0)	NE [NE, NE)	209	2 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.3789

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-505-ae-cox-eoi-cfz-grd345.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	0 (0.0)	NE [NE, NE)	0.9986	NE (NE, NE)	NE
	No	79	0 (0.0)	NE [NE, NE)	186	3 (1.6)	NE [NE, NE)		>999.999 (<.001, NE)	0.2960
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	0 (0.0)	NE [NE, NE)	0.9986	NE (NE, NE)	NE
	No	98	0 (0.0)	NE [NE, NE)	210	3 (1.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.2738

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	0 (0.0)	NE [NE, NE)	205	1 (0.5)	NE [NE, NE)	0.9998	>999.999 (<.001, NE)	0.5053
	No	43	0 (0.0)	NE [NE, NE)	103	2 (1.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.4034
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	1 (0.8)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.5280
	No	88	0 (0.0)	NE [NE, NE)	179	2 (1.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.3620

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	0 (0.0)	NE [NE, NE)	250	3 (1.2)	NE [NE, NE)	0.9990	>999.999 (<.001, NE)	0.2502
	3	27	0 (0.0)	NE [NE, NE)	58	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Prior proteasome inhibitor exposure per IXRS	Yes	138	0 (0.0)	NE [NE, NE)	276	3 (1.1)	NE [NE, NE)	0.9991	>999.999 (<.001, NE)	0.2609
	No	15	0 (0.0)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	0 (0.0)	NE [NE, NE)	0.9987	NE (NE, NE)	NE
	>= 2	87	0 (0.0)	NE [NE, NE)	177	3 (1.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.2691

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Pulmonary hypertension (SMQ) - Narrow										
Total subjects		153	0 (0.0)	NE [NE, NE)	308	3 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.2429

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	0 (0.0)	NE [NE, NE)	283	3 (1.1)	NE [NE, NE)	0.9991	>999.999 (<.001, NE)	0.2498
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	3 (1.7)	NE [NE, NE)	0.9987	>999.999 (<.001, NE)	0.2263
	Female	62	0 (0.0)	NE [NE, NE)	134	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	0 (0.0)	NE [NE, NE)	240	3 (1.3)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.2342
	Asian	20	0 (0.0)	NE [NE, NE)	46	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	2 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.3300
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	1 (1.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.5258
Baseline ECOG PS	0-1	146	0 (0.0)	NE [NE, NE)	294	3 (1.0)	NE [NE, NE)	0.9995	>999.999 (<.001, NE)	0.2381
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	0 (0.0)	NE [NE, NE)	285	2 (0.7)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.3425
	No	17	0 (0.0)	NE [NE, NE)	23	1 (4.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.4386
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	1 (1.0)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.4561
	No	98	0 (0.0)	NE [NE, NE)	209	2 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.3740

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	1 (0.8)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.4716
	No	79	0 (0.0)	NE [NE, NE)	186	2 (1.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.3692
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	1 (1.0)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.4795
	No	98	0 (0.0)	NE [NE, NE)	210	2 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.3496

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	0 (0.0)	NE [NE, NE)	205	2 (1.0)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.3387
	No	43	0 (0.0)	NE [NE, NE)	103	1 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.5162
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	1 (0.8)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.5091
	No	88	0 (0.0)	NE [NE, NE)	179	2 (1.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.3354

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	0 (0.0)	NE [NE, NE)	250	2 (0.8)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.3397
	3	27	0 (0.0)	NE [NE, NE)	58	1 (1.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.4951
Prior proteasome inhibitor exposure per IXRS	Yes	138	0 (0.0)	NE [NE, NE)	276	2 (0.7)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.3304
	No	15	0 (0.0)	NE [NE, NE)	32	1 (3.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.5501

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-505-ae-cox-eoi-cfz-grd345.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	1 (0.8)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.5138
	>= 2	87	0 (0.0)	NE [NE, NE)	177	2 (1.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.3349

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Respiratory failure (SMQ) - Narrow										
Total subjects		153	1 (0.7)	NE [NE, NE)	308	3 (1.0)	NE [NE, NE)		1.273 (0.132, 12.271)	0.8345

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	1 (0.7)	NE [NE, NE)	283	3 (1.1)	NE [NE, NE)	1.0000	1.227 (0.127, 11.835)	0.8593
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	1 (0.6)	NE [NE, NE)	0.9952	>999.999 (<.001, NE)	0.5132
	Female	62	1 (1.6)	NE [NE, NE)	134	2 (1.5)	NE [NE, NE)		0.820 (0.074, 9.069)	0.8716

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	0 (0.0)	NE [NE, NE)	240	3 (1.3)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.2358
	Asian	20	1 (5.0)	NE [12.0, NE)	46	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0635
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	3 (1.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.2437
	Asia Pacific	39	1 (2.6)	NE [NE, NE)	84	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0752
Baseline ECOG PS	0-1	146	1 (0.7)	NE [NE, NE)	294	3 (1.0)	NE [NE, NE)	1.0000	1.304 (0.135, 12.565)	0.8179
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	1 (0.7)	NE [NE, NE)	285	3 (1.1)	NE [NE, NE)	1.0000	1.234 (0.128, 11.896)	0.8555
	No	17	0 (0.0)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to Bortezomib or Ixazomib	Yes	55	1 (1.8)	NE [NE, NE)	99	0 (0.0)	NE [NE, NE)	0.9953	<.001 (<.001, NE)	0.1213
	No	98	0 (0.0)	NE [NE, NE)	209	3 (1.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.2618

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	1 (0.8)	NE [NE, NE)	0.9953	>999.999 (<.001, NE)	0.4723
	No	79	1 (1.3)	NE [NE, NE)	186	2 (1.1)	NE [NE, NE)		0.752 (0.068, 8.318)	0.8153
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	1 (1.0)	NE [NE, NE)	0.9958	>999.999 (<.001, NE)	0.5036
	No	98	1 (1.0)	NE [NE, NE)	210	2 (1.0)	NE [NE, NE)		0.822 (0.074, 9.088)	0.8727

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	1 (0.9)	NE [NE, NE)	205	1 (0.5)	NE [NE, NE)	0.9940	0.425 (0.027, 6.815)	0.5333
	No	43	0 (0.0)	NE [NE, NE)	103	2 (1.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.3632
Refractory to IMiD	Yes	65	1 (1.5)	NE [NE, NE)	129	1 (0.8)	NE [NE, NE)	0.9945	0.362 (0.023, 5.832)	0.4551
	No	88	0 (0.0)	NE [NE, NE)	179	2 (1.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.3354

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	1 (0.8)	NE [NE, NE)	250	1 (0.4)	NE [NE, NE)	0.9958	0.412 (0.026, 6.600)	0.5174
	3	27	0 (0.0)	NE [NE, NE)	58	2 (3.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.3876
Prior proteasome inhibitor exposure per IXRS	Yes	138	1 (0.7)	NE [NE, NE)	276	3 (1.1)	NE [NE, NE)	1.0000	1.294 (0.134, 12.479)	0.8231
	No	15	0 (0.0)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	1 (0.8)	NE [NE, NE)	0.9955	>999.999 (<.001, NE)	0.4829
	>= 2	87	1 (1.1)	NE [NE, NE)	177	2 (1.1)	NE [NE, NE)		0.802 (0.073, 8.854)	0.8569

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Respiratory tract infections (HLGT)										
Total subjects		153	24 (15.7)	NE [18.9, NE)	308	89 (28.9)	NE [NE, NE)		1.674 (1.066, 2.628)	0.0237

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	22 (16.3)	NE [18.9, NE)	283	82 (29.0)	NE [NE, NE)	0.6776	1.613 (1.007, 2.583)	0.0447
	> 75	18	2 (11.1)	NE [NE, NE)	25	7 (28.0)	NE [11.7, NE)		2.403 (0.498, 11.583)	0.2596
Sex	Male	91	15 (16.5)	NE [NE, NE)	174	49 (28.2)	NE [NE, NE)	0.5102	1.482 (0.830, 2.646)	0.1802
	Female	62	9 (14.5)	NE [18.9, NE)	134	40 (29.9)	NE [NE, NE)		2.010 (0.975, 4.143)	0.0535

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Output: t14-06-001-505-ae-cox-eoi-cfz-grd345.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	20 (16.4)	NE [NE, NE)	240	72 (30.0)	NE [NE, NE)	0.8861	1.678 (1.022, 2.754)	0.0386
	Asian	20	4 (20.0)	18.9 [12.0, 18.9)	46	12 (26.1)	NE [NE, NE)		1.175 (0.378, 3.653)	0.7819
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	5 (22.7)	NE [14.9, NE)		>999.999 (<.001, NE)	0.1478
Region	North America	12	1 (8.3)	NE [16.2, NE)	21	9 (42.9)	18.1 [11.1, NE)	0.4840	3.206 (0.396, 25.960)	0.2490

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	15 (14.7)	NE [NE, NE)	203	57 (28.1)	NE [NE, NE)		1.769 (1.001, 3.124)	0.0463
	Asia Pacific	39	8 (20.5)	18.9 [18.9, NE)	84	23 (27.4)	NE [NE, NE)		1.187 (0.530, 2.658)	0.6779
Baseline ECOG PS	0-1	146	24 (16.4)	NE [18.9, NE)	294	87 (29.6)	NE [NE, NE)	0.9823	1.682 (1.070, 2.643)	0.0227
	2	7	0 (0.0)	NE [NE, NE)	13	2 (15.4)	NE [6.0, NE)		>999.999 (<.001, NE)	0.4700

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	20 (14.7)	NE [NE, NE)	285	82 (28.8)	NE [NE, NE)	0.4476	1.791 (1.098, 2.921)	0.0178
	No	17	4 (23.5)	18.9 [7.3, NE)	23	7 (30.4)	NE [9.7, NE)		1.115 (0.325, 3.828)	0.8627
Refractory to Bortezomib or Ixazomib	Yes	55	7 (12.7)	NE [NE, NE)	99	29 (29.3)	NE [17.2, NE)	0.4966	2.065 (0.904, 4.720)	0.0789
	No	98	17 (17.3)	NE [18.9, NE)	209	60 (28.7)	NE [NE, NE)		1.494 (0.871, 2.561)	0.1418

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	11 (14.9)	NE [NE, NE)	122	34 (27.9)	NE [NE, NE)	0.8609	1.577 (0.797, 3.121)	0.1862
	No	79	13 (16.5)	NE [18.9, NE)	186	55 (29.6)	NE [NE, NE)		1.722 (0.941, 3.151)	0.0747
Refractory to Lenalidomide	Yes	55	10 (18.2)	NE [16.2, NE)	98	26 (26.5)	NE [18.1, NE)	0.2199	1.121 (0.537, 2.340)	0.7613
	No	98	14 (14.3)	NE [18.9, NE)	210	63 (30.0)	NE [NE, NE)		2.042 (1.144, 3.644)	0.0136

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	18 (16.4)	NE [18.9, NE)	205	59 (28.8)	NE [NE, NE)	0.6392	1.555 (0.916, 2.639)	0.0989
	No	43	6 (14.0)	NE [NE, NE)	103	30 (29.1)	NE [NE, NE)		1.964 (0.817, 4.721)	0.1241
Refractory to IMiD	Yes	65	11 (16.9)	NE [16.2, NE)	129	33 (25.6)	NE [NE, NE)	0.2471	1.184 (0.596, 2.354)	0.6294
	No	88	13 (14.8)	NE [18.9, NE)	179	56 (31.3)	NE [NE, NE)		2.076 (1.135, 3.796)	0.0153

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	21 (16.7)	NE [18.9, NE)	250	70 (28.0)	NE [NE, NE)	0.6270	1.578 (0.969, 2.571)	0.0644
	3	27	3 (11.1)	NE [NE, NE)	58	19 (32.8)	NE [14.8, NE)		2.207 (0.650, 7.491)	0.1924
Prior proteasome inhibitor exposure per IXRS	Yes	138	21 (15.2)	NE [NE, NE)	276	80 (29.0)	NE [NE, NE)	0.6043	1.745 (1.079, 2.823)	0.0215
	No	15	3 (20.0)	18.9 [NE, NE)	32	9 (28.1)	NE [14.9, NE)		1.190 (0.320, 4.418)	0.7949

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	12 (18.2)	NE [18.9, NE)	131	39 (29.8)	NE [NE, NE)	0.7013	1.520 (0.796, 2.903)	0.2015
	>= 2	87	12 (13.8)	NE [NE, NE)	177	50 (28.2)	NE [NE, NE)		1.828 (0.973, 3.434)	0.0572

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Reversible posterior leukoencephalopathy syndrome (AMQ) - Narrow										
Total subjects		153	0 (0.0)	NE [NE, NE)	308	6 (1.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.1185

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	0 (0.0)	NE [NE, NE)	283	5 (1.8)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.1553
	> 75	18	0 (0.0)	NE [NE, NE)	25	1 (4.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.4795
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	3 (1.7)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.2949
	Female	62	0 (0.0)	NE [NE, NE)	134	3 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.2619

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	0 (0.0)	NE [NE, NE)	240	5 (2.1)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.1419
	Asian	20	0 (0.0)	NE [NE, NE)	46	1 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.5186
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	1 (4.8)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.5403

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	2 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.3167
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	3 (3.6)	NE [NE, NE)		>999.999 (<.001, NE)	0.2968
Baseline ECOG PS	0-1	146	0 (0.0)	NE [NE, NE)	294	6 (2.0)	NE [NE, NE)	0.9994	>999.999 (<.001, NE)	0.1134
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	0 (0.0)	NE [NE, NE)	285	6 (2.1)	NE [NE, NE)	0.9987	>999.999 (<.001, NE)	0.1244
	No	17	0 (0.0)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	2 (2.0)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.2926
	No	98	0 (0.0)	NE [NE, NE)	209	4 (1.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.2376

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-505-ae-cox-eoi-cfz-grd345.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	3 (2.5)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.2327
	No	79	0 (0.0)	NE [NE, NE)	186	3 (1.6)	NE [NE, NE)		>999.999 (<.001, NE)	0.2911
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	3 (3.1)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.2659
	No	98	0 (0.0)	NE [NE, NE)	210	3 (1.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.2663

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	0 (0.0)	NE [NE, NE)	205	4 (2.0)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.1862
	No	43	0 (0.0)	NE [NE, NE)	103	2 (1.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.3909
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	4 (3.1)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.2203
	No	88	0 (0.0)	NE [NE, NE)	179	2 (1.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.3411

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	0 (0.0)	NE [NE, NE)	250	5 (2.0)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.1494
	3	27	0 (0.0)	NE [NE, NE)	58	1 (1.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.5040
Prior proteasome inhibitor exposure per IXRS	Yes	138	0 (0.0)	NE [NE, NE)	276	6 (2.2)	NE [NE, NE)	0.9986	>999.999 (<.001, NE)	0.1184
	No	15	0 (0.0)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	3 (2.3)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.2702
	>= 2	87	0 (0.0)	NE [NE, NE)	177	3 (1.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.2667

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Tumour lysis syndrome (SMQ) - Narrow										
Total subjects		153	1 (0.7)	NE [NE, NE)	308	3 (1.0)	NE [NE, NE)		1.501 (0.156, 14.427)	0.7231

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	1 (0.7)	NE [NE, NE)	283	3 (1.1)	NE [NE, NE)	1.0000	1.442 (0.150, 13.864)	0.7497
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	1 (1.1)	NE [NE, NE)	174	1 (0.6)	NE [NE, NE)	0.9952	0.523 (0.033, 8.364)	0.6411
	Female	62	0 (0.0)	NE [NE, NE)	134	2 (1.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.3342

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	0 (0.0)	NE [NE, NE)	240	3 (1.3)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.2146
	Asian	20	0 (0.0)	NE [NE, NE)	46	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
	Other or Unknown	11	1 (9.1)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.1573
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	1 (1.0)	NE [NE, NE)	203	3 (1.5)	NE [NE, NE)		1.524 (0.159, 14.649)	0.7130
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Baseline ECOG PS	0-1	146	1 (0.7)	NE [NE, NE)	294	3 (1.0)	NE [NE, NE)	0.9999	1.501 (0.156, 14.428)	0.7231
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	1 (0.7)	NE [NE, NE)	285	3 (1.1)	NE [NE, NE)	1.0000	1.443 (0.150, 13.868)	0.7495
	No	17	0 (0.0)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	1 (1.0)	NE [NE, NE)	0.9955	>999.999 (<.001, NE)	0.4538
	No	98	1 (1.0)	NE [NE, NE)	209	2 (1.0)	NE [NE, NE)		0.941 (0.085, 10.373)	0.9601

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	2 (1.6)	NE [NE, NE)	0.9948	>999.999 (<.001, NE)	0.2687
	No	79	1 (1.3)	NE [NE, NE)	186	1 (0.5)	NE [NE, NE)		0.424 (0.027, 6.785)	0.5320
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	2 (2.0)	NE [NE, NE)	0.9957	>999.999 (<.001, NE)	0.2869
	No	98	1 (1.0)	NE [NE, NE)	210	1 (0.5)	NE [NE, NE)		0.467 (0.029, 7.459)	0.5807

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	1 (0.9)	NE [NE, NE)	205	2 (1.0)	NE [NE, NE)	0.9960	1.082 (0.098, 11.933)	0.9487
	No	43	0 (0.0)	NE [NE, NE)	103	1 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.5162
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	2 (1.6)	NE [NE, NE)	0.9951	>999.999 (<.001, NE)	0.3135
	No	88	1 (1.1)	NE [NE, NE)	179	1 (0.6)	NE [NE, NE)		0.492 (0.031, 7.859)	0.6081

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	0 (0.0)	NE [NE, NE)	250	1 (0.4)	NE [NE, NE)	0.9956	>999.999 (<.001, NE)	0.4769
	3	27	1 (3.7)	NE [NE, NE)	58	2 (3.4)	NE [NE, NE)		0.941 (0.085, 10.381)	0.9605
Prior proteasome inhibitor exposure per IXRS	Yes	138	1 (0.7)	NE [NE, NE)	276	3 (1.1)	NE [NE, NE)	0.9999	1.512 (0.157, 14.534)	0.7182
	No	15	0 (0.0)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-505-ae-cox-eoi-cfz-grd345.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.505. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	1 (1.5)	NE [NE, NE)	131	2 (1.5)	NE [NE, NE)	0.9950	1.008 (0.091, 11.113)	0.9950
	>= 2	87	0 (0.0)	NE [NE, NE)	177	1 (0.6)	NE [NE, NE)		>999.999 (<.001, NE)	0.4808

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-505-ae-cox-eoi-cfz-grd345.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Acute renal failure (SMQ) - Narrow										
Total subjects		153	9 (5.9)	NE [NE, NE)	308	7 (2.3)	NE [NE, NE)		0.337 (0.125, 0.907)	0.0239

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-506-sae-cox-eoi-cfz.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	9 (6.7)	NE [NE, NE)	283	6 (2.1)	NE [NE, NE)	0.9926	0.276 (0.098, 0.778)	0.0092
	> 75	18	0 (0.0)	NE [NE, NE)	25	1 (4.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.4096
Sex	Male	91	7 (7.7)	NE [NE, NE)	174	4 (2.3)	NE [NE, NE)	0.4261	0.255 (0.074, 0.875)	0.0191
	Female	62	2 (3.2)	NE [NE, NE)	134	3 (2.2)	NE [NE, NE)		0.631 (0.105, 3.779)	0.6107

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-506-sae-cox-eoi-cfz.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	5 (4.1)	NE [NE, NE)	240	7 (2.9)	NE [NE, NE)	0.9999	0.641 (0.203, 2.026)	0.4456
	Asian	20	3 (15.0)	NE [12.0, NE)	46	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0038
	Other or Unknown	11	1 (9.1)	NE [1.1, NE)	22	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.1380
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	0.9999	NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-506-sae-cox-eoi-cfz.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	5 (4.9)	NE [NE, NE)	203	7 (3.4)	NE [NE, NE)		0.635 (0.201, 2.002)	0.4340
	Asia Pacific	39	4 (10.3)	NE [NE, NE)	84	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0016
Baseline ECOG PS	0-1	146	9 (6.2)	NE [NE, NE)	294	6 (2.0)	NE [NE, NE)	0.9919	0.294 (0.104, 0.827)	0.0136
	2	7	0 (0.0)	NE [NE, NE)	13	1 (7.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.5186

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-506-sae-cox-eoi-cfz.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	8 (5.9)	NE [NE, NE)	285	6 (2.1)	NE [NE, NE)	0.6641	0.314 (0.109, 0.906)	0.0237
	No	17	1 (5.9)	NE [9.5, NE)	23	1 (4.3)	NE [NE, NE)		0.608 (0.038, 9.849)	0.7235
Refractory to Bortezomib or Ixazomib	Yes	55	3 (5.5)	NE [NE, NE)	99	3 (3.0)	NE [NE, NE)	0.5471	0.513 (0.103, 2.545)	0.4052
	No	98	6 (6.1)	NE [NE, NE)	209	4 (1.9)	NE [NE, NE)		0.262 (0.074, 0.930)	0.0259

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-506-sae-cox-eoi-cfz.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	4 (5.4)	NE [NE, NE)	122	2 (1.6)	NE [NE, NE)	0.7185	0.267 (0.049, 1.458)	0.1016
	No	79	5 (6.3)	NE [NE, NE)	186	5 (2.7)	NE [NE, NE)		0.376 (0.109, 1.303)	0.1092
Refractory to Lenalidomide	Yes	55	4 (7.3)	NE [NE, NE)	98	2 (2.0)	NE [NE, NE)	0.5825	0.244 (0.045, 1.336)	0.0780
	No	98	5 (5.1)	NE [NE, NE)	210	5 (2.4)	NE [NE, NE)		0.415 (0.120, 1.437)	0.1524

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-506-sae-cox-eoi-cfz.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	7 (6.4)	NE [NE, NE)	205	5 (2.4)	NE [NE, NE)	0.9196	0.334 (0.106, 1.054)	0.0494
	No	43	2 (4.7)	NE [NE, NE)	103	2 (1.9)	NE [NE, NE)		0.370 (0.052, 2.641)	0.3019
Refractory to IMiD	Yes	65	6 (9.2)	NE [NE, NE)	129	2 (1.6)	NE [NE, NE)	0.1313	0.142 (0.028, 0.704)	0.0054
	No	88	3 (3.4)	NE [NE, NE)	179	5 (2.8)	NE [NE, NE)		0.737 (0.176, 3.089)	0.6767

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-506-sae-cox-eoi-cfz.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	7 (5.6)	NE [NE, NE)	250	5 (2.0)	NE [NE, NE)	0.9891	0.323 (0.102, 1.019)	0.0424
	3	27	2 (7.4)	NE [NE, NE)	58	2 (3.4)	NE [NE, NE)		0.335 (0.047, 2.400)	0.2536
Prior proteasome inhibitor exposure per IXRS	Yes	138	8 (5.8)	NE [NE, NE)	276	6 (2.2)	NE [NE, NE)	0.9109	0.329 (0.114, 0.950)	0.0308
	No	15	1 (6.7)	NE [9.5, NE)	32	1 (3.1)	NE [NE, NE)		0.411 (0.026, 6.609)	0.5167

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-506-sae-cox-eoi-cfz.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	3 (4.5)	NE [NE, NE)	131	2 (1.5)	NE [NE, NE)	0.8407	0.259 (0.043, 1.561)	0.1128
	>= 2	87	6 (6.9)	NE [NE, NE)	177	5 (2.8)	NE [NE, NE)		0.377 (0.115, 1.235)	0.0938

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Output: t14-06-001-506-sae-cox-eoi-cfz.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Cardiac arrhythmias (SMQ) - Narrow										
Total subjects		153	2 (1.3)	NE [NE, NE)	308	7 (2.3)	NE [NE, NE)		1.524 (0.316, 7.343)	0.5967

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	1 (0.7)	NE [NE, NE)	283	4 (1.4)	NE [NE, NE)	0.9535	1.614 (0.180, 14.477)	0.6658
	> 75	18	1 (5.6)	NE [NE, NE)	25	3 (12.0)	NE [NE, NE)		1.838 (0.191, 17.709)	0.5930
Sex	Male	91	2 (2.2)	NE [NE, NE)	174	6 (3.4)	NE [NE, NE)	0.9943	1.395 (0.281, 6.927)	0.6824
	Female	62	0 (0.0)	NE [NE, NE)	134	1 (0.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.5344

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Output: t14-06-001-506-sae-cox-eoi-cfz.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	2 (1.6)	NE [NE, NE)	240	6 (2.5)	NE [NE, NE)	1.0000	1.328 (0.268, 6.592)	0.7273
	Asian	20	0 (0.0)	NE [NE, NE)	46	1 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.5097
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	1 (4.8)	NE [NE, NE)	0.8923	>999.999 (<.001, NE)	0.6650

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-506-sae-cox-eoi-cfz.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	1 (1.0)	NE [NE, NE)	203	4 (2.0)	NE [NE, NE)		1.757 (0.196, 15.730)	0.6098
	Asia Pacific	39	1 (2.6)	NE [NE, NE)	84	2 (2.4)	NE [NE, NE)		0.862 (0.078, 9.517)	0.9034
Baseline ECOG PS	0-1	146	2 (1.4)	NE [NE, NE)	294	6 (2.0)	NE [NE, NE)	0.9931	1.337 (0.270, 6.634)	0.7212
	2	7	0 (0.0)	NE [NE, NE)	13	1 (7.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.6015

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	1 (0.7)	NE [NE, NE)	285	7 (2.5)	NE [NE, NE)	0.9929	2.943 (0.362, 23.947)	0.2896
	No	17	1 (5.9)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.2207
Refractory to Bortezomib or Ixazomib	Yes	55	1 (1.8)	NE [NE, NE)	99	2 (2.0)	NE [NE, NE)	0.6826	1.047 (0.095, 11.544)	0.9701
	No	98	1 (1.0)	NE [NE, NE)	209	5 (2.4)	NE [NE, NE)		2.033 (0.237, 17.446)	0.5087

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	1 (1.4)	NE [NE, NE)	122	3 (2.5)	NE [NE, NE)	0.9937	1.564 (0.161, 15.162)	0.6971
	No	79	1 (1.3)	NE [NE, NE)	186	4 (2.2)	NE [NE, NE)		1.500 (0.168, 13.417)	0.7150
Refractory to Lenalidomide	Yes	55	1 (1.8)	NE [NE, NE)	98	1 (1.0)	NE [NE, NE)	0.3392	0.377 (0.023, 6.174)	0.4778
	No	98	1 (1.0)	NE [NE, NE)	210	6 (2.9)	NE [NE, NE)		2.561 (0.308, 21.281)	0.3666

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CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	1 (0.9)	NE [NE, NE)	205	5 (2.4)	NE [NE, NE)	0.4928	2.344 (0.273, 20.107)	0.4236
	No	43	1 (2.3)	NE [NE, NE)	103	2 (1.9)	NE [NE, NE)		0.703 (0.064, 7.764)	0.7724
Refractory to IMiD	Yes	65	1 (1.5)	NE [NE, NE)	129	3 (2.3)	NE [NE, NE)	0.8322	1.147 (0.118, 11.114)	0.9055
	No	88	1 (1.1)	NE [NE, NE)	179	4 (2.2)	NE [NE, NE)		1.789 (0.200, 16.019)	0.5979

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CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	2 (1.6)	NE [NE, NE)	250	4 (1.6)	NE [NE, NE)	0.9919	0.911 (0.166, 4.986)	0.9144
	3	27	0 (0.0)	NE [NE, NE)	58	3 (5.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.3142
Prior proteasome inhibitor exposure per IXRS	Yes	138	1 (0.7)	NE [NE, NE)	276	7 (2.5)	NE [NE, NE)	0.9923	3.086 (0.379, 25.108)	0.2669
	No	15	1 (6.7)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0986

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	1 (1.5)	NE [NE, NE)	131	4 (3.1)	NE [NE, NE)	0.8475	1.685 (0.188, 15.121)	0.6375
	>= 2	87	1 (1.1)	NE [NE, NE)	177	3 (1.7)	NE [NE, NE)		1.339 (0.139, 12.882)	0.7996

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Cardiac failure (SMQ) - Narrow										
Total subjects		153	8 (5.2)	NE [NE, NE)	308	11 (3.6)	NE [NE, NE)		0.581 (0.233, 1.447)	0.2381

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	7 (5.2)	NE [NE, NE)	283	8 (2.8)	NE [NE, NE)	0.2561	0.455 (0.165, 1.258)	0.1200
	> 75	18	1 (5.6)	NE [12.9, NE)	25	3 (12.0)	NE [NE, NE)		2.053 (0.213, 19.749)	0.5247
Sex	Male	91	4 (4.4)	NE [NE, NE)	174	6 (3.4)	NE [NE, NE)	0.7691	0.649 (0.182, 2.314)	0.5021
	Female	62	4 (6.5)	NE [NE, NE)	134	5 (3.7)	NE [NE, NE)		0.504 (0.135, 1.879)	0.2982

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	8 (6.6)	NE [NE, NE)	240	11 (4.6)	NE [NE, NE)	1.0000	0.600 (0.241, 1.495)	0.2686
	Asian	20	0 (0.0)	NE [NE, NE)	46	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	1 (8.3)	NE [11.5, NE)	21	1 (4.8)	NE [NE, NE)	0.9306	0.478 (0.030, 7.729)	0.5952

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	6 (5.9)	NE [NE, NE)	203	9 (4.4)	NE [NE, NE)		0.658 (0.234, 1.850)	0.4248
	Asia Pacific	39	1 (2.6)	NE [NE, NE)	84	1 (1.2)	NE [NE, NE)		0.327 (0.020, 5.225)	0.4049
Baseline ECOG PS	0-1	146	8 (5.5)	NE [NE, NE)	294	9 (3.1)	NE [NE, NE)	0.9912	0.483 (0.186, 1.255)	0.1271
	2	7	0 (0.0)	NE [NE, NE)	13	2 (15.4)	NE [7.0, NE)		>999.999 (<.001, NE)	0.5186

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	8 (5.9)	NE [NE, NE)	285	8 (2.8)	NE [NE, NE)	0.9875	0.401 (0.150, 1.070)	0.0589
	No	17	0 (0.0)	NE [NE, NE)	23	3 (13.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.1604
Refractory to Bortezomib or Ixazomib	Yes	55	3 (5.5)	NE [NE, NE)	99	1 (1.0)	NE [NE, NE)	0.2118	0.159 (0.016, 1.539)	0.0693
	No	98	5 (5.1)	NE [NE, NE)	209	10 (4.8)	NE [NE, NE)		0.798 (0.272, 2.341)	0.6812

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	4 (5.4)	NE [NE, NE)	122	2 (1.6)	NE [NE, NE)	0.2439	0.255 (0.047, 1.394)	0.0893
	No	79	4 (5.1)	NE [NE, NE)	186	9 (4.8)	NE [NE, NE)		0.839 (0.258, 2.728)	0.7698
Refractory to Lenalidomide	Yes	55	2 (3.6)	NE [NE, NE)	98	1 (1.0)	NE [NE, NE)	0.3879	0.256 (0.023, 2.824)	0.2299
	No	98	6 (6.1)	NE [NE, NE)	210	10 (4.8)	NE [NE, NE)		0.686 (0.249, 1.888)	0.4626

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	4 (3.6)	NE [NE, NE)	205	4 (2.0)	NE [NE, NE)	0.7066	0.463 (0.116, 1.856)	0.2663
	No	43	4 (9.3)	NE [NE, NE)	103	7 (6.8)	NE [NE, NE)		0.638 (0.186, 2.186)	0.4712
Refractory to IMiD	Yes	65	2 (3.1)	NE [NE, NE)	129	1 (0.8)	NE [NE, NE)	0.3294	0.228 (0.021, 2.523)	0.1879
	No	88	6 (6.8)	NE [NE, NE)	179	10 (5.6)	NE [NE, NE)		0.726 (0.264, 1.999)	0.5334

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	6 (4.8)	NE [NE, NE)	250	10 (4.0)	NE [NE, NE)	0.2445	0.733 (0.266, 2.019)	0.5460
	3	27	2 (7.4)	NE [NE, NE)	58	1 (1.7)	NE [NE, NE)		0.171 (0.015, 1.911)	0.1049
Prior proteasome inhibitor exposure per IXRS	Yes	138	7 (5.1)	NE [NE, NE)	276	7 (2.5)	NE [NE, NE)	0.2917	0.413 (0.145, 1.181)	0.0886
	No	15	1 (6.7)	NE [NE, NE)	32	4 (12.5)	NE [NE, NE)		1.670 (0.186, 15.001)	0.6433

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	5 (7.6)	NE [NE, NE)	131	5 (3.8)	NE [NE, NE)	0.4805	0.406 (0.117, 1.408)	0.1419
	>= 2	87	3 (3.4)	NE [NE, NE)	177	6 (3.4)	NE [NE, NE)		0.863 (0.216, 3.456)	0.8366

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Cardiomyopathy (SMQ) - Narrow										
Total subjects		153	0 (0.0)	NE [NE, NE)	308	2 (0.6)	NE [NE, NE)		>999.999 (<.001, NE)	0.3700

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	0 (0.0)	NE [NE, NE)	283	2 (0.7)	NE [NE, NE)	0.9993	>999.999 (<.001, NE)	0.3774
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	2 (1.1)	NE [NE, NE)	0.9989	>999.999 (<.001, NE)	0.3647
	Female	62	0 (0.0)	NE [NE, NE)	134	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

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CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	0 (0.0)	NE [NE, NE)	240	2 (0.8)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.3597
	Asian	20	0 (0.0)	NE [NE, NE)	46	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

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CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	1 (0.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.5066
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	1 (1.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.5604
Baseline ECOG PS	0-1	146	0 (0.0)	NE [NE, NE)	294	2 (0.7)	NE [NE, NE)	0.9998	>999.999 (<.001, NE)	0.3607
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

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CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	0 (0.0)	NE [NE, NE)	285	1 (0.4)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.5171
	No	17	0 (0.0)	NE [NE, NE)	23	1 (4.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.5050
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	1 (1.0)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.4715
	No	98	0 (0.0)	NE [NE, NE)	209	1 (0.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.5435

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	1 (0.8)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.4686
	No	79	0 (0.0)	NE [NE, NE)	186	1 (0.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.5622
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	1 (1.0)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.4904
	No	98	0 (0.0)	NE [NE, NE)	210	1 (0.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.5412

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CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	0 (0.0)	NE [NE, NE)	205	2 (1.0)	NE [NE, NE)	0.9989	>999.999 (<.001, NE)	0.3539
	No	43	0 (0.0)	NE [NE, NE)	103	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	1 (0.8)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.5167
	No	88	0 (0.0)	NE [NE, NE)	179	1 (0.6)	NE [NE, NE)		>999.999 (<.001, NE)	0.5271

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CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	0 (0.0)	NE [NE, NE)	250	1 (0.4)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.5211
	3	27	0 (0.0)	NE [NE, NE)	58	1 (1.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.5590
Prior proteasome inhibitor exposure per IXRS	Yes	138	0 (0.0)	NE [NE, NE)	276	1 (0.4)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.5068
	No	15	0 (0.0)	NE [NE, NE)	32	1 (3.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.5637

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	0 (0.0)	NE [NE, NE)	0.9989	NE (NE, NE)	NE
	>= 2	87	0 (0.0)	NE [NE, NE)	177	2 (1.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.3747

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-506-sae-cox-eoi-cfz.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Dyspnoeas (HLT)										
Total subjects		153	5 (3.3)	NE [NE, NE)	308	4 (1.3)	NE [NE, NE)		0.369 (0.099, 1.378)	0.1227

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	4 (3.0)	NE [NE, NE)	283	4 (1.4)	NE [NE, NE)	0.9935	0.462 (0.116, 1.849)	0.2640
	> 75	18	1 (5.6)	NE [12.6, NE)	25	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.1859
Sex	Male	91	2 (2.2)	NE [NE, NE)	174	3 (1.7)	NE [NE, NE)	0.2724	0.750 (0.125, 4.489)	0.7516
	Female	62	3 (4.8)	NE [NE, NE)	134	1 (0.7)	NE [NE, NE)		0.146 (0.015, 1.410)	0.0537

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	4 (3.3)	NE [NE, NE)	240	3 (1.3)	NE [NE, NE)	1.0000	0.353 (0.079, 1.580)	0.1548
	Asian	20	1 (5.0)	NE [NE, NE)	46	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.1294
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	1 (4.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.5002
Region	North America	12	0 (0.0)	NE [NE, NE)	21	1 (4.8)	NE [NE, NE)	0.7242	>999.999 (<.001, NE)	0.4497

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	2 (2.0)	NE [NE, NE)	203	2 (1.0)	NE [NE, NE)		0.506 (0.071, 3.594)	0.4890
	Asia Pacific	39	3 (7.7)	NE [NE, NE)	84	1 (1.2)	NE [NE, NE)		0.125 (0.013, 1.206)	0.0328
Baseline ECOG PS	0-1	146	3 (2.1)	NE [NE, NE)	294	3 (1.0)	NE [NE, NE)	0.4940	0.453 (0.091, 2.252)	0.3207
	2	7	2 (28.6)	NE [0.0, NE)	13	1 (7.7)	NE [NE, NE)		0.249 (0.023, 2.753)	0.2200

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	5 (3.7)	NE [NE, NE)	285	4 (1.4)	NE [NE, NE)	0.9997	0.356 (0.095, 1.328)	0.1084
	No	17	0 (0.0)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to Bortezomib or Ixazomib	Yes	55	1 (1.8)	NE [NE, NE)	99	1 (1.0)	NE [NE, NE)	0.7677	0.527 (0.033, 8.434)	0.6452
	No	98	4 (4.1)	NE [NE, NE)	209	3 (1.4)	NE [NE, NE)		0.327 (0.073, 1.465)	0.1246

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	2 (2.7)	NE [NE, NE)	122	3 (2.5)	NE [NE, NE)	0.2089	0.883 (0.147, 5.290)	0.8917
	No	79	3 (3.8)	NE [NE, NE)	186	1 (0.5)	NE [NE, NE)		0.127 (0.013, 1.222)	0.0342
Refractory to Lenalidomide	Yes	55	1 (1.8)	NE [NE, NE)	98	2 (2.0)	NE [NE, NE)	0.3001	1.078 (0.098, 11.902)	0.9508
	No	98	4 (4.1)	NE [NE, NE)	210	2 (1.0)	NE [NE, NE)		0.217 (0.040, 1.190)	0.0533

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	4 (3.6)	NE [NE, NE)	205	4 (2.0)	NE [NE, NE)	0.9918	0.512 (0.128, 2.047)	0.3352
	No	43	1 (2.3)	NE [NE, NE)	103	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0660
Refractory to IMiD	Yes	65	1 (1.5)	NE [NE, NE)	129	2 (1.6)	NE [NE, NE)	0.3537	0.961 (0.087, 10.608)	0.9741
	No	88	4 (4.5)	NE [NE, NE)	179	2 (1.1)	NE [NE, NE)		0.230 (0.042, 1.258)	0.0644

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	3 (2.4)	NE [NE, NE)	250	3 (1.2)	NE [NE, NE)	0.5510	0.463 (0.093, 2.300)	0.3347
	3	27	2 (7.4)	NE [NE, NE)	58	1 (1.7)	NE [NE, NE)		0.234 (0.021, 2.578)	0.1956
Prior proteasome inhibitor exposure per IXRS	Yes	138	5 (3.6)	NE [NE, NE)	276	3 (1.1)	NE [NE, NE)	0.9916	0.277 (0.066, 1.163)	0.0610
	No	15	0 (0.0)	NE [NE, NE)	32	1 (3.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.4936

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	3 (4.5)	NE [NE, NE)	131	2 (1.5)	NE [NE, NE)	0.7618	0.296 (0.049, 1.781)	0.1580
	>= 2	87	2 (2.3)	NE [NE, NE)	177	2 (1.1)	NE [NE, NE)		0.477 (0.067, 3.388)	0.4489

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Embolic and thrombotic events, venous (SMQ) - Narrow										
Total subjects		153	8 (5.2)	NE [NE, NE)	308	9 (2.9)	NE [NE, NE)		0.454 (0.175, 1.177)	0.0958

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	8 (5.9)	NE [NE, NE)	283	8 (2.8)	NE [NE, NE)	0.9923	0.392 (0.147, 1.047)	0.0527
	> 75	18	0 (0.0)	NE [NE, NE)	25	1 (4.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.4497
Sex	Male	91	4 (4.4)	NE [NE, NE)	174	7 (4.0)	NE [NE, NE)	0.1927	0.747 (0.218, 2.556)	0.6421
	Female	62	4 (6.5)	NE [NE, NE)	134	2 (1.5)	NE [NE, NE)		0.191 (0.035, 1.046)	0.0330

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	8 (6.6)	NE [NE, NE)	240	8 (3.3)	NE [NE, NE)	1.0000	0.414 (0.155, 1.105)	0.0693
	Asian	20	0 (0.0)	NE [NE, NE)	46	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	1 (4.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.5741
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	0.9490	NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-506-sae-cox-eoi-cfz.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	6 (5.9)	NE [NE, NE)	203	6 (3.0)	NE [NE, NE)		0.400 (0.129, 1.243)	0.1010
	Asia Pacific	39	2 (5.1)	NE [NE, NE)	84	3 (3.6)	NE [NE, NE)		0.578 (0.097, 3.464)	0.5440
Baseline ECOG PS	0-1	146	8 (5.5)	NE [NE, NE)	294	8 (2.7)	NE [NE, NE)	0.9916	0.417 (0.156, 1.111)	0.0710
	2	7	0 (0.0)	NE [NE, NE)	13	1 (7.7)	NE [6.2, NE)		>999.999 (<.001, NE)	0.7389

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	8 (5.9)	NE [NE, NE)	285	8 (2.8)	NE [NE, NE)	0.9924	0.393 (0.147, 1.047)	0.0527
	No	17	0 (0.0)	NE [NE, NE)	23	1 (4.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.5211
Refractory to Bortezomib or Ixazomib	Yes	55	3 (5.5)	NE [NE, NE)	99	1 (1.0)	NE [NE, NE)	0.2801	0.152 (0.016, 1.472)	0.0611
	No	98	5 (5.1)	NE [NE, NE)	209	8 (3.8)	NE [NE, NE)		0.613 (0.200, 1.876)	0.3875

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	3 (4.1)	NE [NE, NE)	122	3 (2.5)	NE [NE, NE)	0.9353	0.474 (0.095, 2.359)	0.3511
	No	79	5 (6.3)	NE [NE, NE)	186	6 (3.2)	NE [NE, NE)		0.435 (0.133, 1.427)	0.1580
Refractory to Lenalidomide	Yes	55	3 (5.5)	NE [NE, NE)	98	3 (3.1)	NE [NE, NE)	0.8662	0.417 (0.083, 2.082)	0.2710
	No	98	5 (5.1)	NE [NE, NE)	210	6 (2.9)	NE [NE, NE)		0.486 (0.148, 1.593)	0.2236

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	5 (4.5)	NE [NE, NE)	205	6 (2.9)	NE [NE, NE)	0.6919	0.523 (0.160, 1.716)	0.2778
	No	43	3 (7.0)	NE [NE, NE)	103	3 (2.9)	NE [NE, NE)		0.344 (0.069, 1.711)	0.1721
Refractory to IMiD	Yes	65	4 (6.2)	NE [NE, NE)	129	4 (3.1)	NE [NE, NE)	0.7188	0.379 (0.094, 1.523)	0.1555
	No	88	4 (4.5)	NE [NE, NE)	179	5 (2.8)	NE [NE, NE)		0.535 (0.144, 1.995)	0.3442

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	6 (4.8)	NE [NE, NE)	250	8 (3.2)	NE [NE, NE)	0.2528	0.586 (0.203, 1.689)	0.3172
	3	27	2 (7.4)	NE [NE, NE)	58	1 (1.7)	NE [NE, NE)		0.126 (0.011, 1.417)	0.0477
Prior proteasome inhibitor exposure per IXRS	Yes	138	8 (5.8)	NE [NE, NE)	276	8 (2.9)	NE [NE, NE)	0.9893	0.408 (0.153, 1.089)	0.0643
	No	15	0 (0.0)	NE [NE, NE)	32	1 (3.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.5485

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	4 (6.1)	NE [NE, NE)	131	3 (2.3)	NE [NE, NE)	0.5369	0.331 (0.074, 1.482)	0.1285
	>= 2	87	4 (4.6)	NE [NE, NE)	177	6 (3.4)	NE [NE, NE)		0.584 (0.165, 2.074)	0.4005

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Haematopoietic erythropenia (SMQ) - Broad										
Total subjects		153	1 (0.7)	NE [NE, NE)	308	8 (2.6)	NE [NE, NE)		3.609 (0.451, 28.863)	0.1954

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	1 (0.7)	NE [NE, NE)	283	8 (2.8)	NE [NE, NE)	0.9998	3.488 (0.436, 27.896)	0.2091
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	1 (1.1)	NE [NE, NE)	174	2 (1.1)	NE [NE, NE)	0.9938	1.024 (0.093, 11.289)	0.9847
	Female	62	0 (0.0)	NE [NE, NE)	134	6 (4.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.1175

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CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	1 (0.8)	NE [NE, NE)	240	8 (3.3)	NE [NE, NE)	1.0000	3.772 (0.472, 30.161)	0.1784
	Asian	20	0 (0.0)	NE [NE, NE)	46	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	1 (1.0)	NE [NE, NE)	203	8 (3.9)	NE [NE, NE)		3.685 (0.461, 29.461)	0.1872
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Baseline ECOG PS	0-1	146	1 (0.7)	NE [NE, NE)	294	8 (2.7)	NE [NE, NE)	0.9998	3.689 (0.461, 29.493)	0.1868
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	1 (0.7)	NE [NE, NE)	285	8 (2.8)	NE [NE, NE)	0.9998	3.482 (0.436, 27.847)	0.2098
	No	17	0 (0.0)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	6 (6.1)	NE [NE, NE)	0.9926	>999.999 (<.001, NE)	0.0707
	No	98	1 (1.0)	NE [NE, NE)	209	2 (1.0)	NE [NE, NE)		0.794 (0.072, 8.770)	0.8503

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	3 (2.5)	NE [NE, NE)	0.9930	>999.999 (<.001, NE)	0.2140
	No	79	1 (1.3)	NE [NE, NE)	186	5 (2.7)	NE [NE, NE)		2.009 (0.235, 17.201)	0.5160
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	3 (3.1)	NE [NE, NE)	0.9939	>999.999 (<.001, NE)	0.2391
	No	98	1 (1.0)	NE [NE, NE)	210	5 (2.4)	NE [NE, NE)		2.169 (0.253, 18.577)	0.4688

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-506-sae-cox-eoi-cfz.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	1 (0.9)	NE [NE, NE)	205	4 (2.0)	NE [NE, NE)	0.9945	1.868 (0.209, 16.727)	0.5707
	No	43	0 (0.0)	NE [NE, NE)	103	4 (3.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.2050
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	3 (2.3)	NE [NE, NE)	0.9936	>999.999 (<.001, NE)	0.2647
	No	88	1 (1.1)	NE [NE, NE)	179	5 (2.8)	NE [NE, NE)		2.313 (0.270, 19.809)	0.4306

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	1 (0.8)	NE [NE, NE)	250	5 (2.0)	NE [NE, NE)	0.9948	2.274 (0.266, 19.476)	0.4406
	3	27	0 (0.0)	NE [NE, NE)	58	3 (5.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.2566
Prior proteasome inhibitor exposure per IXRS	Yes	138	1 (0.7)	NE [NE, NE)	276	8 (2.9)	NE [NE, NE)	0.9998	3.665 (0.458, 29.309)	0.1893
	No	15	0 (0.0)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	1 (1.5)	NE [NE, NE)	131	2 (1.5)	NE [NE, NE)	0.9922	0.936 (0.085, 10.338)	0.9572
	>= 2	87	0 (0.0)	NE [NE, NE)	177	6 (3.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.1031

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Haematopoietic leukopenia (SMQ) - Narrow										
Total subjects		153	1 (0.7)	NE [NE, NE)	308	2 (0.6)	NE [NE, NE)		0.926 (0.084, 10.232)	0.9501

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	1 (0.7)	NE [NE, NE)	283	2 (0.7)	NE [NE, NE)	1.0000	0.894 (0.081, 9.877)	0.9273
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	1 (0.6)	NE [NE, NE)	0.9956	>999.999 (<.001, NE)	0.4719
	Female	62	1 (1.6)	NE [NE, NE)	134	1 (0.7)	NE [NE, NE)		0.421 (0.026, 6.732)	0.5276

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	1 (0.8)	NE [NE, NE)	240	1 (0.4)	NE [NE, NE)	1.0000	0.506 (0.032, 8.096)	0.6238
	Asian	20	0 (0.0)	NE [NE, NE)	46	1 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.5351
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	1 (0.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.4806
	Asia Pacific	39	1 (2.6)	NE [NE, NE)	84	1 (1.2)	NE [NE, NE)		0.426 (0.027, 6.830)	0.5348
Baseline ECOG PS	0-1	146	1 (0.7)	NE [NE, NE)	294	2 (0.7)	NE [NE, NE)	1.0000	0.937 (0.085, 10.349)	0.9578
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	1 (0.7)	NE [NE, NE)	285	2 (0.7)	NE [NE, NE)	1.0000	0.890 (0.081, 9.827)	0.9240
	No	17	0 (0.0)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE
	No	98	1 (1.0)	NE [NE, NE)	209	2 (1.0)	NE [NE, NE)		0.878 (0.079, 9.707)	0.9157

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	1 (0.8)	NE [NE, NE)	0.9956	>999.999 (<.001, NE)	0.4748
	No	79	1 (1.3)	NE [NE, NE)	186	1 (0.5)	NE [NE, NE)		0.419 (0.026, 6.703)	0.5259
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	1 (1.0)	NE [NE, NE)	0.9961	>999.999 (<.001, NE)	0.5064
	No	98	1 (1.0)	NE [NE, NE)	210	1 (0.5)	NE [NE, NE)		0.459 (0.029, 7.334)	0.5720

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	0 (0.0)	NE [NE, NE)	205	1 (0.5)	NE [NE, NE)	0.9964	>999.999 (<.001, NE)	0.4967
	No	43	1 (2.3)	NE [NE, NE)	103	1 (1.0)	NE [NE, NE)		0.416 (0.026, 6.651)	0.5218
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	1 (0.8)	NE [NE, NE)	0.9959	>999.999 (<.001, NE)	0.5208
	No	88	1 (1.1)	NE [NE, NE)	179	1 (0.6)	NE [NE, NE)		0.483 (0.030, 7.722)	0.5988

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	1 (0.8)	NE [NE, NE)	250	1 (0.4)	NE [NE, NE)	0.9965	0.470 (0.029, 7.518)	0.5843
	3	27	0 (0.0)	NE [NE, NE)	58	1 (1.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.5127
Prior proteasome inhibitor exposure per IXRS	Yes	138	1 (0.7)	NE [NE, NE)	276	2 (0.7)	NE [NE, NE)	1.0000	0.935 (0.085, 10.328)	0.9564
	No	15	0 (0.0)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	1 (1.5)	NE [NE, NE)	131	1 (0.8)	NE [NE, NE)	0.9956	0.463 (0.029, 7.409)	0.5768
	>= 2	87	0 (0.0)	NE [NE, NE)	177	1 (0.6)	NE [NE, NE)		>999.999 (<.001, NE)	0.4808

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-506-sae-cox-eoi-cfz.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Haematopoietic thrombocytopenia (SMQ) - Narrow										
Total subjects		153	1 (0.7)	NE [NE, NE)	308	5 (1.6)	NE [NE, NE)		2.415 (0.282, 20.679)	0.4059

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Output: t14-06-001-506-sae-cox-eoi-cfz.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	1 (0.7)	NE [NE, NE)	283	5 (1.8)	NE [NE, NE)	0.9999	2.331 (0.272, 19.953)	0.4263
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	1 (0.6)	NE [NE, NE)	0.9947	>999.999 (<.001, NE)	0.4719
	Female	62	1 (1.6)	NE [NE, NE)	134	4 (3.0)	NE [NE, NE)		1.765 (0.197, 15.808)	0.6067

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	0 (0.0)	NE [NE, NE)	240	5 (2.1)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.1123
	Asian	20	1 (5.0)	NE [NE, NE)	46	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.1099
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	5 (2.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.1161
	Asia Pacific	39	1 (2.6)	NE [NE, NE)	84	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.1259
Baseline ECOG PS	0-1	146	1 (0.7)	NE [NE, NE)	294	5 (1.7)	NE [NE, NE)	0.9999	2.436 (0.285, 20.857)	0.4009
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	1 (0.7)	NE [NE, NE)	285	5 (1.8)	NE [NE, NE)	0.9999	2.321 (0.271, 19.870)	0.4287
	No	17	0 (0.0)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to Bortezomib or Ixazomib	Yes	55	1 (1.8)	NE [NE, NE)	99	2 (2.0)	NE [NE, NE)	0.9931	1.070 (0.097, 11.802)	0.9561
	No	98	0 (0.0)	NE [NE, NE)	209	3 (1.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.2352

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	0 (0.0)	NE [NE, NE)	0.9999	NE (NE, NE)	NE
	No	79	1 (1.3)	NE [NE, NE)	186	5 (2.7)	NE [NE, NE)		2.099 (0.245, 17.968)	0.4887
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	0 (0.0)	NE [NE, NE)	0.9999	NE (NE, NE)	NE
	No	98	1 (1.0)	NE [NE, NE)	210	5 (2.4)	NE [NE, NE)		2.281 (0.266, 19.528)	0.4389

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	1 (0.9)	NE [NE, NE)	205	1 (0.5)	NE [NE, NE)	0.9940	0.469 (0.029, 7.509)	0.5841
	No	43	0 (0.0)	NE [NE, NE)	103	4 (3.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.1928
Refractory to IMiD	Yes	65	1 (1.5)	NE [NE, NE)	129	0 (0.0)	NE [NE, NE)	0.9942	<.001 (<.001, NE)	0.1352
	No	88	0 (0.0)	NE [NE, NE)	179	5 (2.8)	NE [NE, NE)		>999.999 (<.001, NE)	0.1208

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	0 (0.0)	NE [NE, NE)	250	1 (0.4)	NE [NE, NE)	0.9958	>999.999 (<.001, NE)	0.4998
	3	27	1 (3.7)	NE [NE, NE)	58	4 (6.9)	NE [NE, NE)		1.748 (0.195, 15.653)	0.6131
Prior proteasome inhibitor exposure per IXRS	Yes	138	1 (0.7)	NE [NE, NE)	276	5 (1.8)	NE [NE, NE)	0.9999	2.441 (0.285, 20.898)	0.3998
	No	15	0 (0.0)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	2 (1.5)	NE [NE, NE)	0.9943	>999.999 (<.001, NE)	0.3211
	>= 2	87	1 (1.1)	NE [NE, NE)	177	3 (1.7)	NE [NE, NE)		1.417 (0.147, 13.629)	0.7617

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Haemorrhage terms (excl laboratory terms) (SMQ) - Narrow										
Total subjects		153	4 (2.6)	NE [NE, NE)	308	6 (1.9)	NE [NE, NE)		0.688 (0.194, 2.442)	0.5606

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	3 (2.2)	NE [NE, NE)	283	6 (2.1)	NE [NE, NE)	0.9926	0.884 (0.221, 3.540)	0.8615
	> 75	18	1 (5.6)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.2305
Sex	Male	91	1 (1.1)	NE [NE, NE)	174	4 (2.3)	NE [NE, NE)	0.1803	1.871 (0.208, 16.826)	0.5698
	Female	62	3 (4.8)	NE [NE, NE)	134	2 (1.5)	NE [NE, NE)		0.281 (0.047, 1.682)	0.1374

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	4 (3.3)	NE [NE, NE)	240	4 (1.7)	NE [NE, NE)	0.9999	0.463 (0.116, 1.855)	0.2652
	Asian	20	0 (0.0)	NE [NE, NE)	46	1 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.5097
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	1 (4.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.4795
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	4 (3.9)	NE [NE, NE)	203	4 (2.0)	NE [NE, NE)		0.451 (0.113, 1.806)	0.2481
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	2 (2.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.3338
Baseline ECOG PS	0-1	146	4 (2.7)	NE [NE, NE)	294	5 (1.7)	NE [NE, NE)	0.9931	0.576 (0.154, 2.148)	0.4056
	2	7	0 (0.0)	NE [NE, NE)	13	1 (7.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.4631

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	2 (1.5)	NE [NE, NE)	285	6 (2.1)	NE [NE, NE)	0.9908	1.319 (0.266, 6.543)	0.7343
	No	17	2 (11.8)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.1024
Refractory to Bortezomib or Ixazomib	Yes	55	1 (1.8)	NE [NE, NE)	99	4 (4.0)	NE [NE, NE)	0.1669	2.136 (0.239, 19.116)	0.4872
	No	98	3 (3.1)	NE [NE, NE)	209	2 (1.0)	NE [NE, NE)		0.280 (0.047, 1.682)	0.1373

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	3 (4.1)	NE [NE, NE)	122	3 (2.5)	NE [NE, NE)	0.5825	0.551 (0.111, 2.734)	0.4596
	No	79	1 (1.3)	NE [NE, NE)	186	3 (1.6)	NE [NE, NE)		1.194 (0.124, 11.514)	0.8779
Refractory to Lenalidomide	Yes	55	1 (1.8)	NE [NE, NE)	98	3 (3.1)	NE [NE, NE)	0.3761	1.553 (0.161, 14.950)	0.7005
	No	98	3 (3.1)	NE [NE, NE)	210	3 (1.4)	NE [NE, NE)		0.439 (0.088, 2.178)	0.3001

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	3 (2.7)	NE [NE, NE)	205	4 (2.0)	NE [NE, NE)	0.9040	0.665 (0.149, 2.973)	0.5907
	No	43	1 (2.3)	NE [NE, NE)	103	2 (1.9)	NE [NE, NE)		0.745 (0.067, 8.277)	0.8100
Refractory to IMiD	Yes	65	1 (1.5)	NE [NE, NE)	129	3 (2.3)	NE [NE, NE)	0.4404	1.372 (0.142, 13.208)	0.7835
	No	88	3 (3.4)	NE [NE, NE)	179	3 (1.7)	NE [NE, NE)		0.461 (0.093, 2.289)	0.3318

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	3 (2.4)	NE [NE, NE)	250	4 (1.6)	NE [NE, NE)	0.9264	0.633 (0.142, 2.835)	0.5470
	3	27	1 (3.7)	NE [NE, NE)	58	2 (3.4)	NE [NE, NE)		0.742 (0.067, 8.231)	0.8070
Prior proteasome inhibitor exposure per IXRS	Yes	138	2 (1.4)	NE [NE, NE)	276	6 (2.2)	NE [NE, NE)	0.9935	1.384 (0.279, 6.869)	0.6895
	No	15	2 (13.3)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0320

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	2 (3.0)	NE [NE, NE)	131	2 (1.5)	NE [NE, NE)	0.6075	0.493 (0.069, 3.499)	0.4701
	>= 2	87	2 (2.3)	NE [NE, NE)	177	4 (2.3)	NE [NE, NE)		0.880 (0.161, 4.813)	0.8828

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Hypertension (SMQ) - Narrow										
Total subjects		153	3 (2.0)	NE [NE, NE)	308	2 (0.6)	NE [NE, NE)		0.254 (0.042, 1.538)	0.1082

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	3 (2.2)	NE [NE, NE)	283	2 (0.7)	NE [NE, NE)	0.9997	0.248 (0.041, 1.497)	0.1003
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	2 (2.2)	NE [NE, NE)	174	1 (0.6)	NE [NE, NE)	0.7185	0.177 (0.016, 1.994)	0.1158
	Female	62	1 (1.6)	NE [NE, NE)	134	1 (0.7)	NE [NE, NE)		0.426 (0.027, 6.823)	0.5344

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	2 (1.6)	NE [NE, NE)	240	1 (0.4)	NE [NE, NE)	1.0000	0.177 (0.016, 1.987)	0.1149
	Asian	20	0 (0.0)	NE [NE, NE)	46	1 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.5762
	Other or Unknown	11	1 (9.1)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.1573
Region	North America	12	1 (8.3)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	0.9985	<.001 (<.001, NE)	0.1859

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	1 (1.0)	NE [NE, NE)	203	1 (0.5)	NE [NE, NE)		0.445 (0.028, 7.166)	0.5578
	Asia Pacific	39	1 (2.6)	NE [17.3, NE)	84	1 (1.2)	NE [NE, NE)		0.314 (0.020, 5.034)	0.3872
Baseline ECOG PS	0-1	146	3 (2.1)	NE [NE, NE)	294	2 (0.7)	NE [NE, NE)	0.9999	0.262 (0.043, 1.582)	0.1167
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	1 (0.7)	NE [NE, NE)	285	2 (0.7)	NE [NE, NE)	0.9938	0.777 (0.070, 8.629)	0.8368
	No	17	2 (11.8)	NE [17.3, NE)	23	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0567
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	1 (1.0)	NE [NE, NE)	0.9948	>999.999 (<.001, NE)	0.5176
	No	98	3 (3.1)	NE [NE, NE)	209	1 (0.5)	NE [NE, NE)		0.123 (0.013, 1.204)	0.0331

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	2 (2.7)	NE [NE, NE)	122	1 (0.8)	NE [NE, NE)	0.8068	0.188 (0.017, 2.130)	0.1337
	No	79	1 (1.3)	NE [NE, NE)	186	1 (0.5)	NE [NE, NE)		0.377 (0.023, 6.064)	0.4745
Refractory to Lenalidomide	Yes	55	2 (3.6)	NE [17.3, NE)	98	1 (1.0)	NE [NE, NE)	0.7090	0.156 (0.014, 1.791)	0.0908
	No	98	1 (1.0)	NE [NE, NE)	210	1 (0.5)	NE [NE, NE)		0.418 (0.026, 6.712)	0.5250

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	3 (2.7)	NE [NE, NE)	205	1 (0.5)	NE [NE, NE)	0.9948	0.134 (0.014, 1.307)	0.0434
	No	43	0 (0.0)	NE [NE, NE)	103	1 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.5772
Refractory to IMiD	Yes	65	2 (3.1)	NE [17.3, NE)	129	1 (0.8)	NE [NE, NE)	0.6528	0.142 (0.012, 1.629)	0.0718
	No	88	1 (1.1)	NE [NE, NE)	179	1 (0.6)	NE [NE, NE)		0.439 (0.027, 7.057)	0.5504

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	2 (1.6)	NE [NE, NE)	250	1 (0.4)	NE [NE, NE)	0.8425	0.192 (0.017, 2.154)	0.1368
	3	27	1 (3.7)	NE [NE, NE)	58	1 (1.7)	NE [NE, NE)		0.340 (0.020, 5.673)	0.4324
Prior proteasome inhibitor exposure per IXRS	Yes	138	1 (0.7)	NE [NE, NE)	276	2 (0.7)	NE [NE, NE)	0.9935	0.807 (0.073, 8.968)	0.8612
	No	15	2 (13.3)	NE [17.3, NE)	32	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0378

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	2 (3.0)	NE [NE, NE)	131	1 (0.8)	NE [NE, NE)	0.7033	0.226 (0.020, 2.511)	0.1860
	>= 2	87	1 (1.1)	NE [NE, NE)	177	1 (0.6)	NE [NE, NE)		0.299 (0.019, 4.825)	0.3669

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Infusion reaction (AMQ) - Narrow (event on same date of any Carfilzomib dosing)										
Total subjects		153	2 (1.3)	NE [NE, NE)	308	6 (1.9)	NE [NE, NE)		1.269 (0.255, 6.323)	0.7710

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	2 (1.5)	NE [NE, NE)	283	6 (2.1)	NE [NE, NE)	1.0000	1.234 (0.248, 6.140)	0.7976
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	2 (2.2)	NE [NE, NE)	174	4 (2.3)	NE [NE, NE)	0.9938	0.836 (0.151, 4.621)	0.8373
	Female	62	0 (0.0)	NE [NE, NE)	134	2 (1.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.3555

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	1 (0.8)	NE [NE, NE)	240	4 (1.7)	NE [NE, NE)	0.7106	1.684 (0.187, 15.200)	0.6386
	Asian	20	1 (5.0)	NE [13.2, NE)	46	1 (2.2)	NE [NE, NE)		0.359 (0.022, 5.812)	0.4518
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	1 (4.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.5224
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	2 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.3322
	Asia Pacific	39	2 (5.1)	NE [17.3, NE)	84	4 (4.8)	NE [NE, NE)		0.797 (0.145, 4.378)	0.7933
Baseline ECOG PS	0-1	146	2 (1.4)	NE [NE, NE)	294	5 (1.7)	NE [NE, NE)	0.9950	1.061 (0.205, 5.502)	0.9438
	2	7	0 (0.0)	NE [NE, NE)	13	1 (7.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.5002

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	1 (0.7)	NE [NE, NE)	285	5 (1.8)	NE [NE, NE)	0.5116	2.133 (0.249, 18.296)	0.4795
	No	17	1 (5.9)	NE [17.3, NE)	23	1 (4.3)	NE [NE, NE)		0.586 (0.036, 9.621)	0.7051
Refractory to Bortezomib or Ixazomib	Yes	55	1 (1.8)	NE [NE, NE)	99	1 (1.0)	NE [NE, NE)	0.4276	0.466 (0.029, 7.501)	0.5811
	No	98	1 (1.0)	NE [NE, NE)	209	5 (2.4)	NE [NE, NE)		2.017 (0.234, 17.362)	0.5147

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	1 (1.4)	NE [17.3, NE)	122	2 (1.6)	NE [NE, NE)	0.8052	0.930 (0.081, 10.622)	0.9533
	No	79	1 (1.3)	NE [NE, NE)	186	4 (2.2)	NE [NE, NE)		1.535 (0.171, 13.745)	0.6993
Refractory to Lenalidomide	Yes	55	1 (1.8)	NE [17.3, NE)	98	1 (1.0)	NE [NE, NE)	0.3920	0.328 (0.019, 5.703)	0.4238
	No	98	1 (1.0)	NE [NE, NE)	210	5 (2.4)	NE [NE, NE)		2.147 (0.251, 18.398)	0.4753

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	2 (1.8)	NE [NE, NE)	205	5 (2.4)	NE [NE, NE)	0.9950	1.132 (0.218, 5.877)	0.8836
	No	43	0 (0.0)	NE [NE, NE)	103	1 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.5338
Refractory to IMiD	Yes	65	1 (1.5)	NE [17.3, NE)	129	2 (1.6)	NE [NE, NE)	0.6412	0.663 (0.058, 7.616)	0.7402
	No	88	1 (1.1)	NE [NE, NE)	179	4 (2.2)	NE [NE, NE)		1.859 (0.208, 16.646)	0.5737

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	2 (1.6)	NE [NE, NE)	250	6 (2.4)	NE [NE, NE)	0.9999	1.334 (0.268, 6.639)	0.7244
	3	27	0 (0.0)	NE [NE, NE)	58	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Prior proteasome inhibitor exposure per IXRS	Yes	138	1 (0.7)	NE [NE, NE)	276	5 (1.8)	NE [NE, NE)	0.3712	2.234 (0.260, 19.167)	0.4517
	No	15	1 (6.7)	NE [17.3, NE)	32	1 (3.1)	NE [NE, NE)		0.475 (0.030, 7.604)	0.5905

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	3 (2.3)	NE [NE, NE)	0.9932	>999.999 (<.001, NE)	0.2313
	>= 2	87	2 (2.3)	NE [NE, NE)	177	3 (1.7)	NE [NE, NE)		0.572 (0.094, 3.463)	0.5380

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Infusion reaction (AMQ) - Narrow (event on same date of first Carfilzomib dosing)										
Total subjects		153	0 (0.0)	NE [NE, NE)	308	2 (0.6)	NE [NE, NE)		>999.999 (<.001, NE)	0.3184

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-506-sae-cox-eoi-cfz.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	0 (0.0)	NE [NE, NE)	283	2 (0.7)	NE [NE, NE)	0.9992	>999.999 (<.001, NE)	0.3281
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	1 (0.6)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.4696
	Female	62	0 (0.0)	NE [NE, NE)	134	1 (0.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.4964

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	0 (0.0)	NE [NE, NE)	240	1 (0.4)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.4759
	Asian	20	0 (0.0)	NE [NE, NE)	46	1 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.5097
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	1 (0.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.4784
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	1 (1.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.4956
Baseline ECOG PS	0-1	146	0 (0.0)	NE [NE, NE)	294	2 (0.7)	NE [NE, NE)	0.9995	>999.999 (<.001, NE)	0.3184
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	0 (0.0)	NE [NE, NE)	285	2 (0.7)	NE [NE, NE)	0.9992	>999.999 (<.001, NE)	0.3280
	No	17	0 (0.0)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	0 (0.0)	NE [NE, NE)	0.9988	NE (NE, NE)	NE
	No	98	0 (0.0)	NE [NE, NE)	209	2 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.3321

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	1 (0.8)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.4361
	No	79	0 (0.0)	NE [NE, NE)	186	1 (0.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.5146
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	0 (0.0)	NE [NE, NE)	0.9988	NE (NE, NE)	NE
	No	98	0 (0.0)	NE [NE, NE)	210	2 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.3332

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	0 (0.0)	NE [NE, NE)	205	2 (1.0)	NE [NE, NE)	0.9989	>999.999 (<.001, NE)	0.2995
	No	43	0 (0.0)	NE [NE, NE)	103	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	0 (0.0)	NE [NE, NE)	0.9989	NE (NE, NE)	NE
	No	88	0 (0.0)	NE [NE, NE)	179	2 (1.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.3205

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	0 (0.0)	NE [NE, NE)	250	2 (0.8)	NE [NE, NE)	0.9990	>999.999 (<.001, NE)	0.3147
	3	27	0 (0.0)	NE [NE, NE)	58	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Prior proteasome inhibitor exposure per IXRS	Yes	138	0 (0.0)	NE [NE, NE)	276	2 (0.7)	NE [NE, NE)	0.9992	>999.999 (<.001, NE)	0.3167
	No	15	0 (0.0)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	1 (0.8)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.4778
	>= 2	87	0 (0.0)	NE [NE, NE)	177	1 (0.6)	NE [NE, NE)		>999.999 (<.001, NE)	0.4832

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Interstitial lung disease (SMQ) - Narrow										
Total subjects		153	1 (0.7)	NE [NE, NE)	308	5 (1.6)	NE [NE, NE)		2.391 (0.279, 20.472)	0.4115

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	1 (0.7)	NE [NE, NE)	283	4 (1.4)	NE [NE, NE)	0.9956	1.851 (0.207, 16.567)	0.5758
	> 75	18	0 (0.0)	NE [NE, NE)	25	1 (4.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.4193
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	3 (1.7)	NE [NE, NE)	0.9931	>999.999 (<.001, NE)	0.2157
	Female	62	1 (1.6)	NE [NE, NE)	134	2 (1.5)	NE [NE, NE)		0.887 (0.080, 9.793)	0.9221

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	1 (0.8)	NE [NE, NE)	240	4 (1.7)	NE [NE, NE)	1.0000	2.002 (0.224, 17.912)	0.5265
	Asian	20	0 (0.0)	NE [NE, NE)	46	1 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.5271
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	4 (2.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.1619
	Asia Pacific	39	1 (2.6)	NE [NE, NE)	84	1 (1.2)	NE [NE, NE)		0.432 (0.027, 6.914)	0.5412
Baseline ECOG PS	0-1	146	1 (0.7)	NE [NE, NE)	294	5 (1.7)	NE [NE, NE)	0.9999	2.420 (0.283, 20.715)	0.4047
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-506-sae-cox-eoi-cfz.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	1 (0.7)	NE [NE, NE)	285	4 (1.4)	NE [NE, NE)	0.9936	1.840 (0.206, 16.468)	0.5796
	No	17	0 (0.0)	NE [NE, NE)	23	1 (4.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.3980
Refractory to Bortezomib or Ixazomib	Yes	55	1 (1.8)	NE [NE, NE)	99	2 (2.0)	NE [NE, NE)	0.9931	1.084 (0.098, 11.953)	0.9476
	No	98	0 (0.0)	NE [NE, NE)	209	3 (1.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.2482

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	2 (1.6)	NE [NE, NE)	0.9939	>999.999 (<.001, NE)	0.2971
	No	79	1 (1.3)	NE [NE, NE)	186	3 (1.6)	NE [NE, NE)		1.264 (0.131, 12.150)	0.8390
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	0 (0.0)	NE [NE, NE)	0.9999	NE (NE, NE)	NE
	No	98	1 (1.0)	NE [NE, NE)	210	5 (2.4)	NE [NE, NE)		2.278 (0.266, 19.502)	0.4394

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	1 (0.9)	NE [NE, NE)	205	2 (1.0)	NE [NE, NE)	0.9929	0.982 (0.089, 10.832)	0.9881
	No	43	0 (0.0)	NE [NE, NE)	103	3 (2.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.2603
Refractory to IMiD	Yes	65	1 (1.5)	NE [NE, NE)	129	0 (0.0)	NE [NE, NE)	0.9942	<.001 (<.001, NE)	0.1556
	No	88	0 (0.0)	NE [NE, NE)	179	5 (2.8)	NE [NE, NE)		>999.999 (<.001, NE)	0.1200

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	0 (0.0)	NE [NE, NE)	250	4 (1.6)	NE [NE, NE)	0.9931	>999.999 (<.001, NE)	0.1606
	3	27	1 (3.7)	NE [NE, NE)	58	1 (1.7)	NE [NE, NE)		0.427 (0.027, 6.825)	0.5347
Prior proteasome inhibitor exposure per IXRS	Yes	138	1 (0.7)	NE [NE, NE)	276	4 (1.4)	NE [NE, NE)	0.9958	1.939 (0.217, 17.355)	0.5463
	No	15	0 (0.0)	NE [NE, NE)	32	1 (3.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.5271

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	2 (1.5)	NE [NE, NE)	0.9942	>999.999 (<.001, NE)	0.3222
	>= 2	87	1 (1.1)	NE [NE, NE)	177	3 (1.7)	NE [NE, NE)		1.406 (0.146, 13.518)	0.7670

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Ischaemic heart disease (SMQ) - Narrow										
Total subjects		153	3 (2.0)	NE [NE, NE)	308	9 (2.9)	NE [NE, NE)		1.214 (0.327, 4.501)	0.7717

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	2 (1.5)	NE [NE, NE)	283	8 (2.8)	NE [NE, NE)	0.4853	1.584 (0.335, 7.484)	0.5582
	> 75	18	1 (5.6)	NE [NE, NE)	25	1 (4.0)	NE [NE, NE)		0.341 (0.018, 6.511)	0.4591
Sex	Male	91	1 (1.1)	NE [NE, NE)	174	6 (3.4)	NE [NE, NE)	0.3108	2.598 (0.311, 21.721)	0.3604
	Female	62	2 (3.2)	NE [NE, NE)	134	3 (2.2)	NE [NE, NE)		0.585 (0.097, 3.515)	0.5532

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	1 (0.8)	NE [NE, NE)	240	9 (3.8)	NE [NE, NE)	1.0000	3.753 (0.474, 29.721)	0.1786
	Asian	20	1 (5.0)	NE [11.3, NE)	46	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0593
	Other or Unknown	11	1 (9.1)	NE [2.4, NE)	22	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0973
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	2 (2.0)	NE [NE, NE)	203	9 (4.4)	NE [NE, NE)		1.870 (0.403, 8.687)	0.4168
	Asia Pacific	39	1 (2.6)	NE [NE, NE)	84	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0806
Baseline ECOG PS	0-1	146	3 (2.1)	NE [NE, NE)	294	9 (3.1)	NE [NE, NE)	1.0000	1.250 (0.337, 4.630)	0.7383
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	3 (2.2)	NE [NE, NE)	285	8 (2.8)	NE [NE, NE)	0.9936	1.037 (0.274, 3.926)	0.9571
	No	17	0 (0.0)	NE [NE, NE)	23	1 (4.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.4583
Refractory to Bortezomib or Ixazomib	Yes	55	1 (1.8)	NE [NE, NE)	99	0 (0.0)	NE [NE, NE)	0.9901	<.001 (<.001, NE)	0.1103
	No	98	2 (2.0)	NE [NE, NE)	209	9 (4.3)	NE [NE, NE)		1.736 (0.374, 8.065)	0.4761

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	1 (1.4)	NE [NE, NE)	122	4 (3.3)	NE [NE, NE)	0.5930	2.089 (0.233, 18.740)	0.5008
	No	79	2 (2.5)	NE [NE, NE)	186	5 (2.7)	NE [NE, NE)		0.879 (0.170, 4.546)	0.8774
Refractory to Lenalidomide	Yes	55	1 (1.8)	NE [NE, NE)	98	3 (3.1)	NE [NE, NE)	0.9819	1.312 (0.136, 12.653)	0.8136
	No	98	2 (2.0)	NE [NE, NE)	210	6 (2.9)	NE [NE, NE)		1.197 (0.241, 5.949)	0.8261

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	3 (2.7)	NE [NE, NE)	205	4 (2.0)	NE [NE, NE)	0.9931	0.620 (0.138, 2.776)	0.5278
	No	43	0 (0.0)	NE [NE, NE)	103	5 (4.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.2006
Refractory to IMiD	Yes	65	2 (3.1)	NE [NE, NE)	129	4 (3.1)	NE [NE, NE)	0.4641	0.810 (0.148, 4.446)	0.8084
	No	88	1 (1.1)	NE [NE, NE)	179	5 (2.8)	NE [NE, NE)		2.064 (0.240, 17.727)	0.4998

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-506-sae-cox-eoi-cfz.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	2 (1.6)	NE [NE, NE)	250	5 (2.0)	NE [NE, NE)	0.9435	0.993 (0.192, 5.142)	0.9931
	3	27	1 (3.7)	NE [NE, NE)	58	4 (6.9)	NE [NE, NE)		1.365 (0.148, 12.608)	0.7829
Prior proteasome inhibitor exposure per IXRS	Yes	138	3 (2.2)	NE [NE, NE)	276	7 (2.5)	NE [NE, NE)	0.9938	0.916 (0.235, 3.561)	0.8988
	No	15	0 (0.0)	NE [NE, NE)	32	2 (6.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.3671

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	1 (1.5)	NE [NE, NE)	131	6 (4.6)	NE [NE, NE)	0.3171	2.369 (0.284, 19.773)	0.4113
	>= 2	87	2 (2.3)	NE [NE, NE)	177	3 (1.7)	NE [NE, NE)		0.635 (0.106, 3.812)	0.6169

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Liver related investigations, signs and symptoms (SMQ) - Narrow										
Total subjects		153	0 (0.0)	NE [NE, NE)	308	4 (1.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.1757

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	0 (0.0)	NE [NE, NE)	283	4 (1.4)	NE [NE, NE)	0.9989	>999.999 (<.001, NE)	0.1832
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	0 (0.0)	NE [NE, NE)	0.9987	NE (NE, NE)	NE
	Female	62	0 (0.0)	NE [NE, NE)	134	4 (3.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.1902

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	0 (0.0)	NE [NE, NE)	240	2 (0.8)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.3234
	Asian	20	0 (0.0)	NE [NE, NE)	46	2 (4.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.3591
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	2 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.3284
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	2 (2.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.3508
Baseline ECOG PS	0-1	146	0 (0.0)	NE [NE, NE)	294	4 (1.4)	NE [NE, NE)	0.9994	>999.999 (<.001, NE)	0.1722
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	0 (0.0)	NE [NE, NE)	285	2 (0.7)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.3695
	No	17	0 (0.0)	NE [NE, NE)	23	2 (8.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.2189
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	0 (0.0)	NE [NE, NE)	0.9984	NE (NE, NE)	NE
	No	98	0 (0.0)	NE [NE, NE)	209	4 (1.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.1876

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	1 (0.8)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.4323
	No	79	0 (0.0)	NE [NE, NE)	186	3 (1.6)	NE [NE, NE)		>999.999 (<.001, NE)	0.2797
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	0 (0.0)	NE [NE, NE)	0.9984	NE (NE, NE)	NE
	No	98	0 (0.0)	NE [NE, NE)	210	4 (1.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.1869

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	0 (0.0)	NE [NE, NE)	205	3 (1.5)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.2167
	No	43	0 (0.0)	NE [NE, NE)	103	1 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.5217
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	1 (0.8)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.5386
	No	88	0 (0.0)	NE [NE, NE)	179	3 (1.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.2303

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	0 (0.0)	NE [NE, NE)	250	3 (1.2)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.2285
	3	27	0 (0.0)	NE [NE, NE)	58	1 (1.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.5762
Prior proteasome inhibitor exposure per IXRS	Yes	138	0 (0.0)	NE [NE, NE)	276	2 (0.7)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.3587
	No	15	0 (0.0)	NE [NE, NE)	32	2 (6.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.3291

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	1 (0.8)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.4778
	>= 2	87	0 (0.0)	NE [NE, NE)	177	3 (1.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.2518

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Myocardial infarction (SMQ) - Narrow										
Total subjects		153	1 (0.7)	NE [NE, NE)	308	4 (1.3)	NE [NE, NE)		1.398 (0.156, 12.554)	0.7637

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-506-sae-cox-eoi-cfz.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	1 (0.7)	NE [NE, NE)	283	3 (1.1)	NE [NE, NE)	0.9948	1.029 (0.107, 9.929)	0.9804
	> 75	18	0 (0.0)	NE [NE, NE)	25	1 (4.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.6171
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	3 (1.7)	NE [NE, NE)	0.9942	>999.999 (<.001, NE)	0.3097
	Female	62	1 (1.6)	NE [NE, NE)	134	1 (0.7)	NE [NE, NE)		0.348 (0.022, 5.602)	0.4356

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	0 (0.0)	NE [NE, NE)	240	4 (1.7)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.2366
	Asian	20	1 (5.0)	NE [11.3, NE)	46	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0593
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	4 (2.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.2348
	Asia Pacific	39	1 (2.6)	NE [NE, NE)	84	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0806
Baseline ECOG PS	0-1	146	1 (0.7)	NE [NE, NE)	294	4 (1.4)	NE [NE, NE)	1.0000	1.460 (0.163, 13.107)	0.7337
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	1 (0.7)	NE [NE, NE)	285	4 (1.4)	NE [NE, NE)	1.0000	1.360 (0.151, 12.220)	0.7829
	No	17	0 (0.0)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to Bortezomib or Ixazomib	Yes	55	1 (1.8)	NE [NE, NE)	99	0 (0.0)	NE [NE, NE)	0.9949	<.001 (<.001, NE)	0.1103
	No	98	0 (0.0)	NE [NE, NE)	209	4 (1.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.2544

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	2 (1.6)	NE [NE, NE)	0.9951	>999.999 (<.001, NE)	0.3287
	No	79	1 (1.3)	NE [NE, NE)	186	2 (1.1)	NE [NE, NE)		0.618 (0.056, 6.839)	0.6919
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	2 (2.0)	NE [NE, NE)	0.9960	>999.999 (<.001, NE)	0.3658
	No	98	1 (1.0)	NE [NE, NE)	210	2 (1.0)	NE [NE, NE)		0.684 (0.062, 7.573)	0.7557

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	1 (0.9)	NE [NE, NE)	205	2 (1.0)	NE [NE, NE)	0.9957	0.852 (0.077, 9.404)	0.8958
	No	43	0 (0.0)	NE [NE, NE)	103	2 (1.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.4532
Refractory to IMiD	Yes	65	1 (1.5)	NE [NE, NE)	129	2 (1.6)	NE [NE, NE)	0.9943	0.729 (0.066, 8.056)	0.7955
	No	88	0 (0.0)	NE [NE, NE)	179	2 (1.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.4028

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	1 (0.8)	NE [NE, NE)	250	3 (1.2)	NE [NE, NE)	0.9946	1.098 (0.113, 10.622)	0.9357
	3	27	0 (0.0)	NE [NE, NE)	58	1 (1.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.6698
Prior proteasome inhibitor exposure per IXRS	Yes	138	1 (0.7)	NE [NE, NE)	276	4 (1.4)	NE [NE, NE)	1.0000	1.394 (0.155, 12.539)	0.7660
	No	15	0 (0.0)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	3 (2.3)	NE [NE, NE)	0.9947	>999.999 (<.001, NE)	0.3212
	>= 2	87	1 (1.1)	NE [NE, NE)	177	1 (0.6)	NE [NE, NE)		0.386 (0.024, 6.171)	0.4846

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Pulmonary hypertension (SMQ) - Narrow										
Total subjects		153	1 (0.7)	NE [NE, NE)	308	3 (1.0)	NE [NE, NE)		1.342 (0.139, 12.911)	0.7983

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	1 (0.7)	NE [NE, NE)	283	3 (1.1)	NE [NE, NE)	1.0000	1.308 (0.136, 12.581)	0.8157
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	1 (1.1)	NE [NE, NE)	174	3 (1.7)	NE [NE, NE)	1.0000	1.441 (0.150, 13.859)	0.7504
	Female	62	0 (0.0)	NE [NE, NE)	134	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	1 (0.8)	NE [NE, NE)	240	3 (1.3)	NE [NE, NE)	1.0000	1.399 (0.145, 13.460)	0.7700
	Asian	20	0 (0.0)	NE [NE, NE)	46	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	2 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.3300
	Asia Pacific	39	1 (2.6)	NE [NE, NE)	84	1 (1.2)	NE [NE, NE)		0.390 (0.024, 6.242)	0.4902
Baseline ECOG PS	0-1	146	1 (0.7)	NE [NE, NE)	294	3 (1.0)	NE [NE, NE)	1.0000	1.376 (0.143, 13.233)	0.7814
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	0 (0.0)	NE [NE, NE)	285	2 (0.7)	NE [NE, NE)	0.9960	>999.999 (<.001, NE)	0.3425
	No	17	1 (5.9)	NE [NE, NE)	23	1 (4.3)	NE [NE, NE)		0.589 (0.037, 9.424)	0.7053
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	1 (1.0)	NE [NE, NE)	0.9956	>999.999 (<.001, NE)	0.4561
	No	98	1 (1.0)	NE [NE, NE)	209	2 (1.0)	NE [NE, NE)		0.790 (0.072, 8.712)	0.8470

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	1 (0.8)	NE [NE, NE)	0.9951	>999.999 (<.001, NE)	0.4716
	No	79	1 (1.3)	NE [NE, NE)	186	2 (1.1)	NE [NE, NE)		0.785 (0.071, 8.667)	0.8431
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	1 (1.0)	NE [NE, NE)	0.9957	>999.999 (<.001, NE)	0.4795
	No	98	1 (1.0)	NE [NE, NE)	210	2 (1.0)	NE [NE, NE)		0.856 (0.078, 9.448)	0.8987

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	1 (0.9)	NE [NE, NE)	205	2 (1.0)	NE [NE, NE)	0.9961	0.911 (0.083, 10.041)	0.9390
	No	43	0 (0.0)	NE [NE, NE)	103	1 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.5162
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	1 (0.8)	NE [NE, NE)	0.9955	>999.999 (<.001, NE)	0.5091
	No	88	1 (1.1)	NE [NE, NE)	179	2 (1.1)	NE [NE, NE)		0.910 (0.082, 10.042)	0.9384

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	1 (0.8)	NE [NE, NE)	250	2 (0.8)	NE [NE, NE)	0.9959	0.905 (0.082, 9.976)	0.9347
	3	27	0 (0.0)	NE [NE, NE)	58	1 (1.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.4951
Prior proteasome inhibitor exposure per IXRS	Yes	138	0 (0.0)	NE [NE, NE)	276	2 (0.7)	NE [NE, NE)	0.9960	>999.999 (<.001, NE)	0.3304
	No	15	1 (6.7)	NE [5.3, NE)	32	1 (3.1)	NE [NE, NE)		0.352 (0.022, 5.622)	0.4394

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	1 (1.5)	NE [NE, NE)	131	1 (0.8)	NE [NE, NE)	0.9946	0.433 (0.027, 6.923)	0.5422
	>= 2	87	0 (0.0)	NE [NE, NE)	177	2 (1.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.3349

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Respiratory failure (SMQ) - Narrow										
Total subjects		153	1 (0.7)	NE [NE, NE)	308	3 (1.0)	NE [NE, NE)		1.273 (0.132, 12.271)	0.8345

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	1 (0.7)	NE [NE, NE)	283	3 (1.1)	NE [NE, NE)	1.0000	1.227 (0.127, 11.835)	0.8593
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	1 (0.6)	NE [NE, NE)	0.9952	>999.999 (<.001, NE)	0.5132
	Female	62	1 (1.6)	NE [NE, NE)	134	2 (1.5)	NE [NE, NE)		0.820 (0.074, 9.069)	0.8716

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	0 (0.0)	NE [NE, NE)	240	3 (1.3)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.2358
	Asian	20	1 (5.0)	NE [12.0, NE)	46	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0635
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	3 (1.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.2437
	Asia Pacific	39	1 (2.6)	NE [NE, NE)	84	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0752
Baseline ECOG PS	0-1	146	1 (0.7)	NE [NE, NE)	294	3 (1.0)	NE [NE, NE)	1.0000	1.304 (0.135, 12.565)	0.8179
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	1 (0.7)	NE [NE, NE)	285	3 (1.1)	NE [NE, NE)	1.0000	1.234 (0.128, 11.896)	0.8555
	No	17	0 (0.0)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to Bortezomib or Ixazomib	Yes	55	1 (1.8)	NE [NE, NE)	99	0 (0.0)	NE [NE, NE)	0.9953	<.001 (<.001, NE)	0.1213
	No	98	0 (0.0)	NE [NE, NE)	209	3 (1.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.2618

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	1 (0.8)	NE [NE, NE)	0.9953	>999.999 (<.001, NE)	0.4723
	No	79	1 (1.3)	NE [NE, NE)	186	2 (1.1)	NE [NE, NE)		0.752 (0.068, 8.318)	0.8153
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	1 (1.0)	NE [NE, NE)	0.9958	>999.999 (<.001, NE)	0.5036
	No	98	1 (1.0)	NE [NE, NE)	210	2 (1.0)	NE [NE, NE)		0.822 (0.074, 9.088)	0.8727

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	1 (0.9)	NE [NE, NE)	205	1 (0.5)	NE [NE, NE)	0.9940	0.425 (0.027, 6.815)	0.5333
	No	43	0 (0.0)	NE [NE, NE)	103	2 (1.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.3632
Refractory to IMiD	Yes	65	1 (1.5)	NE [NE, NE)	129	1 (0.8)	NE [NE, NE)	0.9945	0.362 (0.023, 5.832)	0.4551
	No	88	0 (0.0)	NE [NE, NE)	179	2 (1.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.3354

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	1 (0.8)	NE [NE, NE)	250	1 (0.4)	NE [NE, NE)	0.9958	0.412 (0.026, 6.600)	0.5174
	3	27	0 (0.0)	NE [NE, NE)	58	2 (3.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.3876
Prior proteasome inhibitor exposure per IXRS	Yes	138	1 (0.7)	NE [NE, NE)	276	3 (1.1)	NE [NE, NE)	1.0000	1.294 (0.134, 12.479)	0.8231
	No	15	0 (0.0)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	1 (0.8)	NE [NE, NE)	0.9955	>999.999 (<.001, NE)	0.4829
	>= 2	87	1 (1.1)	NE [NE, NE)	177	2 (1.1)	NE [NE, NE)		0.802 (0.073, 8.854)	0.8569

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Respiratory tract infections (HLGT)										
Total subjects		153	22 (14.4)	NE [NE, NE)	308	74 (24.0)	NE [NE, NE)		1.482 (0.920, 2.387)	0.1031

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	20 (14.8)	NE [NE, NE)	283	66 (23.3)	NE [NE, NE)	0.4375	1.386 (0.840, 2.287)	0.1994
	> 75	18	2 (11.1)	NE [NE, NE)	25	8 (32.0)	NE [4.2, NE)		2.766 (0.587, 13.038)	0.1796
Sex	Male	91	15 (16.5)	NE [NE, NE)	174	45 (25.9)	NE [NE, NE)	0.5827	1.346 (0.749, 2.418)	0.3186
	Female	62	7 (11.3)	NE [NE, NE)	134	29 (21.6)	NE [NE, NE)		1.786 (0.782, 4.078)	0.1627

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	19 (15.6)	NE [NE, NE)	240	60 (25.0)	NE [NE, NE)	0.8496	1.420 (0.846, 2.381)	0.1814
	Asian	20	2 (10.0)	NE [12.0, NE)	46	11 (23.9)	NE [NE, NE)		2.200 (0.487, 9.938)	0.2937
	Other or Unknown	11	1 (9.1)	NE [2.1, NE)	22	3 (13.6)	NE [NE, NE)		1.194 (0.124, 11.512)	0.8780
Region	North America	12	1 (8.3)	NE [16.2, NE)	21	8 (38.1)	NE [11.1, NE)	0.6302	2.941 (0.357, 24.211)	0.2932

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	14 (13.7)	NE [NE, NE)	203	43 (21.2)	NE [NE, NE)		1.382 (0.756, 2.528)	0.2905
	Asia Pacific	39	7 (17.9)	NE [NE, NE)	84	23 (27.4)	NE [NE, NE)		1.377 (0.590, 3.213)	0.4573
Baseline ECOG PS	0-1	146	22 (15.1)	NE [NE, NE)	294	72 (24.5)	NE [NE, NE)	0.9828	1.481 (0.918, 2.389)	0.1047
	2	7	0 (0.0)	NE [NE, NE)	13	2 (15.4)	NE [14.2, NE)		>999.999 (<.001, NE)	0.5186

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	20 (14.7)	NE [NE, NE)	285	70 (24.6)	NE [NE, NE)	0.7976	1.483 (0.902, 2.440)	0.1177
	No	17	2 (11.8)	NE [NE, NE)	23	4 (17.4)	NE [NE, NE)		1.368 (0.249, 7.507)	0.7171
Refractory to Bortezomib or Ixazomib	Yes	55	6 (10.9)	NE [NE, NE)	99	24 (24.2)	NE [NE, NE)	0.3966	2.001 (0.816, 4.905)	0.1222
	No	98	16 (16.3)	NE [NE, NE)	209	50 (23.9)	NE [NE, NE)		1.284 (0.731, 2.257)	0.3827

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	11 (14.9)	NE [NE, NE)	122	31 (25.4)	NE [NE, NE)	0.9072	1.430 (0.716, 2.853)	0.3076
	No	79	11 (13.9)	NE [NE, NE)	186	43 (23.1)	NE [NE, NE)		1.535 (0.791, 2.976)	0.2012
Refractory to Lenalidomide	Yes	55	9 (16.4)	NE [16.2, NE)	98	25 (25.5)	NE [NE, NE)	0.5876	1.218 (0.564, 2.628)	0.6149
	No	98	13 (13.3)	NE [NE, NE)	210	49 (23.3)	NE [NE, NE)		1.642 (0.890, 3.026)	0.1086

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CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	16 (14.5)	NE [NE, NE)	205	52 (25.4)	NE [NE, NE)	0.8578	1.519 (0.867, 2.664)	0.1412
	No	43	6 (14.0)	NE [NE, NE)	103	22 (21.4)	NE [NE, NE)		1.404 (0.569, 3.466)	0.4589
Refractory to IMiD	Yes	65	12 (18.5)	NE [16.2, NE)	129	32 (24.8)	NE [NE, NE)	0.2422	1.048 (0.537, 2.046)	0.8896
	No	88	10 (11.4)	NE [NE, NE)	179	42 (23.5)	NE [NE, NE)		1.948 (0.977, 3.882)	0.0537

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	18 (14.3)	NE [NE, NE)	250	56 (22.4)	NE [NE, NE)	0.9460	1.438 (0.845, 2.447)	0.1779
	3	27	4 (14.8)	NE [7.0, NE)	58	18 (31.0)	NE [14.8, NE)		1.511 (0.508, 4.499)	0.4542
Prior proteasome inhibitor exposure per IXRS	Yes	138	20 (14.5)	NE [NE, NE)	276	69 (25.0)	NE [NE, NE)	0.6070	1.532 (0.931, 2.523)	0.0904
	No	15	2 (13.3)	NE [NE, NE)	32	5 (15.6)	NE [NE, NE)		1.039 (0.201, 5.367)	0.9634

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	9 (13.6)	NE [NE, NE)	131	31 (23.7)	NE [NE, NE)	0.8314	1.566 (0.745, 3.291)	0.2320
	>= 2	87	13 (14.9)	NE [NE, NE)	177	43 (24.3)	NE [NE, NE)		1.407 (0.756, 2.621)	0.2792

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Reversible posterior leukoencephalopathy syndrome (AMQ) - Narrow										
Total subjects		153	0 (0.0)	NE [NE, NE)	308	3 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.2745

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	0 (0.0)	NE [NE, NE)	283	3 (1.1)	NE [NE, NE)	0.9991	>999.999 (<.001, NE)	0.2806
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	1 (0.6)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.5525
	Female	62	0 (0.0)	NE [NE, NE)	134	2 (1.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.3741

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-506-sae-cox-eoi-cfz.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	0 (0.0)	NE [NE, NE)	240	2 (0.8)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.3442
	Asian	20	0 (0.0)	NE [NE, NE)	46	1 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.5186
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	1 (4.8)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.5403

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	1 (0.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.4784
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	1 (1.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.5338
Baseline ECOG PS	0-1	146	0 (0.0)	NE [NE, NE)	294	3 (1.0)	NE [NE, NE)	0.9996	>999.999 (<.001, NE)	0.2685
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	0 (0.0)	NE [NE, NE)	285	3 (1.1)	NE [NE, NE)	0.9990	>999.999 (<.001, NE)	0.2835
	No	17	0 (0.0)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	1 (1.0)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.4579
	No	98	0 (0.0)	NE [NE, NE)	209	2 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.4097

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	1 (0.8)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.5079
	No	79	0 (0.0)	NE [NE, NE)	186	2 (1.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.3829
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	1 (1.0)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.5425
	No	98	0 (0.0)	NE [NE, NE)	210	2 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.3574

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	0 (0.0)	NE [NE, NE)	205	1 (0.5)	NE [NE, NE)	0.9998	>999.999 (<.001, NE)	0.5230
	No	43	0 (0.0)	NE [NE, NE)	103	2 (1.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.3909
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	1 (0.8)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.5586
	No	88	0 (0.0)	NE [NE, NE)	179	2 (1.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.3411

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	0 (0.0)	NE [NE, NE)	250	2 (0.8)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.3811
	3	27	0 (0.0)	NE [NE, NE)	58	1 (1.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.5040
Prior proteasome inhibitor exposure per IXRS	Yes	138	0 (0.0)	NE [NE, NE)	276	3 (1.1)	NE [NE, NE)	0.9990	>999.999 (<.001, NE)	0.2770
	No	15	0 (0.0)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	3 (2.3)	NE [NE, NE)	0.9988	>999.999 (<.001, NE)	0.2702
	>= 2	87	0 (0.0)	NE [NE, NE)	177	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Tumour lysis syndrome (SMQ) - Narrow										
Total subjects		153	1 (0.7)	NE [NE, NE)	308	2 (0.6)	NE [NE, NE)		0.998 (0.090, 11.004)	0.9986

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	1 (0.7)	NE [NE, NE)	283	2 (0.7)	NE [NE, NE)	1.0000	0.958 (0.087, 10.566)	0.9724
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	1 (1.1)	NE [NE, NE)	174	1 (0.6)	NE [NE, NE)	0.9958	0.523 (0.033, 8.364)	0.6411
	Female	62	0 (0.0)	NE [NE, NE)	134	1 (0.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.4964

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	0 (0.0)	NE [NE, NE)	240	2 (0.8)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.3118
	Asian	20	0 (0.0)	NE [NE, NE)	46	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
	Other or Unknown	11	1 (9.1)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.1573
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	1 (1.0)	NE [NE, NE)	203	2 (1.0)	NE [NE, NE)		1.012 (0.092, 11.156)	0.9925
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Baseline ECOG PS	0-1	146	1 (0.7)	NE [NE, NE)	294	2 (0.7)	NE [NE, NE)	1.0000	0.998 (0.090, 11.003)	0.9985
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	1 (0.7)	NE [NE, NE)	285	2 (0.7)	NE [NE, NE)	1.0000	0.958 (0.087, 10.569)	0.9726
	No	17	0 (0.0)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE
	No	98	1 (1.0)	NE [NE, NE)	209	2 (1.0)	NE [NE, NE)		0.941 (0.085, 10.373)	0.9601

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-506-sae-cox-eoi-cfz.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	1 (0.8)	NE [NE, NE)	0.9955	>999.999 (<.001, NE)	0.4361
	No	79	1 (1.3)	NE [NE, NE)	186	1 (0.5)	NE [NE, NE)		0.424 (0.027, 6.785)	0.5320
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	1 (1.0)	NE [NE, NE)	0.9960	>999.999 (<.001, NE)	0.4538
	No	98	1 (1.0)	NE [NE, NE)	210	1 (0.5)	NE [NE, NE)		0.467 (0.029, 7.459)	0.5807

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	1 (0.9)	NE [NE, NE)	205	1 (0.5)	NE [NE, NE)	0.9964	0.539 (0.034, 8.621)	0.6573
	No	43	0 (0.0)	NE [NE, NE)	103	1 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.5162
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	1 (0.8)	NE [NE, NE)	0.9957	>999.999 (<.001, NE)	0.4778
	No	88	1 (1.1)	NE [NE, NE)	179	1 (0.6)	NE [NE, NE)		0.492 (0.031, 7.859)	0.6081

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	0 (0.0)	NE [NE, NE)	250	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE
	3	27	1 (3.7)	NE [NE, NE)	58	2 (3.4)	NE [NE, NE)		0.941 (0.085, 10.381)	0.9605
Prior proteasome inhibitor exposure per IXRS	Yes	138	1 (0.7)	NE [NE, NE)	276	2 (0.7)	NE [NE, NE)	1.0000	1.005 (0.091, 11.082)	0.9968
	No	15	0 (0.0)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	1 (1.5)	NE [NE, NE)	131	2 (1.5)	NE [NE, NE)	1.0000	1.008 (0.091, 11.113)	0.9950
	>= 2	87	0 (0.0)	NE [NE, NE)	177	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab
<Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Daratumumab-related infusion reaction (AMQ) - Narrow (event on same date or next date of any Daratumumab dosing)										
Total subjects		153	0 (0.0)	NE [NE, NE)	308	56 (18.2)	NE [NE, NE)		>999.999 (<.001, NE)	<.0001

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Output: t14-06-001-507-ae-cox-eoi-dar.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	0 (0.0)	NE [NE, NE)	283	52 (18.4)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	<.0001
	> 75	18	0 (0.0)	NE [NE, NE)	25	4 (16.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.0790
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	26 (14.9)	NE [NE, NE)	0.9998	>999.999 (<.001, NE)	0.0001
	Female	62	0 (0.0)	NE [NE, NE)	134	30 (22.4)	NE [NE, NE)		>999.999 (<.001, NE)	<.0001

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	0 (0.0)	NE [NE, NE)	240	38 (15.8)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	<.0001
	Asian	20	0 (0.0)	NE [NE, NE)	46	12 (26.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.0141
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	6 (27.3)	NE [1.9, NE)		>999.999 (<.001, NE)	0.0674
Region	North America	12	0 (0.0)	NE [NE, NE)	21	4 (19.0)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.1142

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	34 (16.7)	NE [NE, NE)		>999.999 (<.001, NE)	<.0001
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	18 (21.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.0022
Baseline ECOG PS	0-1	146	0 (0.0)	NE [NE, NE)	294	52 (17.7)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	<.0001
	2	7	0 (0.0)	NE [NE, NE)	13	3 (23.1)	NE [1.9, NE)		>999.999 (<.001, NE)	0.1934

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	0 (0.0)	NE [NE, NE)	285	50 (17.5)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	<.0001
	No	17	0 (0.0)	NE [NE, NE)	23	6 (26.1)	NE [11.0, NE)		>999.999 (<.001, NE)	0.0299
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	17 (17.2)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.0013
	No	98	0 (0.0)	NE [NE, NE)	209	39 (18.7)	NE [NE, NE)		>999.999 (<.001, NE)	<.0001

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	20 (16.4)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.0003
	No	79	0 (0.0)	NE [NE, NE)	186	36 (19.4)	NE [NE, NE)		>999.999 (<.001, NE)	<.0001
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	12 (12.2)	NE [NE, NE)	0.9997	>999.999 (<.001, NE)	0.0086
	No	98	0 (0.0)	NE [NE, NE)	210	44 (21.0)	NE [NE, NE)		>999.999 (<.001, NE)	<.0001

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	0 (0.0)	NE [NE, NE)	205	39 (19.0)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	<.0001
	No	43	0 (0.0)	NE [NE, NE)	103	17 (16.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.0055
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	15 (11.6)	NE [NE, NE)	0.9996	>999.999 (<.001, NE)	0.0052
	No	88	0 (0.0)	NE [NE, NE)	179	41 (22.9)	NE [NE, NE)		>999.999 (<.001, NE)	<.0001

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	0 (0.0)	NE [NE, NE)	250	46 (18.4)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	<.0001
	3	27	0 (0.0)	NE [NE, NE)	58	10 (17.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.0294
Prior proteasome inhibitor exposure per IXRS	Yes	138	0 (0.0)	NE [NE, NE)	276	50 (18.1)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	<.0001
	No	15	0 (0.0)	NE [NE, NE)	32	6 (18.8)	NE [NE, NE)		>999.999 (<.001, NE)	0.0842

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-507-ae-cox-eoi-dar.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	26 (19.8)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.0001
	>= 2	87	0 (0.0)	NE [NE, NE)	177	30 (16.9)	NE [NE, NE)		>999.999 (<.001, NE)	<.0001

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Daratumumab-related infusion reaction (AMQ) - Narrow (event on same date or next date of first Daratumumab dosing)										
Total subjects		153	0 (0.0)	NE [NE, NE)	308	38 (12.3)	NE [NE, NE)		>999.999 (<.001, NE)	<.0001

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	0 (0.0)	NE [NE, NE)	283	35 (12.4)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	<.0001
	> 75	18	0 (0.0)	NE [NE, NE)	25	3 (12.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.1321
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	19 (10.9)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.0011
	Female	62	0 (0.0)	NE [NE, NE)	134	19 (14.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.0019

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	0 (0.0)	NE [NE, NE)	240	23 (9.6)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.0004
	Asian	20	0 (0.0)	NE [NE, NE)	46	10 (21.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.0247
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	5 (22.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.0932
Region	North America	12	0 (0.0)	NE [NE, NE)	21	3 (14.3)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.1763

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	20 (9.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.0011
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	15 (17.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.0050
Baseline ECOG PS	0-1	146	0 (0.0)	NE [NE, NE)	294	35 (11.9)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	<.0001
	2	7	0 (0.0)	NE [NE, NE)	13	2 (15.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.2863

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Output: t14-06-001-507-ae-cox-eoi-dar.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	0 (0.0)	NE [NE, NE)	285	33 (11.6)	NE [NE, NE)	0.9998	>999.999 (<.001, NE)	<.0001
	No	17	0 (0.0)	NE [NE, NE)	23	5 (21.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.0424
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	10 (10.1)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.0151
	No	98	0 (0.0)	NE [NE, NE)	209	28 (13.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.0001

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	14 (11.5)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.0026
	No	79	0 (0.0)	NE [NE, NE)	186	24 (12.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.0008
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	7 (7.1)	NE [NE, NE)	0.9997	>999.999 (<.001, NE)	0.0431
	No	98	0 (0.0)	NE [NE, NE)	210	31 (14.8)	NE [NE, NE)		>999.999 (<.001, NE)	<.0001

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	0 (0.0)	NE [NE, NE)	205	29 (14.1)	NE [NE, NE)	0.9998	>999.999 (<.001, NE)	<.0001
	No	43	0 (0.0)	NE [NE, NE)	103	9 (8.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.0461
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	10 (7.8)	NE [NE, NE)	0.9997	>999.999 (<.001, NE)	0.0215
	No	88	0 (0.0)	NE [NE, NE)	179	28 (15.6)	NE [NE, NE)		>999.999 (<.001, NE)	<.0001

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	0 (0.0)	NE [NE, NE)	250	33 (13.2)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	<.0001
	3	27	0 (0.0)	NE [NE, NE)	58	5 (8.6)	NE [NE, NE)		>999.999 (<.001, NE)	0.1190
Prior proteasome inhibitor exposure per IXRS	Yes	138	0 (0.0)	NE [NE, NE)	276	33 (12.0)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	<.0001
	No	15	0 (0.0)	NE [NE, NE)	32	5 (15.6)	NE [NE, NE)		>999.999 (<.001, NE)	0.1091

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	20 (15.3)	NE [NE, NE)	0.9998	>999.999 (<.001, NE)	0.0008
	>= 2	87	0 (0.0)	NE [NE, NE)	177	18 (10.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.0021

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Haemorrhage terms (excl laboratory terms) (SMQ) - Narrow										
Total subjects		153	18 (11.8)	NE [NE, NE)	308	44 (14.3)	NE [NE, NE)		1.068 (0.616, 1.850)	0.8154

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	14 (10.4)	NE [NE, NE)	283	38 (13.4)	NE [NE, NE)	0.7913	1.156 (0.625, 2.135)	0.6442
	> 75	18	4 (22.2)	NE [7.8, NE)	25	6 (24.0)	NE [11.7, NE)		0.867 (0.241, 3.118)	0.8265
Sex	Male	91	5 (5.5)	NE [NE, NE)	174	23 (13.2)	NE [NE, NE)	0.0499	2.145 (0.814, 5.651)	0.1137
	Female	62	13 (21.0)	NE [NE, NE)	134	21 (15.7)	NE [NE, NE)		0.643 (0.322, 1.287)	0.2091

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-507-ae-cox-eoi-dar.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	12 (9.8)	NE [NE, NE)	240	35 (14.6)	NE [NE, NE)	0.1356	1.325 (0.687, 2.555)	0.3997
	Asian	20	3 (15.0)	NE [NE, NE)	46	8 (17.4)	NE [NE, NE)		1.054 (0.279, 3.985)	0.9385
	Other or Unknown	11	3 (27.3)	NE [7.2, NE)	22	1 (4.5)	NE [NE, NE)		0.113 (0.012, 1.100)	0.0240
Region	North America	12	4 (33.3)	14.7 [6.9, 14.7)	21	7 (33.3)	NE [11.7, NE)	0.8432	0.658 (0.187, 2.320)	0.5127

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-507-ae-cox-eoi-dar.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	8 (7.8)	NE [NE, NE)	203	21 (10.3)	NE [NE, NE)		1.164 (0.515, 2.631)	0.7149
	Asia Pacific	39	6 (15.4)	NE [NE, NE)	84	16 (19.0)	NE [NE, NE)		1.134 (0.443, 2.902)	0.7936
Baseline ECOG PS	0-1	146	18 (12.3)	NE [NE, NE)	294	41 (13.9)	NE [NE, NE)	0.9844	1.015 (0.583, 1.769)	0.9575
	2	7	0 (0.0)	NE [NE, NE)	13	3 (23.1)	NE [8.2, NE)		>999.999 (<.001, NE)	0.4631

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Output: t14-06-001-507-ae-cox-eoi-dar.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	16 (11.8)	NE [NE, NE)	285	39 (13.7)	NE [NE, NE)	0.5403	1.009 (0.563, 1.809)	0.9752
	No	17	2 (11.8)	NE [NE, NE)	23	5 (21.7)	NE [15.1, NE)		1.813 (0.349, 9.410)	0.4724
Refractory to Bortezomib or Ixazomib	Yes	55	3 (5.5)	NE [NE, NE)	99	17 (17.2)	NE [NE, NE)	0.0426	3.116 (0.913, 10.639)	0.0558
	No	98	15 (15.3)	NE [NE, NE)	209	27 (12.9)	NE [NE, NE)		0.699 (0.371, 1.316)	0.2650

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	12 (16.2)	NE [NE, NE)	122	16 (13.1)	NE [NE, NE)	0.0872	0.682 (0.322, 1.447)	0.3158
	No	79	6 (7.6)	NE [NE, NE)	186	28 (15.1)	NE [NE, NE)		1.823 (0.754, 4.406)	0.1757
Refractory to Lenalidomide	Yes	55	8 (14.5)	NE [NE, NE)	98	15 (15.3)	NE [NE, NE)	0.4719	0.852 (0.358, 2.023)	0.7158
	No	98	10 (10.2)	NE [NE, NE)	210	29 (13.8)	NE [NE, NE)		1.251 (0.609, 2.568)	0.5414

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	15 (13.6)	NE [NE, NE)	205	28 (13.7)	NE [NE, NE)	0.2292	0.886 (0.473, 1.662)	0.7057
	No	43	3 (7.0)	NE [NE, NE)	103	16 (15.5)	NE [NE, NE)		1.982 (0.577, 6.809)	0.2679
Refractory to IMiD	Yes	65	8 (12.3)	NE [NE, NE)	129	18 (14.0)	NE [NE, NE)	0.6798	0.936 (0.405, 2.164)	0.8771
	No	88	10 (11.4)	NE [NE, NE)	179	26 (14.5)	NE [NE, NE)		1.172 (0.565, 2.432)	0.6690

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	17 (13.5)	NE [NE, NE)	250	34 (13.6)	NE [NE, NE)	0.2083	0.900 (0.502, 1.614)	0.7237
	3	27	1 (3.7)	NE [NE, NE)	58	10 (17.2)	NE [NE, NE)		3.450 (0.439, 27.081)	0.2100
Prior proteasome inhibitor exposure per IXRS	Yes	138	16 (11.6)	NE [NE, NE)	276	39 (14.1)	NE [NE, NE)	0.9884	1.062 (0.593, 1.903)	0.8397
	No	15	2 (13.3)	NE [NE, NE)	32	5 (15.6)	NE [NE, NE)		1.126 (0.218, 5.817)	0.8869

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	8 (12.1)	NE [NE, NE)	131	19 (14.5)	NE [NE, NE)	0.9539	1.035 (0.452, 2.369)	0.9337
	>= 2	87	10 (11.5)	NE [NE, NE)	177	25 (14.1)	NE [NE, NE)		1.110 (0.532, 2.314)	0.7812

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Intravascular hemolysis (JMQ)										
Total subjects		153	5 (3.3)	NE [NE, NE)	308	2 (0.6)	NE [NE, NE)		0.169 (0.033, 0.874)	0.0161

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	4 (3.0)	NE [NE, NE)	283	2 (0.7)	NE [NE, NE)	0.9936	0.202 (0.037, 1.103)	0.0405
	> 75	18	1 (5.6)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.2305
Sex	Male	91	4 (4.4)	NE [NE, NE)	174	1 (0.6)	NE [NE, NE)	0.4835	0.106 (0.012, 0.953)	0.0146
	Female	62	1 (1.6)	NE [NE, NE)	134	1 (0.7)	NE [NE, NE)		0.409 (0.026, 6.534)	0.5129

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	5 (4.1)	NE [NE, NE)	240	2 (0.8)	NE [NE, NE)	1.0000	0.176 (0.034, 0.907)	0.0190
	Asian	20	0 (0.0)	NE [NE, NE)	46	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	0.9450	NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	2 (2.0)	NE [NE, NE)	203	1 (0.5)	NE [NE, NE)		0.211 (0.019, 2.334)	0.1616
	Asia Pacific	39	3 (7.7)	NE [NE, NE)	84	1 (1.2)	NE [NE, NE)		0.133 (0.014, 1.278)	0.0394
Baseline ECOG PS	0-1	146	5 (3.4)	NE [NE, NE)	294	1 (0.3)	NE [NE, NE)	0.9997	0.087 (0.010, 0.749)	0.0049
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	4 (2.9)	NE [NE, NE)	285	1 (0.4)	NE [NE, NE)	0.3381	0.103 (0.011, 0.919)	0.0124
	No	17	1 (5.9)	NE [NE, NE)	23	1 (4.3)	NE [NE, NE)		0.556 (0.035, 8.930)	0.6745
Refractory to Bortezomib or Ixazomib	Yes	55	1 (1.8)	NE [NE, NE)	99	0 (0.0)	NE [NE, NE)	0.9948	<.001 (<.001, NE)	0.1726
	No	98	4 (4.1)	NE [NE, NE)	209	2 (1.0)	NE [NE, NE)		0.191 (0.035, 1.047)	0.0331

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-507-ae-cox-eoi-dar.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	1 (1.4)	NE [NE, NE)	122	1 (0.8)	NE [NE, NE)	0.3510	0.530 (0.033, 8.478)	0.6482
	No	79	4 (5.1)	NE [NE, NE)	186	1 (0.5)	NE [NE, NE)		0.092 (0.010, 0.823)	0.0075
Refractory to Lenalidomide	Yes	55	1 (1.8)	NE [NE, NE)	98	0 (0.0)	NE [NE, NE)	0.9944	<.001 (<.001, NE)	0.1482
	No	98	4 (4.1)	NE [NE, NE)	210	2 (1.0)	NE [NE, NE)		0.207 (0.038, 1.131)	0.0444

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-507-ae-cox-eoi-dar.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	3 (2.7)	NE [NE, NE)	205	2 (1.0)	NE [NE, NE)	0.9937	0.295 (0.049, 1.774)	0.1566
	No	43	2 (4.7)	NE [NE, NE)	103	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0241
Refractory to IMiD	Yes	65	1 (1.5)	NE [NE, NE)	129	0 (0.0)	NE [NE, NE)	0.9943	<.001 (<.001, NE)	0.1292
	No	88	4 (4.5)	NE [NE, NE)	179	2 (1.1)	NE [NE, NE)		0.218 (0.040, 1.191)	0.0533

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	5 (4.0)	NE [NE, NE)	250	2 (0.8)	NE [NE, NE)	0.9998	0.178 (0.034, 0.919)	0.0201
	3	27	0 (0.0)	NE [NE, NE)	58	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Prior proteasome inhibitor exposure per IXRS	Yes	138	4 (2.9)	NE [NE, NE)	276	1 (0.4)	NE [NE, NE)	0.5236	0.108 (0.012, 0.969)	0.0155
	No	15	1 (6.7)	NE [3.3, NE)	32	1 (3.1)	NE [NE, NE)		0.314 (0.020, 5.030)	0.3873

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	3 (4.5)	NE [NE, NE)	131	1 (0.8)	NE [NE, NE)	0.8275	0.142 (0.015, 1.366)	0.0489
	>= 2	87	2 (2.3)	NE [NE, NE)	177	1 (0.6)	NE [NE, NE)		0.216 (0.020, 2.383)	0.1685

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-507-ae-cox-eoi-dar.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Opportunistic infections (JMQ)										
Total subjects		153	6 (3.9)	NE [NE, NE)	308	28 (9.1)	NE [NE, NE)		2.098 (0.868, 5.069)	0.0923

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	6 (4.4)	NE [NE, NE)	283	26 (9.2)	NE [NE, NE)	0.9896	1.887 (0.776, 4.588)	0.1541
	> 75	18	0 (0.0)	NE [NE, NE)	25	2 (8.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.2611
Sex	Male	91	4 (4.4)	NE [NE, NE)	174	13 (7.5)	NE [NE, NE)	0.4290	1.503 (0.489, 4.617)	0.4735
	Female	62	2 (3.2)	NE [NE, NE)	134	15 (11.2)	NE [NE, NE)		3.184 (0.728, 13.926)	0.1040

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	5 (4.1)	NE [NE, NE)	240	18 (7.5)	NE [NE, NE)	0.9099	1.629 (0.604, 4.392)	0.3306
	Asian	20	0 (0.0)	NE [NE, NE)	46	4 (8.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.2124
	Other or Unknown	11	1 (9.1)	NE [2.7, NE)	22	6 (27.3)	NE [3.7, NE)		2.610 (0.314, 21.689)	0.3563
Region	North America	12	1 (8.3)	NE [4.4, NE)	21	5 (23.8)	NE [5.6, NE)	0.8084	2.865 (0.335, 24.531)	0.3145

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	4 (3.9)	NE [NE, NE)	203	15 (7.4)	NE [NE, NE)		1.684 (0.558, 5.078)	0.3496
	Asia Pacific	39	1 (2.6)	NE [NE, NE)	84	8 (9.5)	NE [NE, NE)		3.321 (0.415, 26.568)	0.2300
Baseline ECOG PS	0-1	146	6 (4.1)	NE [NE, NE)	294	27 (9.2)	NE [NE, NE)	0.9998	2.071 (0.855, 5.018)	0.0994
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	6 (4.4)	NE [NE, NE)	285	27 (9.5)	NE [NE, NE)	0.9902	1.951 (0.805, 4.727)	0.1317
	No	17	0 (0.0)	NE [NE, NE)	23	1 (4.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.4583
Refractory to Bortezomib or Ixazomib	Yes	55	4 (7.3)	NE [NE, NE)	99	10 (10.1)	NE [NE, NE)	0.2448	1.275 (0.399, 4.070)	0.6808
	No	98	2 (2.0)	NE [NE, NE)	209	18 (8.6)	NE [NE, NE)		3.838 (0.890, 16.549)	0.0521

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	3 (4.1)	NE [NE, NE)	122	13 (10.7)	NE [NE, NE)	0.8289	2.321 (0.660, 8.165)	0.1768
	No	79	3 (3.8)	NE [NE, NE)	186	15 (8.1)	NE [NE, NE)		1.940 (0.562, 6.705)	0.2856
Refractory to Lenalidomide	Yes	55	1 (1.8)	NE [NE, NE)	98	11 (11.2)	NE [NE, NE)	0.2510	5.342 (0.687, 41.523)	0.0728
	No	98	5 (5.1)	NE [NE, NE)	210	17 (8.1)	NE [NE, NE)		1.454 (0.536, 3.943)	0.4586

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	4 (3.6)	NE [NE, NE)	205	21 (10.2)	NE [NE, NE)	0.5043	2.535 (0.869, 7.389)	0.0775
	No	43	2 (4.7)	NE [NE, NE)	103	7 (6.8)	NE [NE, NE)		1.311 (0.272, 6.323)	0.7348
Refractory to IMiD	Yes	65	3 (4.6)	NE [NE, NE)	129	15 (11.6)	NE [NE, NE)	0.8920	2.182 (0.630, 7.560)	0.2071
	No	88	3 (3.4)	NE [NE, NE)	179	13 (7.3)	NE [NE, NE)		1.959 (0.558, 6.877)	0.2846

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	5 (4.0)	NE [NE, NE)	250	26 (10.4)	NE [NE, NE)	0.3253	2.458 (0.943, 6.403)	0.0570
	3	27	1 (3.7)	NE [NE, NE)	58	2 (3.4)	NE [NE, NE)		0.599 (0.053, 6.786)	0.6755
Prior proteasome inhibitor exposure per IXRS	Yes	138	6 (4.3)	NE [NE, NE)	276	27 (9.8)	NE [NE, NE)	0.9912	2.053 (0.847, 4.974)	0.1038
	No	15	0 (0.0)	NE [NE, NE)	32	1 (3.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.5637

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	2 (3.0)	NE [NE, NE)	131	9 (6.9)	NE [NE, NE)	0.9639	2.018 (0.436, 9.347)	0.3590
	>= 2	87	4 (4.6)	NE [NE, NE)	177	19 (10.7)	NE [NE, NE)		2.130 (0.724, 6.266)	0.1599

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-507-ae-cox-eoi-dar.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Second primary malignancies: Malignant tumours (SMQ) - Narrow										
Total subjects		153	2 (1.3)	NE [NE, NE)	308	3 (1.0)	NE [NE, NE)		0.605 (0.101, 3.630)	0.5789

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Output: t14-06-001-507-ae-cox-eoi-dar.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	2 (1.5)	NE [NE, NE)	283	2 (0.7)	NE [NE, NE)	0.9947	0.368 (0.052, 2.613)	0.2974
	> 75	18	0 (0.0)	NE [NE, NE)	25	1 (4.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.4142
Sex	Male	91	2 (2.2)	NE [NE, NE)	174	2 (1.1)	NE [NE, NE)	0.9954	0.414 (0.058, 2.955)	0.3637
	Female	62	0 (0.0)	NE [NE, NE)	134	1 (0.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.5332

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	2 (1.6)	NE [NE, NE)	240	2 (0.8)	NE [NE, NE)	1.0000	0.412 (0.058, 2.939)	0.3611
	Asian	20	0 (0.0)	NE [NE, NE)	46	1 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.5403
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	1 (4.8)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.5403

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	2 (2.0)	NE [NE, NE)	203	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0246
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	2 (2.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.3842
Baseline ECOG PS	0-1	146	2 (1.4)	NE [NE, NE)	294	3 (1.0)	NE [NE, NE)	1.0000	0.627 (0.105, 3.756)	0.6057
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	2 (1.5)	NE [NE, NE)	285	2 (0.7)	NE [NE, NE)	0.9941	0.404 (0.057, 2.872)	0.3487
	No	17	0 (0.0)	NE [NE, NE)	23	1 (4.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.5211
Refractory to Bortezomib or Ixazomib	Yes	55	1 (1.8)	NE [NE, NE)	99	1 (1.0)	NE [NE, NE)	0.7724	0.440 (0.027, 7.041)	0.5504
	No	98	1 (1.0)	NE [NE, NE)	209	2 (1.0)	NE [NE, NE)		0.772 (0.070, 8.560)	0.8326

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	1 (1.4)	NE [NE, NE)	122	1 (0.8)	NE [NE, NE)	0.8272	0.476 (0.030, 7.614)	0.5915
	No	79	1 (1.3)	NE [NE, NE)	186	2 (1.1)	NE [NE, NE)		0.735 (0.067, 8.127)	0.8013
Refractory to Lenalidomide	Yes	55	1 (1.8)	NE [NE, NE)	98	1 (1.0)	NE [NE, NE)	0.7229	0.416 (0.026, 6.653)	0.5220
	No	98	1 (1.0)	NE [NE, NE)	210	2 (1.0)	NE [NE, NE)		0.821 (0.074, 9.063)	0.8716

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	1 (0.9)	NE [NE, NE)	205	2 (1.0)	NE [NE, NE)	0.6190	0.811 (0.073, 8.960)	0.8642
	No	43	1 (2.3)	NE [NE, NE)	103	1 (1.0)	NE [NE, NE)		0.370 (0.023, 5.932)	0.4643
Refractory to IMiD	Yes	65	1 (1.5)	NE [NE, NE)	129	1 (0.8)	NE [NE, NE)	0.6651	0.371 (0.023, 5.932)	0.4653
	No	88	1 (1.1)	NE [NE, NE)	179	2 (1.1)	NE [NE, NE)		0.863 (0.078, 9.534)	0.9045

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	2 (1.6)	NE [NE, NE)	250	3 (1.2)	NE [NE, NE)	0.9999	0.654 (0.109, 3.922)	0.6400
	3	27	0 (0.0)	NE [NE, NE)	58	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Prior proteasome inhibitor exposure per IXRS	Yes	138	2 (1.4)	NE [NE, NE)	276	2 (0.7)	NE [NE, NE)	0.9938	0.422 (0.059, 3.004)	0.3745
	No	15	0 (0.0)	NE [NE, NE)	32	1 (3.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.5812

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	1 (1.5)	NE [NE, NE)	131	1 (0.8)	NE [NE, NE)	0.7307	0.429 (0.027, 6.878)	0.5382
	>= 2	87	1 (1.1)	NE [NE, NE)	177	2 (1.1)	NE [NE, NE)		0.802 (0.072, 8.882)	0.8568

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Tumour lysis syndrome (SMQ) - Narrow										
Total subjects		153	1 (0.7)	NE [NE, NE)	308	3 (1.0)	NE [NE, NE)		1.501 (0.156, 14.427)	0.7231

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	1 (0.7)	NE [NE, NE)	283	3 (1.1)	NE [NE, NE)	1.0000	1.442 (0.150, 13.864)	0.7497
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	1 (1.1)	NE [NE, NE)	174	1 (0.6)	NE [NE, NE)	0.9952	0.523 (0.033, 8.364)	0.6411
	Female	62	0 (0.0)	NE [NE, NE)	134	2 (1.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.3342

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	0 (0.0)	NE [NE, NE)	240	3 (1.3)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.2146
	Asian	20	0 (0.0)	NE [NE, NE)	46	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
	Other or Unknown	11	1 (9.1)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.1573
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-507-ae-cox-eoi-dar.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	1 (1.0)	NE [NE, NE)	203	3 (1.5)	NE [NE, NE)		1.524 (0.159, 14.649)	0.7130
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Baseline ECOG PS	0-1	146	1 (0.7)	NE [NE, NE)	294	3 (1.0)	NE [NE, NE)	0.9999	1.501 (0.156, 14.428)	0.7231
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	1 (0.7)	NE [NE, NE)	285	3 (1.1)	NE [NE, NE)	1.0000	1.443 (0.150, 13.868)	0.7495
	No	17	0 (0.0)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	1 (1.0)	NE [NE, NE)	0.9955	>999.999 (<.001, NE)	0.4538
	No	98	1 (1.0)	NE [NE, NE)	209	2 (1.0)	NE [NE, NE)		0.941 (0.085, 10.373)	0.9601

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	2 (1.6)	NE [NE, NE)	0.9948	>999.999 (<.001, NE)	0.2687
	No	79	1 (1.3)	NE [NE, NE)	186	1 (0.5)	NE [NE, NE)		0.424 (0.027, 6.785)	0.5320
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	2 (2.0)	NE [NE, NE)	0.9957	>999.999 (<.001, NE)	0.2869
	No	98	1 (1.0)	NE [NE, NE)	210	1 (0.5)	NE [NE, NE)		0.467 (0.029, 7.459)	0.5807

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	1 (0.9)	NE [NE, NE)	205	2 (1.0)	NE [NE, NE)	0.9960	1.082 (0.098, 11.933)	0.9487
	No	43	0 (0.0)	NE [NE, NE)	103	1 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.5162
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	2 (1.6)	NE [NE, NE)	0.9951	>999.999 (<.001, NE)	0.3135
	No	88	1 (1.1)	NE [NE, NE)	179	1 (0.6)	NE [NE, NE)		0.492 (0.031, 7.859)	0.6081

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	0 (0.0)	NE [NE, NE)	250	1 (0.4)	NE [NE, NE)	0.9956	>999.999 (<.001, NE)	0.4769
	3	27	1 (3.7)	NE [NE, NE)	58	2 (3.4)	NE [NE, NE)		0.941 (0.085, 10.381)	0.9605
Prior proteasome inhibitor exposure per IXRS	Yes	138	1 (0.7)	NE [NE, NE)	276	3 (1.1)	NE [NE, NE)	0.9999	1.512 (0.157, 14.534)	0.7182
	No	15	0 (0.0)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	1 (1.5)	NE [NE, NE)	131	2 (1.5)	NE [NE, NE)	0.9950	1.008 (0.091, 11.113)	0.9950
	>= 2	87	0 (0.0)	NE [NE, NE)	177	1 (0.6)	NE [NE, NE)		>999.999 (<.001, NE)	0.4808

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab
<Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Viral infection (JMQ)										
Total subjects		153	22 (14.4)	NE [NE, NE)	308	63 (20.5)	NE [NE, NE)		1.285 (0.790, 2.089)	0.3108

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	21 (15.6)	NE [NE, NE)	283	59 (20.8)	NE [NE, NE)	0.4837	1.207 (0.733, 1.987)	0.4591
	> 75	18	1 (5.6)	NE [12.9, NE)	25	4 (16.0)	NE [NE, NE)		2.758 (0.308, 24.681)	0.3439
Sex	Male	91	16 (17.6)	NE [NE, NE)	174	35 (20.1)	NE [NE, NE)	0.1901	0.958 (0.529, 1.735)	0.8879
	Female	62	6 (9.7)	NE [NE, NE)	134	28 (20.9)	NE [NE, NE)		2.053 (0.850, 4.959)	0.1024

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	18 (14.8)	NE [NE, NE)	240	47 (19.6)	NE [NE, NE)	0.7711	1.165 (0.676, 2.007)	0.5829
	Asian	20	2 (10.0)	NE [12.9, NE)	46	9 (19.6)	NE [NE, NE)		1.910 (0.412, 8.850)	0.3999
	Other or Unknown	11	2 (18.2)	NE [2.1, NE)	22	7 (31.8)	NE [3.7, NE)		1.607 (0.333, 7.744)	0.5508
Region	North America	12	3 (25.0)	NE [2.2, NE)	21	10 (47.6)	17.4 [4.1, NE)	0.3541	1.775 (0.485, 6.495)	0.3799

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	15 (14.7)	NE [NE, NE)	203	33 (16.3)	NE [NE, NE)		0.983 (0.533, 1.811)	0.9555
	Asia Pacific	39	4 (10.3)	NE [NE, NE)	84	20 (23.8)	NE [NE, NE)		2.140 (0.730, 6.268)	0.1549
Baseline ECOG PS	0-1	146	22 (15.1)	NE [NE, NE)	294	61 (20.7)	NE [NE, NE)	0.9824	1.273 (0.781, 2.073)	0.3315
	2	7	0 (0.0)	NE [NE, NE)	13	2 (15.4)	NE [11.5, NE)		>999.999 (<.001, NE)	0.5002

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab
<Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	20 (14.7)	NE [NE, NE)	285	60 (21.1)	NE [NE, NE)	0.7408	1.294 (0.780, 2.148)	0.3171
	No	17	2 (11.8)	NE [9.3, NE)	23	3 (13.0)	NE [NE, NE)		1.017 (0.169, 6.134)	0.9850
Refractory to Bortezomib or Ixazomib	Yes	55	7 (12.7)	NE [NE, NE)	99	19 (19.2)	NE [NE, NE)	0.8075	1.382 (0.580, 3.292)	0.4631
	No	98	15 (15.3)	NE [NE, NE)	209	44 (21.1)	NE [NE, NE)		1.235 (0.687, 2.220)	0.4801

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	14 (18.9)	NE [NE, NE)	122	24 (19.7)	NE [NE, NE)	0.1050	0.835 (0.430, 1.619)	0.5936
	No	79	8 (10.1)	NE [NE, NE)	186	39 (21.0)	NE [NE, NE)		2.009 (0.939, 4.299)	0.0668
Refractory to Lenalidomide	Yes	55	11 (20.0)	NE [12.2, NE)	98	21 (21.4)	NE [NE, NE)	0.1775	0.830 (0.397, 1.734)	0.6194
	No	98	11 (11.2)	NE [NE, NE)	210	42 (20.0)	NE [NE, NE)		1.710 (0.880, 3.322)	0.1091

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
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[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Output: t14-06-001-507-ae-cox-eoi-dar.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	17 (15.5)	NE [NE, NE)	205	41 (20.0)	NE [NE, NE)	0.4704	1.159 (0.658, 2.043)	0.6081
	No	43	5 (11.6)	NE [NE, NE)	103	22 (21.4)	NE [NE, NE)		1.720 (0.651, 4.544)	0.2678
Refractory to IMiD	Yes	65	13 (20.0)	NE [12.2, NE)	129	29 (22.5)	NE [NE, NE)	0.1962	0.901 (0.466, 1.743)	0.7582
	No	88	9 (10.2)	NE [NE, NE)	179	34 (19.0)	NE [NE, NE)		1.784 (0.856, 3.720)	0.1176

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-507-ae-cox-eoi-dar.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	16 (12.7)	NE [NE, NE)	250	54 (21.6)	NE [NE, NE)	0.0338	1.615 (0.924, 2.823)	0.0887
	3	27	6 (22.2)	NE [11.1, NE)	58	9 (15.5)	NE [NE, NE)		0.439 (0.152, 1.269)	0.1189
Prior proteasome inhibitor exposure per IXRS	Yes	138	20 (14.5)	NE [NE, NE)	276	60 (21.7)	NE [NE, NE)	0.3862	1.359 (0.819, 2.256)	0.2329
	No	15	2 (13.3)	NE [9.3, NE)	32	3 (9.4)	NE [NE, NE)		0.675 (0.112, 4.053)	0.6654

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	5 (7.6)	NE [NE, NE)	131	25 (19.1)	NE [NE, NE)	0.1188	2.329 (0.891, 6.087)	0.0755
	>= 2	87	17 (19.5)	NE [NE, NE)	177	38 (21.5)	NE [NE, NE)		0.962 (0.542, 1.708)	0.8961

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Daratumumab-related infusion reaction (AMQ) - Narrow (event on same date or next date of any Daratumumab dosing)										
Total subjects		153	0 (0.0)	NE [NE, NE)	308	7 (2.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.0673

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	0 (0.0)	NE [NE, NE)	283	6 (2.1)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.0985
	> 75	18	0 (0.0)	NE [NE, NE)	25	1 (4.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.3961
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	5 (2.9)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.1168
	Female	62	0 (0.0)	NE [NE, NE)	134	2 (1.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.3416

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	0 (0.0)	NE [NE, NE)	240	4 (1.7)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.1675
	Asian	20	0 (0.0)	NE [NE, NE)	46	2 (4.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.3473
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	1 (4.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.5224
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	4 (2.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.1706
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	3 (3.6)	NE [NE, NE)		>999.999 (<.001, NE)	0.2358
Baseline ECOG PS	0-1	146	0 (0.0)	NE [NE, NE)	294	6 (2.0)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.0896
	2	7	0 (0.0)	NE [NE, NE)	13	1 (7.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.5002

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	0 (0.0)	NE [NE, NE)	285	5 (1.8)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.1247
	No	17	0 (0.0)	NE [NE, NE)	23	2 (8.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.2730
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	2 (2.0)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.3001
	No	98	0 (0.0)	NE [NE, NE)	209	5 (2.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.1315

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	5 (4.1)	NE [NE, NE)	0.9997	>999.999 (<.001, NE)	0.0921
	No	79	0 (0.0)	NE [NE, NE)	186	2 (1.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.3558
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	3 (3.1)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.2291
	No	98	0 (0.0)	NE [NE, NE)	210	4 (1.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.1698

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	0 (0.0)	NE [NE, NE)	205	6 (2.9)	NE [NE, NE)	0.9998	>999.999 (<.001, NE)	0.0802
	No	43	0 (0.0)	NE [NE, NE)	103	1 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.5182
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	3 (2.3)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.2544
	No	88	0 (0.0)	NE [NE, NE)	179	4 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.1585

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	0 (0.0)	NE [NE, NE)	250	7 (2.8)	NE [NE, NE)	0.9983	>999.999 (<.001, NE)	0.0624
	3	27	0 (0.0)	NE [NE, NE)	58	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Prior proteasome inhibitor exposure per IXRS	Yes	138	0 (0.0)	NE [NE, NE)	276	6 (2.2)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.0837
	No	15	0 (0.0)	NE [NE, NE)	32	1 (3.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.5637

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	2 (1.5)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.3142
	>= 2	87	0 (0.0)	NE [NE, NE)	177	5 (2.8)	NE [NE, NE)		>999.999 (<.001, NE)	0.1276

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Daratumumab-related infusion reaction (AMQ) - Narrow (event on same date or next date of first Daratumumab dosing)										
Total subjects		153	0 (0.0)	NE [NE, NE)	308	4 (1.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.1573

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-508-ae-cox-eoi-dar-grd345.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	0 (0.0)	NE [NE, NE)	283	3 (1.1)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.2305
	> 75	18	0 (0.0)	NE [NE, NE)	25	1 (4.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.3961
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	3 (1.7)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.2086
	Female	62	0 (0.0)	NE [NE, NE)	134	1 (0.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.4964

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-508-ae-cox-eoi-dar-grd345.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	0 (0.0)	NE [NE, NE)	240	2 (0.8)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.3126
	Asian	20	0 (0.0)	NE [NE, NE)	46	2 (4.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.3473
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	2 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.3153
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	2 (2.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.3332
Baseline ECOG PS	0-1	146	0 (0.0)	NE [NE, NE)	294	4 (1.4)	NE [NE, NE)	0.9992	>999.999 (<.001, NE)	0.1573
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	0 (0.0)	NE [NE, NE)	285	3 (1.1)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.2304
	No	17	0 (0.0)	NE [NE, NE)	23	1 (4.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.3899
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	0 (0.0)	NE [NE, NE)	0.9984	NE (NE, NE)	NE
	No	98	0 (0.0)	NE [NE, NE)	209	4 (1.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.1687

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	2 (1.6)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.2695
	No	79	0 (0.0)	NE [NE, NE)	186	2 (1.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.3558
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	0 (0.0)	NE [NE, NE)	0.9984	NE (NE, NE)	NE
	No	98	0 (0.0)	NE [NE, NE)	210	4 (1.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.1698

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	0 (0.0)	NE [NE, NE)	205	3 (1.5)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.2031
	No	43	0 (0.0)	NE [NE, NE)	103	1 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.5182
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	0 (0.0)	NE [NE, NE)	0.9984	NE (NE, NE)	NE
	No	88	0 (0.0)	NE [NE, NE)	179	4 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.1585

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	0 (0.0)	NE [NE, NE)	250	4 (1.6)	NE [NE, NE)	0.9986	>999.999 (<.001, NE)	0.1540
	3	27	0 (0.0)	NE [NE, NE)	58	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Prior proteasome inhibitor exposure per IXRS	Yes	138	0 (0.0)	NE [NE, NE)	276	4 (1.4)	NE [NE, NE)	0.9989	>999.999 (<.001, NE)	0.1558
	No	15	0 (0.0)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	2 (1.5)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.3142
	>= 2	87	0 (0.0)	NE [NE, NE)	177	2 (1.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.3205

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Haemorrhage terms (excl laboratory terms) (SMQ) - Narrow										
Total subjects		153	4 (2.6)	NE [NE, NE)	308	6 (1.9)	NE [NE, NE)		0.687 (0.194, 2.438)	0.5590

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	3 (2.2)	NE [NE, NE)	283	6 (2.1)	NE [NE, NE)	0.9925	0.883 (0.221, 3.538)	0.8609
	> 75	18	1 (5.6)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.2305
Sex	Male	91	1 (1.1)	NE [NE, NE)	174	3 (1.7)	NE [NE, NE)	0.3745	1.517 (0.158, 14.588)	0.7163
	Female	62	3 (4.8)	NE [NE, NE)	134	3 (2.2)	NE [NE, NE)		0.408 (0.082, 2.026)	0.2570

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	4 (3.3)	NE [NE, NE)	240	4 (1.7)	NE [NE, NE)	0.9999	0.463 (0.115, 1.854)	0.2647
	Asian	20	0 (0.0)	NE [NE, NE)	46	1 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.5097
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	1 (4.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.4795
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	4 (3.9)	NE [NE, NE)	203	4 (2.0)	NE [NE, NE)		0.453 (0.113, 1.811)	0.2501
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	2 (2.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.3338
Baseline ECOG PS	0-1	146	4 (2.7)	NE [NE, NE)	294	5 (1.7)	NE [NE, NE)	0.9931	0.575 (0.154, 2.145)	0.4045
	2	7	0 (0.0)	NE [NE, NE)	13	1 (7.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.4631

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-508-ae-cox-eoi-dar-grd345.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	2 (1.5)	NE [NE, NE)	285	5 (1.8)	NE [NE, NE)	0.4192	1.136 (0.220, 5.856)	0.8792
	No	17	2 (11.8)	NE [NE, NE)	23	1 (4.3)	NE [NE, NE)		0.310 (0.028, 3.483)	0.3166
Refractory to Bortezomib or Ixazomib	Yes	55	1 (1.8)	NE [NE, NE)	99	4 (4.0)	NE [NE, NE)	0.1642	2.136 (0.239, 19.116)	0.4872
	No	98	3 (3.1)	NE [NE, NE)	209	2 (1.0)	NE [NE, NE)		0.277 (0.046, 1.666)	0.1338

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	3 (4.1)	NE [NE, NE)	122	3 (2.5)	NE [NE, NE)	0.5782	0.551 (0.111, 2.734)	0.4596
	No	79	1 (1.3)	NE [NE, NE)	186	3 (1.6)	NE [NE, NE)		1.200 (0.125, 11.569)	0.8743
Refractory to Lenalidomide	Yes	55	1 (1.8)	NE [NE, NE)	98	3 (3.1)	NE [NE, NE)	0.3796	1.553 (0.161, 14.950)	0.7005
	No	98	3 (3.1)	NE [NE, NE)	210	3 (1.4)	NE [NE, NE)		0.440 (0.089, 2.183)	0.3016

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	3 (2.7)	NE [NE, NE)	205	4 (2.0)	NE [NE, NE)	0.8988	0.665 (0.149, 2.973)	0.5907
	No	43	1 (2.3)	NE [NE, NE)	103	2 (1.9)	NE [NE, NE)		0.757 (0.068, 8.398)	0.8204
Refractory to IMiD	Yes	65	1 (1.5)	NE [NE, NE)	129	3 (2.3)	NE [NE, NE)	0.4467	1.372 (0.142, 13.208)	0.7835
	No	88	3 (3.4)	NE [NE, NE)	179	3 (1.7)	NE [NE, NE)		0.465 (0.094, 2.305)	0.3365

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	3 (2.4)	NE [NE, NE)	250	4 (1.6)	NE [NE, NE)	0.9141	0.629 (0.141, 2.817)	0.5412
	3	27	1 (3.7)	NE [NE, NE)	58	2 (3.4)	NE [NE, NE)		0.742 (0.067, 8.231)	0.8070
Prior proteasome inhibitor exposure per IXRS	Yes	138	2 (1.4)	NE [NE, NE)	276	5 (1.8)	NE [NE, NE)	0.2433	1.194 (0.232, 6.157)	0.8320
	No	15	2 (13.3)	NE [NE, NE)	32	1 (3.1)	NE [NE, NE)		0.199 (0.018, 2.200)	0.1432

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	2 (3.0)	NE [NE, NE)	131	3 (2.3)	NE [NE, NE)	0.9896	0.684 (0.114, 4.116)	0.6766
	>= 2	87	2 (2.3)	NE [NE, NE)	177	3 (1.7)	NE [NE, NE)		0.681 (0.114, 4.082)	0.6727

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Intravascular hemolysis (JMQ)										
Total subjects		153	1 (0.7)	NE [NE, NE)	308	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.1343

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	1 (0.7)	NE [NE, NE)	283	0 (0.0)	NE [NE, NE)	0.9997	<.001 (<.001, NE)	0.1297
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	1 (1.1)	NE [NE, NE)	174	0 (0.0)	NE [NE, NE)	0.9994	<.001 (<.001, NE)	0.1534
	Female	62	0 (0.0)	NE [NE, NE)	134	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	1 (0.8)	NE [NE, NE)	240	0 (0.0)	NE [NE, NE)	1.0000	<.001 (<.001, NE)	0.1419
	Asian	20	0 (0.0)	NE [NE, NE)	46	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
	Asia Pacific	39	1 (2.6)	NE [NE, NE)	84	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.1172
Baseline ECOG PS	0-1	146	1 (0.7)	NE [NE, NE)	294	0 (0.0)	NE [NE, NE)	0.9998	<.001 (<.001, NE)	0.1380
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	0 (0.0)	NE [NE, NE)	285	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE
	No	17	1 (5.9)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.2037
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	0 (0.0)	NE [NE, NE)	0.9994	NE (NE, NE)	NE
	No	98	1 (1.0)	NE [NE, NE)	209	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.1157

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	1 (1.4)	NE [NE, NE)	122	0 (0.0)	NE [NE, NE)	0.9991	<.001 (<.001, NE)	0.1627
	No	79	0 (0.0)	NE [NE, NE)	186	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to Lenalidomide	Yes	55	1 (1.8)	NE [NE, NE)	98	0 (0.0)	NE [NE, NE)	0.9992	<.001 (<.001, NE)	0.1482
	No	98	0 (0.0)	NE [NE, NE)	210	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	1 (0.9)	NE [NE, NE)	205	0 (0.0)	NE [NE, NE)	0.9993	<.001 (<.001, NE)	0.1419
	No	43	0 (0.0)	NE [NE, NE)	103	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to IMiD	Yes	65	1 (1.5)	NE [NE, NE)	129	0 (0.0)	NE [NE, NE)	0.9994	<.001 (<.001, NE)	0.1292
	No	88	0 (0.0)	NE [NE, NE)	179	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-508-ae-cox-eoi-dar-grd345.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	1 (0.8)	NE [NE, NE)	250	0 (0.0)	NE [NE, NE)	0.9996	<.001 (<.001, NE)	0.1431
	3	27	0 (0.0)	NE [NE, NE)	58	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Prior proteasome inhibitor exposure per IXRS	Yes	138	0 (0.0)	NE [NE, NE)	276	0 (0.0)	NE [NE, NE)	NE	NE (NE, NE)	NE
	No	15	1 (6.7)	NE [3.3, NE)	32	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0833

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	0 (0.0)	NE [NE, NE)	0.9992	NE (NE, NE)	NE
	>= 2	87	1 (1.1)	NE [NE, NE)	177	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.1297

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Opportunistic infections (JMQ)										
Total subjects		153	0 (0.0)	NE [NE, NE)	308	3 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.2693

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	0 (0.0)	NE [NE, NE)	283	3 (1.1)	NE [NE, NE)	0.9991	>999.999 (<.001, NE)	0.2770
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	1 (0.6)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.5279
	Female	62	0 (0.0)	NE [NE, NE)	134	2 (1.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.3739

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	0 (0.0)	NE [NE, NE)	240	2 (0.8)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.3694
	Asian	20	0 (0.0)	NE [NE, NE)	46	1 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.5453
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	2 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.3725
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	1 (1.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.5375
Baseline ECOG PS	0-1	146	0 (0.0)	NE [NE, NE)	294	3 (1.0)	NE [NE, NE)	0.9998	>999.999 (<.001, NE)	0.2600
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	0 (0.0)	NE [NE, NE)	285	3 (1.1)	NE [NE, NE)	0.9991	>999.999 (<.001, NE)	0.2772
	No	17	0 (0.0)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	0 (0.0)	NE [NE, NE)	0.9986	NE (NE, NE)	NE
	No	98	0 (0.0)	NE [NE, NE)	209	3 (1.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.2810

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	0 (0.0)	NE [NE, NE)	0.9986	NE (NE, NE)	NE
	No	79	0 (0.0)	NE [NE, NE)	186	3 (1.6)	NE [NE, NE)		>999.999 (<.001, NE)	0.2984
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	0 (0.0)	NE [NE, NE)	0.9986	NE (NE, NE)	NE
	No	98	0 (0.0)	NE [NE, NE)	210	3 (1.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.2747

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	0 (0.0)	NE [NE, NE)	205	0 (0.0)	NE [NE, NE)	0.9991	NE (NE, NE)	NE
	No	43	0 (0.0)	NE [NE, NE)	103	3 (2.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.3229
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	0 (0.0)	NE [NE, NE)	0.9986	NE (NE, NE)	NE
	No	88	0 (0.0)	NE [NE, NE)	179	3 (1.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.2658

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	0 (0.0)	NE [NE, NE)	250	3 (1.2)	NE [NE, NE)	0.9991	>999.999 (<.001, NE)	0.2488
	3	27	0 (0.0)	NE [NE, NE)	58	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Prior proteasome inhibitor exposure per IXRS	Yes	138	0 (0.0)	NE [NE, NE)	276	3 (1.1)	NE [NE, NE)	0.9991	>999.999 (<.001, NE)	0.2652
	No	15	0 (0.0)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	1 (0.8)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.5260
	>= 2	87	0 (0.0)	NE [NE, NE)	177	2 (1.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.3696

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Second primary malignancies: Malignant tumours (SMQ) - Narrow										
Total subjects		153	2 (1.3)	NE [NE, NE)	308	2 (0.6)	NE [NE, NE)		0.384 (0.054, 2.731)	0.3210

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	2 (1.5)	NE [NE, NE)	283	2 (0.7)	NE [NE, NE)	0.9999	0.368 (0.052, 2.613)	0.2974
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	2 (2.2)	NE [NE, NE)	174	1 (0.6)	NE [NE, NE)	0.9945	0.191 (0.017, 2.114)	0.1317
	Female	62	0 (0.0)	NE [NE, NE)	134	1 (0.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.5332

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-508-ae-cox-eoi-dar-grd345.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	2 (1.6)	NE [NE, NE)	240	1 (0.4)	NE [NE, NE)	1.0000	0.192 (0.017, 2.123)	0.1329
	Asian	20	0 (0.0)	NE [NE, NE)	46	1 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.5403
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	1 (4.8)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.5403

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	2 (2.0)	NE [NE, NE)	203	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0246
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	1 (1.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.5862
Baseline ECOG PS	0-1	146	2 (1.4)	NE [NE, NE)	294	2 (0.7)	NE [NE, NE)	NE	0.401 (0.056, 2.850)	0.3443
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	2 (1.5)	NE [NE, NE)	285	1 (0.4)	NE [NE, NE)	0.9957	0.193 (0.018, 2.131)	0.1339
	No	17	0 (0.0)	NE [NE, NE)	23	1 (4.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.5211
Refractory to Bortezomib or Ixazomib	Yes	55	1 (1.8)	NE [NE, NE)	99	1 (1.0)	NE [NE, NE)	0.9400	0.440 (0.027, 7.041)	0.5504
	No	98	1 (1.0)	NE [NE, NE)	209	1 (0.5)	NE [NE, NE)		0.351 (0.022, 5.632)	0.4394

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	1 (1.4)	NE [NE, NE)	122	1 (0.8)	NE [NE, NE)	0.8940	0.476 (0.030, 7.614)	0.5915
	No	79	1 (1.3)	NE [NE, NE)	186	1 (0.5)	NE [NE, NE)		0.345 (0.022, 5.528)	0.4311
Refractory to Lenalidomide	Yes	55	1 (1.8)	NE [NE, NE)	98	1 (1.0)	NE [NE, NE)	0.9935	0.416 (0.026, 6.653)	0.5220
	No	98	1 (1.0)	NE [NE, NE)	210	1 (0.5)	NE [NE, NE)		0.390 (0.024, 6.244)	0.4901

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	1 (0.9)	NE [NE, NE)	205	2 (1.0)	NE [NE, NE)	0.9941	0.811 (0.073, 8.960)	0.8642
	No	43	1 (2.3)	NE [NE, NE)	103	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0815
Refractory to IMiD	Yes	65	1 (1.5)	NE [NE, NE)	129	1 (0.8)	NE [NE, NE)	0.9360	0.371 (0.023, 5.932)	0.4653
	No	88	1 (1.1)	NE [NE, NE)	179	1 (0.6)	NE [NE, NE)		0.409 (0.026, 6.551)	0.5140

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	2 (1.6)	NE [NE, NE)	250	2 (0.8)	NE [NE, NE)	0.9999	0.419 (0.059, 2.980)	0.3699
	3	27	0 (0.0)	NE [NE, NE)	58	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Prior proteasome inhibitor exposure per IXRS	Yes	138	2 (1.4)	NE [NE, NE)	276	1 (0.4)	NE [NE, NE)	0.9949	0.201 (0.018, 2.218)	0.1458
	No	15	0 (0.0)	NE [NE, NE)	32	1 (3.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.5812

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	1 (1.5)	NE [NE, NE)	131	1 (0.8)	NE [NE, NE)	0.9717	0.429 (0.027, 6.878)	0.5382
	>= 2	87	1 (1.1)	NE [NE, NE)	177	1 (0.6)	NE [NE, NE)		0.364 (0.023, 5.823)	0.4560

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Tumour lysis syndrome (SMQ) - Narrow										
Total subjects		153	1 (0.7)	NE [NE, NE)	308	3 (1.0)	NE [NE, NE)		1.501 (0.156, 14.427)	0.7231

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	1 (0.7)	NE [NE, NE)	283	3 (1.1)	NE [NE, NE)	1.0000	1.442 (0.150, 13.864)	0.7497
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	1 (1.1)	NE [NE, NE)	174	1 (0.6)	NE [NE, NE)	0.9952	0.523 (0.033, 8.364)	0.6411
	Female	62	0 (0.0)	NE [NE, NE)	134	2 (1.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.3342

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	0 (0.0)	NE [NE, NE)	240	3 (1.3)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.2146
	Asian	20	0 (0.0)	NE [NE, NE)	46	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
	Other or Unknown	11	1 (9.1)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.1573
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	1 (1.0)	NE [NE, NE)	203	3 (1.5)	NE [NE, NE)		1.524 (0.159, 14.649)	0.7130
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Baseline ECOG PS	0-1	146	1 (0.7)	NE [NE, NE)	294	3 (1.0)	NE [NE, NE)	0.9999	1.501 (0.156, 14.428)	0.7231
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	1 (0.7)	NE [NE, NE)	285	3 (1.1)	NE [NE, NE)	1.0000	1.443 (0.150, 13.868)	0.7495
	No	17	0 (0.0)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	1 (1.0)	NE [NE, NE)	0.9955	>999.999 (<.001, NE)	0.4538
	No	98	1 (1.0)	NE [NE, NE)	209	2 (1.0)	NE [NE, NE)		0.941 (0.085, 10.373)	0.9601

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-508-ae-cox-eoi-dar-grd345.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	2 (1.6)	NE [NE, NE)	0.9948	>999.999 (<.001, NE)	0.2687
	No	79	1 (1.3)	NE [NE, NE)	186	1 (0.5)	NE [NE, NE)		0.424 (0.027, 6.785)	0.5320
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	2 (2.0)	NE [NE, NE)	0.9957	>999.999 (<.001, NE)	0.2869
	No	98	1 (1.0)	NE [NE, NE)	210	1 (0.5)	NE [NE, NE)		0.467 (0.029, 7.459)	0.5807

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	1 (0.9)	NE [NE, NE)	205	2 (1.0)	NE [NE, NE)	0.9960	1.082 (0.098, 11.933)	0.9487
	No	43	0 (0.0)	NE [NE, NE)	103	1 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.5162
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	2 (1.6)	NE [NE, NE)	0.9951	>999.999 (<.001, NE)	0.3135
	No	88	1 (1.1)	NE [NE, NE)	179	1 (0.6)	NE [NE, NE)		0.492 (0.031, 7.859)	0.6081

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	0 (0.0)	NE [NE, NE)	250	1 (0.4)	NE [NE, NE)	0.9956	>999.999 (<.001, NE)	0.4769
	3	27	1 (3.7)	NE [NE, NE)	58	2 (3.4)	NE [NE, NE)		0.941 (0.085, 10.381)	0.9605
Prior proteasome inhibitor exposure per IXRS	Yes	138	1 (0.7)	NE [NE, NE)	276	3 (1.1)	NE [NE, NE)	0.9999	1.512 (0.157, 14.534)	0.7182
	No	15	0 (0.0)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	1 (1.5)	NE [NE, NE)	131	2 (1.5)	NE [NE, NE)	0.9950	1.008 (0.091, 11.113)	0.9950
	>= 2	87	0 (0.0)	NE [NE, NE)	177	1 (0.6)	NE [NE, NE)		>999.999 (<.001, NE)	0.4808

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Viral infection (JMQ)										
Total subjects		153	3 (2.0)	NE [NE, NE)	308	19 (6.2)	NE [NE, NE)		2.672 (0.789, 9.047)	0.1004

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	3 (2.2)	NE [NE, NE)	283	18 (6.4)	NE [NE, NE)	0.9922	2.427 (0.714, 8.254)	0.1425
	> 75	18	0 (0.0)	NE [NE, NE)	25	1 (4.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.3961
Sex	Male	91	1 (1.1)	NE [NE, NE)	174	12 (6.9)	NE [NE, NE)	0.3213	4.961 (0.643, 38.268)	0.0883
	Female	62	2 (3.2)	NE [NE, NE)	134	7 (5.2)	NE [NE, NE)		1.474 (0.306, 7.103)	0.6262

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	3 (2.5)	NE [NE, NE)	240	16 (6.7)	NE [NE, NE)	0.9999	2.245 (0.652, 7.724)	0.1878
	Asian	20	0 (0.0)	NE [NE, NE)	46	2 (4.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.3484
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	1 (4.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.5727
Region	North America	12	1 (8.3)	NE [16.2, NE)	21	3 (14.3)	NE [NE, NE)	0.8883	0.923 (0.088, 9.735)	0.9472

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	2 (2.0)	NE [NE, NE)	203	11 (5.4)	NE [NE, NE)		2.321 (0.513, 10.488)	0.2600
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	5 (6.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.1341
Baseline ECOG PS	0-1	146	3 (2.1)	NE [NE, NE)	294	19 (6.5)	NE [NE, NE)	0.9998	2.746 (0.811, 9.295)	0.0904
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	3 (2.2)	NE [NE, NE)	285	19 (6.7)	NE [NE, NE)	0.9997	2.573 (0.760, 8.712)	0.1151
	No	17	0 (0.0)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	6 (6.1)	NE [NE, NE)	0.9908	>999.999 (<.001, NE)	0.0931
	No	98	3 (3.1)	NE [NE, NE)	209	13 (6.2)	NE [NE, NE)		1.713 (0.487, 6.028)	0.3959

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	3 (4.1)	NE [NE, NE)	122	7 (5.7)	NE [NE, NE)	0.9879	1.022 (0.261, 3.999)	0.9747
	No	79	0 (0.0)	NE [NE, NE)	186	12 (6.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.0303
Refractory to Lenalidomide	Yes	55	3 (5.5)	NE [NE, NE)	98	6 (6.1)	NE [NE, NE)	0.9866	0.718 (0.175, 2.945)	0.6443
	No	98	0 (0.0)	NE [NE, NE)	210	13 (6.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.0182

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	3 (2.7)	NE [NE, NE)	205	14 (6.8)	NE [NE, NE)	0.9916	2.133 (0.611, 7.445)	0.2242
	No	43	0 (0.0)	NE [NE, NE)	103	5 (4.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.1958
Refractory to IMiD	Yes	65	3 (4.6)	NE [NE, NE)	129	9 (7.0)	NE [NE, NE)	0.9875	1.068 (0.284, 4.010)	0.9222
	No	88	0 (0.0)	NE [NE, NE)	179	10 (5.6)	NE [NE, NE)		>999.999 (<.001, NE)	0.0339

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	3 (2.4)	NE [NE, NE)	250	16 (6.4)	NE [NE, NE)	0.9917	2.408 (0.700, 8.280)	0.1501
	3	27	0 (0.0)	NE [NE, NE)	58	3 (5.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.4281
Prior proteasome inhibitor exposure per IXRS	Yes	138	3 (2.2)	NE [NE, NE)	276	19 (6.9)	NE [NE, NE)	0.9997	2.685 (0.793, 9.092)	0.0987
	No	15	0 (0.0)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-508-ae-cox-eoi-dar-grd345.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.508. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	8 (6.1)	NE [NE, NE)	0.9893	>999.999 (<.001, NE)	0.0652
	>= 2	87	3 (3.4)	NE [NE, NE)	177	11 (6.2)	NE [NE, NE)		1.522 (0.424, 5.471)	0.5166

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-508-ae-cox-eoi-dar-grd345.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Daratumumab-related infusion reaction (AMQ) - Narrow (event on same date or next date of any Daratumumab dosing)										
Total subjects		153	0 (0.0)	NE [NE, NE)	308	4 (1.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.1667

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-509-sae-cox-eoi-dar.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	0 (0.0)	NE [NE, NE)	283	4 (1.4)	NE [NE, NE)	0.9989	>999.999 (<.001, NE)	0.1741
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	2 (1.1)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.3090
	Female	62	0 (0.0)	NE [NE, NE)	134	2 (1.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.3555

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-509-sae-cox-eoi-dar.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	0 (0.0)	NE [NE, NE)	240	2 (0.8)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.3271
	Asian	20	0 (0.0)	NE [NE, NE)	46	1 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.5097
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	1 (4.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.5224
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-509-sae-cox-eoi-dar.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	2 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.3322
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	2 (2.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.3355
Baseline ECOG PS	0-1	146	0 (0.0)	NE [NE, NE)	294	3 (1.0)	NE [NE, NE)	0.9997	>999.999 (<.001, NE)	0.2293
	2	7	0 (0.0)	NE [NE, NE)	13	1 (7.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.5002

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-509-sae-cox-eoi-dar.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	0 (0.0)	NE [NE, NE)	285	4 (1.4)	NE [NE, NE)	0.9989	>999.999 (<.001, NE)	0.1753
	No	17	0 (0.0)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	1 (1.0)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.4637
	No	98	0 (0.0)	NE [NE, NE)	209	3 (1.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.2472

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-509-sae-cox-eoi-dar.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	2 (1.6)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.2758
	No	79	0 (0.0)	NE [NE, NE)	186	2 (1.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.3681
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	1 (1.0)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.4637
	No	98	0 (0.0)	NE [NE, NE)	210	3 (1.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.2453

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-509-sae-cox-eoi-dar.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	0 (0.0)	NE [NE, NE)	205	3 (1.5)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.2074
	No	43	0 (0.0)	NE [NE, NE)	103	1 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.5338
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	1 (0.8)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.4884
	No	88	0 (0.0)	NE [NE, NE)	179	3 (1.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.2318

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-509-sae-cox-eoi-dar.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	0 (0.0)	NE [NE, NE)	250	4 (1.6)	NE [NE, NE)	0.9987	>999.999 (<.001, NE)	0.1599
	3	27	0 (0.0)	NE [NE, NE)	58	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Prior proteasome inhibitor exposure per IXRS	Yes	138	0 (0.0)	NE [NE, NE)	276	4 (1.4)	NE [NE, NE)	0.9989	>999.999 (<.001, NE)	0.1646
	No	15	0 (0.0)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-509-sae-cox-eoi-dar.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	2 (1.5)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.3319
	>= 2	87	0 (0.0)	NE [NE, NE)	177	2 (1.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.3260

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Daratumumab-related infusion reaction (AMQ) - Narrow (event on same date or next date of first Daratumumab dosing)										
Total subjects		153	0 (0.0)	NE [NE, NE)	308	2 (0.6)	NE [NE, NE)		>999.999 (<.001, NE)	0.3184

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-509-sae-cox-eoi-dar.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	0 (0.0)	NE [NE, NE)	283	2 (0.7)	NE [NE, NE)	0.9992	>999.999 (<.001, NE)	0.3281
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	1 (0.6)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.4696
	Female	62	0 (0.0)	NE [NE, NE)	134	1 (0.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.4964

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-509-sae-cox-eoi-dar.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	0 (0.0)	NE [NE, NE)	240	1 (0.4)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.4759
	Asian	20	0 (0.0)	NE [NE, NE)	46	1 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.5097
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-509-sae-cox-eoi-dar.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	1 (0.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.4784
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	1 (1.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.4956
Baseline ECOG PS	0-1	146	0 (0.0)	NE [NE, NE)	294	2 (0.7)	NE [NE, NE)	0.9995	>999.999 (<.001, NE)	0.3184
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-509-sae-cox-eoi-dar.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	0 (0.0)	NE [NE, NE)	285	2 (0.7)	NE [NE, NE)	0.9992	>999.999 (<.001, NE)	0.3280
	No	17	0 (0.0)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	0 (0.0)	NE [NE, NE)	0.9988	NE (NE, NE)	NE
	No	98	0 (0.0)	NE [NE, NE)	209	2 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.3321

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	1 (0.8)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.4361
	No	79	0 (0.0)	NE [NE, NE)	186	1 (0.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.5146
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	0 (0.0)	NE [NE, NE)	0.9988	NE (NE, NE)	NE
	No	98	0 (0.0)	NE [NE, NE)	210	2 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.3332

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	0 (0.0)	NE [NE, NE)	205	2 (1.0)	NE [NE, NE)	0.9989	>999.999 (<.001, NE)	0.2995
	No	43	0 (0.0)	NE [NE, NE)	103	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	0 (0.0)	NE [NE, NE)	0.9989	NE (NE, NE)	NE
	No	88	0 (0.0)	NE [NE, NE)	179	2 (1.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.3205

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
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Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	0 (0.0)	NE [NE, NE)	250	2 (0.8)	NE [NE, NE)	0.9990	>999.999 (<.001, NE)	0.3147
	3	27	0 (0.0)	NE [NE, NE)	58	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Prior proteasome inhibitor exposure per IXRS	Yes	138	0 (0.0)	NE [NE, NE)	276	2 (0.7)	NE [NE, NE)	0.9992	>999.999 (<.001, NE)	0.3167
	No	15	0 (0.0)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
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Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	1 (0.8)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.4778
	>= 2	87	0 (0.0)	NE [NE, NE)	177	1 (0.6)	NE [NE, NE)		>999.999 (<.001, NE)	0.4832

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-509-sae-cox-eoi-dar.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Haemorrhage terms (excl laboratory terms) (SMQ) - Narrow										
Total subjects		153	4 (2.6)	NE [NE, NE)	308	6 (1.9)	NE [NE, NE)		0.688 (0.194, 2.442)	0.5606

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
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Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	3 (2.2)	NE [NE, NE)	283	6 (2.1)	NE [NE, NE)	0.9926	0.884 (0.221, 3.540)	0.8615
	> 75	18	1 (5.6)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.2305
Sex	Male	91	1 (1.1)	NE [NE, NE)	174	4 (2.3)	NE [NE, NE)	0.1803	1.871 (0.208, 16.826)	0.5698
	Female	62	3 (4.8)	NE [NE, NE)	134	2 (1.5)	NE [NE, NE)		0.281 (0.047, 1.682)	0.1374

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	4 (3.3)	NE [NE, NE)	240	4 (1.7)	NE [NE, NE)	0.9999	0.463 (0.116, 1.855)	0.2652
	Asian	20	0 (0.0)	NE [NE, NE)	46	1 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.5097
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	1 (4.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.4795
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	4 (3.9)	NE [NE, NE)	203	4 (2.0)	NE [NE, NE)		0.451 (0.113, 1.806)	0.2481
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	2 (2.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.3338
Baseline ECOG PS	0-1	146	4 (2.7)	NE [NE, NE)	294	5 (1.7)	NE [NE, NE)	0.9931	0.576 (0.154, 2.148)	0.4056
	2	7	0 (0.0)	NE [NE, NE)	13	1 (7.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.4631

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	2 (1.5)	NE [NE, NE)	285	6 (2.1)	NE [NE, NE)	0.9908	1.319 (0.266, 6.543)	0.7343
	No	17	2 (11.8)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.1024
Refractory to Bortezomib or Ixazomib	Yes	55	1 (1.8)	NE [NE, NE)	99	4 (4.0)	NE [NE, NE)	0.1669	2.136 (0.239, 19.116)	0.4872
	No	98	3 (3.1)	NE [NE, NE)	209	2 (1.0)	NE [NE, NE)		0.280 (0.047, 1.682)	0.1373

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	3 (4.1)	NE [NE, NE)	122	3 (2.5)	NE [NE, NE)	0.5825	0.551 (0.111, 2.734)	0.4596
	No	79	1 (1.3)	NE [NE, NE)	186	3 (1.6)	NE [NE, NE)		1.194 (0.124, 11.514)	0.8779
Refractory to Lenalidomide	Yes	55	1 (1.8)	NE [NE, NE)	98	3 (3.1)	NE [NE, NE)	0.3761	1.553 (0.161, 14.950)	0.7005
	No	98	3 (3.1)	NE [NE, NE)	210	3 (1.4)	NE [NE, NE)		0.439 (0.088, 2.178)	0.3001

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-509-sae-cox-eoi-dar.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	3 (2.7)	NE [NE, NE)	205	4 (2.0)	NE [NE, NE)	0.9040	0.665 (0.149, 2.973)	0.5907
	No	43	1 (2.3)	NE [NE, NE)	103	2 (1.9)	NE [NE, NE)		0.745 (0.067, 8.277)	0.8100
Refractory to IMiD	Yes	65	1 (1.5)	NE [NE, NE)	129	3 (2.3)	NE [NE, NE)	0.4404	1.372 (0.142, 13.208)	0.7835
	No	88	3 (3.4)	NE [NE, NE)	179	3 (1.7)	NE [NE, NE)		0.461 (0.093, 2.289)	0.3318

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	3 (2.4)	NE [NE, NE)	250	4 (1.6)	NE [NE, NE)	0.9264	0.633 (0.142, 2.835)	0.5470
	3	27	1 (3.7)	NE [NE, NE)	58	2 (3.4)	NE [NE, NE)		0.742 (0.067, 8.231)	0.8070
Prior proteasome inhibitor exposure per IXRS	Yes	138	2 (1.4)	NE [NE, NE)	276	6 (2.2)	NE [NE, NE)	0.9935	1.384 (0.279, 6.869)	0.6895
	No	15	2 (13.3)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0320

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	2 (3.0)	NE [NE, NE)	131	2 (1.5)	NE [NE, NE)	0.6075	0.493 (0.069, 3.499)	0.4701
	>= 2	87	2 (2.3)	NE [NE, NE)	177	4 (2.3)	NE [NE, NE)		0.880 (0.161, 4.813)	0.8828

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Opportunistic infections (JMQ)										
Total subjects		153	0 (0.0)	NE [NE, NE)	308	3 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.2523

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	0 (0.0)	NE [NE, NE)	283	2 (0.7)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.3614
	> 75	18	0 (0.0)	NE [NE, NE)	25	1 (4.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.4193
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	1 (0.6)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.4781
	Female	62	0 (0.0)	NE [NE, NE)	134	2 (1.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.3776

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	0 (0.0)	NE [NE, NE)	240	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE
	Asian	20	0 (0.0)	NE [NE, NE)	46	3 (6.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.2793
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	3 (3.6)	NE [NE, NE)		>999.999 (<.001, NE)	0.2728
Baseline ECOG PS	0-1	146	0 (0.0)	NE [NE, NE)	294	3 (1.0)	NE [NE, NE)	0.9996	>999.999 (<.001, NE)	0.2462
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	0 (0.0)	NE [NE, NE)	285	3 (1.1)	NE [NE, NE)	0.9991	>999.999 (<.001, NE)	0.2598
	No	17	0 (0.0)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	2 (2.0)	NE [NE, NE)	0.9998	>999.999 (<.001, NE)	0.3067
	No	98	0 (0.0)	NE [NE, NE)	209	1 (0.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.5407

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	1 (0.8)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.4664
	No	79	0 (0.0)	NE [NE, NE)	186	2 (1.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.3872
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	1 (1.0)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.4843
	No	98	0 (0.0)	NE [NE, NE)	210	2 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.3679

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	0 (0.0)	NE [NE, NE)	205	2 (1.0)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.3339
	No	43	0 (0.0)	NE [NE, NE)	103	1 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.5551
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	2 (1.6)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.3486
	No	88	0 (0.0)	NE [NE, NE)	179	1 (0.6)	NE [NE, NE)		>999.999 (<.001, NE)	0.5178

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	0 (0.0)	NE [NE, NE)	250	3 (1.2)	NE [NE, NE)	0.9990	>999.999 (<.001, NE)	0.2402
	3	27	0 (0.0)	NE [NE, NE)	58	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Prior proteasome inhibitor exposure per IXRS	Yes	138	0 (0.0)	NE [NE, NE)	276	3 (1.1)	NE [NE, NE)	0.9991	>999.999 (<.001, NE)	0.2467
	No	15	0 (0.0)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
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Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	0 (0.0)	NE [NE, NE)	0.9986	NE (NE, NE)	NE
	>= 2	87	0 (0.0)	NE [NE, NE)	177	3 (1.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.2558

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-509-sae-cox-eoi-dar.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Second primary malignancies: Malignant tumours (SMQ) - Narrow										
Total subjects		153	0 (0.0)	NE [NE, NE)	308	2 (0.6)	NE [NE, NE)		>999.999 (<.001, NE)	0.3905

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	0 (0.0)	NE [NE, NE)	283	2 (0.7)	NE [NE, NE)	0.9992	>999.999 (<.001, NE)	0.4021
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	1 (0.6)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.5655
	Female	62	0 (0.0)	NE [NE, NE)	134	1 (0.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.5332

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	0 (0.0)	NE [NE, NE)	240	1 (0.4)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.5555
	Asian	20	0 (0.0)	NE [NE, NE)	46	1 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.5403
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	1 (4.8)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.5403

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	1 (1.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.5862
Baseline ECOG PS	0-1	146	0 (0.0)	NE [NE, NE)	294	2 (0.7)	NE [NE, NE)	NE	>999.999 (<.001, NE)	0.3799
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-509-sae-cox-eoi-dar.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	0 (0.0)	NE [NE, NE)	285	1 (0.4)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.5360
	No	17	0 (0.0)	NE [NE, NE)	23	1 (4.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.5211
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	1 (1.0)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.5216
	No	98	0 (0.0)	NE [NE, NE)	209	1 (0.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.5723

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	1 (0.8)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.4916
	No	79	0 (0.0)	NE [NE, NE)	186	1 (0.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.5689
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	1 (1.0)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.5206
	No	98	0 (0.0)	NE [NE, NE)	210	1 (0.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.5441

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	0 (0.0)	NE [NE, NE)	205	2 (1.0)	NE [NE, NE)	0.9989	>999.999 (<.001, NE)	0.3734
	No	43	0 (0.0)	NE [NE, NE)	103	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	1 (0.8)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.5403
	No	88	0 (0.0)	NE [NE, NE)	179	1 (0.6)	NE [NE, NE)		>999.999 (<.001, NE)	0.5308

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	0 (0.0)	NE [NE, NE)	250	2 (0.8)	NE [NE, NE)	0.9993	>999.999 (<.001, NE)	0.3701
	3	27	0 (0.0)	NE [NE, NE)	58	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Prior proteasome inhibitor exposure per IXRS	Yes	138	0 (0.0)	NE [NE, NE)	276	1 (0.4)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.5294
	No	15	0 (0.0)	NE [NE, NE)	32	1 (3.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.5812

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	1 (0.8)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.5292
	>= 2	87	0 (0.0)	NE [NE, NE)	177	1 (0.6)	NE [NE, NE)		>999.999 (<.001, NE)	0.5579

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
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Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Tumour lysis syndrome (SMQ) - Narrow										
Total subjects		153	1 (0.7)	NE [NE, NE)	308	2 (0.6)	NE [NE, NE)		0.998 (0.090, 11.004)	0.9986

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	1 (0.7)	NE [NE, NE)	283	2 (0.7)	NE [NE, NE)	1.0000	0.958 (0.087, 10.566)	0.9724
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	1 (1.1)	NE [NE, NE)	174	1 (0.6)	NE [NE, NE)	0.9958	0.523 (0.033, 8.364)	0.6411
	Female	62	0 (0.0)	NE [NE, NE)	134	1 (0.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.4964

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	0 (0.0)	NE [NE, NE)	240	2 (0.8)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.3118
	Asian	20	0 (0.0)	NE [NE, NE)	46	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
	Other or Unknown	11	1 (9.1)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.1573
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	1 (1.0)	NE [NE, NE)	203	2 (1.0)	NE [NE, NE)		1.012 (0.092, 11.156)	0.9925
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Baseline ECOG PS	0-1	146	1 (0.7)	NE [NE, NE)	294	2 (0.7)	NE [NE, NE)	1.0000	0.998 (0.090, 11.003)	0.9985
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-509-sae-cox-eoi-dar.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	1 (0.7)	NE [NE, NE)	285	2 (0.7)	NE [NE, NE)	1.0000	0.958 (0.087, 10.569)	0.9726
	No	17	0 (0.0)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE
	No	98	1 (1.0)	NE [NE, NE)	209	2 (1.0)	NE [NE, NE)		0.941 (0.085, 10.373)	0.9601

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	1 (0.8)	NE [NE, NE)	0.9955	>999.999 (<.001, NE)	0.4361
	No	79	1 (1.3)	NE [NE, NE)	186	1 (0.5)	NE [NE, NE)		0.424 (0.027, 6.785)	0.5320
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	1 (1.0)	NE [NE, NE)	0.9960	>999.999 (<.001, NE)	0.4538
	No	98	1 (1.0)	NE [NE, NE)	210	1 (0.5)	NE [NE, NE)		0.467 (0.029, 7.459)	0.5807

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	1 (0.9)	NE [NE, NE)	205	1 (0.5)	NE [NE, NE)	0.9964	0.539 (0.034, 8.621)	0.6573
	No	43	0 (0.0)	NE [NE, NE)	103	1 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.5162
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	1 (0.8)	NE [NE, NE)	0.9957	>999.999 (<.001, NE)	0.4778
	No	88	1 (1.1)	NE [NE, NE)	179	1 (0.6)	NE [NE, NE)		0.492 (0.031, 7.859)	0.6081

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	0 (0.0)	NE [NE, NE)	250	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE
	3	27	1 (3.7)	NE [NE, NE)	58	2 (3.4)	NE [NE, NE)		0.941 (0.085, 10.381)	0.9605
Prior proteasome inhibitor exposure per IXRS	Yes	138	1 (0.7)	NE [NE, NE)	276	2 (0.7)	NE [NE, NE)	1.0000	1.005 (0.091, 11.082)	0.9968
	No	15	0 (0.0)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	1 (1.5)	NE [NE, NE)	131	2 (1.5)	NE [NE, NE)	1.0000	1.008 (0.091, 11.113)	0.9950
	>= 2	87	0 (0.0)	NE [NE, NE)	177	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
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Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Viral infection (JMQ)										
Total subjects		153	3 (2.0)	NE [NE, NE)	308	17 (5.5)	NE [NE, NE)		2.444 (0.715, 8.358)	0.1411

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	3 (2.2)	NE [NE, NE)	283	16 (5.7)	NE [NE, NE)	0.9924	2.209 (0.642, 7.595)	0.1969
	> 75	18	0 (0.0)	NE [NE, NE)	25	1 (4.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.3961
Sex	Male	91	2 (2.2)	NE [NE, NE)	174	10 (5.7)	NE [NE, NE)	0.8431	2.090 (0.455, 9.594)	0.3322
	Female	62	1 (1.6)	NE [NE, NE)	134	7 (5.2)	NE [NE, NE)		2.995 (0.368, 24.355)	0.2811

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	2 (1.6)	NE [NE, NE)	240	12 (5.0)	NE [NE, NE)	0.7210	2.513 (0.560, 11.269)	0.2127
	Asian	20	0 (0.0)	NE [NE, NE)	46	3 (6.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.2554
	Other or Unknown	11	1 (9.1)	NE [2.1, NE)	22	2 (9.1)	NE [NE, NE)		0.775 (0.070, 8.583)	0.8350
Region	North America	12	1 (8.3)	NE [16.2, NE)	21	4 (19.0)	NE [17.4, NE)	0.9798	1.515 (0.160, 14.349)	0.7152

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	2 (2.0)	NE [NE, NE)	203	6 (3.0)	NE [NE, NE)		1.320 (0.266, 6.562)	0.7335
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	7 (8.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.0842
Baseline ECOG PS	0-1	146	3 (2.1)	NE [NE, NE)	294	17 (5.8)	NE [NE, NE)	0.9998	2.506 (0.733, 8.567)	0.1294
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	3 (2.2)	NE [NE, NE)	285	17 (6.0)	NE [NE, NE)	0.9998	2.355 (0.689, 8.054)	0.1594
	No	17	0 (0.0)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to Bortezomib or Ixazomib	Yes	55	1 (1.8)	NE [NE, NE)	99	6 (6.1)	NE [NE, NE)	0.8267	2.992 (0.359, 24.951)	0.2878
	No	98	2 (2.0)	NE [NE, NE)	209	11 (5.3)	NE [NE, NE)		2.177 (0.481, 9.852)	0.3006

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	3 (4.1)	NE [NE, NE)	122	8 (6.6)	NE [NE, NE)	0.9888	1.243 (0.326, 4.733)	0.7493
	No	79	0 (0.0)	NE [NE, NE)	186	9 (4.8)	NE [NE, NE)		>999.999 (<.001, NE)	0.0588
Refractory to Lenalidomide	Yes	55	2 (3.6)	NE [NE, NE)	98	7 (7.1)	NE [NE, NE)	0.4597	1.354 (0.275, 6.656)	0.7082
	No	98	1 (1.0)	NE [NE, NE)	210	10 (4.8)	NE [NE, NE)		4.350 (0.557, 33.999)	0.1258

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	3 (2.7)	NE [NE, NE)	205	14 (6.8)	NE [NE, NE)	0.9923	2.142 (0.614, 7.478)	0.2213
	No	43	0 (0.0)	NE [NE, NE)	103	3 (2.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.2848
Refractory to IMiD	Yes	65	3 (4.6)	NE [NE, NE)	129	11 (8.5)	NE [NE, NE)	0.9893	1.413 (0.389, 5.124)	0.5973
	No	88	0 (0.0)	NE [NE, NE)	179	6 (3.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.0967

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-509-sae-cox-eoi-dar.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	2 (1.6)	NE [NE, NE)	250	13 (5.2)	NE [NE, NE)	0.5431	2.957 (0.666, 13.133)	0.1348
	3	27	1 (3.7)	NE [NE, NE)	58	4 (6.9)	NE [NE, NE)		1.062 (0.116, 9.731)	0.9577
Prior proteasome inhibitor exposure per IXRS	Yes	138	3 (2.2)	NE [NE, NE)	276	17 (6.2)	NE [NE, NE)	0.9998	2.457 (0.718, 8.404)	0.1388
	No	15	0 (0.0)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-509-sae-cox-eoi-dar.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.509. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	8 (6.1)	NE [NE, NE)	0.9895	>999.999 (<.001, NE)	0.0612
	>= 2	87	3 (3.4)	NE [NE, NE)	177	9 (5.1)	NE [NE, NE)		1.275 (0.344, 4.725)	0.7159

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-509-sae-cox-eoi-dar.rtf (Date Generated: 25MAY2020:20:34) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.514. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Blood and lymphatic system disorders										
Thrombocytopenia										
Total subjects		153	45 (29.4)	NE [NE, NE)	308	115 (37.3)	NE [NE, NE)		1.351 (0.957, 1.908)	0.0880

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc-pt.sas
Output: t14-06-001-514-ae-cox-soc-pt-ge10.rtf (Date Generated: 26MAY2020:01:04) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.514. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	No. of Events (%)	Median (months) (95%CI)	KdD (N = 308) N	No. of Events (%)	Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Anaemia										
Total subjects		153	48 (31.4)	NE [17.5, NE)	308	101 (32.8)	NE [NE, NE)		1.044 (0.740, 1.472)	0.8106
Neutropenia										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc-pt.sas
Output: t14-06-001-514-ae-cox-soc-pt-ge10.rtf (Date Generated: 26MAY2020:01:04) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.514. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	15 (9.8)	NE [NE, NE)	308	43 (14.0)	NE [NE, NE)		1.326 (0.736, 2.390)	0.3454
Lymphopenia										
Total subjects		153	12 (7.8)	NE [NE, NE)	308	27 (8.8)	NE [NE, NE)		1.105 (0.560, 2.182)	0.7752

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc-pt.sas
Output: t14-06-001-514-ae-cox-soc-pt-ge10.rtf (Date Generated: 26MAY2020:01:04) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.514. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Leukopenia										
Total subjects		153	6 (3.9)	NE [NE, NE)	308	20 (6.5)	NE [NE, NE)		1.636 (0.657, 4.076)	0.2852
Cardiac disorders										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc-pt.sas
Output: t14-06-001-514-ae-cox-soc-pt-ge10.rtf (Date Generated: 26MAY2020:01:04) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.514. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Tachycardia										
Total subjects		153	7 (4.6)	NE [NE, NE)	308	13 (4.2)	NE [NE, NE)		0.822 (0.327, 2.063)	0.6750
Cardiac failure										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc-pt.sas
Output: t14-06-001-514-ae-cox-soc-pt-ge10.rtf (Date Generated: 26MAY2020:01:04) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.514. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
SOC PT Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	6 (3.9)	NE [NE, NE)	308	10 (3.2)	NE [NE, NE)		0.666 (0.241, 1.839)	0.4299
Eye disorders										
Cataract										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc-pt.sas
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Table 14-6.1.514. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
SOC PT Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	5 (3.3)	NE [NE, NE)	308	17 (5.5)	NE [NE, NE)		1.350 (0.497, 3.663)	0.5546
Gastrointestinal disorders										
Diarrhoea										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc-pt.sas
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Table 14-6.1.514. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	 No. of Events (%)	 Median (months) (95%CI)	KdD (N = 308) N	 No. of Events (%)	 Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	 p-value (2-sided)[b]
Total subjects		153	22 (14.4)	NE [NE, NE)	308	97 (31.5)	NE [NE, NE)		2.163 (1.362, 3.437)	0.0008
Age – at baseline (years)	<= 75	135	20 (14.8)	NE [NE, NE)	283	90 (31.8)	NE [NE, NE)	0.8021	2.113 (1.301, 3.430)	0.0020
	> 75	18	2 (11.1)	NE [16.9, NE)	25	7 (28.0)	NE [9.3, NE)		2.411 (0.498, 11.673)	0.2590

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc-pt.sas
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Table 14-6.1.514. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Sex	Male	91	10 (11.0)	NE [NE, NE)	174	51 (29.3)	NE [NE, NE)	0.4248	2.582 (1.310, 5.088)	0.0045
	Female	62	12 (19.4)	NE [16.8, NE)	134	46 (34.3)	NE [15.7, NE)		1.776 (0.941, 3.353)	0.0724
Race	White	122	12 (9.8)	NE [NE, NE)	240	72 (30.0)	NE [NE, NE)	0.0621	3.083 (1.673, 5.680)	0.0001

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc-pt.sas
Output: t14-06-001-514-ae-cox-soc-pt-ge10.rtf (Date Generated: 26MAY2020:01:04) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.514. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Asian	20	8 (40.0)	NE [1.6, NE)	46	19 (41.3)	17.7 [10.2, NE)		0.911 (0.398, 2.086)	0.8199
	Other or Unknown	11	2 (18.2)	NE [4.6, NE)	22	6 (27.3)	NE [7.2, NE)		1.270 (0.255, 6.325)	0.7696
Region	North America	12	5 (41.7)	15.6 [3.9, 15.6)	21	10 (47.6)	9.3 [5.7, NE)	0.0392	1.016 (0.343, 3.004)	0.9774

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc-pt.sas
Output: t14-06-001-514-ae-cox-soc-pt-ge10.rtf (Date Generated: 26MAY2020:01:04) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.514. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	6 (5.9)	NE [NE, NE)	203	54 (26.6)	NE [NE, NE)		4.552 (1.958, 10.583)	0.0001
	Asia Pacific	39	11 (28.2)	NE [13.8, NE)	84	33 (39.3)	NE [11.1, NE)		1.346 (0.680, 2.664)	0.3936
Baseline ECOG PS	0-1	146	22 (15.1)	NE [NE, NE)	294	94 (32.0)	NE [NE, NE)	0.9797	2.147 (1.350, 3.416)	0.0010

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc-pt.sas
Output: t14-06-001-514-ae-cox-soc-pt-ge10.rtf (Date Generated: 26MAY2020:01:04) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.514. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	2	7	0 (0.0)	NE [NE, NE)	13	3 (23.1)	NE [2.2, NE)		>999.999 (<.001, NE)	0.3723
Prior Bortezomib or Ixazomib exposure	Yes	136	20 (14.7)	NE [NE, NE)	285	91 (31.9)	NE [NE, NE)	0.9264	2.157 (1.329, 3.501)	0.0014
	No	17	2 (11.8)	NE [NE, NE)	23	6 (26.1)	NE [8.6, NE)		2.080 (0.418, 10.346)	0.3606

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.514. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Refractory to Bortezomib or Ixazomib	Yes	55	9 (16.4)	NE [NE, NE)	99	28 (28.3)	NE [NE, NE)	0.4567	1.722 (0.813, 3.651)	0.1510
	No	98	13 (13.3)	NE [NE, NE)	209	69 (33.0)	NE [NE, NE)		2.469 (1.365, 4.467)	0.0020
Prior Lenalidomide exposure	Yes	74	12 (16.2)	NE [16.9, NE)	122	44 (36.1)	NE [15.6, NE)	0.9962	2.201 (1.162, 4.171)	0.0129

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	No	79	10 (12.7)	NE [NE, NE)	186	53 (28.5)	NE [NE, NE)		2.236 (1.137, 4.395)	0.0166
Refractory to Lenalidomide	Yes	55	9 (16.4)	NE [16.8, NE)	98	36 (36.7)	NE [10.4, NE)	0.9806	2.153 (1.035, 4.478)	0.0353
	No	98	13 (13.3)	NE [NE, NE)	210	61 (29.0)	NE [NE, NE)		2.183 (1.199, 3.972)	0.0088

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	 No. of Events (%)	 Median (months) (95%CI)	KdD (N = 308) N	 No. of Events (%)	 Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	 p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	20 (18.2)	NE [NE, NE)	205	72 (35.1)	NE [16.2, NE)	0.1871	1.894 (1.154, 3.110)	0.0102
	No	43	2 (4.7)	NE [NE, NE)	103	25 (24.3)	NE [NE, NE)		5.349 (1.267, 22.583)	0.0105
Refractory to IMiD	Yes	65	11 (16.9)	NE [16.8, NE)	129	44 (34.1)	NE [16.2, NE)	0.6931	1.931 (0.996, 3.743)	0.0471

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	 No. of Events (%)	 Median (months) (95%CI)	KdD (N = 308) N	 No. of Events (%)	 Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	 p-value (2-sided)[b]
	No	88	11 (12.5)	NE [NE, NE)	179	53 (29.6)	NE [NE, NE)		2.356 (1.231, 4.512)	0.0077
ISS stage per IXRS	1 or 2	126	19 (15.1)	NE [NE, NE)	250	81 (32.4)	NE [NE, NE)	0.9009	2.193 (1.331, 3.615)	0.0016
	3	27	3 (11.1)	NE [NE, NE)	58	16 (27.6)	NE [15.6, NE)		1.938 (0.562, 6.683)	0.2860

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior proteasome inhibitor exposure per IXRS	Yes	138	20 (14.5)	NE [NE, NE)	276	88 (31.9)	NE [NE, NE)	0.9092	2.178 (1.340, 3.540)	0.0013
	No	15	2 (13.3)	NE [NE, NE)	32	9 (28.1)	NE [16.2, NE)		2.107 (0.455, 9.766)	0.3298
Number of prior lines of therapy per IXRS	1	66	11 (16.7)	NE [NE, NE)	131	40 (30.5)	NE [NE, NE)	0.4868	1.816 (0.932, 3.540)	0.0754

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	No. of Events (%)	Median (months) (95%CI)	KdD (N = 308) N	No. of Events (%)	Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	>= 2	87	11 (12.6)	NE [NE, NE)	177	57 (32.2)	NE [NE, NE)		2.500 (1.311, 4.769)	0.0040
Nausea										
Total subjects		153	20 (13.1)	NE [NE, NE)	308	56 (18.2)	NE [NE, NE)		1.321 (0.793, 2.203)	0.2862

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.514. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Vomiting										
Total subjects		153	13 (8.5)	NE [NE, NE)	308	37 (12.0)	NE [NE, NE)		1.291 (0.685, 2.431)	0.4330
Constipation										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	6 (3.9)	NE [NE, NE)	308	22 (7.1)	NE [NE, NE)		1.670 (0.677, 4.120)	0.2609
Abdominal pain										
Total subjects		153	7 (4.6)	NE [NE, NE)	308	12 (3.9)	NE [NE, NE)		0.733 (0.287, 1.869)	0.5137

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
General disorders and administration site conditions										
Fatigue										
Total subjects		153	28 (18.3)	NE [NE, NE)	308	75 (24.4)	NE [NE, NE)		1.294 (0.838, 1.999)	0.2434

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
SOC PT Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Pyrexia										
Total subjects		153	23 (15.0)	NE [NE, NE)	308	60 (19.5)	NE [NE, NE)		1.247 (0.771, 2.019)	0.3677
Oedema peripheral										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	14 (9.2)	NE [NE, NE)	308	33 (10.7)	NE [NE, NE)		1.050 (0.562, 1.964)	0.8768
Asthenia										
Total subjects		153	17 (11.1)	NE [NE, NE)	308	30 (9.7)	NE [NE, NE)		0.787 (0.434, 1.428)	0.4293

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
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SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Chills										
Total subjects		153	6 (3.9)	NE [NE, NE)	308	17 (5.5)	NE [NE, NE)		1.290 (0.508, 3.277)	0.5946
Chest pain										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc-pt.sas
Output: t14-06-001-514-ae-cox-soc-pt-ge10.rtf (Date Generated: 26MAY2020:01:04) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.514. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	 No. of Events (%)	 Median (months) (95%CI)	KdD (N = 308) N	 No. of Events (%)	 Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	 p-value (2-sided)[b]
Total subjects		153	7 (4.6)	NE [NE, NE)	308	13 (4.2)	NE [NE, NE)		0.825 (0.329, 2.071)	0.6816
Pain										
Total subjects		153	2 (1.3)	NE [NE, NE)	308	13 (4.2)	NE [NE, NE)		3.050 (0.687, 13.529)	0.1226

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Oedema										
Total subjects		153	8 (5.2)	NE [NE, NE)	308	11 (3.6)	NE [NE, NE)		0.606 (0.244, 1.508)	0.2769
Influenza like illness										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	 No. of Events (%)	 Median (months) (95%CI)	KdD (N = 308) N	 No. of Events (%)	 Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	 p-value (2-sided)[b]
Total subjects		153	3 (2.0)	NE [NE, NE)	308	11 (3.6)	NE [NE, NE)		1.657 (0.462, 5.944)	0.4335
Malaise										
Total subjects		153	4 (2.6)	NE [NE, NE)	308	10 (3.2)	NE [NE, NE)		1.139 (0.356, 3.639)	0.8264

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Infections and infestations										
Upper respiratory tract infection										
Total subjects		153	35 (22.9)	NE [NE, NE)	308	90 (29.2)	NE [18.9, NE)		1.109 (0.750, 1.639)	0.6059

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc-pt.sas
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Table 14-6.1.514. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Pneumonia										
Total subjects		153	19 (12.4)	NE [NE, NE)	308	55 (17.9)	NE [NE, NE)		1.215 (0.721, 2.049)	0.4637
Bronchitis										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	18 (11.8)	NE [NE, NE)	308	52 (16.9)	NE [NE, NE)		1.297 (0.758, 2.218)	0.3411
Influenza										
Total subjects		153	10 (6.5)	NE [NE, NE)	308	34 (11.0)	NE [NE, NE)		1.514 (0.747, 3.067)	0.2457

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Respiratory tract infection										
Total subjects		153	8 (5.2)	NE [NE, NE)	308	31 (10.1)	NE [NE, NE)		1.639 (0.753, 3.567)	0.2087
Nasopharyngitis										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	 No. of Events (%)	 Median (months) (95%CI)	KdD (N = 308) N	 No. of Events (%)	 Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	 p-value (2-sided)[b]
Total subjects		153	13 (8.5)	NE [NE, NE)	308	27 (8.8)	NE [NE, NE)		0.889 (0.458, 1.726)	0.7275
Urinary tract infection										
Total subjects		153	4 (2.6)	NE [NE, NE)	308	18 (5.8)	NE [NE, NE)		1.925 (0.651, 5.695)	0.2282

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Lower respiratory tract infection										
Total subjects		153	4 (2.6)	NE [NE, NE)	308	17 (5.5)	NE [NE, NE)		1.751 (0.588, 5.218)	0.3082
Conjunctivitis										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
SOC PT Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	3 (2.0)	NE [NE, NE)	308	16 (5.2)	NE [NE, NE)		2.341 (0.681, 8.044)	0.1640
Sinusitis										
Total subjects		153	4 (2.6)	NE [NE, NE)	308	15 (4.9)	NE [NE, NE)		1.592 (0.528, 4.802)	0.4051

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Pharyngitis										
Total subjects		153	4 (2.6)	NE [NE, NE)	308	13 (4.2)	NE [NE, NE)		1.340 (0.437, 4.116)	0.6074
Viral infection										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	6 (3.9)	NE [NE, NE)	308	12 (3.9)	NE [NE, NE)		0.857 (0.321, 2.290)	0.7575
Sepsis										
Total subjects		153	2 (1.3)	NE [NE, NE)	308	12 (3.9)	NE [NE, NE)		2.775 (0.621, 12.410)	0.1631

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Injury, poisoning and procedural complications										
Infusion related reaction										
Total subjects		153	3 (2.0)	NE [NE, NE)	308	24 (7.8)	NE [NE, NE)		4.072 (1.226, 13.527)	0.0133

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age – at baseline (years)	<= 75	135	3 (2.2)	NE [NE, NE)	283	23 (8.1)	NE [NE, NE)	0.9912	3.748 (1.125, 12.481)	0.0215
	> 75	18	0 (0.0)	NE [NE, NE)	25	1 (4.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.3961
Sex	Male	91	2 (2.2)	NE [NE, NE)	174	14 (8.0)	NE [NE, NE)	0.8577	3.691 (0.839, 16.243)	0.0657

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Female	62	1 (1.6)	NE [NE, NE)	134	10 (7.5)	NE [NE, NE)		4.820 (0.617, 37.652)	0.0972
Race	White	122	2 (1.6)	NE [NE, NE)	240	14 (5.8)	NE [NE, NE)	0.9977	3.621 (0.823, 15.930)	0.0692
	Asian	20	1 (5.0)	NE [10.4, NE)	46	7 (15.2)	NE [NE, NE)		3.163 (0.389, 25.731)	0.2640

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	3 (13.6)	NE [NE, NE)		>999.999 (<.001, NE)	0.2059
Region	North America	12	2 (16.7)	NE [8.5, NE)	21	2 (9.5)	NE [NE, NE)	0.3676	0.519 (0.072, 3.725)	0.5062
	Europe	102	0 (0.0)	NE [NE, NE)	203	13 (6.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.0093

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Asia Pacific	39	1 (2.6)	NE [NE, NE)	84	9 (10.7)	NE [NE, NE)		4.290 (0.543, 33.880)	0.1344
Baseline ECOG PS	0-1	146	3 (2.1)	NE [NE, NE)	294	22 (7.5)	NE [NE, NE)	0.9916	3.731 (1.117, 12.465)	0.0222
	2	7	0 (0.0)	NE [NE, NE)	13	1 (7.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.4631

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Prior Bortezomib or Ixazomib exposure	Yes	136	3 (2.2)	NE [NE, NE)	285	21 (7.4)	NE [NE, NE)	0.9907	3.407 (1.016, 11.422)	0.0356
	No	17	0 (0.0)	NE [NE, NE)	23	3 (13.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.1263
Refractory to Bortezomib or Ixazomib	Yes	55	1 (1.8)	NE [NE, NE)	99	7 (7.1)	NE [NE, NE)	0.9778	3.858 (0.474, 31.380)	0.1748

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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	No	98	2 (2.0)	NE [NE, NE)	209	17 (8.1)	NE [NE, NE)		4.135 (0.955, 17.899)	0.0400
Prior Lenalidomide exposure	Yes	74	3 (4.1)	NE [NE, NE)	122	7 (5.7)	NE [NE, NE)	0.9866	1.382 (0.357, 5.356)	0.6484
	No	79	0 (0.0)	NE [NE, NE)	186	17 (9.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.0057

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Refractory to Lenalidomide	Yes	55	3 (5.5)	NE [NE, NE)	98	5 (5.1)	NE [NE, NE)	0.9848	0.884 (0.210, 3.714)	0.8569
	No	98	0 (0.0)	NE [NE, NE)	210	19 (9.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.0022
Prior IMiD exposure	Yes	110	3 (2.7)	NE [NE, NE)	205	18 (8.8)	NE [NE, NE)	0.9908	3.317 (0.977, 11.264)	0.0433

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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	No	43	0 (0.0)	NE [NE, NE)	103	6 (5.8)	NE [NE, NE)		>999.999 (<.001, NE)	0.1080
Refractory to IMiD	Yes	65	3 (4.6)	NE [NE, NE)	129	7 (5.4)	NE [NE, NE)	0.9857	1.137 (0.293, 4.410)	0.8646
	No	88	0 (0.0)	NE [NE, NE)	179	17 (9.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.0029

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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ISS stage per IXRS	1 or 2	126	3 (2.4)	NE [NE, NE)	250	22 (8.8)	NE [NE, NE)	0.9898	3.831 (1.147, 12.797)	0.0194
	3	27	0 (0.0)	NE [NE, NE)	58	2 (3.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.3617
Prior proteasome inhibitor exposure per IXRS	Yes	138	3 (2.2)	NE [NE, NE)	276	20 (7.2)	NE [NE, NE)	0.9913	3.397 (1.009, 11.431)	0.0367

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
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	No	15	0 (0.0)	NE [NE, NE)	32	4 (12.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.1567
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	12 (9.2)	NE [NE, NE)	0.9879	>999.999 (<.001, NE)	0.0114
	>= 2	87	3 (3.4)	NE [NE, NE)	177	12 (6.8)	NE [NE, NE)		1.960 (0.553, 6.949)	0.2942

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Fall										
Total subjects		153	6 (3.9)	NE [NE, NE)	308	14 (4.5)	NE [NE, NE)		0.966 (0.370, 2.521)	0.9445
Contusion										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
SOC PT Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	2 (1.3)	NE [NE, NE)	308	12 (3.9)	NE [NE, NE)		2.475 (0.553, 11.074)	0.2202
Investigations										
Alanine aminotransferase increased										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Total subjects		153	3 (2.0)	NE [NE, NE)	308	12 (3.9)	NE [NE, NE)		1.975 (0.557, 6.999)	0.2825
Weight decreased										
Total subjects		153	4 (2.6)	NE [NE, NE)	308	11 (3.6)	NE [NE, NE)		1.187 (0.377, 3.740)	0.7682

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc-pt.sas
Output: t14-06-001-514-ae-cox-soc-pt-ge10.rtf (Date Generated: 26MAY2020:01:04) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.514. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Metabolism and nutrition disorders										
Hyperglycaemia										
Total subjects		153	11 (7.2)	NE [NE, NE)	308	28 (9.1)	NE [NE, NE)		1.120 (0.556, 2.254)	0.7511

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	 No. of Events (%)	 Median (months) (95%CI)	KdD (N = 308) N	 No. of Events (%)	 Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	 p-value (2-sided)[b]
Decreased appetite										
Total subjects		153	9 (5.9)	NE [NE, NE)	308	27 (8.8)	NE [NE, NE)		1.291 (0.605, 2.752)	0.5074
Hypokalaemia										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	9 (5.9)	NE [NE, NE)	308	18 (5.8)	NE [NE, NE)		0.889 (0.399, 1.983)	0.7749
Hypocalcaemia										
Total subjects		153	4 (2.6)	NE [NE, NE)	308	15 (4.9)	NE [NE, NE)		1.624 (0.538, 4.900)	0.3848

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Hypomagnesaemia										
Total subjects		153	3 (2.0)	NE [NE, NE)	308	11 (3.6)	NE [NE, NE)		1.701 (0.474, 6.101)	0.4096
Musculoskeletal and connective tissue disorders										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Back pain										
Total subjects		153	15 (9.8)	NE [NE, NE)	308	50 (16.2)	NE [NE, NE)		1.424 (0.799, 2.537)	0.2278
Muscle spasms										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	 No. of Events (%)	 Median (months) (95%CI)	KdD (N = 308) N	 No. of Events (%)	 Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	 p-value (2-sided)[b]
Total subjects		153	18 (11.8)	NE [NE, NE)	308	36 (11.7)	NE [NE, NE)		0.889 (0.505, 1.567)	0.6844
Arthralgia										
Total subjects		153	8 (5.2)	NE [NE, NE)	308	26 (8.4)	NE [NE, NE)		1.382 (0.625, 3.056)	0.4228

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
SOC PT Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Pain in extremity										
Total subjects		153	10 (6.5)	NE [NE, NE)	308	19 (6.2)	NE [NE, NE)		0.836 (0.388, 1.799)	0.6462
Myalgia										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	4 (2.6)	NE [NE, NE)	308	14 (4.5)	NE [NE, NE)		1.424 (0.466, 4.349)	0.5323
Musculoskeletal chest pain										
Total subjects		153	5 (3.3)	NE [NE, NE)	308	13 (4.2)	NE [NE, NE)		1.133 (0.403, 3.185)	0.8129

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	No. of Events (%)	Median (months) (95%CI)	KdD (N = 308) N	No. of Events (%)	Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Muscular weakness										
Total subjects		153	6 (3.9)	NE [NE, NE)	308	11 (3.6)	NE [NE, NE)		0.735 (0.271, 1.993)	0.5435
Nervous system disorders										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Headache										
Total subjects		153	18 (11.8)	NE [NE, NE)	308	41 (13.3)	NE [NE, NE)		1.059 (0.608, 1.844)	0.8430
Neuropathy peripheral										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
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[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.514. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
SOC PT Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	5 (3.3)	NE [NE, NE)	308	25 (8.1)	NE [NE, NE)		2.213 (0.846, 5.786)	0.0966
Dizziness										
Total subjects		153	4 (2.6)	NE [NE, NE)	308	23 (7.5)	NE [NE, NE)		2.561 (0.885, 7.412)	0.0719

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.514. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Peripheral sensory neuropathy										
Total subjects		153	2 (1.3)	NE [NE, NE)	308	20 (6.5)	NE [NE, NE)		4.599 (1.074, 19.690)	0.0238
Age – at baseline (years)	<= 75	135	2 (1.5)	NE [NE, NE)	283	18 (6.4)	NE [NE, NE)	0.9921	3.994 (0.926, 17.228)	0.0446

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.514. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	> 75	18	0 (0.0)	NE [NE, NE)	25	2 (8.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.2563
Sex	Male	91	2 (2.2)	NE [NE, NE)	174	10 (5.7)	NE [NE, NE)	0.9899	2.490 (0.545, 11.371)	0.2228
	Female	62	0 (0.0)	NE [NE, NE)	134	10 (7.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.0418

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	1 (0.8)	NE [NE, NE)	240	11 (4.6)	NE [NE, NE)	0.9330	5.165 (0.666, 40.072)	0.0797
	Asian	20	1 (5.0)	NE [NE, NE)	46	7 (15.2)	NE [NE, NE)		3.015 (0.371, 24.507)	0.2777
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	2 (9.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.4259

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Output: t14-06-001-514-ae-cox-soc-pt-ge10.rtf (Date Generated: 26MAY2020:01:04) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.514. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Region	North America	12	0 (0.0)	NE [NE, NE)	21	5 (23.8)	NE [9.3, NE)	0.9983	>999.999 (<.001, NE)	0.0928
	Europe	102	1 (1.0)	NE [NE, NE)	203	7 (3.4)	NE [NE, NE)		3.119 (0.383, 25.436)	0.2625
	Asia Pacific	39	1 (2.6)	NE [NE, NE)	84	8 (9.5)	NE [NE, NE)		3.619 (0.453, 28.939)	0.1943

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Baseline ECOG PS	0-1	146	2 (1.4)	NE [NE, NE)	294	18 (6.1)	NE [NE, NE)	0.9917	4.188 (0.971, 18.065)	0.0367
	2	7	0 (0.0)	NE [NE, NE)	13	2 (15.4)	NE [2.5, NE)		>999.999 (<.001, NE)	0.3977
Prior Bortezomib or Ixazomib exposure	Yes	136	1 (0.7)	NE [NE, NE)	285	18 (6.3)	NE [NE, NE)	0.2745	7.899 (1.054, 59.201)	0.0169

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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	No	17	1 (5.9)	NE [NE, NE)	23	2 (8.7)	NE [NE, NE)		1.411 (0.128, 15.598)	0.7780
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	3 (3.0)	NE [NE, NE)	0.9916	>999.999 (<.001, NE)	0.2245
	No	98	2 (2.0)	NE [NE, NE)	209	17 (8.1)	NE [NE, NE)		3.664 (0.846, 15.873)	0.0628

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Prior Lenalidomide exposure	Yes	74	1 (1.4)	NE [NE, NE)	122	6 (4.9)	NE [NE, NE)	0.7197	3.393 (0.408, 28.212)	0.2288
	No	79	1 (1.3)	NE [NE, NE)	186	14 (7.5)	NE [NE, NE)		5.592 (0.735, 42.562)	0.0609
Refractory to Lenalidomide	Yes	55	1 (1.8)	NE [NE, NE)	98	5 (5.1)	NE [NE, NE)	0.5256	2.644 (0.308, 22.666)	0.3556

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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	No	98	1 (1.0)	NE [NE, NE)	210	15 (7.1)	NE [NE, NE)		6.516 (0.860, 49.369)	0.0365
Prior IMiD exposure	Yes	110	2 (1.8)	NE [NE, NE)	205	13 (6.3)	NE [NE, NE)	0.9915	3.134 (0.706, 13.915)	0.1129
	No	43	0 (0.0)	NE [NE, NE)	103	7 (6.8)	NE [NE, NE)		>999.999 (<.001, NE)	0.0925

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Refractory to IMiD	Yes	65	1 (1.5)	NE [NE, NE)	129	6 (4.7)	NE [NE, NE)	0.5608	2.851 (0.343, 23.703)	0.3099
	No	88	1 (1.1)	NE [NE, NE)	179	14 (7.8)	NE [NE, NE)		6.420 (0.844, 48.857)	0.0389
ISS stage per IXRS	1 or 2	126	2 (1.6)	NE [NE, NE)	250	18 (7.2)	NE [NE, NE)	0.9918	4.430 (1.028, 19.093)	0.0288

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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	3	27	0 (0.0)	NE [NE, NE)	58	2 (3.4)	NE [18.2, NE)		>999.999 (<.001, NE)	0.5170
Prior proteasome inhibitor exposure per IXRS	Yes	138	1 (0.7)	NE [NE, NE)	276	18 (6.5)	NE [NE, NE)	0.1453	8.338 (1.113, 62.481)	0.0134
	No	15	1 (6.7)	NE [4.9, NE)	32	2 (6.3)	NE [NE, NE)		0.870 (0.079, 9.641)	0.9098

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
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Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	10 (7.6)	NE [NE, NE)	0.9893	>999.999 (<.001, NE)	0.0287
	>= 2	87	2 (2.3)	NE [NE, NE)	177	10 (5.6)	NE [NE, NE)		2.234 (0.489, 10.201)	0.2866
Psychiatric disorders										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Insomnia										
Total subjects		153	17 (11.1)	NE [NE, NE)	308	55 (17.9)	NE [NE, NE)		1.519 (0.882, 2.618)	0.1286
Agitation										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
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<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
SOC PT Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	5 (3.3)	NE [NE, NE)	308	10 (3.2)	NE [NE, NE)		0.914 (0.312, 2.678)	0.8694
Renal and urinary disorders										
Acute kidney injury										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Total subjects		153	9 (5.9)	NE [NE, NE)	308	12 (3.9)	NE [NE, NE)		0.579 (0.244, 1.377)	0.2108
Respiratory, thoracic and mediastinal disorders										
Dyspnoea										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Total subjects		153	34 (22.2)	NE [NE, NE)	308	61 (19.8)	NE [NE, NE)		0.810 (0.532, 1.234)	0.3253
Cough										
Total subjects		153	30 (19.6)	NE [NE, NE)	308	52 (16.9)	NE [NE, NE)		0.751 (0.478, 1.178)	0.2105

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc-pt.sas
Output: t14-06-001-514-ae-cox-soc-pt-ge10.rtf (Date Generated: 26MAY2020:01:04) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.514. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Productive cough										
Total subjects		153	6 (3.9)	NE [NE, NE)	308	21 (6.8)	NE [NE, NE)		1.567 (0.632, 3.887)	0.3278
Dysphonia										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc-pt.sas
Output: t14-06-001-514-ae-cox-soc-pt-ge10.rtf (Date Generated: 26MAY2020:01:04) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.514. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
SOC PT Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	3 (2.0)	NE [NE, NE)	308	13 (4.2)	NE [NE, NE)		2.081 (0.593, 7.308)	0.2424
Oropharyngeal pain										
Total subjects		153	3 (2.0)	NE [NE, NE)	308	12 (3.9)	NE [NE, NE)		1.787 (0.504, 6.343)	0.3624

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc-pt.sas
Output: t14-06-001-514-ae-cox-soc-pt-ge10.rtf (Date Generated: 26MAY2020:01:04) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.514. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Dyspnoea exertional										
Total subjects		153	2 (1.3)	NE [NE, NE)	308	11 (3.6)	NE [NE, NE)		2.493 (0.552, 11.258)	0.2190
Rhinorrhoea										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc-pt.sas
Output: t14-06-001-514-ae-cox-soc-pt-ge10.rtf (Date Generated: 26MAY2020:01:04) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.514. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	 No. of Events (%)	 Median (months) (95%CI)	KdD (N = 308) N	 No. of Events (%)	 Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	 p-value (2-sided)[b]
Total subjects		153	1 (0.7)	NE [NE, NE)	308	11 (3.6)	NE [NE, NE)		5.124 (0.661, 39.701)	0.0812
Skin and subcutaneous tissue disorders										
Rash										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc-pt.sas
Output: t14-06-001-514-ae-cox-soc-pt-ge10.rtf (Date Generated: 26MAY2020:01:04) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.514. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	10 (6.5)	NE [NE, NE)	308	17 (5.5)	NE [NE, NE)		0.705 (0.321, 1.548)	0.3809
Pruritus										
Total subjects		153	4 (2.6)	NE [NE, NE)	308	14 (4.5)	NE [NE, NE)		1.512 (0.497, 4.598)	0.4639

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc-pt.sas
Output: t14-06-001-514-ae-cox-soc-pt-ge10.rtf (Date Generated: 26MAY2020:01:04) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.514. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Vascular disorders										
Hypertension										
Total subjects		153	42 (27.5)	NE [17.3, NE)	308	94 (30.5)	NE [NE, NE)		0.997 (0.692, 1.435)	0.9845

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc-pt.sas
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Table 14-6.1.514. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
SOC PT Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Hypotension										
Total subjects		153	4 (2.6)	NE [NE, NE)	308	13 (4.2)	NE [NE, NE)		1.458 (0.475, 4.477)	0.5078
Phlebitis										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc-pt.sas
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Table 14-6.1.514. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
SOC PT Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	5 (3.3)	NE [NE, NE)	308	11 (3.6)	NE [NE, NE)		0.989 (0.343, 2.852)	0.9842

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc-pt.sas
Output: t14-06-001-514-ae-cox-soc-pt-ge10.rtf (Date Generated: 26MAY2020:01:04) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.513. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Blood and lymphatic system disorders										
Total subjects		153	89 (58.2)	3.2 [2.1, 11.9)	308	168 (54.5)	5.9 [1.7, 16.6)		0.947 (0.732, 1.225)	0.6651
Cardiac disorders										
Total subjects		153	31 (20.3)	NE [NE, NE)	308	75 (24.4)	NE [NE, NE)		1.084 (0.713, 1.648)	0.7067

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc.sas
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Table 14-6.1.513. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Ear and labyrinth disorders										
Total subjects		153	6 (3.9)	NE [NE, NE)	308	14 (4.5)	NE [NE, NE)		1.023 (0.393, 2.667)	0.9624
Endocrine disorders										
Total subjects		153	9 (5.9)	NE [NE, NE)	308	11 (3.6)	NE [NE, NE)		0.472 (0.194, 1.146)	0.0899

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Eye disorders										
Total subjects		153	16 (10.5)	NE [NE, NE)	308	48 (15.6)	NE [NE, NE)		1.302 (0.739, 2.296)	0.3607
Gastrointestinal disorders										
Total subjects		153	50 (32.7)	NE [15.6, NE)	308	171 (55.5)	9.4 [6.0, 11.2)		1.896 (1.384, 2.599)	<.0001

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc.sas
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Table 14-6.1.513. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age – at baseline (years)	<= 75	135	44 (32.6)	NE [15.2, NE)	283	160 (56.5)	9.2 [5.7, 11.2)	0.5166	1.945 (1.393, 2.716)	<.0001
	> 75	18	6 (33.3)	16.9 [1.8, NE)	25	11 (44.0)	9.9 [3.7, NE)		1.290 (0.476, 3.494)	0.6183
Sex	Male	91	24 (26.4)	NE [16.9, NE)	174	94 (54.0)	10.2 [6.4, 15.7)	0.1148	2.357 (1.505, 3.691)	0.0001
	Female	62	26 (41.9)	NE [6.9, NE)	134	77 (57.5)	6.3 [4.1, 11.2)		1.427 (0.915, 2.227)	0.1179

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	33 (27.0)	NE [NE, NE)	240	120 (50.0)	11.2 [8.3, 16.1)	0.2212	2.064 (1.404, 3.035)	0.0002
	Asian	20	14 (70.0)	1.3 [0.3, 6.8)	46	38 (82.6)	1.4 [0.6, 6.2)		1.122 (0.607, 2.076)	0.7130
	Other or Unknown	11	3 (27.3)	16.9 [1.7, NE)	22	13 (59.1)	5.6 [0.3, NE)		2.489 (0.708, 8.745)	0.1447
Region	North America	12	7 (58.3)	7.3 [1.5, 15.6)	21	19 (90.5)	1.0 [0.1, 4.3)	0.2348	3.149 (1.303, 7.611)	0.0079

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc.sas
Output: t14-06-001-513-ae-cox-soc-ge10.rtf (Date Generated: 26MAY2020:01:02) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.513. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	20 (19.6)	NE [NE, NE)	203	88 (43.3)	16.1 [10.9, NE)		2.368 (1.457, 3.848)	0.0003
	Asia Pacific	39	23 (59.0)	5.0 [1.0, 15.2)	84	64 (76.2)	1.9 [0.7, 6.2)		1.463 (0.908, 2.357)	0.1181
Baseline ECOG PS	0-1	146	49 (33.6)	NE [15.6, NE)	294	164 (55.8)	9.2 [6.0, 11.1)	0.8985	1.887 (1.372, 2.597)	<.0001
	2	7	1 (14.3)	NE [1.3, NE)	13	6 (46.2)	15.6 [0.6, NE)		2.165 (0.241, 19.472)	0.4851

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Output: t14-06-001-513-ae-cox-soc-ge10.rtf (Date Generated: 26MAY2020:01:02) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.513. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	44 (32.4)	NE [15.6, NE)	285	156 (54.7)	9.9 [6.2, 12.1)	0.6396	1.875 (1.342, 2.620)	0.0002
	No	17	6 (35.3)	NE [1.5, NE)	23	15 (65.2)	6.0 [0.3, 9.7)		2.359 (0.913, 6.096)	0.0707
Refractory to Bortezomib or Ixazomib	Yes	55	15 (27.3)	NE [NE, NE)	99	46 (46.5)	13.3 [6.8, NE)	0.6863	1.729 (0.965, 3.097)	0.0625
	No	98	35 (35.7)	NE [14.3, NE)	209	125 (59.8)	7.3 [4.1, 10.2)		1.976 (1.358, 2.875)	0.0003

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	22 (29.7)	NE [15.6, NE)	122	68 (55.7)	6.8 [4.0, 15.6)	0.4379	2.173 (1.343, 3.516)	0.0012
	No	79	28 (35.4)	NE [14.3, NE)	186	103 (55.4)	10.2 [6.2, 13.3)		1.691 (1.113, 2.567)	0.0130
Refractory to Lenalidomide	Yes	55	17 (30.9)	16.9 [14.1, NE)	98	55 (56.1)	7.2 [4.0, 15.7)	0.7139	2.037 (1.182, 3.512)	0.0090
	No	98	33 (33.7)	NE [14.4, NE)	210	116 (55.2)	10.2 [6.0, 13.3)		1.816 (1.233, 2.673)	0.0022

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	40 (36.4)	NE [14.1, NE)	205	120 (58.5)	6.8 [3.7, 9.9)	0.4385	1.800 (1.258, 2.574)	0.0011
	No	43	10 (23.3)	NE [NE, NE)	103	51 (49.5)	11.6 [7.0, NE)		2.468 (1.253, 4.862)	0.0070
Refractory to IMiD	Yes	65	21 (32.3)	16.9 [14.1, NE)	129	71 (55.0)	7.2 [4.1, 11.8)	0.9898	1.873 (1.150, 3.050)	0.0104
	No	88	29 (33.0)	NE [14.4, NE)	179	100 (55.9)	10.4 [6.0, 13.4)		1.898 (1.255, 2.869)	0.0021

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	44 (34.9)	NE [14.4, NE)	250	148 (59.2)	7.0 [4.1, 10.4)	0.6403	1.987 (1.419, 2.782)	<.0001
	3	27	6 (22.2)	NE [NE, NE)	58	23 (39.7)	15.7 [9.4, NE)		1.552 (0.630, 3.823)	0.3376
Prior proteasome inhibitor exposure per IXRS	Yes	138	45 (32.6)	NE [15.6, NE)	276	151 (54.7)	9.9 [6.2, 12.1)	0.6173	1.846 (1.323, 2.575)	0.0003
	No	15	5 (33.3)	NE [1.0, NE)	32	20 (62.5)	3.5 [0.3, 11.8)		2.364 (0.885, 6.312)	0.0786

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	20 (30.3)	NE [NE, NE)	131	77 (58.8)	8.7 [5.6, 11.1)	0.3811	2.236 (1.367, 3.658)	0.0010
	>= 2	87	30 (34.5)	16.9 [14.1, NE)	177	94 (53.1)	9.4 [4.1, 15.7)		1.670 (1.107, 2.519)	0.0141
General disorders and administration site conditions										
Total subjects		153	74 (48.4)	8.4 [4.8, NE)	308	182 (59.1)	4.2 [2.9, 7.4)		1.334 (1.018, 1.748)	0.0367

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
SOC Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age – at baseline (years)	<= 75	135	65 (48.1)	9.8 [4.8, NE)	283	165 (58.3)	4.3 [2.8, 7.7)	0.9063	1.332 (0.999, 1.775)	0.0510
	> 75	18	9 (50.0)	8.4 [2.1, NE)	25	17 (68.0)	4.0 [1.4, 9.1)		1.408 (0.625, 3.170)	0.4080
Sex	Male	91	42 (46.2)	11.5 [4.8, NE)	174	99 (56.9)	5.6 [2.8, 9.4)	0.9584	1.321 (0.921, 1.896)	0.1293
	Female	62	32 (51.6)	6.0 [2.4, NE)	134	83 (61.9)	4.0 [1.6, 8.3)		1.349 (0.897, 2.029)	0.1548

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	53 (43.4)	14.9 [6.0, NE)	240	134 (55.8)	6.1 [3.8, 9.4)	0.2731	1.364 (0.992, 1.875)	0.0555
	Asian	20	15 (75.0)	3.0 [1.2, 7.8)	46	30 (65.2)	2.4 [1.0, 5.7)		0.976 (0.524, 1.817)	0.9355
	Other or Unknown	11	6 (54.5)	6.0 [0.9, NE)	22	18 (81.8)	1.0 [0.3, 4.0)		2.244 (0.886, 5.683)	0.0782
Region	North America	12	10 (83.3)	1.3 [0.2, 4.7)	21	19 (90.5)	1.3 [0.3, 2.8)	0.5522	1.027 (0.473, 2.234)	0.9578

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Most Frequent Adverse Events by MedDRA SOC <Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	40 (39.2)	NE [8.4, NE)	203	108 (53.2)	8.2 [4.0, 15.6)		1.506 (1.048, 2.165)	0.0265
	Asia Pacific	39	24 (61.5)	4.8 [2.2, 7.8)	84	55 (65.5)	3.0 [1.3, 4.9)		1.142 (0.706, 1.848)	0.5893
Baseline ECOG PS	0-1	146	70 (47.9)	9.8 [4.8, NE)	294	173 (58.8)	4.3 [2.8, 8.2)	0.4985	1.358 (1.028, 1.792)	0.0310
	2	7	4 (57.1)	5.6 [0.3, 5.6)	13	8 (61.5)	4.0 [0.3, NE)		0.899 (0.259, 3.115)	0.8767

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	65 (47.8)	9.8 [4.8, NE)	285	172 (60.4)	4.0 [2.8, 6.5)	0.1654	1.408 (1.059, 1.874)	0.0186
	No	17	9 (52.9)	8.4 [1.0, NE)	23	10 (43.5)	NE [1.3, NE)		0.794 (0.322, 1.958)	0.6227
Refractory to Bortezomib or Ixazomib	Yes	55	20 (36.4)	NE [7.8, NE)	99	52 (52.5)	5.6 [2.2, NE)	0.1570	1.746 (1.042, 2.926)	0.0328
	No	98	54 (55.1)	6.0 [2.8, 13.7)	209	130 (62.2)	4.0 [2.6, 7.4)		1.148 (0.835, 1.577)	0.3970

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
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[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	37 (50.0)	8.3 [2.3, NE)	122	78 (63.9)	2.8 [1.3, 7.7)	0.8539	1.408 (0.952, 2.083)	0.0861
	No	79	37 (46.8)	9.8 [4.8, NE)	186	104 (55.9)	4.9 [3.2, 10.6)		1.330 (0.914, 1.936)	0.1358
Refractory to Lenalidomide	Yes	55	26 (47.3)	6.0 [2.1, NE)	98	59 (60.2)	2.8 [1.2, 9.5)	0.9577	1.377 (0.867, 2.188)	0.1750
	No	98	48 (49.0)	9.8 [4.8, NE)	210	123 (58.6)	4.4 [3.1, 7.4)		1.335 (0.956, 1.864)	0.0896

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc.sas
Output: t14-06-001-513-ae-cox-soc-ge10.rtf (Date Generated: 26MAY2020:01:02) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.513. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	54 (49.1)	7.8 [3.9, NE)	205	127 (62.0)	4.0 [1.9, 6.1)	0.8270	1.380 (1.003, 1.898)	0.0471
	No	43	20 (46.5)	10.8 [4.8, NE)	103	55 (53.4)	6.9 [3.2, NE)		1.280 (0.767, 2.137)	0.3487
Refractory to IMiD	Yes	65	28 (43.1)	14.9 [3.0, NE)	129	83 (64.3)	2.8 [1.3, 6.5)	0.1666	1.688 (1.099, 2.591)	0.0157
	No	88	46 (52.3)	8.3 [4.7, NE)	179	99 (55.3)	4.9 [3.2, 13.4)		1.133 (0.798, 1.608)	0.4904

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	59 (46.8)	10.8 [6.0, NE)	250	149 (59.6)	4.3 [2.9, 7.7)	0.3627	1.411 (1.044, 1.908)	0.0249
	3	27	15 (55.6)	4.3 [0.7, NE)	58	33 (56.9)	4.2 [1.1, 15.4)		1.034 (0.560, 1.908)	0.9178
Prior proteasome inhibitor exposure per IXRS	Yes	138	67 (48.6)	9.8 [4.8, NE)	276	166 (60.1)	4.2 [2.8, 6.5)	0.4932	1.377 (1.037, 1.829)	0.0273
	No	15	7 (46.7)	8.4 [1.0, NE)	32	16 (50.0)	13.4 [1.9, NE)		1.036 (0.425, 2.525)	0.9355

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.513. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	33 (50.0)	8.4 [4.3, NE)	131	78 (59.5)	5.7 [2.8, 8.6)	0.7326	1.264 (0.841, 1.899)	0.2598
	>= 2	87	41 (47.1)	10.8 [3.9, NE)	177	104 (58.8)	4.0 [1.7, 8.5)		1.395 (0.972, 2.003)	0.0720
Hepatobiliary disorders										
Total subjects		153	9 (5.9)	NE [NE, NE)	308	27 (8.8)	NE [NE, NE)		1.357 (0.638, 2.889)	0.4258

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Immune system disorders										
Total subjects		153	1 (0.7)	NE [NE, NE)	308	18 (5.8)	NE [NE, NE)		8.023 (1.071, 60.106)	0.0158
Age – at baseline (years)	<= 75	135	1 (0.7)	NE [NE, NE)	283	18 (6.4)	NE [NE, NE)	0.9995	7.772 (1.037, 58.231)	0.0181
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	9 (5.2)	NE [NE, NE)	0.9894	>999.999 (<.001, NE)	0.0421
	Female	62	1 (1.6)	NE [NE, NE)	134	9 (6.7)	NE [NE, NE)		3.785 (0.479, 29.892)	0.1747
Race	White	122	1 (0.8)	NE [NE, NE)	240	10 (4.2)	NE [NE, NE)	0.9999	4.486 (0.574, 35.081)	0.1169
	Asian	20	0 (0.0)	NE [NE, NE)	46	4 (8.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.2083

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	4 (18.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.2184
Region	North America	12	0 (0.0)	NE [NE, NE)	21	3 (14.3)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.1888
	Europe	102	1 (1.0)	NE [NE, NE)	203	9 (4.4)	NE [NE, NE)		4.036 (0.511, 31.871)	0.1517
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	6 (7.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.1286

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Baseline ECOG PS	0-1	146	1 (0.7)	NE [NE, NE)	294	18 (6.1)	NE [NE, NE)	0.9996	8.221 (1.098, 61.583)	0.0142
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Prior Bortezomib or Ixazomib exposure	Yes	136	1 (0.7)	NE [NE, NE)	285	17 (6.0)	NE [NE, NE)	0.9935	7.379 (0.982, 55.451)	0.0225
	No	17	0 (0.0)	NE [NE, NE)	23	1 (4.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.5050

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.513. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	2 (2.0)	NE [NE, NE)	0.9931	>999.999 (<.001, NE)	0.2988
	No	98	1 (1.0)	NE [NE, NE)	209	16 (7.7)	NE [NE, NE)		6.700 (0.888, 50.533)	0.0327
Prior Lenalidomide exposure	Yes	74	1 (1.4)	NE [NE, NE)	122	6 (4.9)	NE [NE, NE)	0.9896	3.147 (0.378, 26.192)	0.2633
	No	79	0 (0.0)	NE [NE, NE)	186	12 (6.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.0300

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	4 (4.1)	NE [NE, NE)	0.9924	>999.999 (<.001, NE)	0.1717
	No	98	1 (1.0)	NE [NE, NE)	210	14 (6.7)	NE [NE, NE)		6.028 (0.793, 45.852)	0.0479
Prior IMiD exposure	Yes	110	1 (0.9)	NE [NE, NE)	205	14 (6.8)	NE [NE, NE)	0.9931	6.813 (0.896, 51.830)	0.0315
	No	43	0 (0.0)	NE [NE, NE)	103	4 (3.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.2245

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	5 (3.9)	NE [NE, NE)	0.9919	>999.999 (<.001, NE)	0.1565
	No	88	1 (1.1)	NE [NE, NE)	179	13 (7.3)	NE [NE, NE)		5.969 (0.781, 45.635)	0.0501
ISS stage per IXRS	1 or 2	126	1 (0.8)	NE [NE, NE)	250	16 (6.4)	NE [NE, NE)	0.9931	7.498 (0.994, 56.544)	0.0214
	3	27	0 (0.0)	NE [NE, NE)	58	2 (3.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.4009

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior proteasome inhibitor exposure per IXRS	Yes	138	1 (0.7)	NE [NE, NE)	276	16 (5.8)	NE [NE, NE)	0.9905	7.297 (0.967, 55.041)	0.0238
	No	15	0 (0.0)	NE [NE, NE)	32	2 (6.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.4092
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	10 (7.6)	NE [NE, NE)	0.9907	>999.999 (<.001, NE)	0.0303
	>= 2	87	1 (1.1)	NE [NE, NE)	177	8 (4.5)	NE [NE, NE)		3.367 (0.421, 26.933)	0.2240

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc.sas
Output: t14-06-001-513-ae-cox-soc-ge10.rtf (Date Generated: 26MAY2020:01:02) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.513. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Infections and infestations										
Total subjects		153	102 (66.7)	3.3 [2.6, 6.3)	308	250 (81.2)	3.5 [2.4, 4.4)		1.215 (0.965, 1.531)	0.0973
Injury, poisoning and procedural complications										

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc.sas
Output: t14-06-001-513-ae-cox-soc-ge10.rtf (Date Generated: 26MAY2020:01:02) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.513. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	25 (16.3)	NE [NE, NE)	308	61 (19.8)	NE [NE, NE)		1.139 (0.714, 1.816)	0.6076
Investigations										
Total subjects		153	33 (21.6)	NE [NE, NE)	308	65 (21.1)	NE [NE, NE)		0.876 (0.576, 1.334)	0.5375

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc.sas
Output: t14-06-001-513-ae-cox-soc-ge10.rtf (Date Generated: 26MAY2020:01:02) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.513. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
SOC Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Metabolism and nutrition disorders										
Total subjects		153	37 (24.2)	NE [NE, NE)	308	105 (34.1)	NE [NE, NE)		1.350 (0.928, 1.965)	0.1153
Musculoskeletal and connective tissue disorders										

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc.sas
Output: t14-06-001-513-ae-cox-soc-ge10.rtf (Date Generated: 26MAY2020:01:02) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.513. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	57 (37.3)	NE [14.1, NE)	308	132 (42.9)	18.0 [13.8, NE)		1.017 (0.745, 1.388)	0.9142
Neoplasms benign, malignant and unspecified (incl cysts and polyps)										
Total subjects		153	10 (6.5)	NE [NE, NE)	308	16 (5.2)	NE [NE, NE)		0.674 (0.305, 1.487)	0.3252

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc.sas
Output: t14-06-001-513-ae-cox-soc-ge10.rtf (Date Generated: 26MAY2020:01:02) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.513. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Nervous system disorders										
Total subjects		153	45 (29.4)	NE [14.5, NE)	308	123 (39.9)	NE [15.5, NE)		1.329 (0.944, 1.871)	0.1027
Psychiatric disorders										

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc.sas
Output: t14-06-001-513-ae-cox-soc-ge10.rtf (Date Generated: 26MAY2020:01:02) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.513. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	33 (21.6)	NE [NE, NE)	308	77 (25.0)	NE [NE, NE)		1.064 (0.707, 1.600)	0.7656
Renal and urinary disorders										
Total subjects		153	20 (13.1)	NE [NE, NE)	308	37 (12.0)	NE [NE, NE)		0.837 (0.485, 1.444)	0.5210

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc.sas
Output: t14-06-001-513-ae-cox-soc-ge10.rtf (Date Generated: 26MAY2020:01:02) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.513. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Reproductive system and breast disorders										
Total subjects		153	7 (4.6)	NE [NE, NE)	308	12 (3.9)	NE [NE, NE)		0.713 (0.280, 1.818)	0.4773
Respiratory, thoracic and mediastinal disorders										

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc.sas
Output: t14-06-001-513-ae-cox-soc-ge10.rtf (Date Generated: 26MAY2020:01:02) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.513. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	70 (45.8)	12.9 [6.1, NE)	308	150 (48.7)	13.0 [9.1, NE)		1.041 (0.784, 1.383)	0.7897
Skin and subcutaneous tissue disorders										
Total subjects		153	28 (18.3)	NE [NE, NE)	308	70 (22.7)	NE [20.5, NE)		1.105 (0.712, 1.715)	0.6607

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc.sas
Output: t14-06-001-513-ae-cox-soc-ge10.rtf (Date Generated: 26MAY2020:01:02) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.513. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Vascular disorders										
Total subjects		153	57 (37.3)	16.8 [10.0, NE)	308	124 (40.3)	NE [14.8, NE)		0.949 (0.693, 1.300)	0.7464

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc.sas
Output: t14-06-001-513-ae-cox-soc-ge10.rtf (Date Generated: 26MAY2020:01:02) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.515. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
SOC Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Blood and lymphatic system disorders										
Total subjects		153	54 (35.3)	NE [17.3, NE)	308	114 (37.0)	NE [NE, NE)		1.084 (0.784, 1.500)	0.6336
Cardiac disorders										

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc-sub.sas
Output: t14-06-001-515-ae-cox-soc-grd345-ge5pct.rtf (Date Generated: 26MAY2020:01:00) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.515. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	16 (10.5)	NE [NE, NE)	308	28 (9.1)	NE [NE, NE)		0.722 (0.390, 1.336)	0.2973
Gastrointestinal disorders										
Total subjects		153	5 (3.3)	NE [NE, NE)	308	16 (5.2)	NE [NE, NE)		1.400 (0.512, 3.825)	0.5101

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc-sub.sas
Output: t14-06-001-515-ae-cox-soc-grd345-ge5pct.rtf (Date Generated: 26MAY2020:01:00) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.515. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC <Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
General disorders and administration site conditions										
Total subjects		153	21 (13.7)	NE [NE, NE)	308	47 (15.3)	NE [NE, NE)		0.983 (0.588, 1.646)	0.9498
Infections and infestations										

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc-sub.sas
Output: t14-06-001-515-ae-cox-soc-grd345-ge5pct.rtf (Date Generated: 26MAY2020:01:00) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.515. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	45 (29.4)	NE [18.9, NE)	308	115 (37.3)	NE [17.5, NE)		1.140 (0.808, 1.610)	0.4551
Investigations										
Total subjects		153	8 (5.2)	NE [NE, NE)	308	22 (7.1)	NE [NE, NE)		1.285 (0.572, 2.889)	0.5420

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc-sub.sas
Output: t14-06-001-515-ae-cox-soc-grd345-ge5pct.rtf (Date Generated: 26MAY2020:01:00) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.515. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Metabolism and nutrition disorders										
Total subjects		153	10 (6.5)	NE [NE, NE)	308	33 (10.7)	NE [NE, NE)		1.510 (0.744, 3.066)	0.2504
Musculoskeletal and connective tissue disorders										

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc-sub.sas
Output: t14-06-001-515-ae-cox-soc-grd345-ge5pct.rtf (Date Generated: 26MAY2020:01:00) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.515. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC <Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	8 (5.2)	NE [NE, NE)	308	24 (7.8)	NE [NE, NE)		1.281 (0.575, 2.856)	0.5432
Neoplasms benign, malignant and unspecified (incl cysts and polyps)										
Total subjects		153	8 (5.2)	NE [NE, NE)	308	13 (4.2)	NE [NE, NE)		0.692 (0.287, 1.673)	0.4115

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.515. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
SOC Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Nervous system disorders										
Total subjects		153	4 (2.6)	NE [NE, NE)	308	16 (5.2)	NE [NE, NE)		1.701 (0.568, 5.094)	0.3371
Psychiatric disorders										

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.515. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC <Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	5 (3.3)	NE [NE, NE)	308	20 (6.5)	NE [NE, NE)		1.812 (0.679, 4.831)	0.2282
Renal and urinary disorders										
Total subjects		153	14 (9.2)	NE [NE, NE)	308	14 (4.5)	NE [NE, NE)		0.450 (0.214, 0.944)	0.0301

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.515. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC <Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age – at baseline (years)	<= 75	135	14 (10.4)	NE [NE, NE)	283	11 (3.9)	NE [NE, NE)	0.9896	0.339 (0.154, 0.748)	0.0049
	> 75	18	0 (0.0)	NE [NE, NE)	25	3 (12.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.1839
Sex	Male	91	11 (12.1)	NE [NE, NE)	174	10 (5.7)	NE [NE, NE)	0.7788	0.431 (0.183, 1.015)	0.0474

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.515. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
SOC Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Female	62	3 (4.8)	NE [NE, NE)	134	4 (3.0)	NE [NE, NE)		0.571 (0.128, 2.555)	0.4581
Race	White	122	9 (7.4)	NE [NE, NE)	240	14 (5.8)	NE [NE, NE)	0.9999	0.739 (0.319, 1.708)	0.4769
	Asian	20	3 (15.0)	NE [11.5, NE)	46	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0036

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.515. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC <Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Other or Unknown	11	2 (18.2)	NE [1.1, NE)	22	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0219
Region	North America	12	0 (0.0)	NE [NE, NE)	21	1 (4.8)	NE [NE, NE)	0.1406	>999.999 (<.001, NE)	0.4795
	Europe	102	8 (7.8)	NE [NE, NE)	203	12 (5.9)	NE [NE, NE)		0.703 (0.287, 1.720)	0.4374

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.515. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC <Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Asia Pacific	39	6 (15.4)	NE [NE, NE)	84	1 (1.2)	NE [NE, NE)		0.066 (0.008, 0.548)	0.0008
Baseline ECOG PS	0-1	146	14 (9.6)	NE [NE, NE)	294	12 (4.1)	NE [NE, NE)	0.9888	0.392 (0.181, 0.848)	0.0137
	2	7	0 (0.0)	NE [NE, NE)	13	2 (15.4)	NE [3.3, NE)		>999.999 (<.001, NE)	0.4070

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.515. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC <Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	12 (8.8)	NE [NE, NE)	285	13 (4.6)	NE [NE, NE)	0.7505	0.474 (0.216, 1.039)	0.0564
	No	17	2 (11.8)	NE [9.5, NE)	23	1 (4.3)	NE [NE, NE)		0.272 (0.024, 3.031)	0.2572
Refractory to Bortezomib or Ixazomib	Yes	55	4 (7.3)	NE [NE, NE)	99	5 (5.1)	NE [NE, NE)	0.5236	0.652 (0.175, 2.432)	0.5214

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.515. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC <Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	No	98	10 (10.2)	NE [NE, NE)	209	9 (4.3)	NE [NE, NE)		0.375 (0.152, 0.924)	0.0266
Prior Lenalidomide exposure	Yes	74	7 (9.5)	NE [NE, NE)	122	6 (4.9)	NE [NE, NE)	0.9821	0.459 (0.154, 1.369)	0.1522
	No	79	7 (8.9)	NE [NE, NE)	186	8 (4.3)	NE [NE, NE)		0.451 (0.163, 1.245)	0.1150

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.515. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC <Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Refractory to Lenalidomide	Yes	55	6 (10.9)	NE [NE, NE)	98	5 (5.1)	NE [NE, NE)	0.8185	0.402 (0.122, 1.321)	0.1203
	No	98	8 (8.2)	NE [NE, NE)	210	9 (4.3)	NE [NE, NE)		0.487 (0.188, 1.263)	0.1311
Prior IMiD exposure	Yes	110	11 (10.0)	NE [NE, NE)	205	9 (4.4)	NE [NE, NE)	0.5534	0.393 (0.163, 0.950)	0.0316

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.515. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	No	43	3 (7.0)	NE [NE, NE)	103	5 (4.9)	NE [NE, NE)		0.639 (0.152, 2.680)	0.5371
Refractory to IMiD	Yes	65	8 (12.3)	NE [NE, NE)	129	6 (4.7)	NE [NE, NE)	0.4290	0.324 (0.112, 0.937)	0.0284
	No	88	6 (6.8)	NE [NE, NE)	179	8 (4.5)	NE [NE, NE)		0.612 (0.212, 1.765)	0.3594

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
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Table 14-6.1.515. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC <Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	11 (8.7)	NE [NE, NE)	250	5 (2.0)	NE [NE, NE)	0.0580	0.208 (0.072, 0.599)	0.0013
	3	27	3 (11.1)	NE [NE, NE)	58	9 (15.5)	NE [NE, NE)		1.168 (0.315, 4.327)	0.8158
Prior proteasome inhibitor exposure per IXRS	Yes	138	12 (8.7)	NE [NE, NE)	276	13 (4.7)	NE [NE, NE)	0.4694	0.499 (0.227, 1.094)	0.0765

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
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[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.515. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC <Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	No	15	2 (13.3)	NE [9.5, NE)	32	1 (3.1)	NE [NE, NE)		0.191 (0.017, 2.117)	0.1320
Number of prior lines of therapy per IXRS	1	66	5 (7.6)	NE [NE, NE)	131	4 (3.1)	NE [NE, NE)	0.7059	0.354 (0.095, 1.323)	0.1067
	>= 2	87	9 (10.3)	NE [NE, NE)	177	10 (5.6)	NE [NE, NE)		0.500 (0.203, 1.233)	0.1247

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc-sub.sas
Output: t14-06-001-515-ae-cox-soc-grd345-ge5pct.rtf (Date Generated: 26MAY2020:01:00) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.515. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC <Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Respiratory, thoracic and mediastinal disorders										
Total subjects		153	14 (9.2)	NE [NE, NE)	308	40 (13.0)	NE [NE, NE)		1.318 (0.717, 2.425)	0.3719
Vascular disorders										

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc-sub.sas
Output: t14-06-001-515-ae-cox-soc-grd345-ge5pct.rtf (Date Generated: 26MAY2020:01:00) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.515. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
SOC Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	25 (16.3)	NE [NE, NE)	308	60 (19.5)	NE [NE, NE)		1.041 (0.652, 1.661)	0.8656

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Output: t14-06-001-515-ae-cox-soc-grd345-ge5pct.rtf (Date Generated: 26MAY2020:01:00) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.516. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC and PT
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
SOC PT Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Blood and lymphatic system disorders										
Thrombocytopenia										
Total subjects		153	25 (16.3)	NE [NE, NE)	308	75 (24.4)	NE [NE, NE)		1.557 (0.990, 2.449)	0.0543

Includes PT where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc-pt-sub.sas
Output: t14-06-001-516-ae-cox-soc-pt-grd345-ge5pct.rtf (Date Generated: 26MAY2020:00:57) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.516. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	No. of Events (%)	Median (months) (95%CI)	KdD (N = 308) N	No. of Events (%)	Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Anaemia										
Total subjects		153	22 (14.4)	NE [NE, NE)	308	51 (16.6)	NE [NE, NE)		1.123 (0.681, 1.852)	0.6489
Neutropenia										

Includes PT where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc-pt-sub.sas
Output: t14-06-001-516-ae-cox-soc-pt-grd345-ge5pct.rtf (Date Generated: 26MAY2020:00:57) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.516. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	No. of Events (%)	Median (months) (95%CI)	KdD (N = 308) N	No. of Events (%)	Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	9 (5.9)	NE [NE, NE)	308	26 (8.4)	NE [NE, NE)		1.323 (0.619, 2.827)	0.4684
Lymphopenia										
Total subjects		153	11 (7.2)	NE [NE, NE)	308	21 (6.8)	NE [NE, NE)		0.934 (0.450, 1.939)	0.8527

Includes PT where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc-pt-sub.sas
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Table 14-6.1.516. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	 No. of Events (%)	 Median (months) (95%CI)	KdD (N = 308) N	 No. of Events (%)	 Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	 p-value (2-sided)[b]
General disorders and administration site conditions										
Fatigue										
Total subjects		153	7 (4.6)	NE [NE, NE)	308	24 (7.8)	NE [NE, NE)		1.492 (0.642, 3.467)	0.3484

Includes PT where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc-pt-sub.sas
Output: t14-06-001-516-ae-cox-soc-pt-grd345-ge5pct.rtf (Date Generated: 26MAY2020:00:57) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.516. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	No. of Events (%)	Median (months) (95%CI)	KdD (N = 308) N	No. of Events (%)	Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Infections and infestations										
Pneumonia										
Total subjects		153	13 (8.5)	NE [NE, NE)	308	41 (13.3)	NE [NE, NE)		1.326 (0.710, 2.477)	0.3738

Includes PT where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc-pt-sub.sas
Output: t14-06-001-516-ae-cox-soc-pt-grd345-ge5pct.rtf (Date Generated: 26MAY2020:00:57) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.516. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	No. of Events (%)	Median (months) (95%CI)	KdD (N = 308) N	No. of Events (%)	Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Vascular disorders										
Hypertension										
Total subjects		153	20 (13.1)	NE [NE, NE)	308	54 (17.5)	NE [NE, NE)		1.198 (0.717, 2.002)	0.4904

Includes PT where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc-pt-sub.sas
Output: t14-06-001-516-ae-cox-soc-pt-grd345-ge5pct.rtf (Date Generated: 26MAY2020:00:57) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.517. Cox Regression of Most Frequent Serious Adverse Events by MedDRA SOC
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
SOC Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Blood and lymphatic system disorders										
Total subjects		153	6 (3.9)	NE [NE, NE)	308	16 (5.2)	NE [NE, NE)		1.240 (0.485, 3.170)	0.6534
Cardiac disorders										

Includes SOC where at least 5% subjects with at least one serious adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc-sub.sas
Output: t14-06-001-517-sae-cox-soc-ge5pct.rtf (Date Generated: 26MAY2020:01:00) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.517. Cox Regression of Most Frequent Serious Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	11 (7.2)	NE [NE, NE)	308	28 (9.1)	NE [NE, NE)		1.056 (0.525, 2.125)	0.8773
General disorders and administration site conditions										
Total subjects		153	6 (3.9)	NE [NE, NE)	308	23 (7.5)	NE [NE, NE)		1.729 (0.703, 4.251)	0.2275

Includes SOC where at least 5% subjects with at least one serious adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.517. Cox Regression of Most Frequent Serious Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Infections and infestations										
Total subjects		153	38 (24.8)	NE [NE, NE)	308	91 (29.5)	NE [NE, NE)		1.041 (0.712, 1.521)	0.8345
Renal and urinary disorders										

Includes SOC where at least 5% subjects with at least one serious adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc-sub.sas
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Table 14-6.1.517. Cox Regression of Most Frequent Serious Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	10 (6.5)	NE [NE, NE)	308	8 (2.6)	NE [NE, NE)		0.351 (0.138, 0.890)	0.0211
Age – at baseline (years)	<= 75	135	10 (7.4)	NE [NE, NE)	283	7 (2.5)	NE [NE, NE)	0.9922	0.294 (0.112, 0.774)	0.0084
	> 75	18	0 (0.0)	NE [NE, NE)	25	1 (4.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.4096

Includes SOC where at least 5% subjects with at least one serious adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc-sub.sas
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Table 14-6.1.517. Cox Regression of Most Frequent Serious Adverse Events by MedDRA SOC <Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Sex	Male	91	8 (8.8)	NE [NE, NE)	174	5 (2.9)	NE [NE, NE)	0.4695	0.285 (0.093, 0.874)	0.0193
	Female	62	2 (3.2)	NE [NE, NE)	134	3 (2.2)	NE [NE, NE)		0.631 (0.105, 3.779)	0.6107
Race	White	122	6 (4.9)	NE [NE, NE)	240	8 (3.3)	NE [NE, NE)	0.9999	0.618 (0.214, 1.786)	0.3700

Includes SOC where at least 5% subjects with at least one serious adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc-sub.sas
Output: t14-06-001-517-sae-cox-soc-ge5pct.rtf (Date Generated: 26MAY2020:01:00) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.517. Cox Regression of Most Frequent Serious Adverse Events by MedDRA SOC
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
SOC Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Asian	20	3 (15.0)	NE [12.0, NE)	46	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0038
	Other or Unknown	11	1 (9.1)	NE [1.1, NE)	22	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.1380
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	0.9999	NE (NE, NE)	NE

Includes SOC where at least 5% subjects with at least one serious adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc-sub.sas
Output: t14-06-001-517-sae-cox-soc-ge5pct.rtf (Date Generated: 26MAY2020:01:00) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.517. Cox Regression of Most Frequent Serious Adverse Events by MedDRA SOC <Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	6 (5.9)	NE [NE, NE)	203	8 (3.9)	NE [NE, NE)		0.612 (0.212, 1.765)	0.3588
	Asia Pacific	39	4 (10.3)	NE [NE, NE)	84	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0016
Baseline ECOG PS	0-1	146	10 (6.8)	NE [NE, NE)	294	7 (2.4)	NE [NE, NE)	0.9911	0.312 (0.119, 0.821)	0.0126

Includes SOC where at least 5% subjects with at least one serious adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc-sub.sas
Output: t14-06-001-517-sae-cox-soc-ge5pct.rtf (Date Generated: 26MAY2020:01:00) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.517. Cox Regression of Most Frequent Serious Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	2	7	0 (0.0)	NE [NE, NE)	13	1 (7.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.5186
Prior Bortezomib or Ixazomib exposure	Yes	136	9 (6.6)	NE [NE, NE)	285	7 (2.5)	NE [NE, NE)	0.6809	0.329 (0.122, 0.886)	0.0208
	No	17	1 (5.9)	NE [9.5, NE)	23	1 (4.3)	NE [NE, NE)		0.608 (0.038, 9.849)	0.7235

Includes SOC where at least 5% subjects with at least one serious adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc-sub.sas
Output: t14-06-001-517-sae-cox-soc-ge5pct.rtf (Date Generated: 26MAY2020:01:00) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.517. Cox Regression of Most Frequent Serious Adverse Events by MedDRA SOC <Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Refractory to Bortezomib or Ixazomib	Yes	55	3 (5.5)	NE [NE, NE)	99	3 (3.0)	NE [NE, NE)	0.5830	0.513 (0.103, 2.545)	0.4052
	No	98	7 (7.1)	NE [NE, NE)	209	5 (2.4)	NE [NE, NE)		0.286 (0.091, 0.905)	0.0232
Prior Lenalidomide exposure	Yes	74	4 (5.4)	NE [NE, NE)	122	2 (1.6)	NE [NE, NE)	0.7069	0.267 (0.049, 1.458)	0.1016

Includes SOC where at least 5% subjects with at least one serious adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc-sub.sas
Output: t14-06-001-517-sae-cox-soc-ge5pct.rtf (Date Generated: 26MAY2020:01:00) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.517. Cox Regression of Most Frequent Serious Adverse Events by MedDRA SOC <Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	No	79	6 (7.6)	NE [NE, NE)	186	6 (3.2)	NE [NE, NE)		0.383 (0.123, 1.190)	0.0853
Refractory to Lenalidomide	Yes	55	4 (7.3)	NE [NE, NE)	98	2 (2.0)	NE [NE, NE)	0.5740	0.244 (0.045, 1.336)	0.0780
	No	98	6 (6.1)	NE [NE, NE)	210	6 (2.9)	NE [NE, NE)		0.421 (0.136, 1.307)	0.1229

Includes SOC where at least 5% subjects with at least one serious adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc-sub.sas
Output: t14-06-001-517-sae-cox-soc-ge5pct.rtf (Date Generated: 26MAY2020:01:00) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.517. Cox Regression of Most Frequent Serious Adverse Events by MedDRA SOC <Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	7 (6.4)	NE [NE, NE)	205	5 (2.4)	NE [NE, NE)	0.8974	0.334 (0.106, 1.054)	0.0494
	No	43	3 (7.0)	NE [NE, NE)	103	3 (2.9)	NE [NE, NE)		0.386 (0.078, 1.917)	0.2269
Refractory to IMiD	Yes	65	6 (9.2)	NE [NE, NE)	129	2 (1.6)	NE [NE, NE)	0.1370	0.142 (0.028, 0.704)	0.0054

Includes SOC where at least 5% subjects with at least one serious adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc-sub.sas
Output: t14-06-001-517-sae-cox-soc-ge5pct.rtf (Date Generated: 26MAY2020:01:00) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.517. Cox Regression of Most Frequent Serious Adverse Events by MedDRA SOC <Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	No	88	4 (4.5)	NE [NE, NE)	179	6 (3.4)	NE [NE, NE)		0.673 (0.190, 2.390)	0.5392
ISS stage per IXRS	1 or 2	126	7 (5.6)	NE [NE, NE)	250	5 (2.0)	NE [NE, NE)	0.9836	0.323 (0.102, 1.019)	0.0424
	3	27	3 (11.1)	NE [NE, NE)	58	3 (5.2)	NE [NE, NE)		0.357 (0.071, 1.783)	0.1902

Includes SOC where at least 5% subjects with at least one serious adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc-sub.sas
Output: t14-06-001-517-sae-cox-soc-ge5pct.rtf (Date Generated: 26MAY2020:01:00) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.517. Cox Regression of Most Frequent Serious Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior proteasome inhibitor exposure per IXRS	Yes	138	9 (6.5)	NE [NE, NE)	276	7 (2.5)	NE [NE, NE)	0.9347	0.346 (0.128, 0.930)	0.0277
	No	15	1 (6.7)	NE [9.5, NE)	32	1 (3.1)	NE [NE, NE)		0.411 (0.026, 6.609)	0.5167
Number of prior lines of therapy per IXRS	1	66	4 (6.1)	NE [NE, NE)	131	3 (2.3)	NE [NE, NE)	0.9245	0.310 (0.069, 1.394)	0.1068

Includes SOC where at least 5% subjects with at least one serious adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc-sub.sas
Output: t14-06-001-517-sae-cox-soc-ge5pct.rtf (Date Generated: 26MAY2020:01:00) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.517. Cox Regression of Most Frequent Serious Adverse Events by MedDRA SOC <Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	>= 2	87	6 (6.9)	NE [NE, NE)	177	5 (2.8)	NE [NE, NE)		0.377 (0.115, 1.235)	0.0938
Respiratory, thoracic and mediastinal disorders										
Total subjects		153	15 (9.8)	NE [NE, NE)	308	34 (11.0)	NE [NE, NE)		1.028 (0.560, 1.889)	0.9275

Includes SOC where at least 5% subjects with at least one serious adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc-sub.sas
Output: t14-06-001-517-sae-cox-soc-ge5pct.rtf (Date Generated: 26MAY2020:01:00) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.518. Cox Regression of Most Frequent Serious Adverse Events by MedDRA SOC and PT
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
SOC PT Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Infections and infestations										
Pneumonia										
Total subjects		153	14 (9.2)	NE [NE, NE)	308	38 (12.3)	NE [NE, NE)		1.154 (0.625, 2.133)	0.6460

Includes PT where at least 5% subjects with at least one serious adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-ae-cox-soc-pt-sub.sas
Output: t14-06-001-518-sae-cox-soc-pt-ge5pct.rtf (Date Generated: 26MAY2020:00:57) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.2.501. Logistic Regression of TEAEs Leading to any Study Treatment Discontinuation <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Total subjects		153	38 (24.8)	(18.2, 32.5)	308	69 (22.4)	(17.9, 27.5)		-0.024 (-0.107, 0.058)	0.874 (0.555, 1.376)	0.902 (0.639, 1.274)	0.5602
Age – at baseline (years)	<= 75	135	31 (23.0)	(16.2, 31.0)	283	59 (20.8)	(16.3, 26.1)	0.8026	-0.021 (-0.106, 0.064)	0.884 (0.540, 1.447)	0.908 (0.619, 1.332)	0.6135
	> 75	18	7 (38.9)	(17.3, 64.3)	25	10 (40.0)	(21.1, 61.3)		0.011 (-0.285, 0.307)	1.048 (0.303, 3.621)	1.029 (0.485, 2.182)	1.0000

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-teae-logr-distrt.sas
Output: t14-06-002-501-teae-logr-disany.rtf (Date Generated: 25MAY2020:22:22) Source Data: adam.adsl, adam.adae, adam.adbase

Table 14-6.2.501. Logistic Regression of TEAEs Leading to any Study Treatment Discontinuation <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Sex	Male	91	28 (30.8)	(21.5, 41.3)	174	37 (21.3)	(15.4, 28.1)	0.0466	-0.095 (-0.208, 0.018)	0.608 (0.342, 1.079)	0.691 (0.454, 1.052)	0.0991
	Female	62	10 (16.1)	(8.0, 27.7)	134	32 (23.9)	(16.9, 32.0)		0.078 (-0.039, 0.194)	1.631 (0.744, 3.575)	1.481 (0.778, 2.817)	0.2636

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-teae-logr-distrt.sas
Output: t14-06-002-501-teae-logr-disany.rtf (Date Generated: 25MAY2020:22:22) Source Data: adam.adsl, adam.adae, adam.adbase

Table 14-6.2.501. Logistic Regression of TEAEs Leading to any Study Treatment Discontinuation <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Race	White	122	28 (23.0)	(15.8, 31.4)	240	57 (23.8)	(18.5, 29.6)	0.0725	0.008 (-0.084, 0.100)	1.046 (0.624, 1.752)	1.035 (0.696, 1.538)	0.8964
	Asian	20	4 (20.0)	(5.7, 43.7)	46	9 (19.6)	(9.4, 33.9)		-0.004 (-0.214, 0.205)	0.973 (0.261, 3.627)	0.978 (0.341, 2.808)	1.0000
	Other or Unknown	11	6 (54.5)	(23.4, 83.3)	22	3 (13.6)	(2.9, 34.9)		-0.409 (-0.736, -0.082)	0.132 (0.024, 0.721)	0.250 (0.077, 0.815)	0.0334

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-teae-logr-distrt.sas
Output: t14-06-002-501-teae-logr-disany.rtf (Date Generated: 25MAY2020:22:22) Source Data: adam.adsl, adam.adae, adam.adbase

Table 14-6.2.501. Logistic Regression of TEAEs Leading to any Study Treatment Discontinuation <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Region	North America	12	3 (25.0)	(5.5, 57.2)	21	4 (19.0)	(5.4, 41.9)	0.7293	-0.060 (-0.357, 0.238)	0.706 (0.129, 3.868)	0.762 (0.204, 2.847)	0.6856
	Europe	102	25 (24.5)	(16.5, 34.0)	203	41 (20.2)	(14.9, 26.4)		-0.043 (-0.143, 0.057)	0.780 (0.442, 1.374)	0.824 (0.532, 1.275)	0.4613
	Asia Pacific	39	10 (25.6)	(13.0, 42.1)	84	24 (28.6)	(19.2, 39.5)		0.029 (-0.138, 0.197)	1.160 (0.491, 2.743)	1.114 (0.592, 2.097)	0.8301

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

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Table 14-6.2.501. Logistic Regression of TEAEs Leading to any Study Treatment Discontinuation <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Baseline ECOG PS	0-1	146	37 (25.3)	(18.5, 33.2)	294	64 (21.8)	(17.2, 26.9)	0.2216	-0.036 (-0.121, 0.049)	0.820 (0.515, 1.304)	0.859 (0.604, 1.222)	0.4021
	2	7	1 (14.3)	(0.4, 57.9)	13	5 (38.5)	(13.9, 68.4)		0.242 (-0.129, 0.612)	3.750 (0.342, 41.081)	2.692 (0.387, 18.744)	0.3544

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

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Table 14-6.2.501. Logistic Regression of TEAEs Leading to any Study Treatment Discontinuation <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	32 (23.5)	(16.7, 31.6)	285	61 (21.4)	(16.8, 26.6)	0.8891	-0.021 (-0.107, 0.064)	0.885 (0.544, 1.440)	0.910 (0.625, 1.325)	0.6177
	No	17	6 (35.3)	(14.2, 61.7)	23	8 (34.8)	(16.4, 57.3)		-0.005 (-0.304, 0.294)	0.978 (0.263, 3.637)	0.986 (0.420, 2.312)	1.0000

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

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Table 14-6.2.501. Logistic Regression of TEAEs Leading to any Study Treatment Discontinuation <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Refractory to Bortezomib or Ixazomib	Yes	55	8 (14.5)	(6.5, 26.7)	99	18 (18.2)	(11.1, 27.2)	0.2807	0.036 (-0.084, 0.157)	1.306 (0.527, 3.234)	1.250 (0.582, 2.686)	0.6569
	No	98	30 (30.6)	(21.7, 40.7)	209	51 (24.4)	(18.7, 30.8)		-0.062 (-0.170, 0.046)	0.732 (0.429, 1.247)	0.797 (0.544, 1.168)	0.2680

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

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Table 14-6.2.501. Logistic Regression of TEAEs Leading to any Study Treatment Discontinuation <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	23 (31.1)	(20.8, 42.9)	122	27 (22.1)	(15.1, 30.5)	0.1501	-0.089 (-0.218, 0.039)	0.630 (0.328, 1.210)	0.712 (0.443, 1.145)	0.1790
	No	79	15 (19.0)	(11.0, 29.4)	186	42 (22.6)	(16.8, 29.3)		0.036 (-0.069, 0.141)	1.244 (0.644, 2.405)	1.189 (0.702, 2.015)	0.6244

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

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Table 14-6.2.501. Logistic Regression of TEAEs Leading to any Study Treatment Discontinuation <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Refractory to Lenalidomide	Yes	55	16 (29.1)	(17.6, 42.9)	98	22 (22.4)	(14.6, 32.0)	0.4747	-0.066 (-0.212, 0.079)	0.706 (0.333, 1.495)	0.772 (0.444, 1.341)	0.4360
	No	98	22 (22.4)	(14.6, 32.0)	210	47 (22.4)	(16.9, 28.6)		-0.001 (-0.101, 0.099)	0.996 (0.561, 1.770)	0.997 (0.638, 1.557)	1.0000

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

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Table 14-6.2.501. Logistic Regression of TEAEs Leading to any Study Treatment Discontinuation <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	28 (25.5)	(17.6, 34.6)	205	49 (23.9)	(18.2, 30.3)	0.7781	-0.016 (-0.116, 0.085)	0.920 (0.538, 1.572)	0.939 (0.628, 1.404)	0.7842
	No	43	10 (23.3)	(11.8, 38.6)	103	20 (19.4)	(12.3, 28.4)		-0.038 (-0.186, 0.109)	0.795 (0.337, 1.878)	0.835 (0.427, 1.633)	0.6551

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

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Table 14-6.2.501. Logistic Regression of TEAEs Leading to any Study Treatment Discontinuation <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Refractory to IMiD	Yes	65	17 (26.2)	(16.0, 38.5)	129	33 (25.6)	(18.3, 34.0)	0.6850	-0.006 (-0.136, 0.125)	0.971 (0.492, 1.916)	0.978 (0.591, 1.618)	1.0000
	No	88	21 (23.9)	(15.4, 34.1)	179	36 (20.1)	(14.5, 26.7)		-0.038 (-0.144, 0.069)	0.803 (0.436, 1.480)	0.843 (0.525, 1.354)	0.5261

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-teae-logr-distrt.sas
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Table 14-6.2.501. Logistic Regression of TEAEs Leading to any Study Treatment Discontinuation <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	29 (23.0)	(16.0, 31.4)	250	56 (22.4)	(17.4, 28.1)	0.3740	-0.006 (-0.096, 0.084)	0.966 (0.580, 1.608)	0.973 (0.656, 1.443)	0.8967
	3	27	9 (33.3)	(16.5, 54.0)	58	13 (22.4)	(12.5, 35.3)		-0.109 (-0.317, 0.098)	0.578 (0.210, 1.587)	0.672 (0.328, 1.377)	0.2995

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

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Table 14-6.2.501. Logistic Regression of TEAEs Leading to any Study Treatment Discontinuation <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Prior proteasome inhibitor exposure per IXRS	Yes	138	32 (23.2)	(16.4, 31.1)	276	61 (22.1)	(17.3, 27.5)	0.3751	-0.011 (-0.097, 0.075)	0.940 (0.578, 1.529)	0.953 (0.655, 1.388)	0.8038
	No	15	6 (40.0)	(16.3, 67.7)	32	8 (25.0)	(11.5, 43.4)		-0.150 (-0.440, 0.140)	0.500 (0.135, 1.847)	0.625 (0.264, 1.481)	0.3239

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

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Table 14-6.2.501. Logistic Regression of TEAEs Leading to any Study Treatment Discontinuation <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	18 (27.3)	(17.0, 39.6)	131	32 (24.4)	(17.3, 32.7)	0.9541	-0.028 (-0.159, 0.102)	0.862 (0.440, 1.689)	0.896 (0.545, 1.471)	0.7294
	>= 2	87	20 (23.0)	(14.6, 33.2)	177	37 (20.9)	(15.2, 27.6)		-0.021 (-0.128, 0.086)	0.885 (0.478, 1.641)	0.909 (0.563, 1.469)	0.7509

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-teae-logr-distrt.sas
Output: t14-06-002-501-teae-logr-disany.rtf (Date Generated: 25MAY2020:22:22) Source Data: adam.adsl, adam.adae, adam.adbase

Table 14-6.2.502. Logistic Regression of TEAEs Leading to Discontinuation of Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Total subjects		153	33 (21.6)	(15.3, 28.9)	308	65 (21.1)	(16.7, 26.1)		-0.005 (-0.084, 0.075)	0.973 (0.606, 1.560)	0.978 (0.675, 1.419)	0.9043
Age – at baseline (years)	<= 75	135	26 (19.3)	(13.0, 26.9)	283	55 (19.4)	(15.0, 24.5)	0.9590	0.002 (-0.079, 0.083)	1.011 (0.602, 1.700)	1.009 (0.664, 1.534)	1.0000
	> 75	18	7 (38.9)	(17.3, 64.3)	25	10 (40.0)	(21.1, 61.3)		0.011 (-0.285, 0.307)	1.048 (0.303, 3.621)	1.029 (0.485, 2.182)	1.0000

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-teae-logr-distrt.sas
Output: t14-06-002-502-teae-logr-discfz.rtf (Date Generated: 25MAY2020:22:22) Source Data: adam.adsl, adam.adae, adam.adbase

Table 14-6.2.502. Logistic Regression of TEAEs Leading to Discontinuation of Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Sex	Male	91	25 (27.5)	(18.6, 37.8)	174	34 (19.5)	(13.9, 26.2)	0.0285	-0.079 (-0.188, 0.030)	0.641 (0.354, 1.161)	0.711 (0.454, 1.115)	0.1622
	Female	62	8 (12.9)	(5.7, 23.9)	134	31 (23.1)	(16.3, 31.2)		0.102 (-0.008, 0.212)	2.032 (0.873, 4.725)	1.793 (0.876, 3.671)	0.1237

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-teae-logr-distrt.sas
Output: t14-06-002-502-teae-logr-discfz.rtf (Date Generated: 25MAY2020:22:22) Source Data: adam.adsl, adam.adae, adam.adbase

Table 14-6.2.502. Logistic Regression of TEAEs Leading to Discontinuation of Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Race	White	122	26 (21.3)	(14.4, 29.6)	240	55 (22.9)	(17.8, 28.8)	0.0608	0.016 (-0.074, 0.106)	1.098 (0.648, 1.860)	1.075 (0.712, 1.624)	0.7903
	Asian	20	2 (10.0)	(1.2, 31.7)	46	8 (17.4)	(7.8, 31.4)		0.074 (-0.097, 0.245)	1.895 (0.365, 9.845)	1.739 (0.405, 7.473)	0.7108
	Other or Unknown	11	5 (45.5)	(16.7, 76.6)	22	2 (9.1)	(1.1, 29.2)		-0.364 (-0.681, -0.046)	0.120 (0.018, 0.784)	0.200 (0.046, 0.871)	0.0274

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

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Table 14-6.2.502. Logistic Regression of TEAEs Leading to Discontinuation of Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Region	North America	12	1 (8.3)	(0.2, 38.5)	21	3 (14.3)	(3.0, 36.3)	0.7793	0.060 (-0.157, 0.276)	1.833 (0.169, 19.893)	1.714 (0.200, 14.705)	1.0000
	Europe	102	23 (22.5)	(14.9, 31.9)	203	41 (20.2)	(14.9, 26.4)		-0.024 (-0.122, 0.075)	0.869 (0.488, 1.548)	0.896 (0.570, 1.407)	0.6564
	Asia Pacific	39	9 (23.1)	(11.1, 39.3)	84	21 (25.0)	(16.2, 35.6)		0.019 (-0.142, 0.181)	1.111 (0.455, 2.716)	1.083 (0.548, 2.143)	1.0000

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

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Table 14-6.2.502. Logistic Regression of TEAEs Leading to Discontinuation of Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Baseline ECOG PS	0-1	146	32 (21.9)	(15.5, 29.5)	294	61 (20.7)	(16.3, 25.8)	0.4046	-0.012 (-0.093, 0.070)	0.933 (0.575, 1.512)	0.947 (0.648, 1.383)	0.8046
	2	7	1 (14.3)	(0.4, 57.9)	13	4 (30.8)	(9.1, 61.4)		0.165 (-0.196, 0.526)	2.667 (0.237, 30.066)	2.154 (0.295, 15.746)	0.6126

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

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Table 14-6.2.502. Logistic Regression of TEAEs Leading to Discontinuation of Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	27 (19.9)	(13.5, 27.6)	285	57 (20.0)	(15.5, 25.1)	0.9649	0.001 (-0.080, 0.083)	1.009 (0.605, 1.683)	1.007 (0.669, 1.518)	1.0000
	No	17	6 (35.3)	(14.2, 61.7)	23	8 (34.8)	(16.4, 57.3)		-0.005 (-0.304, 0.294)	0.978 (0.263, 3.637)	0.986 (0.420, 2.312)	1.0000

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

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Table 14-6.2.502. Logistic Regression of TEAEs Leading to Discontinuation of Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Refractory to Bortezomib or Ixazomib	Yes	55	6 (10.9)	(4.1, 22.2)	99	17 (17.2)	(10.3, 26.1)	0.1843	0.063 (-0.048, 0.174)	1.693 (0.626, 4.583)	1.574 (0.659, 3.759)	0.3520
	No	98	27 (27.6)	(19.0, 37.5)	209	48 (23.0)	(17.4, 29.3)		-0.046 (-0.151, 0.059)	0.784 (0.453, 1.356)	0.834 (0.556, 1.251)	0.3953

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

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Table 14-6.2.502. Logistic Regression of TEAEs Leading to Discontinuation of Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	18 (24.3)	(15.1, 35.7)	122	24 (19.7)	(13.0, 27.8)	0.3470	-0.047 (-0.167, 0.074)	0.762 (0.381, 1.525)	0.809 (0.472, 1.386)	0.4754
	No	79	15 (19.0)	(11.0, 29.4)	186	41 (22.0)	(16.3, 28.7)		0.031 (-0.074, 0.136)	1.206 (0.623, 2.335)	1.161 (0.684, 1.972)	0.6251

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

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Table 14-6.2.502. Logistic Regression of TEAEs Leading to Discontinuation of Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Refractory to Lenalidomide	Yes	55	13 (23.6)	(13.2, 37.0)	98	19 (19.4)	(12.1, 28.6)	0.4996	-0.042 (-0.179, 0.094)	0.777 (0.350, 1.727)	0.820 (0.440, 1.530)	0.5411
	No	98	20 (20.4)	(12.9, 29.7)	210	46 (21.9)	(16.5, 28.1)		0.015 (-0.082, 0.112)	1.094 (0.606, 1.974)	1.073 (0.673, 1.712)	0.8816

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

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Table 14-6.2.502. Logistic Regression of TEAEs Leading to Discontinuation of Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	23 (20.9)	(13.7, 29.7)	205	45 (22.0)	(16.5, 28.2)	0.5794	0.010 (-0.084, 0.105)	1.064 (0.604, 1.874)	1.050 (0.672, 1.640)	0.8864
	No	43	10 (23.3)	(11.8, 38.6)	103	20 (19.4)	(12.3, 28.4)		-0.038 (-0.186, 0.109)	0.795 (0.337, 1.878)	0.835 (0.427, 1.633)	0.6551

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

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Table 14-6.2.502. Logistic Regression of TEAEs Leading to Discontinuation of Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Refractory to IMiD	Yes	65	14 (21.5)	(12.3, 33.5)	129	30 (23.3)	(16.3, 31.5)	0.6460	0.017 (-0.107, 0.141)	1.104 (0.538, 2.265)	1.080 (0.617, 1.890)	0.8572
	No	88	19 (21.6)	(13.5, 31.6)	179	35 (19.6)	(14.0, 26.1)		-0.020 (-0.124, 0.083)	0.883 (0.471, 1.654)	0.906 (0.551, 1.488)	0.7465

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

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Table 14-6.2.502. Logistic Regression of TEAEs Leading to Discontinuation of Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	24 (19.0)	(12.6, 27.0)	250	52 (20.8)	(15.9, 26.4)	0.2599	0.018 (-0.068, 0.103)	1.116 (0.651, 1.914)	1.092 (0.708, 1.685)	0.7858
	3	27	9 (33.3)	(16.5, 54.0)	58	13 (22.4)	(12.5, 35.3)		-0.109 (-0.317, 0.098)	0.578 (0.210, 1.587)	0.672 (0.328, 1.377)	0.2995

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

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Table 14-6.2.502. Logistic Regression of TEAEs Leading to Discontinuation of Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Prior proteasome inhibitor exposure per IXRS	Yes	138	28 (20.3)	(13.9, 28.0)	276	57 (20.7)	(16.0, 25.9)	0.5582	0.004 (-0.079, 0.086)	1.023 (0.616, 1.698)	1.018 (0.680, 1.524)	1.0000
	No	15	5 (33.3)	(11.8, 61.6)	32	8 (25.0)	(11.5, 43.4)		-0.083 (-0.365, 0.198)	0.667 (0.175, 2.543)	0.750 (0.295, 1.908)	0.7278

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

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Table 14-6.2.502. Logistic Regression of TEAEs Leading to Discontinuation of Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	16 (24.2)	(14.5, 36.4)	131	30 (22.9)	(16.0, 31.1)	0.8537	-0.013 (-0.139, 0.113)	0.928 (0.463, 1.860)	0.945 (0.556, 1.604)	0.8595
	>= 2	87	17 (19.5)	(11.8, 29.4)	177	35 (19.8)	(14.2, 26.4)		0.002 (-0.100, 0.104)	1.015 (0.532, 1.937)	1.012 (0.602, 1.701)	1.0000

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

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Table 14-6.2.503. Logistic Regression of TEAEs Leading to Discontinuation of Dexamethasone <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Total subjects		153	37 (24.2)	(17.6, 31.8)	308	33 (10.7)	(7.5, 14.7)		-0.135 (-0.211, -0.059)	0.376 (0.224, 0.631)	0.443 (0.289, 0.679)	0.0003
Age – at baseline (years)	<= 75	135	30 (22.2)	(15.5, 30.2)	283	28 (9.9)	(6.7, 14.0)	0.9767	-0.123 (-0.202, -0.045)	0.384 (0.219, 0.675)	0.445 (0.278, 0.714)	0.0013
	> 75	18	7 (38.9)	(17.3, 64.3)	25	5 (20.0)	(6.8, 40.7)		-0.189 (-0.463, 0.086)	0.393 (0.101, 1.536)	0.514 (0.194, 1.363)	0.3014

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-teae-logr-distrt.sas
Output: t14-06-002-503-teae-logr-disdex.rtf (Date Generated: 25MAY2020:22:22) Source Data: adam.adsl, adam.adae, adam.adbase

Table 14-6.2.503. Logistic Regression of TEAEs Leading to Discontinuation of Dexamethasone <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Sex	Male	91	27 (29.7)	(20.5, 40.2)	174	21 (12.1)	(7.6, 17.9)	0.4220	-0.176 (-0.282, -0.070)	0.325 (0.171, 0.617)	0.407 (0.244, 0.678)	0.0007
	Female	62	10 (16.1)	(8.0, 27.7)	134	12 (9.0)	(4.7, 15.1)		-0.072 (-0.175, 0.032)	0.511 (0.208, 1.258)	0.555 (0.254, 1.215)	0.1503

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

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		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Race	White	122	28 (23.0)	(15.8, 31.4)	240	26 (10.8)	(7.2, 15.5)	0.2073	-0.121 (-0.206, -0.037)	0.408 (0.227, 0.733)	0.472 (0.290, 0.768)	0.0030
	Asian	20	3 (15.0)	(3.2, 37.9)	46	5 (10.9)	(3.6, 23.6)		-0.041 (-0.222, 0.139)	0.691 (0.148, 3.220)	0.725 (0.191, 2.744)	0.6901
	Other or Unknown	11	6 (54.5)	(23.4, 83.3)	22	2 (9.1)	(1.1, 29.2)		-0.455 (-0.772, -0.137)	0.083 (0.013, 0.544)	0.167 (0.040, 0.695)	0.0082

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

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Table 14-6.2.503. Logistic Regression of TEAEs Leading to Discontinuation of Dexamethasone <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Region	North America	12	3 (25.0)	(5.5, 57.2)	21	1 (4.8)	(0.1, 23.8)	0.5198	-0.202 (-0.464, 0.059)	0.150 (0.014, 1.647)	0.190 (0.022, 1.634)	0.1250
	Europe	102	25 (24.5)	(16.5, 34.0)	203	20 (9.9)	(6.1, 14.8)		-0.147 (-0.240, -0.054)	0.337 (0.177, 0.642)	0.402 (0.235, 0.688)	0.0010
	Asia Pacific	39	9 (23.1)	(11.1, 39.3)	84	12 (14.3)	(7.6, 23.6)		-0.088 (-0.240, 0.064)	0.556 (0.212, 1.456)	0.619 (0.285, 1.346)	0.3027

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

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		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Baseline ECOG PS	0-1	146	36 (24.7)	(17.9, 32.5)	294	28 (9.5)	(6.4, 13.5)	0.0498	-0.151 (-0.229, -0.074)	0.322 (0.187, 0.553)	0.386 (0.246, 0.607)	<.0001
	2	7	1 (14.3)	(0.4, 57.9)	13	5 (38.5)	(13.9, 68.4)		0.242 (-0.129, 0.612)	3.750 (0.342, 41.081)	2.692 (0.387, 18.744)	0.3544

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

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Table 14-6.2.503. Logistic Regression of TEAEs Leading to Discontinuation of Dexamethasone <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	31 (22.8)	(16.0, 30.8)	285	30 (10.5)	(7.2, 14.7)	0.6620	-0.123 (-0.202, -0.044)	0.398 (0.230, 0.691)	0.462 (0.292, 0.730)	0.0017
	No	17	6 (35.3)	(14.2, 61.7)	23	3 (13.0)	(2.8, 33.6)		-0.223 (-0.488, 0.043)	0.275 (0.057, 1.321)	0.370 (0.107, 1.272)	0.1338

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

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		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Refractory to Bortezomib or Ixazomib	Yes	55	7 (12.7)	(5.3, 24.5)	99	12 (12.1)	(6.4, 20.2)	0.0279	-0.006 (-0.115, 0.103)	0.946 (0.349, 2.562)	0.952 (0.398, 2.278)	1.0000
	No	98	30 (30.6)	(21.7, 40.7)	209	21 (10.0)	(6.3, 14.9)		-0.206 (-0.306, -0.106)	0.253 (0.136, 0.472)	0.328 (0.198, 0.543)	<.0001

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

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		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	22 (29.7)	(19.7, 41.5)	122	15 (12.3)	(7.0, 19.5)	0.5462	-0.174 (-0.294, -0.055)	0.331 (0.159, 0.691)	0.414 (0.229, 0.746)	0.0043
	No	79	15 (19.0)	(11.0, 29.4)	186	18 (9.7)	(5.8, 14.9)		-0.093 (-0.189, 0.003)	0.457 (0.217, 0.961)	0.510 (0.271, 0.960)	0.0428

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

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		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Refractory to Lenalidomide	Yes	55	15 (27.3)	(16.1, 41.0)	98	14 (14.3)	(8.0, 22.8)	0.6338	-0.130 (-0.266, 0.007)	0.444 (0.196, 1.009)	0.524 (0.274, 1.003)	0.0559
	No	98	22 (22.4)	(14.6, 32.0)	210	19 (9.0)	(5.5, 13.8)		-0.134 (-0.225, -0.043)	0.344 (0.176, 0.671)	0.403 (0.229, 0.709)	0.0020

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	27 (24.5)	(16.8, 33.7)	205	24 (11.7)	(7.6, 16.9)	0.6661	-0.128 (-0.220, -0.037)	0.408 (0.222, 0.749)	0.477 (0.290, 0.785)	0.0040
	No	43	10 (23.3)	(11.8, 38.6)	103	9 (8.7)	(4.1, 15.9)		-0.145 (-0.283, -0.008)	0.316 (0.118, 0.845)	0.376 (0.164, 0.859)	0.0285

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Refractory to IMiD	Yes	65	16 (24.6)	(14.8, 36.9)	129	18 (14.0)	(8.5, 21.2)	0.3174	-0.107 (-0.227, 0.014)	0.497 (0.234, 1.054)	0.567 (0.310, 1.037)	0.0740
	No	88	21 (23.9)	(15.4, 34.1)	179	15 (8.4)	(4.8, 13.4)		-0.155 (-0.253, -0.057)	0.292 (0.142, 0.600)	0.351 (0.191, 0.647)	0.0010

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	29 (23.0)	(16.0, 31.4)	250	25 (10.0)	(6.6, 14.4)	0.9724	-0.130 (-0.213, -0.048)	0.372 (0.207, 0.667)	0.434 (0.266, 0.709)	0.0010
	3	27	8 (29.6)	(13.8, 50.2)	58	8 (13.8)	(6.1, 25.4)		-0.158 (-0.352, 0.035)	0.380 (0.125, 1.157)	0.466 (0.196, 1.108)	0.1337

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
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		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Prior proteasome inhibitor exposure per IXRS	Yes	138	31 (22.5)	(15.8, 30.3)	276	29 (10.5)	(7.2, 14.7)	0.4271	-0.120 (-0.198, -0.041)	0.405 (0.233, 0.706)	0.468 (0.294, 0.743)	0.0017
	No	15	6 (40.0)	(16.3, 67.7)	32	4 (12.5)	(3.5, 29.0)		-0.275 (-0.548, -0.002)	0.214 (0.049, 0.933)	0.313 (0.103, 0.945)	0.0540

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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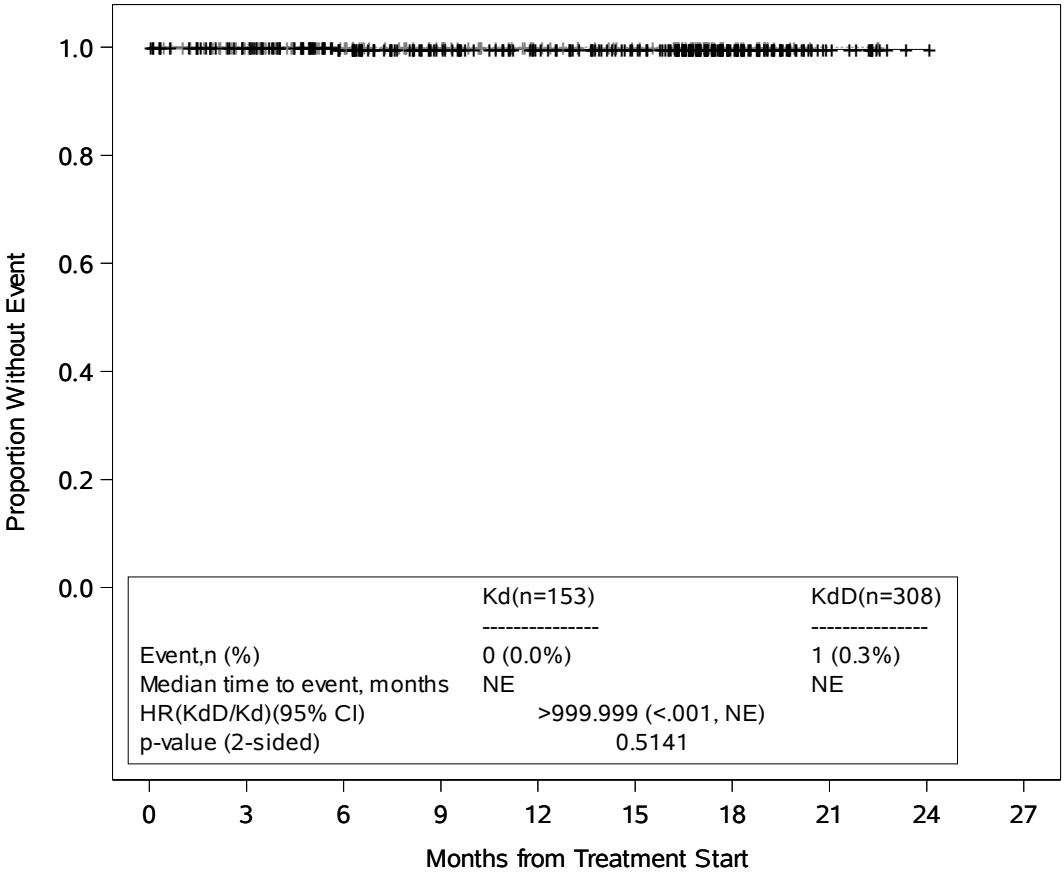
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	18 (27.3)	(17.0, 39.6)	131	12 (9.2)	(4.8, 15.5)	0.2785	-0.181 (-0.299, -0.063)	0.269 (0.120, 0.601)	0.336 (0.172, 0.655)	0.0014
	>= 2	87	19 (21.8)	(13.7, 32.0)	177	21 (11.9)	(7.5, 17.6)		-0.100 (-0.199, -0.001)	0.482 (0.243, 0.954)	0.543 (0.309, 0.956)	0.0440

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020/tables/t-teae-logr-distrt.sas
Output: t14-06-002-503-teae-logr-disdex.rtf (Date Generated: 25MAY2020:22:22) Source Data: adam.adsl, adam.adae, adam.adbase

Figure 14-6.1.541. KM Curves of Adverse Events of Interest for Carfilzomib - Hepatitis B Reactivation (AMQ)
<Safety Population>

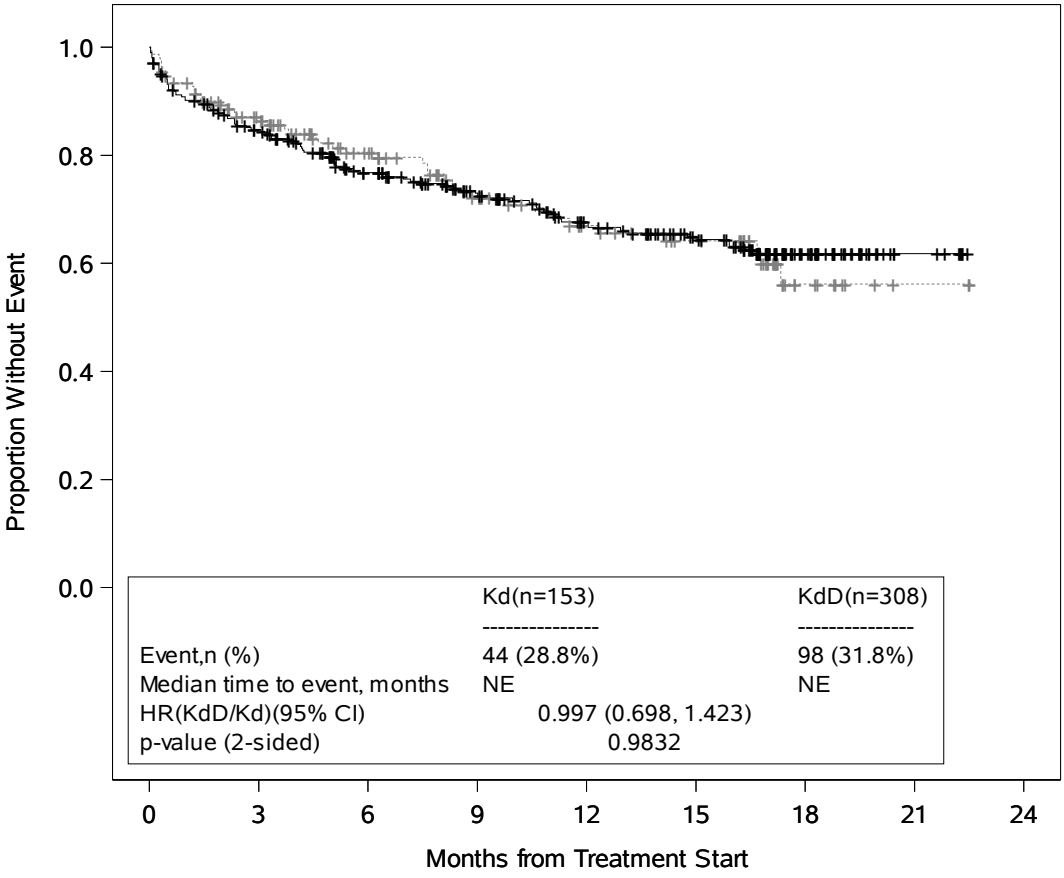


Number of Subjects at Risk:

Kd	153	132	108	88	68	58	18	2	0	
KdD	308	289	252	214	193	171	75	14	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-cfz.sas.
Output: f14-06-001-541-ae-cox-hepb-cfz.rtf (Date Generated: 27MAY20:22:31:11).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.542. KM Curves of Adverse Events of Interest for Carfilzomib - Hypertension (SMQ) - Narrow
<Safety Population>

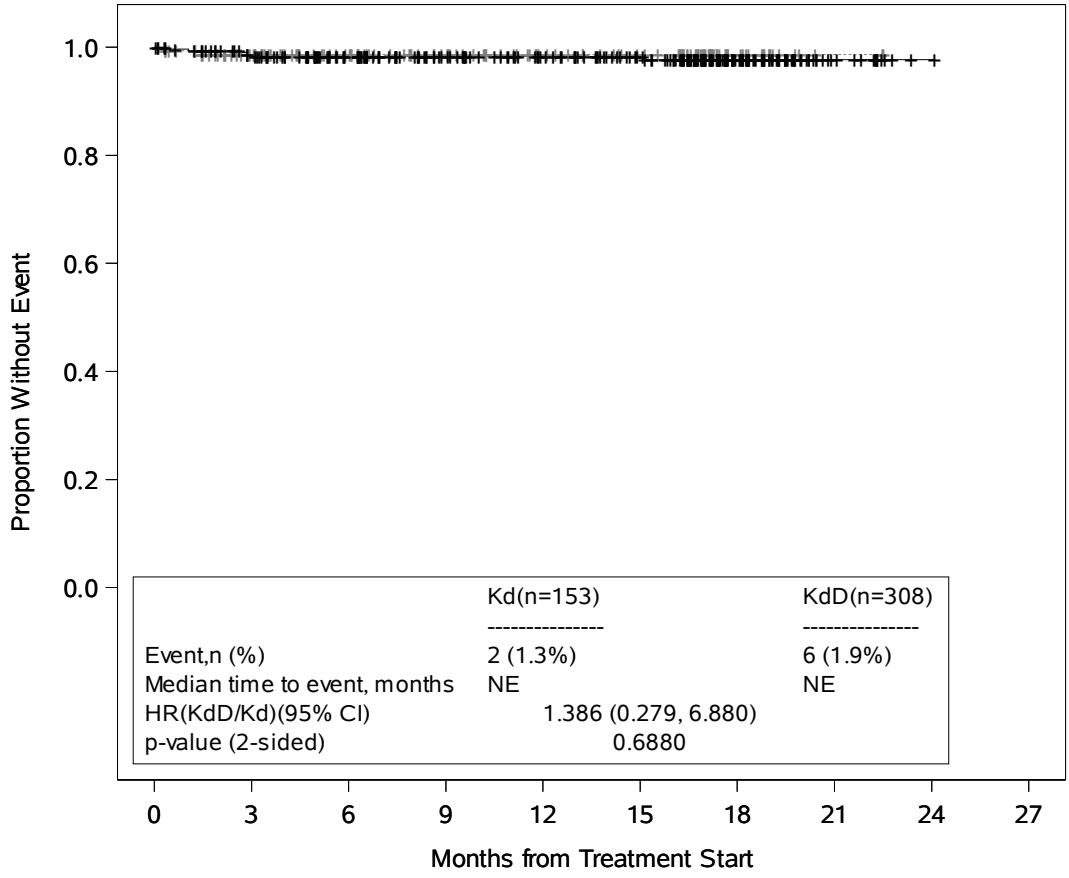


Number of Subjects at Risk:

Kd	153	116	87	63	48	40	10	2	0
KdD	308	247	198	161	130	108	45	8	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-cfz.sas.
Output: f14-06-001-542-ae-cox-hyper-cfz.rtf (Date Generated: 27MAY20:22:31:13).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.545. KM Curves of Adverse Events of Interest for Carfilzomib - Interstitial Lung Disease (SMQ) - Narrow
<Safety Population>

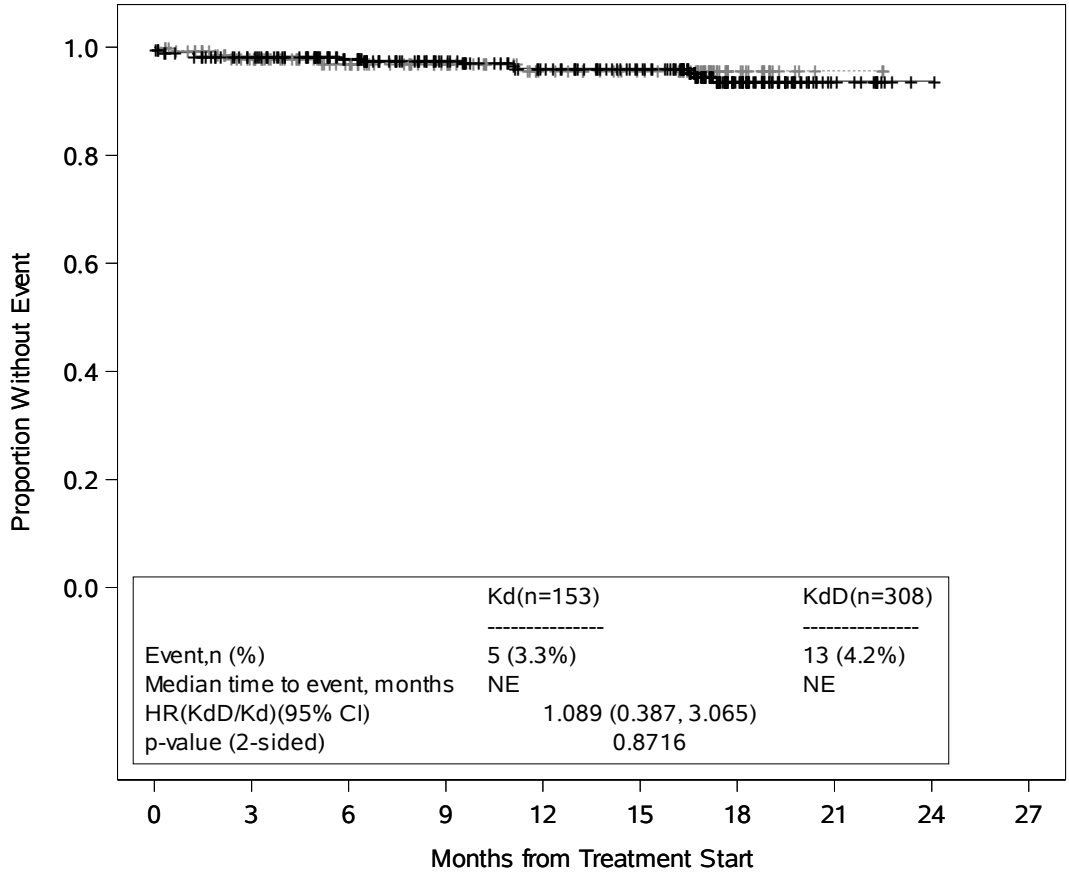


Number of Subjects at Risk:

Kd	153	131	107	87	68	58	18	2	0	
KdD	308	284	249	212	191	169	74	14	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-cfz.sas.
Output: f14-06-001-545-ae-cox-lung-cfz.rtf (Date Generated: 27MAY20:22:31:19).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.546. KM Curves of Adverse Events of Interest for Carfilzomib - Ischaemic Heart Disease (SMQ) - Narrow
<Safety Population>

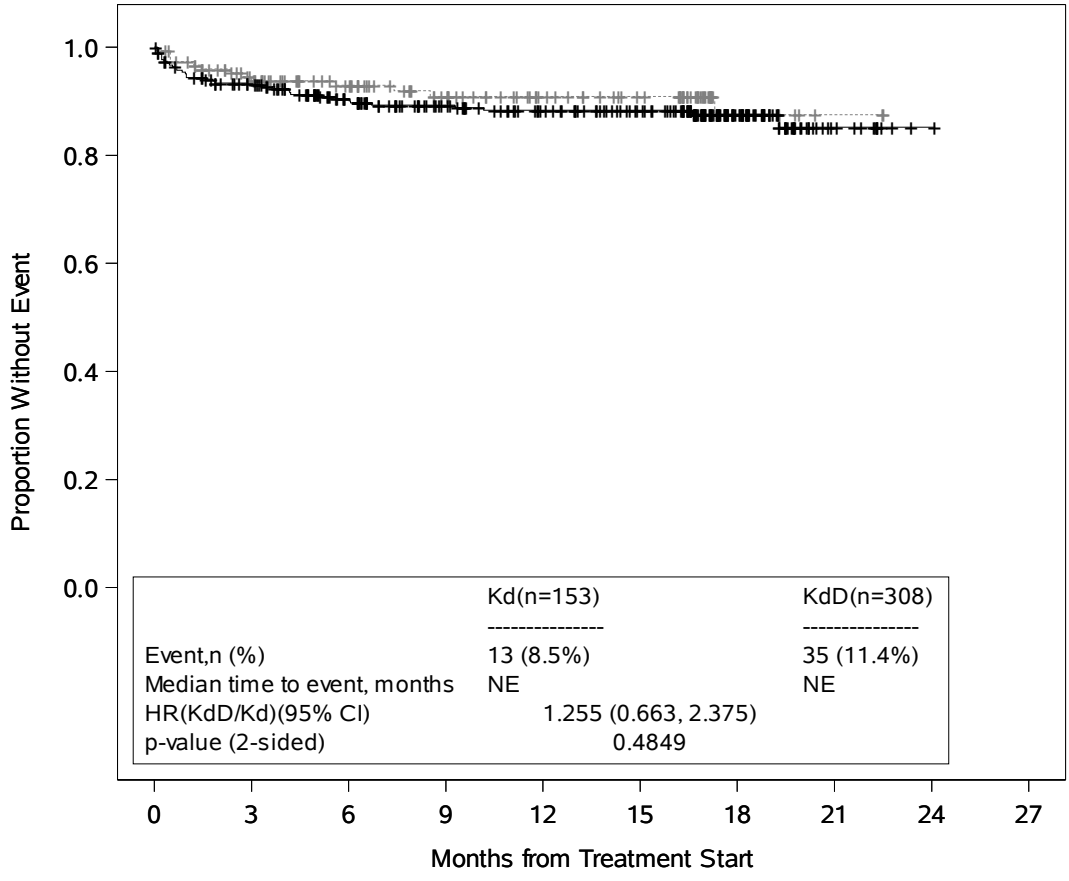


Number of Subjects at Risk:

Kd	153	129	104	85	65	56	18	2	0	
KdD	308	284	248	209	186	165	72	14	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-cfz.sas.
Output: f14-06-001-546-ae-cox-heart-cfz.rtf (Date Generated: 27MAY20:22:31:21).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.547. KM Curves of Adverse Events of Interest for Carfilzomib - Liver Related Investigations, Signs and Symptoms (SMQ) - Narrow <Safety Population>

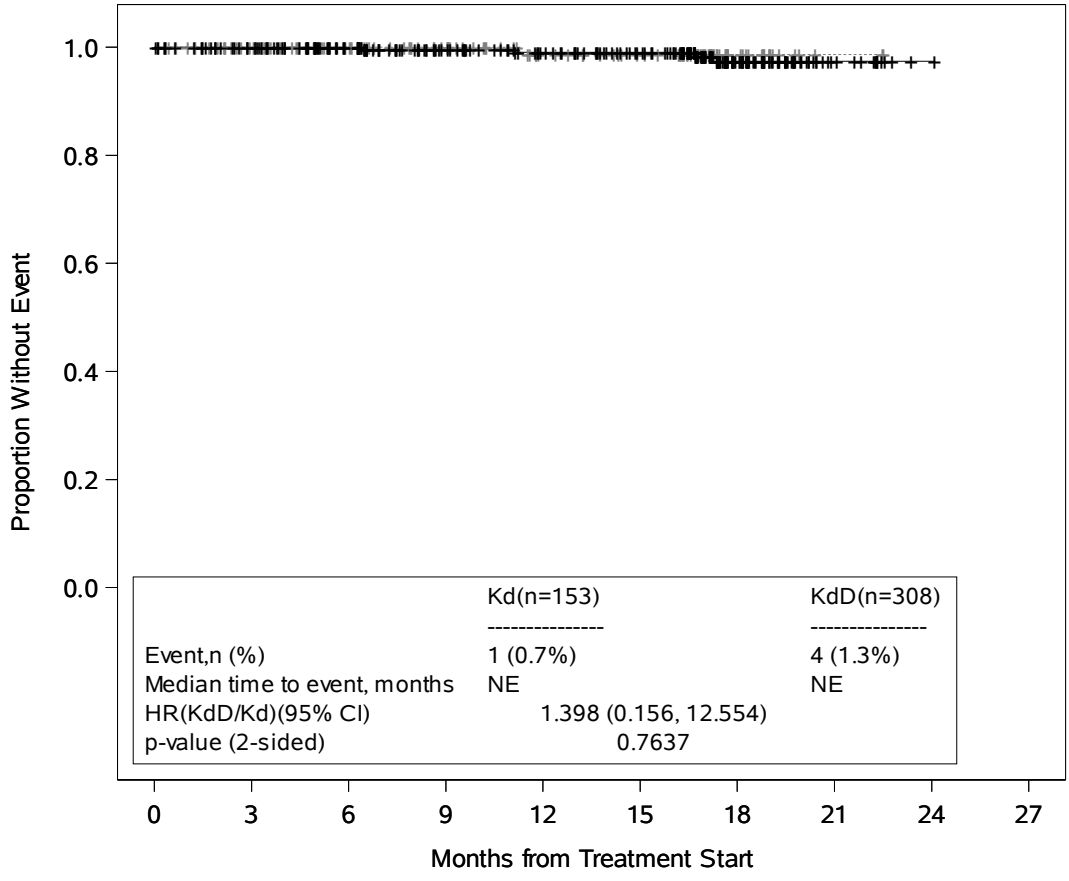


Number of Subjects at Risk:

Kd	153	126	104	83	66	56	16	2	0	
KdD	308	269	228	194	172	151	69	12	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-cfz.sas.
Output: f14-06-001-547-ae-cox-liverel-cfz.rtf (Date Generated: 27MAY20:22:31:23).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.548. KM Curves of Adverse Events of Interest for Carfilzomib - Myocardial Infarction (SMQ) - Narrow
<Safety Population>

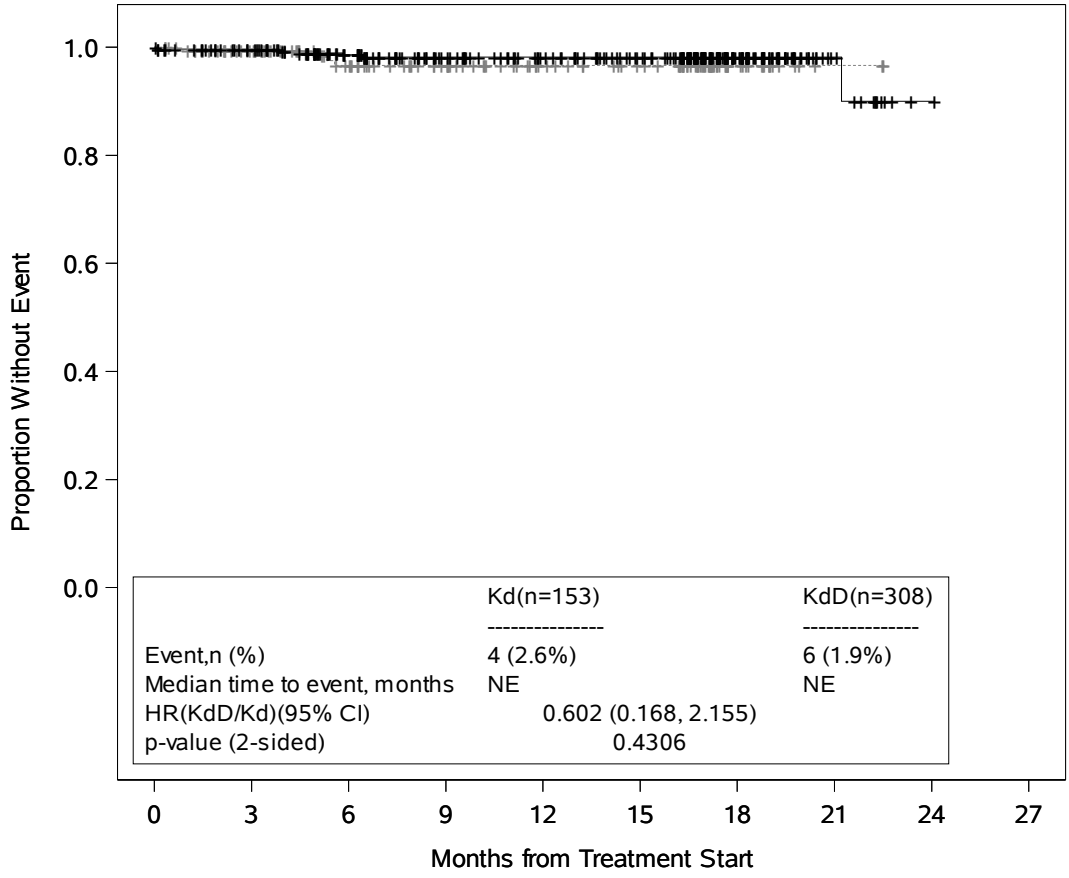


Number of Subjects at Risk:

Kd	153	132	108	88	67	58	18	2	0	
KdD	308	289	253	214	192	170	74	14	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-cfz.sas.
Output: f14-06-001-548-ae-cox-myo-cfz.rtf (Date Generated: 27MAY20:22:31:25).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.550. KM Curves of Adverse Events of Interest for Carfilzomib - Pulmonary Hypertension (SMQ) - Narrow
<Safety Population>

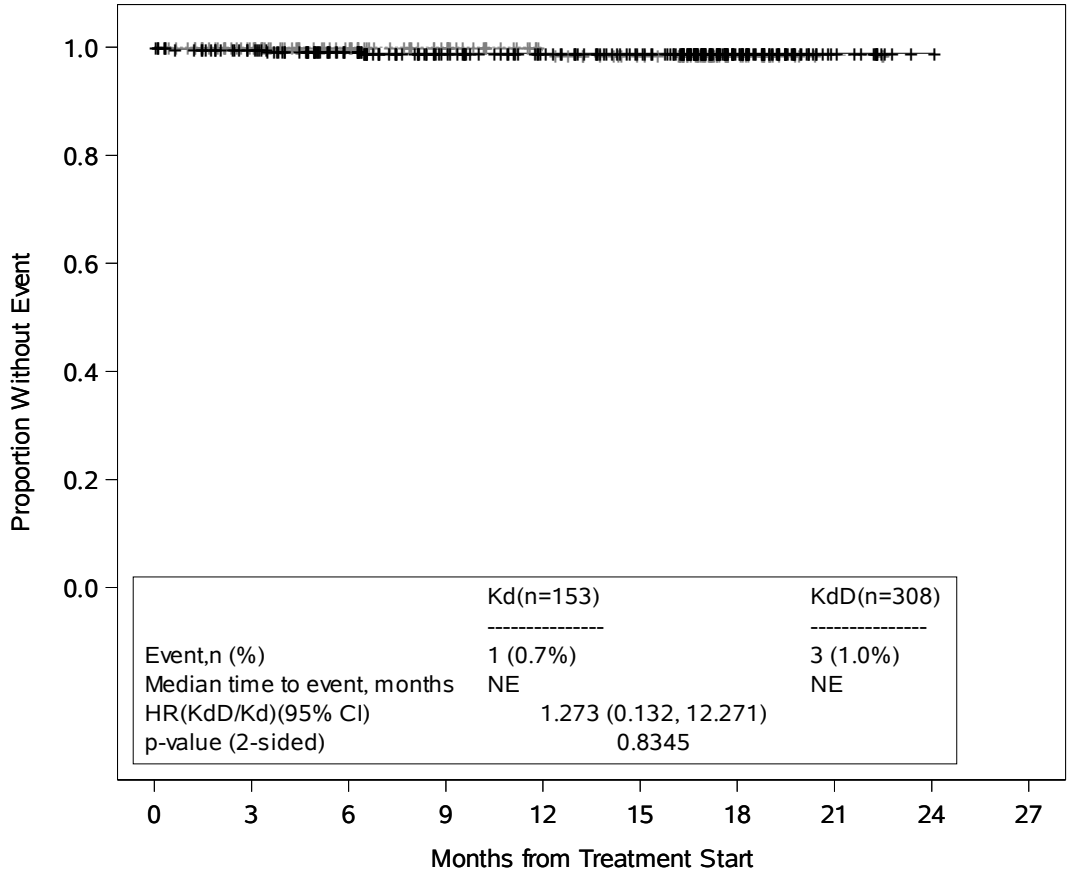


Number of Subjects at Risk:

Kd	153	131	105	85	66	57	17	2	0	
KdD	308	288	250	210	189	167	73	13	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-cfz.sas.
Output: f14-06-001-550-ae-cox-pulhyp-cfz.rtf (Date Generated: 27MAY20:22:31:29).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.551. KM Curves of Adverse Events of Interest for Carfilzomib - Respiratory Failure (SMQ) - Narrow
<Safety Population>

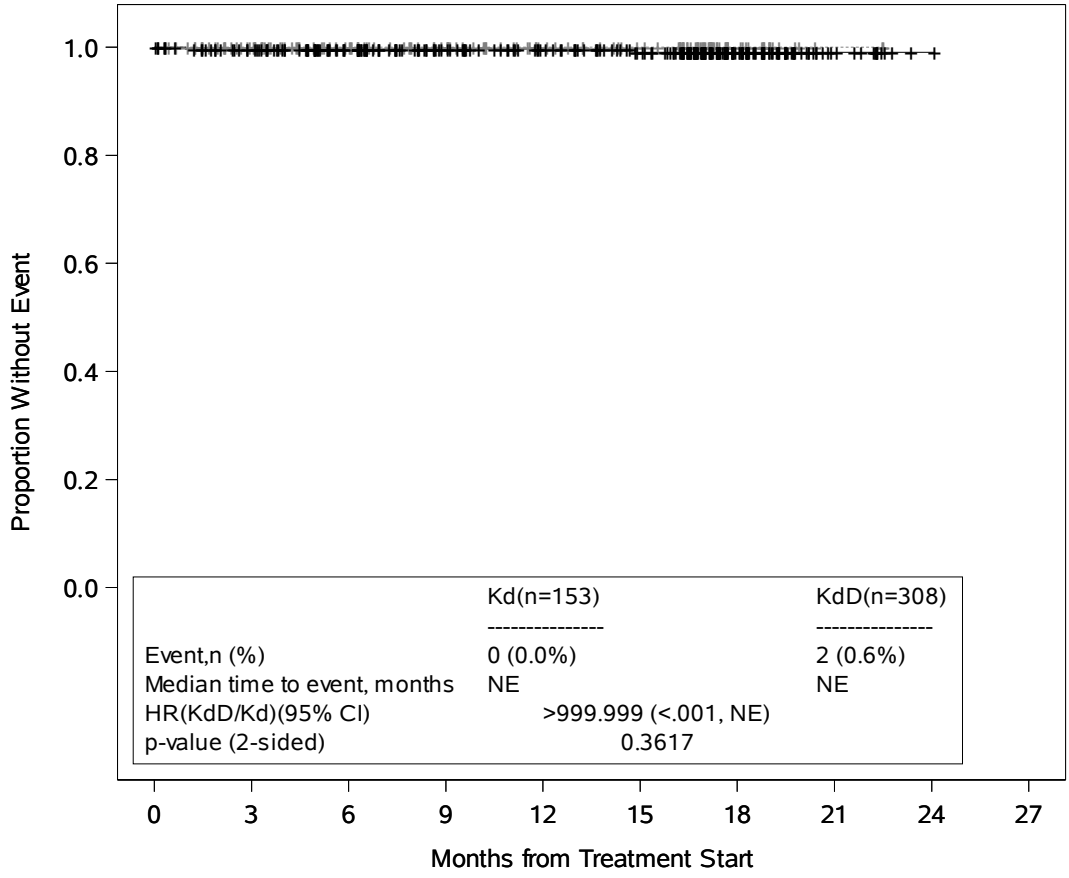


Number of Subjects at Risk:

Kd	153	132	108	88	67	58	18	2	0	
KdD	308	288	252	214	193	171	75	14	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-cfz.sas.
Output: f14-06-001-551-ae-cox-resfai-cfz.rtf (Date Generated: 27MAY20:22:31:31).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.554. KM Curves of Adverse Events of Interest for Carfilzomib - Torsade de Pointes/QT Prolongation (SMQ) - Narrow <Safety Population>

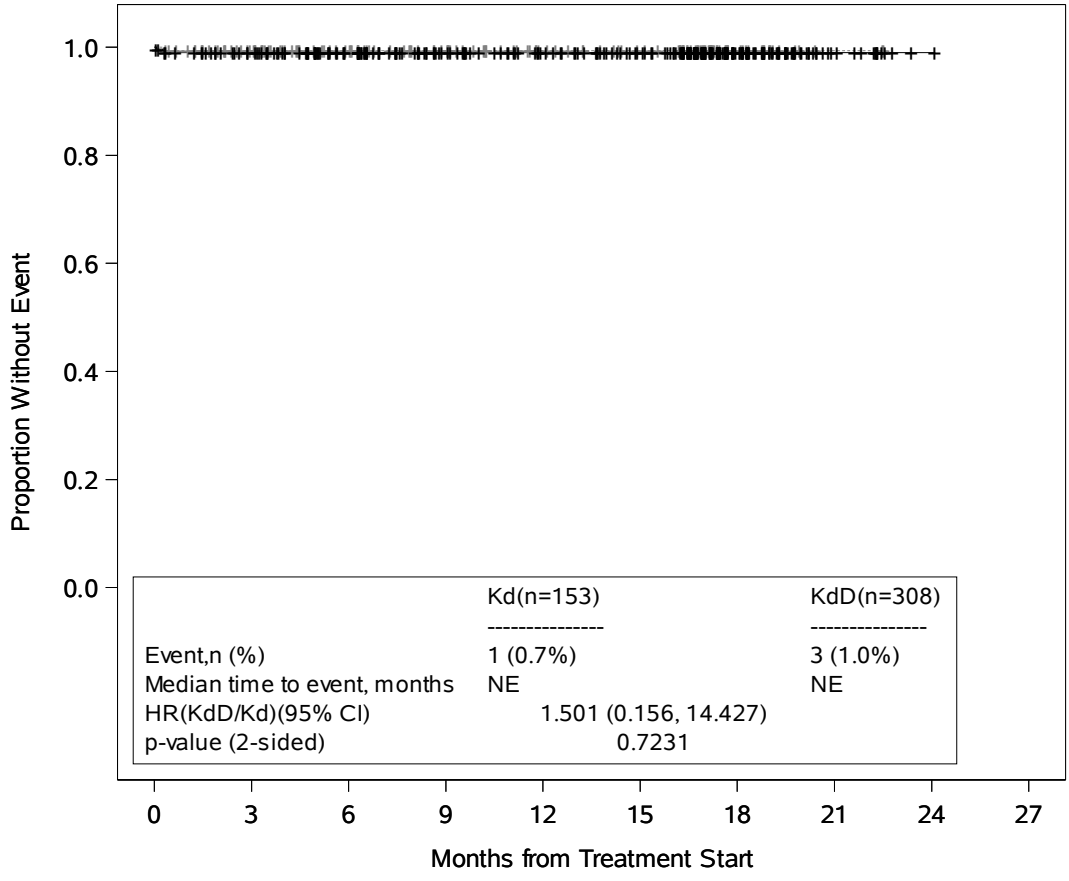


Number of Subjects at Risk:

Kd	153	132	108	88	68	58	18	2	0	
KdD	308	288	252	213	192	170	74	14	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-cfz.sas.
Output: f14-06-001-554-ae-cox-tors-cfz.rtf (Date Generated: 27MAY20:22:31:37).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.555. KM Curves of Adverse Events of Interest for Carfilzomib - Tumour Lysis Syndrome (SMQ) - Narrow
<Safety Population>

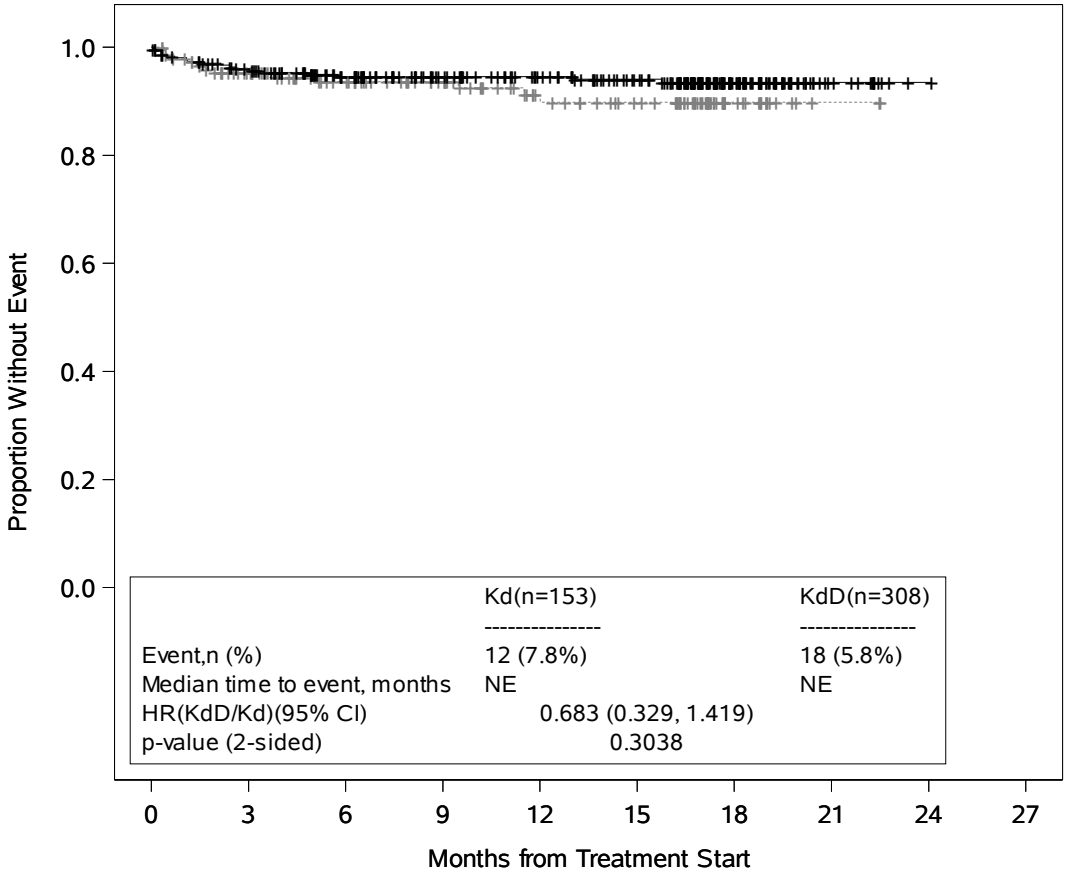


Number of Subjects at Risk:

Kd	153	132	108	88	68	58	18	2	0	
KdD	308	287	252	213	192	171	75	14	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-cfz.sas.
Output: f14-06-001-555-ae-cox-tumour-cfz.rtf (Date Generated: 27MAY20:22:31:39).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.530. KM Curves of Adverse Events of Interest for Carfilzomib - Acute Renal Failure (SMQ) - Narrow
<Safety Population>

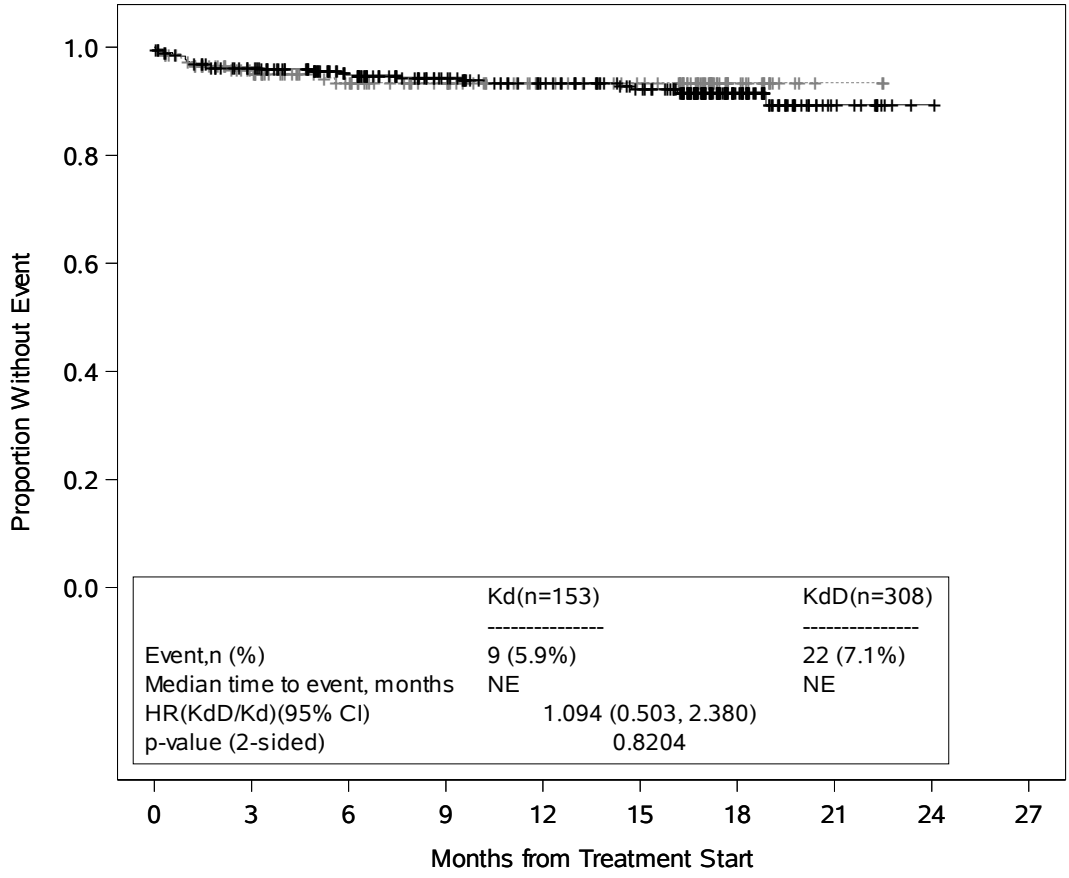


Number of Subjects at Risk:

Kd	153	128	106	87	66	56	17	2	0	
KdD	308	280	245	209	188	165	73	14	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-cfz.sas.
Output: f14-06-001-530-ae-cox-acute-cfz.rtf (Date Generated: 27MAY20:22:30:47).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.531. KM Curves of Adverse Events of Interest for Carfilzomib - Cardiac Arrhythmias (SMQ) - Narrow
<Safety Population>

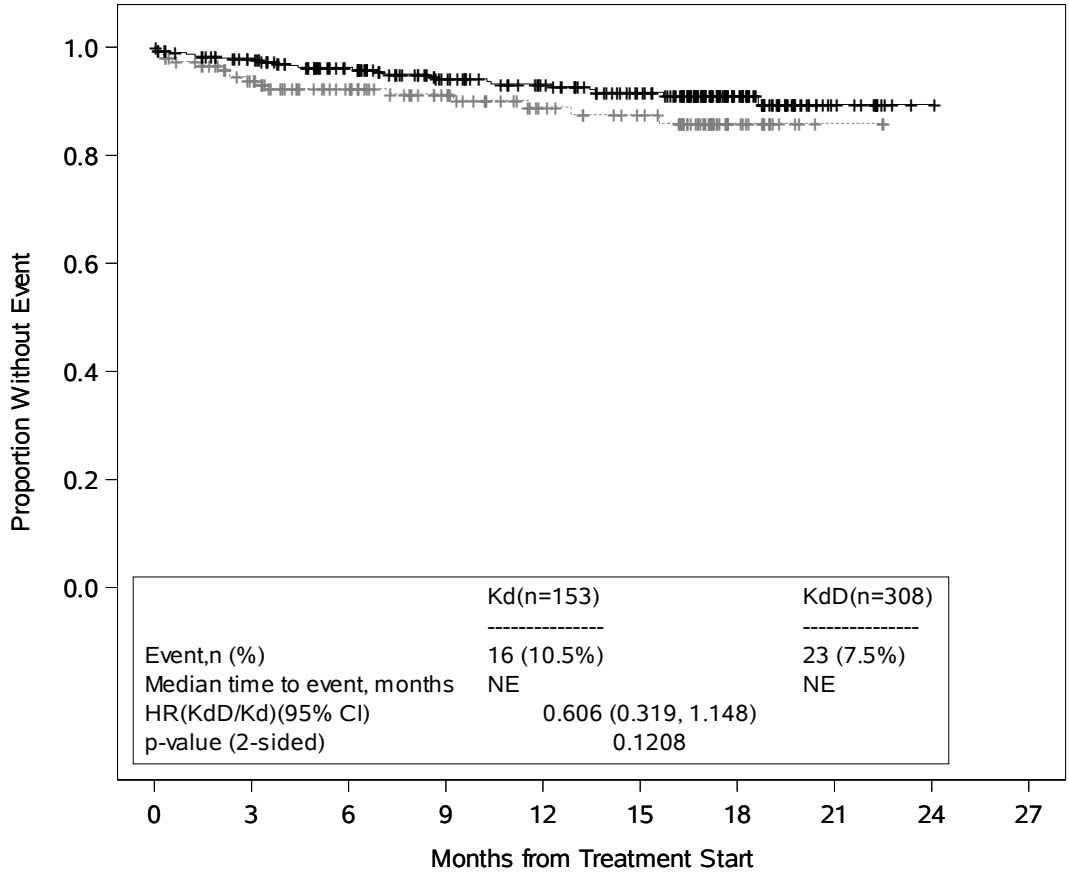


Number of Subjects at Risk:

Kd	153	126	103	86	66	58	18	2	0	
KdD	308	278	240	202	182	162	68	13	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-cfz.sas.
Output: f14-06-001-531-ae-cox-cardarr-cfz.rtf (Date Generated: 27MAY20:22:30:50).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.532. KM Curves of Adverse Events of Interest for Carfilzomib - Cardiac Failure (SMQ) - Narrow
<Safety Population>

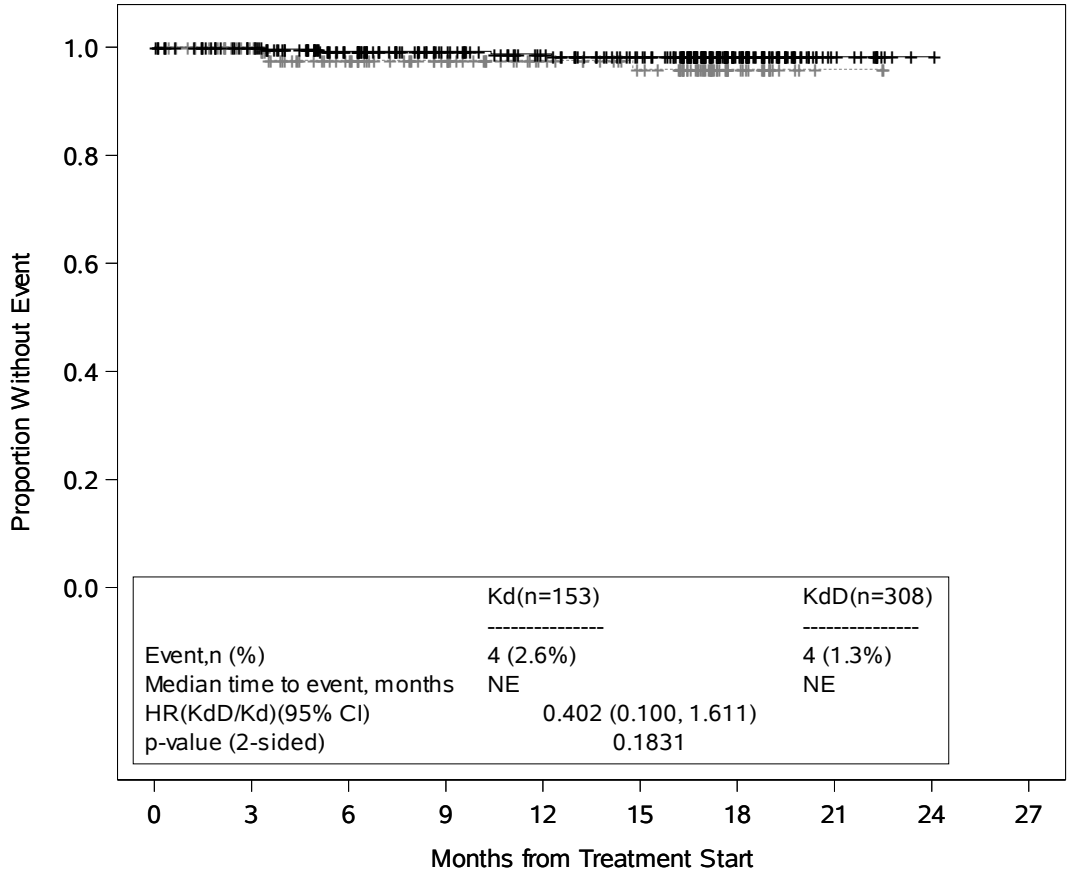


Number of Subjects at Risk:

Kd	153	128	105	84	65	57	18	2	0	
KdD	308	285	248	207	188	165	72	14	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-cfz.sas.
Output: f14-06-001-532-ae-cox-cardfai-cfz.rtf (Date Generated: 27MAY20:22:30:52).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.533. KM Curves of Adverse Events of Interest for Carfilzomib - Cardiomyopathy (SMQ) - Narrow
<Safety Population>

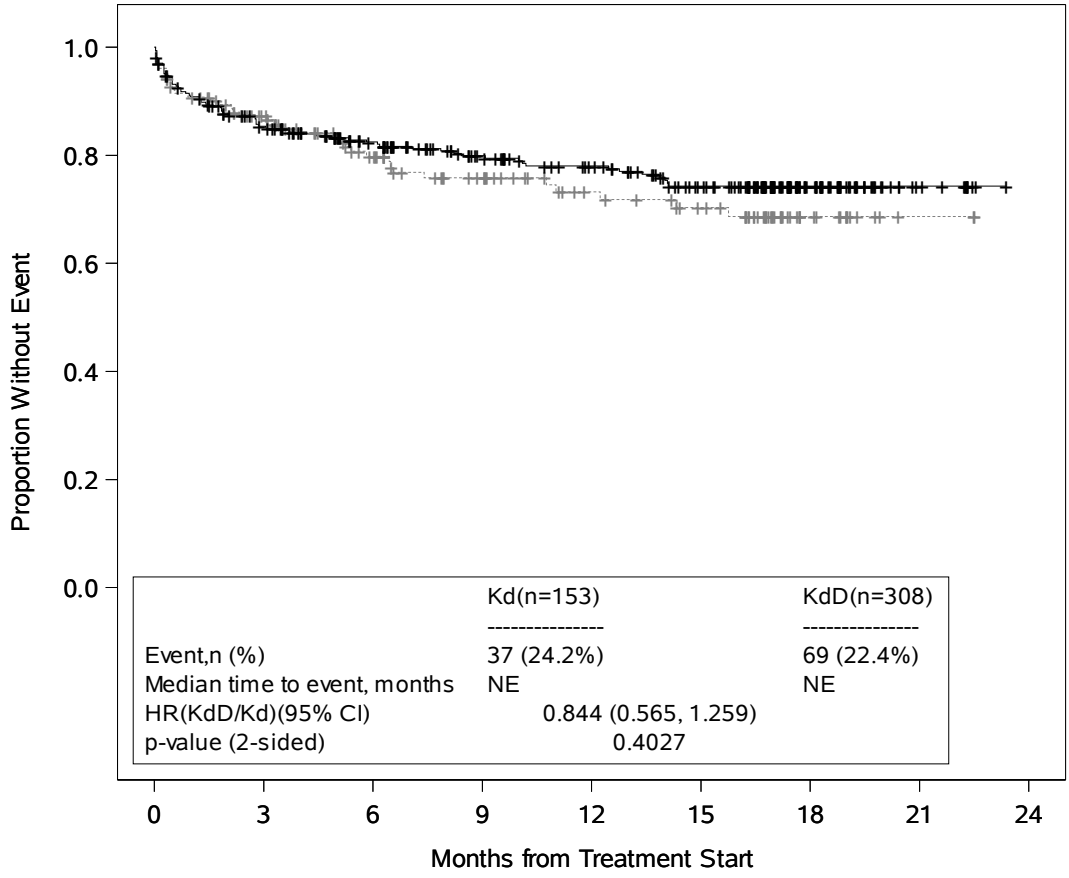


Number of Subjects at Risk:

Kd	153	132	106	86	67	57	18	2	0	
KdD	308	289	251	212	191	170	75	14	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-cfz.sas.
Output: f14-06-001-533-ae-cox-cardio-cfz.rtf (Date Generated: 27MAY20:22:30:54).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.534. KM Curves of Adverse Events of Interest for Carfilzomib - Dyspnoeas (HLT)
<Safety Population>

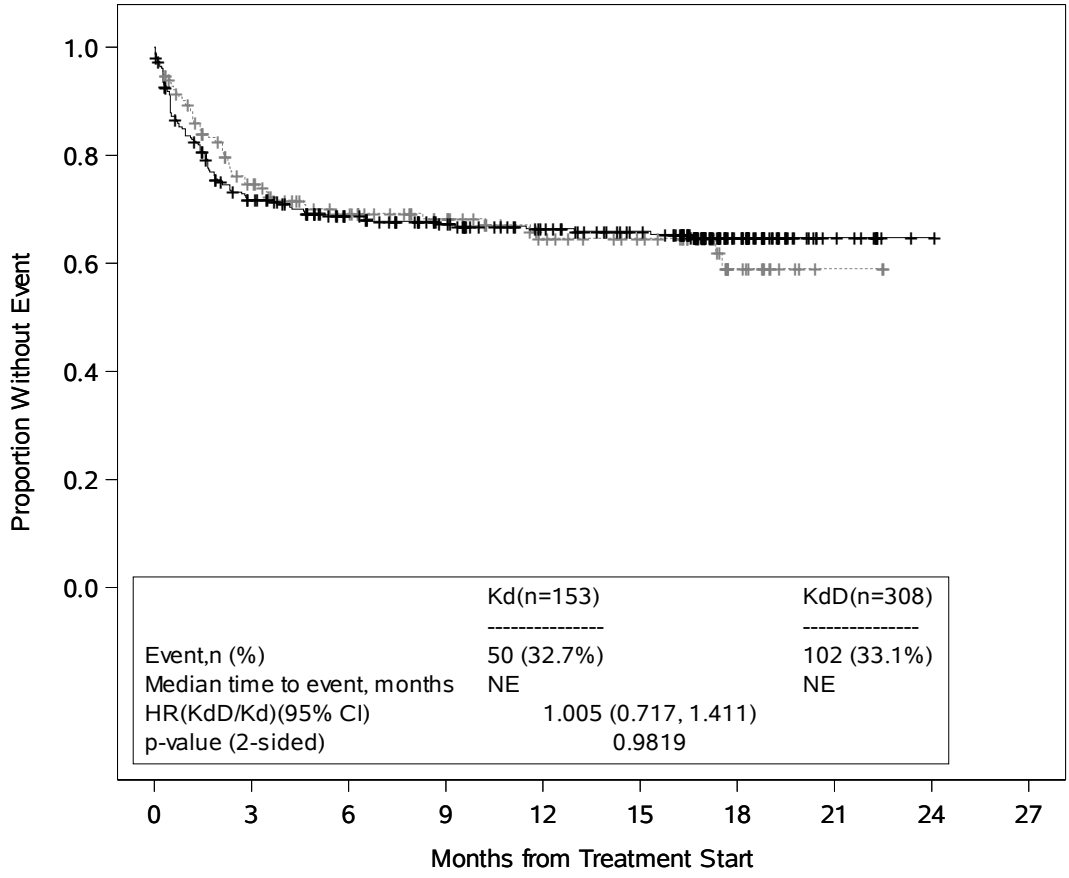


Number of Subjects at Risk:

Kd	153	118	88	68	52	44	14	2	0
KdD	308	246	210	175	156	129	53	11	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-cfz.sas.
Output: f14-06-001-534-ae-cox-dysp-cfz.rtf (Date Generated: 27MAY20:22:30:56).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.536. KM Curves of Adverse Events of Interest for Carfilzomib - Haematopoietic Erythropenia (SMQ) - Broad
<Safety Population>

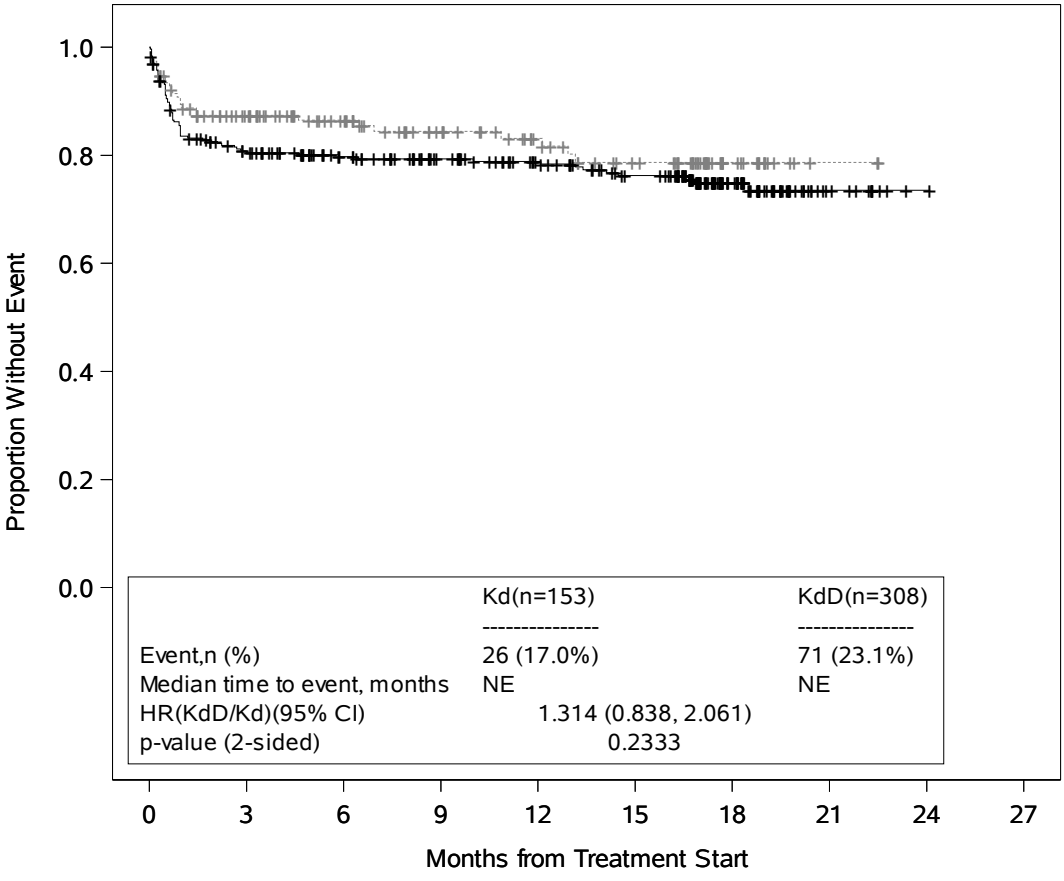


Number of Subjects at Risk:

Kd	153	102	83	67	50	43	14	2	0	
KdD	308	208	178	156	136	121	55	12	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-cfz.sas.
Output: f14-06-001-536-ae-cox-haeery-cfz.rtf (Date Generated: 27MAY20:22:31:01).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.537. KM Curves of Adverse Events of Interest for Carfilzomib - Haematopoietic Leukopenia (SMQ) - Narrow
<Safety Population>

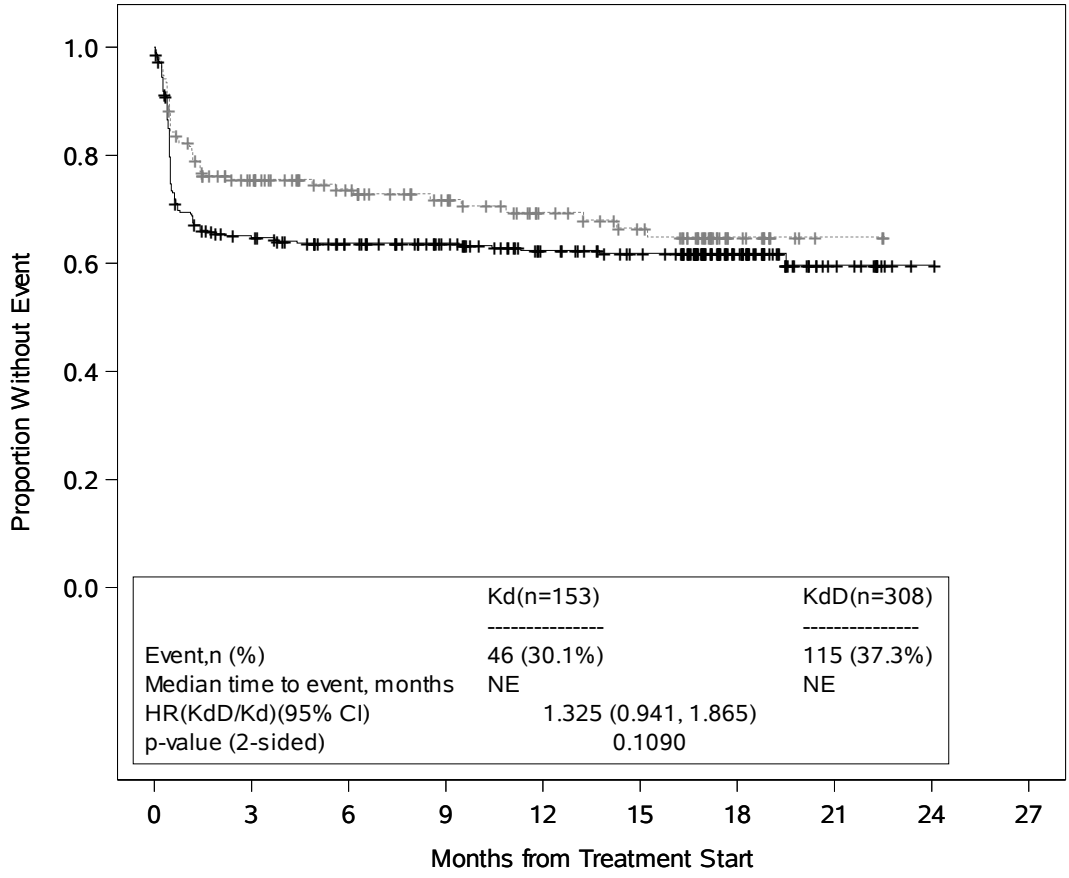


Number of Subjects at Risk:

Kd	153	116	93	72	58	46	17	2	0	
KdD	308	233	203	179	159	139	66	12	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-cfz.sas.
Output: f14-06-001-537-ae-cox-haeleu-cfz.rtf (Date Generated: 27MAY20:22:31:03).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.538. KM Curves of Adverse Events of Interest for Carfilzomib - Haematopoietic Thrombocytopenia (SMQ) - Narrow <Safety Population>

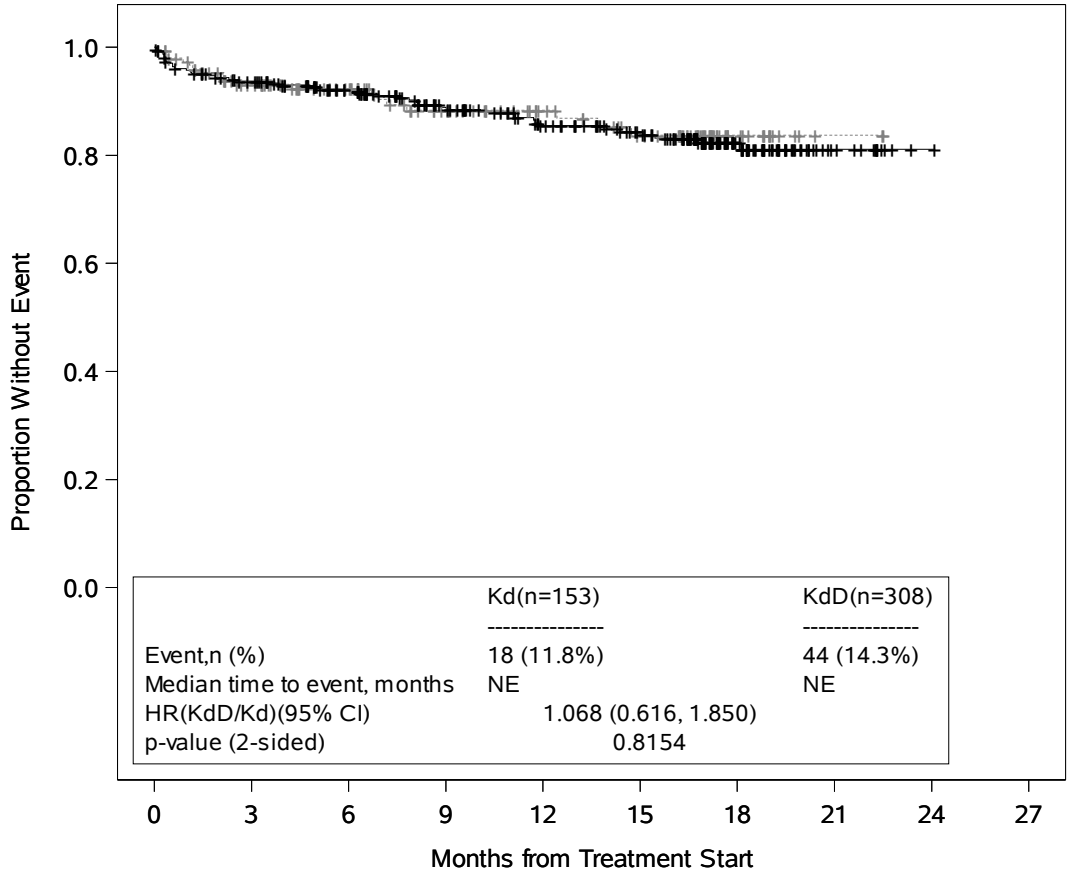


Number of Subjects at Risk:

Kd	153	101	81	66	51	42	14	2	0	
KdD	308	189	170	151	129	117	58	14	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-cfz.sas.
Output: f14-06-001-538-ae-cox-haethr-cfz.rtf (Date Generated: 27MAY20:22:31:05).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.539. KM Curves of Adverse Events of Interest for Carfilzomib - Haemorrhage Terms (Excl Laboratory Terms) (SMQ) - Narrow <Safety Population>

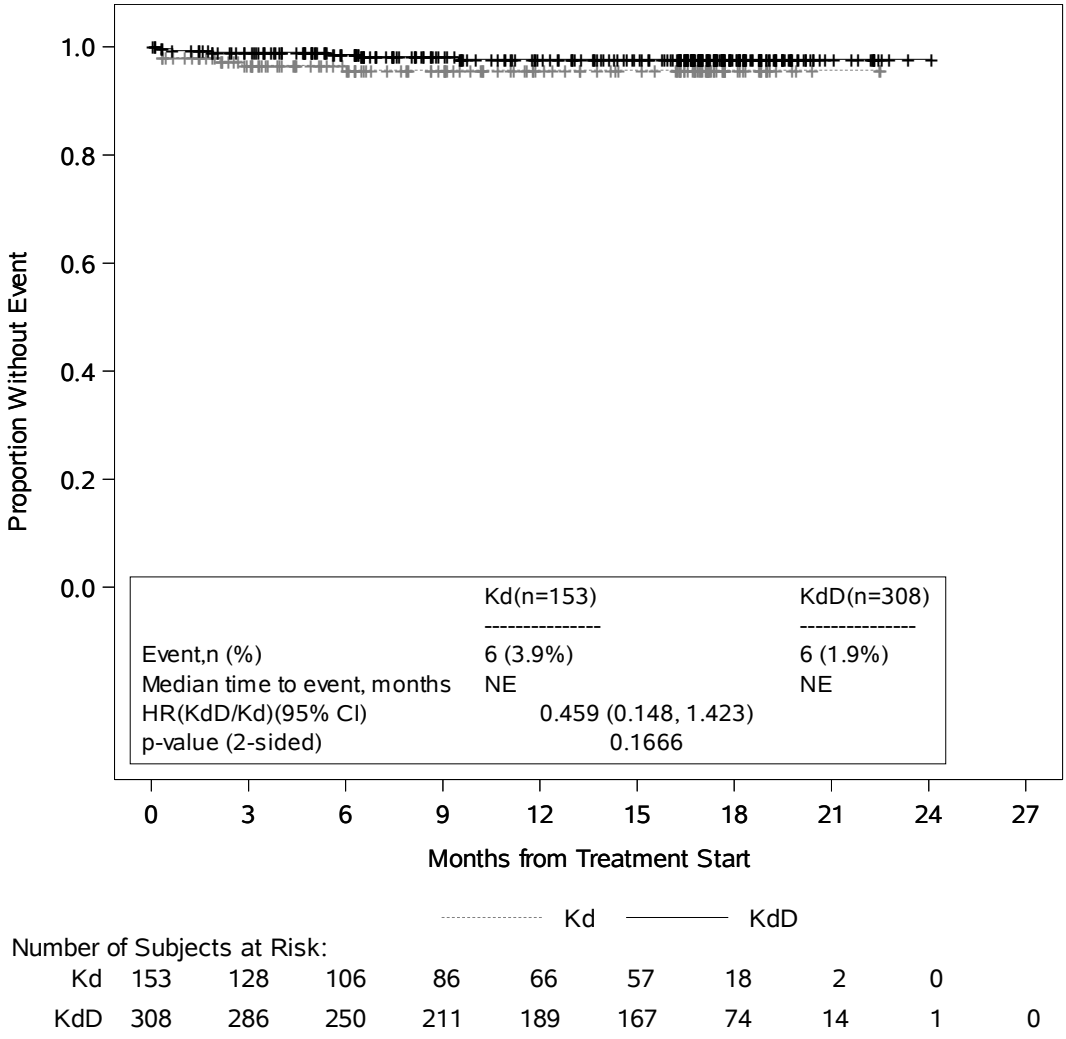


Number of Subjects at Risk:

Kd	153	124	103	80	62	51	16	2	0	
KdD	308	273	239	196	168	146	64	14	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-cfz.sas.
Output: f14-06-001-539-ae-cox-haeterm-cfz.rtf (Date Generated: 27MAY20:22:31:07).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.540. KM Curves of Adverse Events of Interest for Carfilzomib - Hepatic Failure, Fibrosis and Cirrhosis and Other Liver Damage-related Conditions (SMQ) - Narrow
<Safety Population>

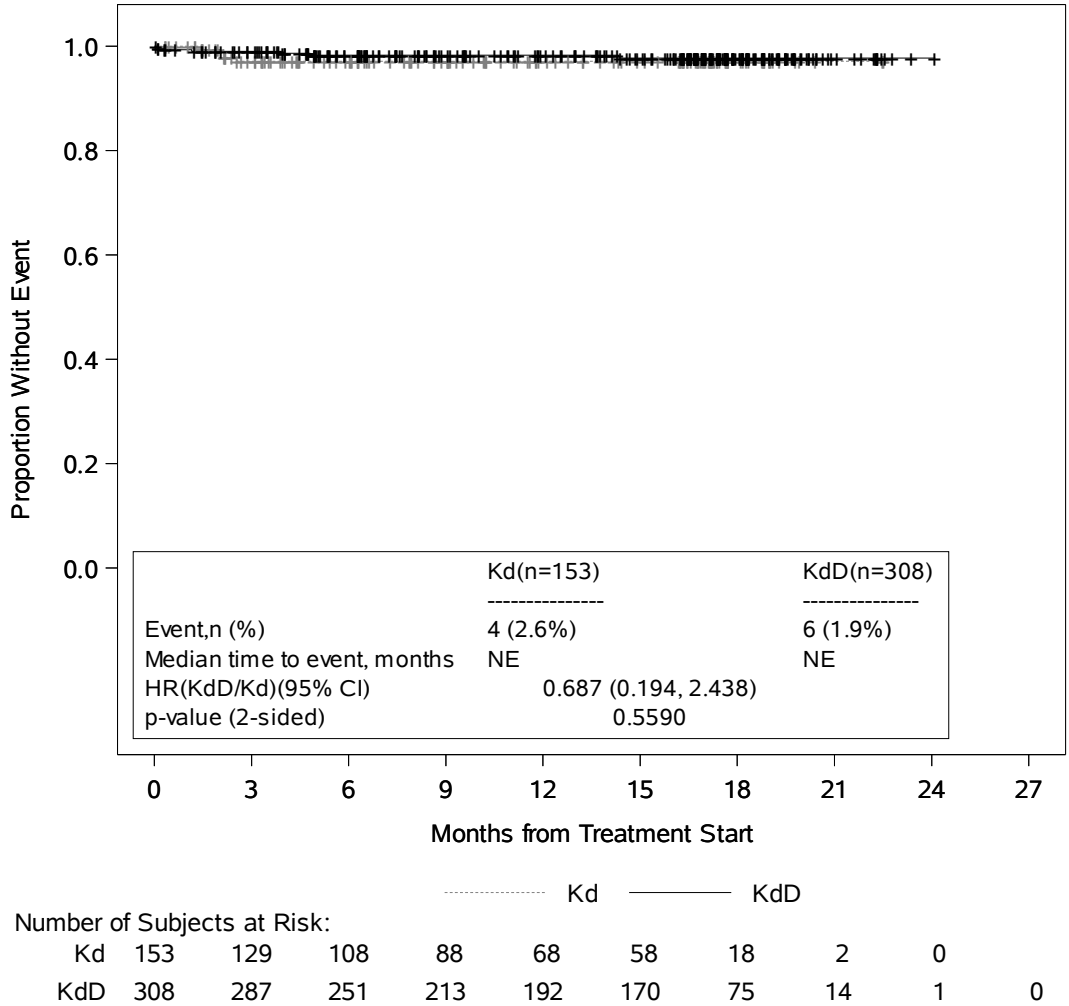


Number of Subjects at Risk:

Kd	153	128	106	86	66	57	18	2	0	
KdD	308	286	250	211	189	167	74	14	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-cfz.sas.
Output: f14-06-001-540-ae-cox-hepliver-cfz.rtf (Date Generated: 27MAY20:22:31:09).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.565. KM Curves of Grade ≥3 Adverse Events of Interest for Carfilzomib - Haemorrhage Terms (Excl Laboratory Terms) (SMQ) - Narrow <Safety Population>

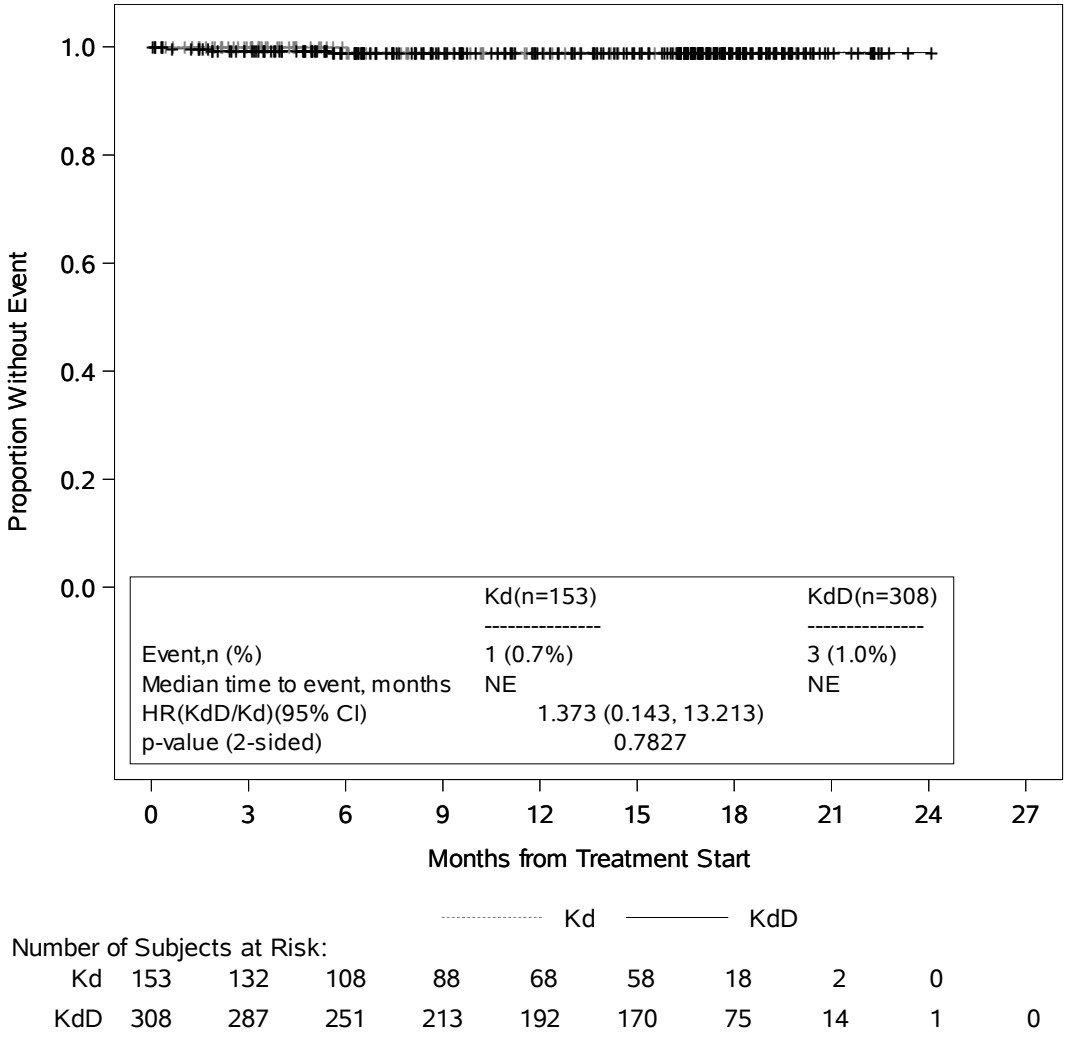


Number of Subjects at Risk:

Kd	153	129	108	88	68	58	18	2	0	
KdD	308	287	251	213	192	170	75	14	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-cfz-sub.sas.
Output: f14-06-001-565-ae-cox-haeterm-cfz-grd345.rtf (Date Generated: 27MAY20:04:38: 18).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.566. KM Curves of Grade ≥3 Adverse Events of Interest for Carfilzomib - Hepatic Failure, Fibrosis and Cirrhosis and Other Liver Damage-related Conditions (SMQ) - Narrow
<Safety Population>

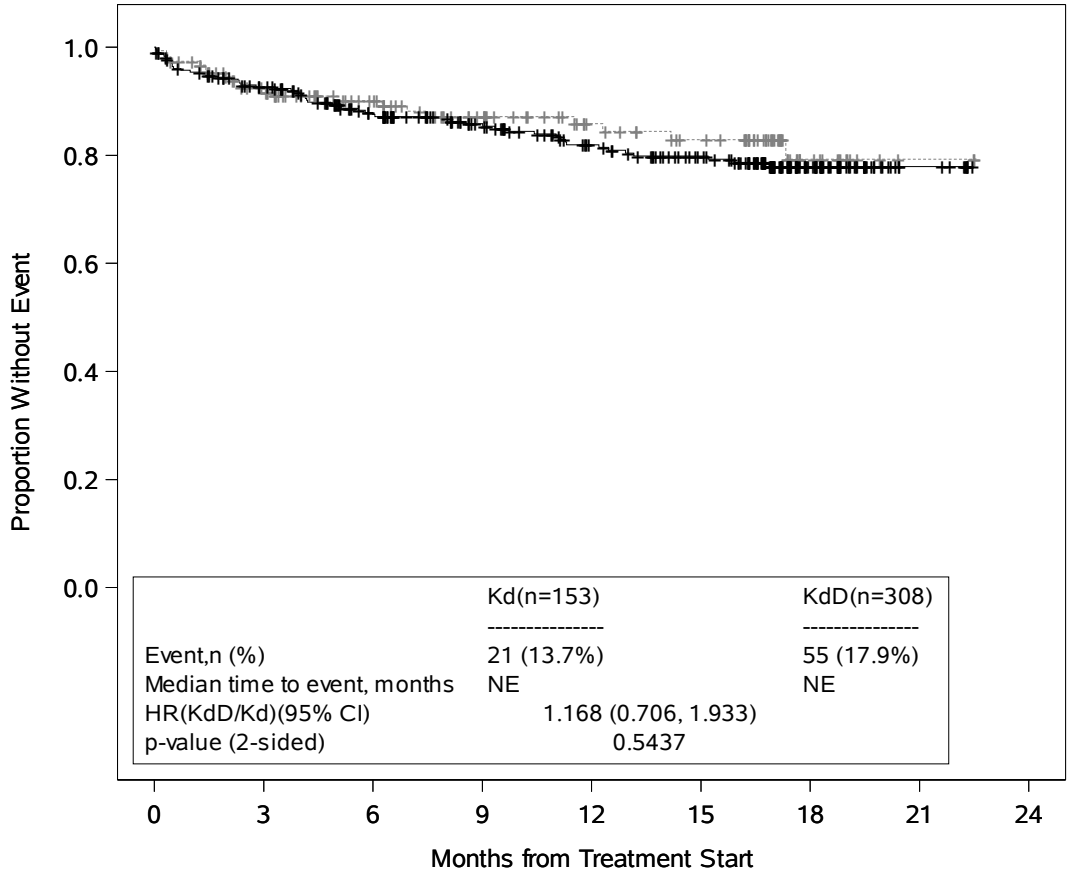


Number of Subjects at Risk:

Kd	153	132	108	88	68	58	18	2	0	
KdD	308	287	251	213	192	170	75	14	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-cfz-sub.sas.
Output: f14-06-001-566-ae-cox-hepliver-cfz-grd345.rtf (Date Generated: 27MAY20:04:38:19).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.567. KM Curves of Grade ≥3 Adverse Events of Interest for Carfilzomib - Hypertension (SMQ) - Narrow
<Safety Population>

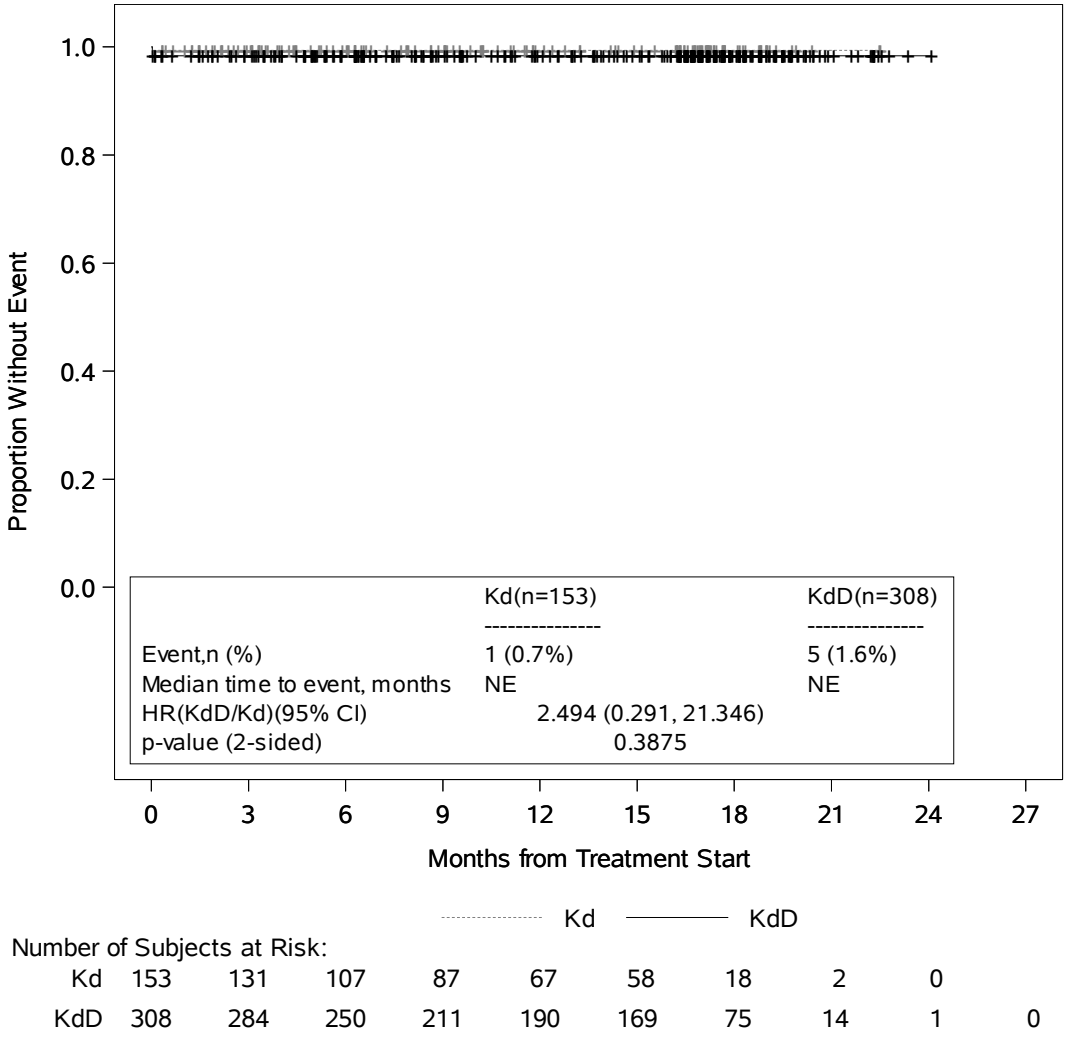


Number of Subjects at Risk:

Kd	153	124	99	78	60	51	14	2	0
KdD	308	267	225	188	159	137	57	9	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-cfz-sub.sas.
Output: f14-06-001-567-ae-cox-hyper-cfz-grd345.rtf (Date Generated: 27MAY20:04:38:21).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.569. KM Curves of Grade ≥3 Adverse Events of Interest for Carfilzomib - Infusion Reaction (AMQ) - Narrow (Event on Same Date of First Carfilzomib Dosing)
<Safety Population>

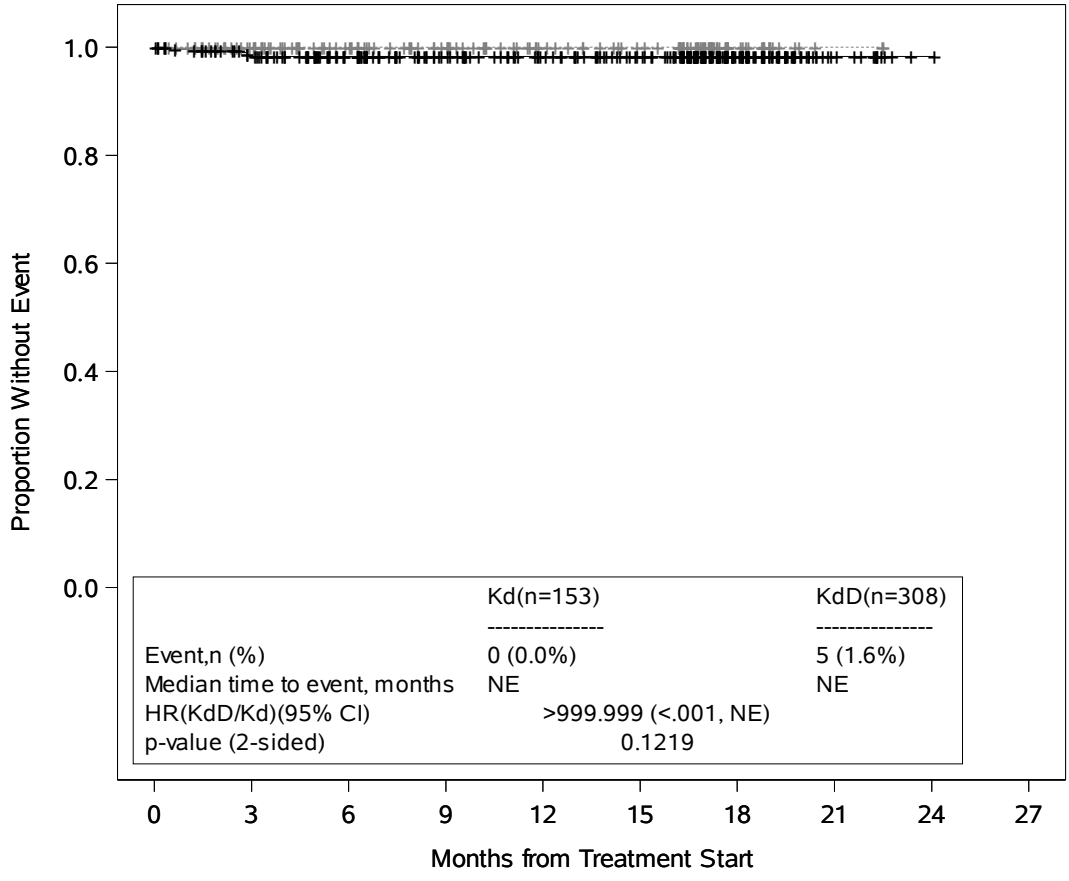


Number of Subjects at Risk:

Kd	153	131	107	87	67	58	18	2	0	
KdD	308	284	250	211	190	169	75	14	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-cfz-sub.sas.
Output: f14-06-001-569-ae-cox-infst-cfz-grd345.rtf (Date Generated: 27MAY20:04:38:24).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.570. KM Curves of Grade ≥3 Adverse Events of Interest for Carfilzomib - Interstitial Lung Disease (SMQ) - Narrow
<Safety Population>

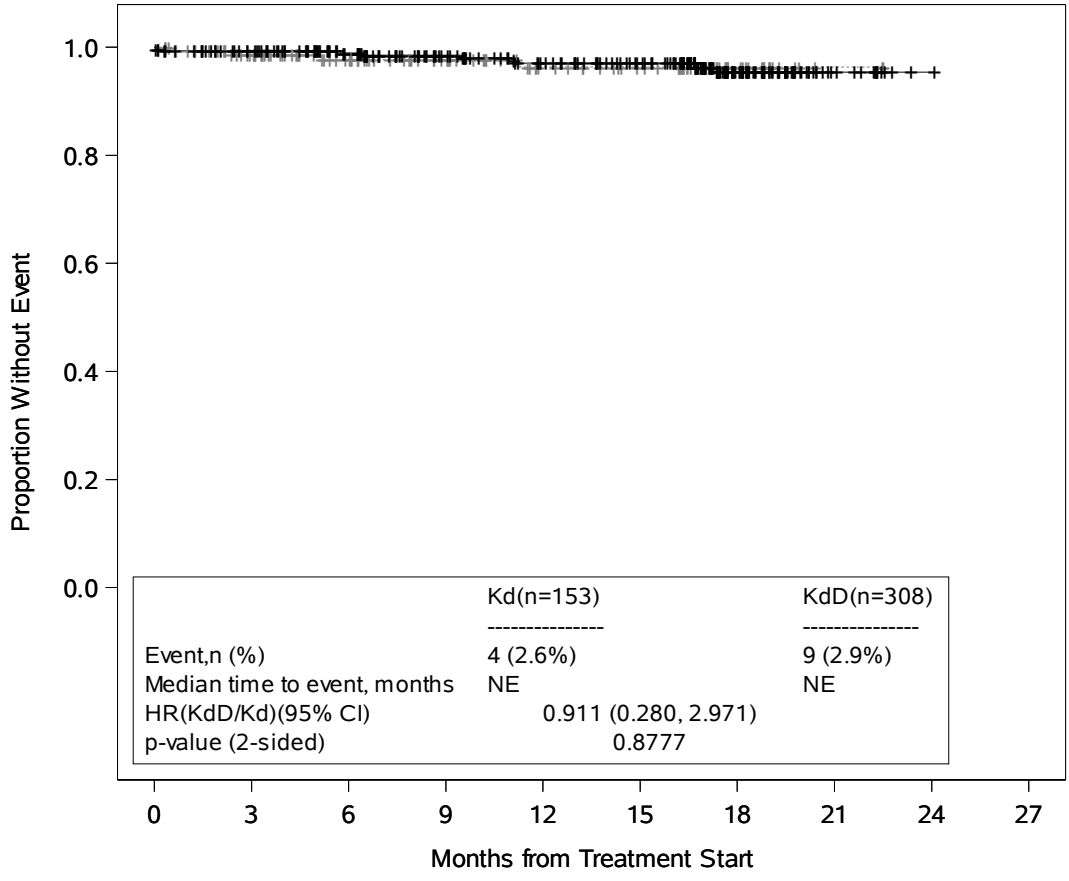


Number of Subjects at Risk:

Kd	153	132	108	88	68	58	18	2	0	
KdD	308	284	249	212	191	169	74	14	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-cfz-sub.sas.
Output: f14-06-001-570-ae-cox-lung-cfz-grd345.rtf (Date Generated: 27MAY20:04:38:25).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.571. KM Curves of Grade ≥3 Adverse Events of Interest for Carfilzomib - Ischaemic Heart Disease (SMQ) - Narrow <Safety Population>

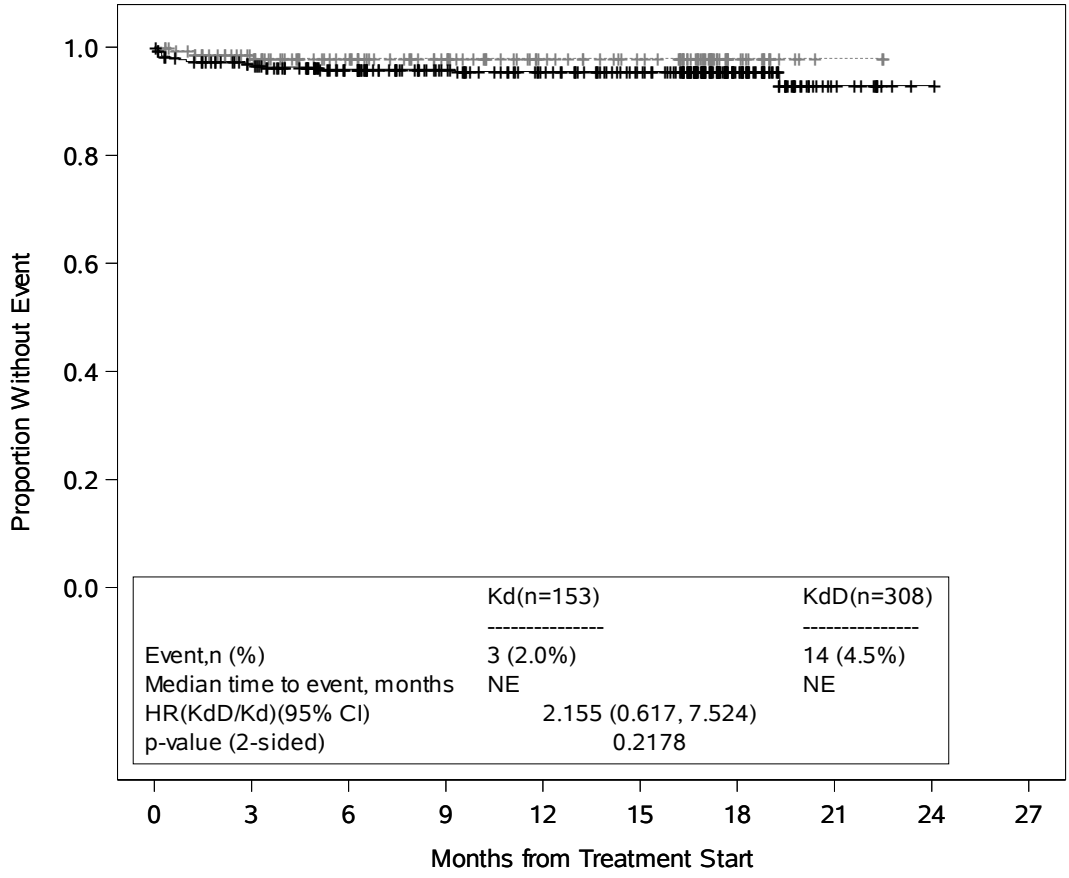


Number of Subjects at Risk:

Kd	153	130	105	86	66	57	18	2	0	
KdD	308	287	251	212	189	168	74	14	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-cfz-sub.sas.
Output: f14-06-001-571-ae-cox-heart-cfz-grd345.rtf (Date Generated: 27MAY20:04:38:27).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.572. KM Curves of Grade ≥3 Adverse Events of Interest for Carfilzomib - Liver Related Investigations, Signs and Symptoms (SMQ) - Narrow <Safety Population>

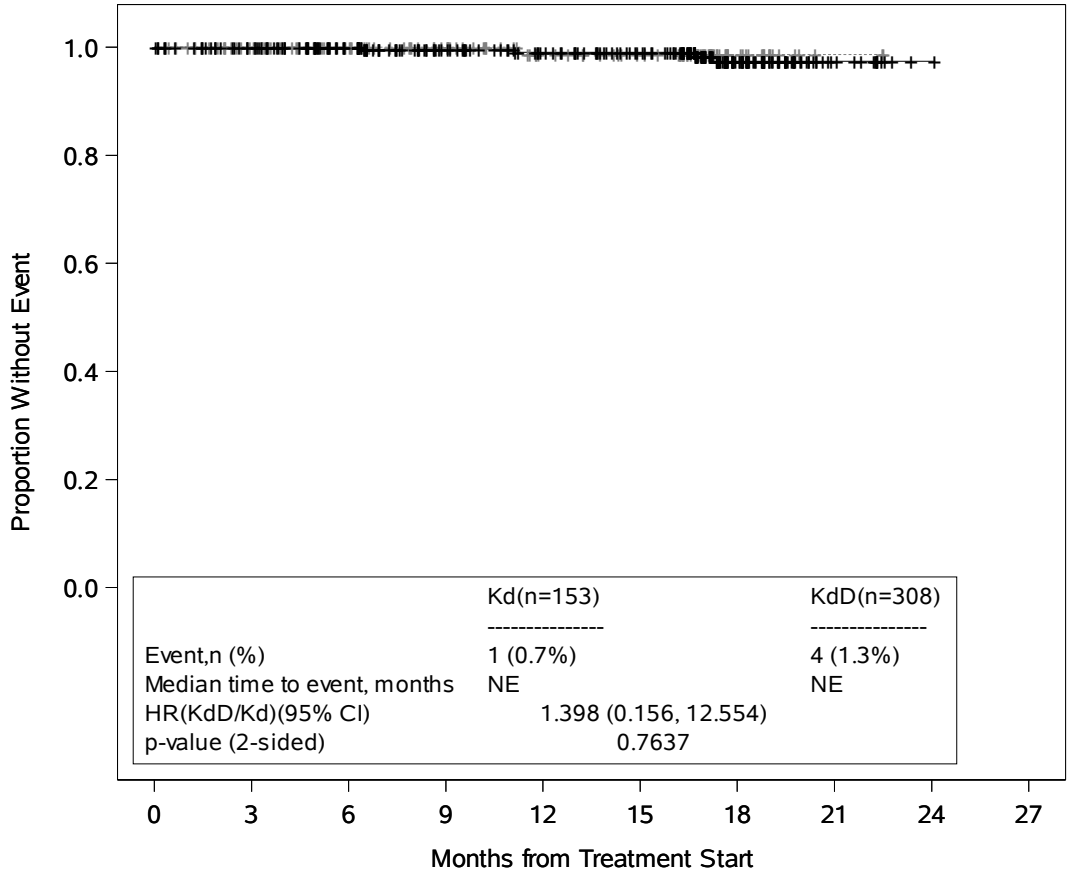


Number of Subjects at Risk:

Kd	153	131	107	87	67	57	17	2	0	
KdD	308	280	243	207	185	163	72	13	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-cfz-sub.sas.
Output: f14-06-001-572-ae-cox-liverel-cfz-grd345.rtf (Date Generated: 27MAY20:04:38:29).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.573. KM Curves of Grade ≥3 Adverse Events of Interest for Carfilzomib - Myocardial Infarction (SMQ) - Narrow
<Safety Population>

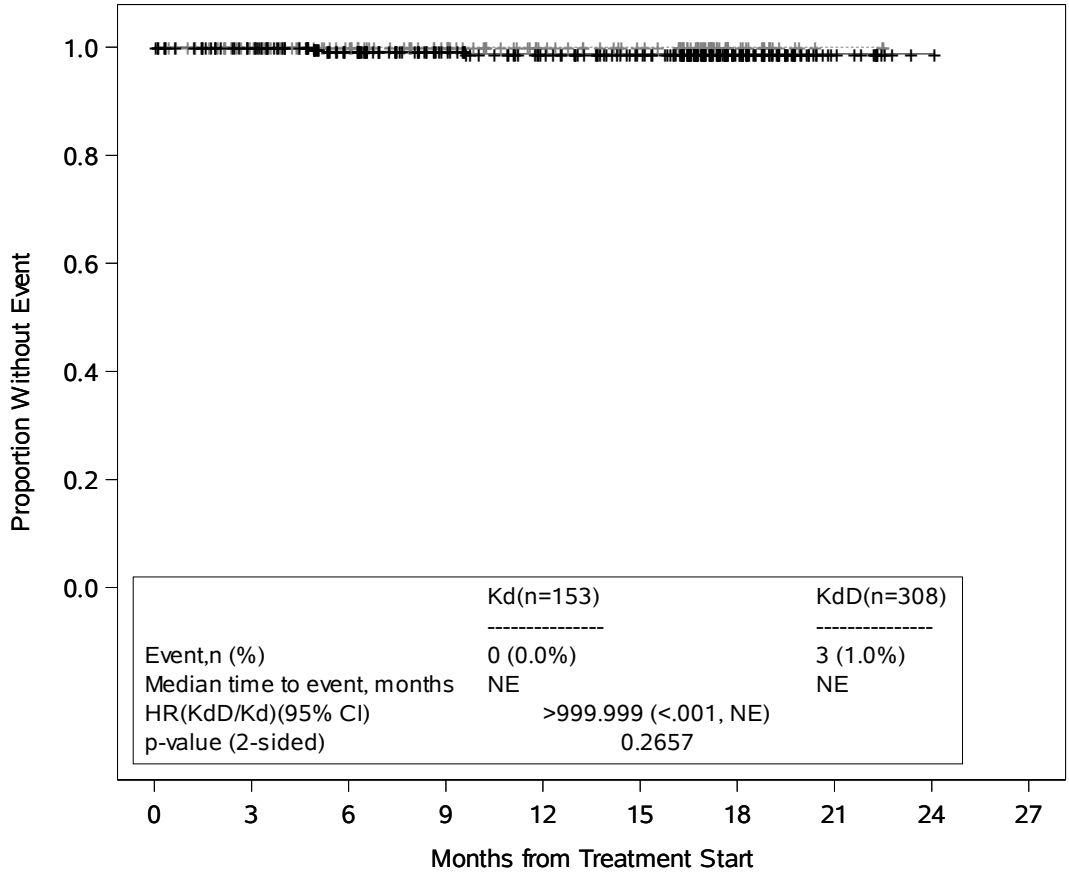


Number of Subjects at Risk:

Kd	153	132	108	88	67	58	18	2	0	
KdD	308	289	253	214	192	170	74	14	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-cfz-sub.sas.
Output: f14-06-001-573-ae-cox-myo-cfz-grd345.rtf (Date Generated: 27MAY20:04:38:30).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.574. KM Curves of Grade ≥3 Adverse Events of Interest for Carfilzomib - Peripheral Neuropathy (SMQ) - Narrow <Safety Population>

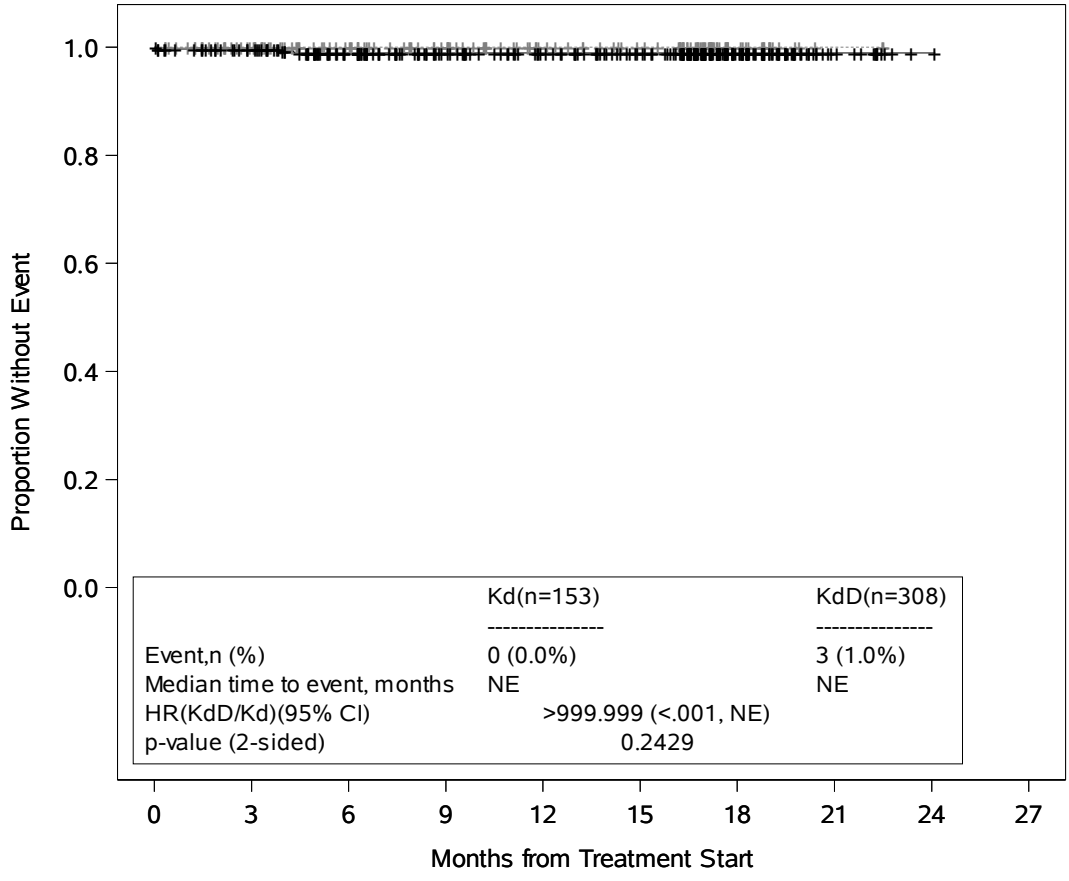


Number of Subjects at Risk:

Kd	153	132	108	88	68	58	18	2	0	
KdD	308	289	252	213	192	170	74	14	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-cfz-sub.sas.
Output: f14-06-001-574-ae-cox-perneu-cfz-grd345.rtf (Date Generated: 27MAY20:04:38:32).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.575. KM Curves of Grade ≥3 Adverse Events of Interest for Carfilzomib - Pulmonary Hypertension (SMQ) - Narrow <Safety Population>

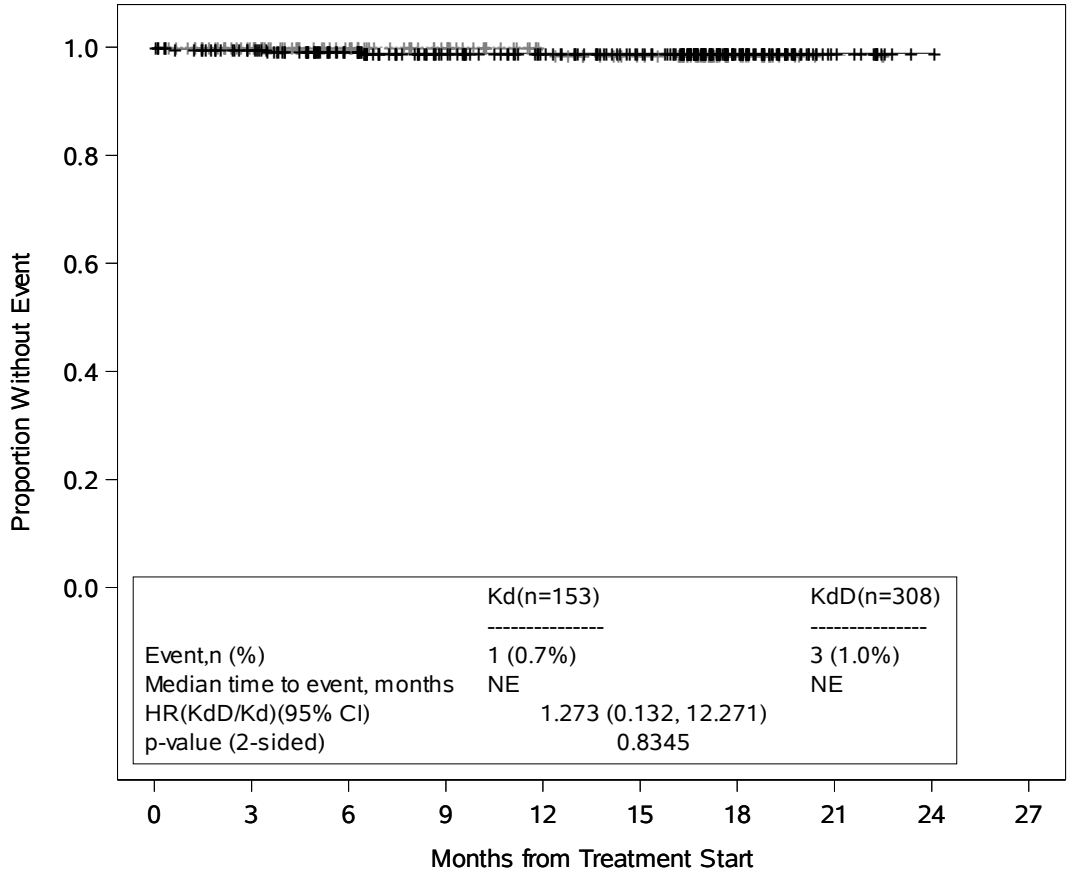


Number of Subjects at Risk:

Kd	153	132	108	88	68	58	18	2	0	
KdD	308	288	251	212	191	169	74	13	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-cfz-sub.sas.
Output: f14-06-001-575-ae-cox-pulhyp-cfz-grd345.rtf (Date Generated: 27MAY20:04:38:34).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.576. KM Curves of Grade ≥3 Adverse Events of Interest for Carfilzomib - Respiratory Failure (SMQ) - Narrow
<Safety Population>

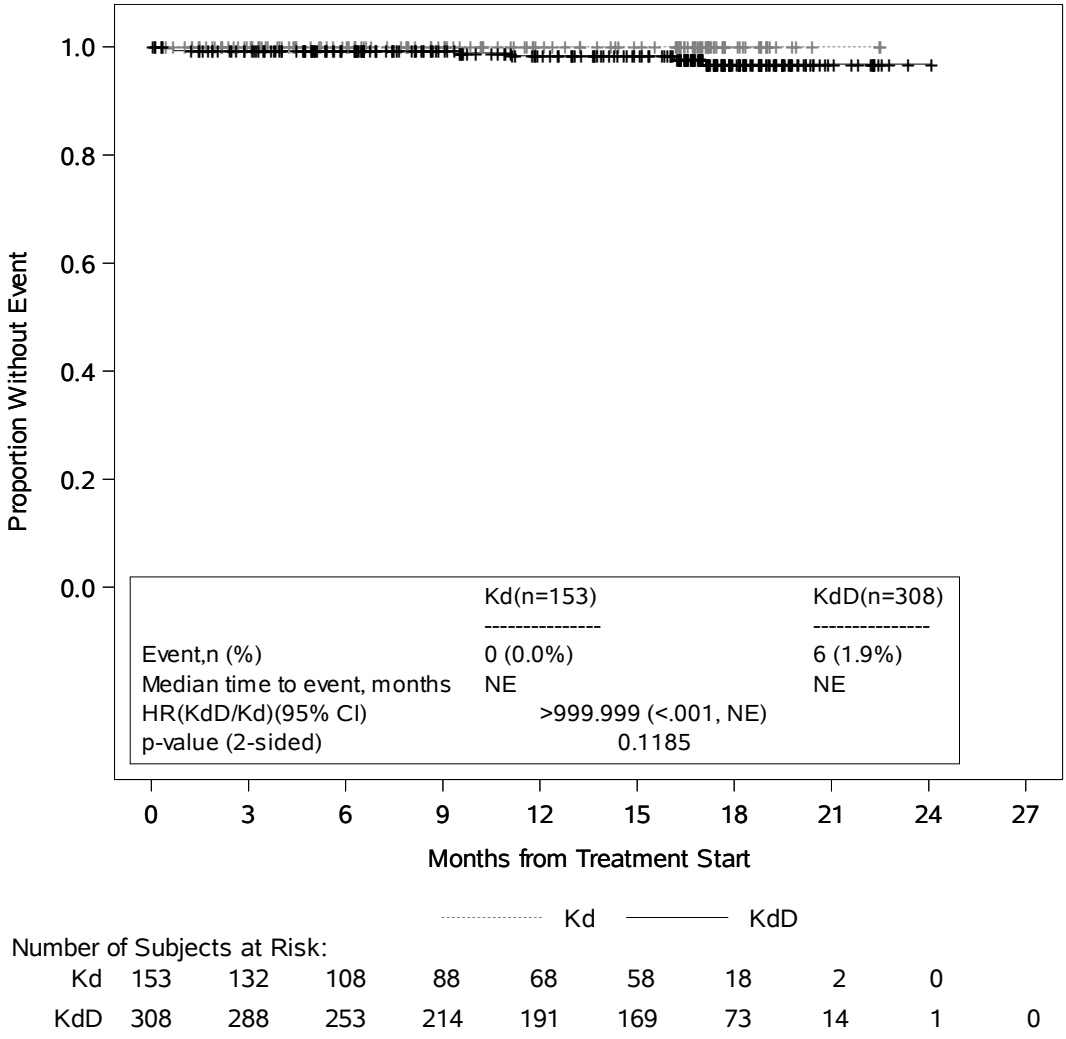


Number of Subjects at Risk:

Kd	153	132	108	88	67	58	18	2	0	
KdD	308	288	252	214	193	171	75	14	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-cfz-sub.sas.
Output: f14-06-001-576-ae-cox-resfai-cfz-grd345.rtf (Date Generated: 27MAY20:04:38:35).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.578. KM Curves of Grade ≥3 Adverse Events of Interest for Carfilzomib - Reversible Posterior Leukoencephalopathy Syndrome (AMQ) - Narrow
<Safety Population>

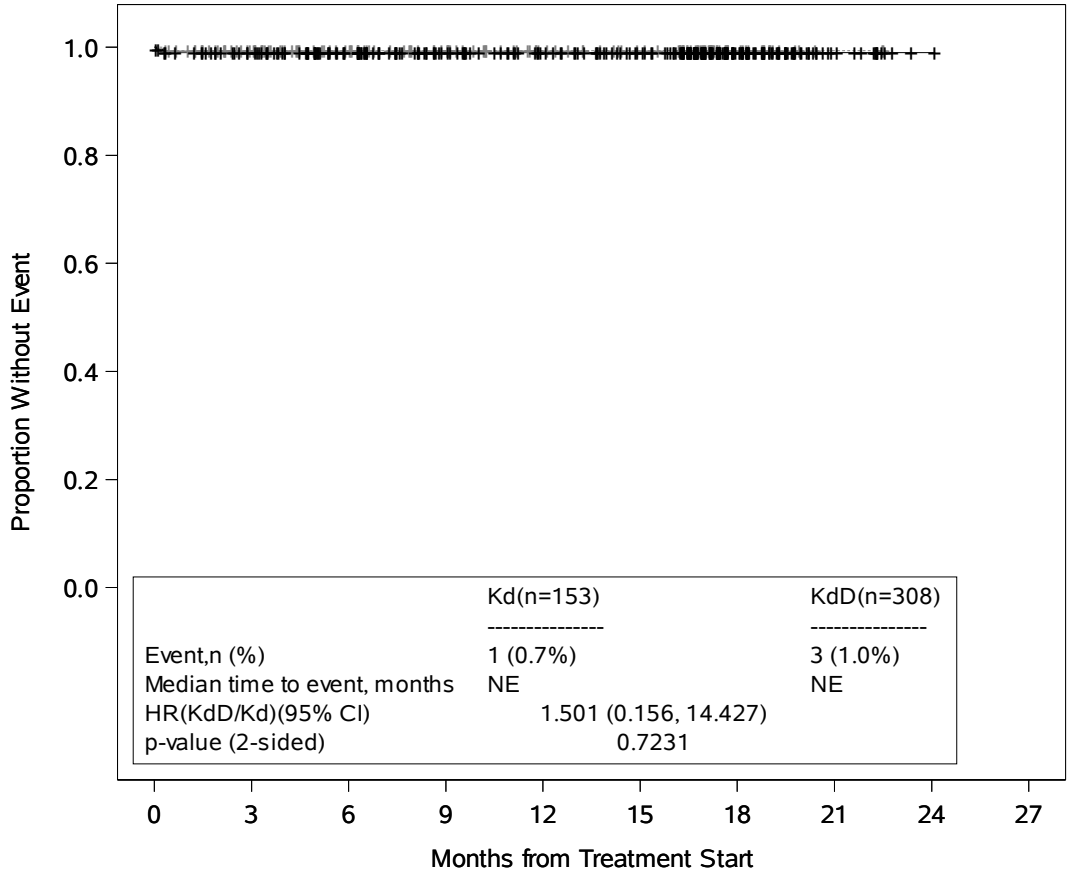


Number of Subjects at Risk:

Kd	153	132	108	88	68	58	18	2	0	
KdD	308	288	253	214	191	169	73	14	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-cfz-sub.sas.
Output: f14-06-001-578-ae-cox-leusyn-cfz-grd345.rtf (Date Generated: 27MAY20:04:38:38).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.579. KM Curves of Grade ≥3 Adverse Events of Interest for Carfilzomib - Tumour Lysis Syndrome (SMQ) - Narrow <Safety Population>

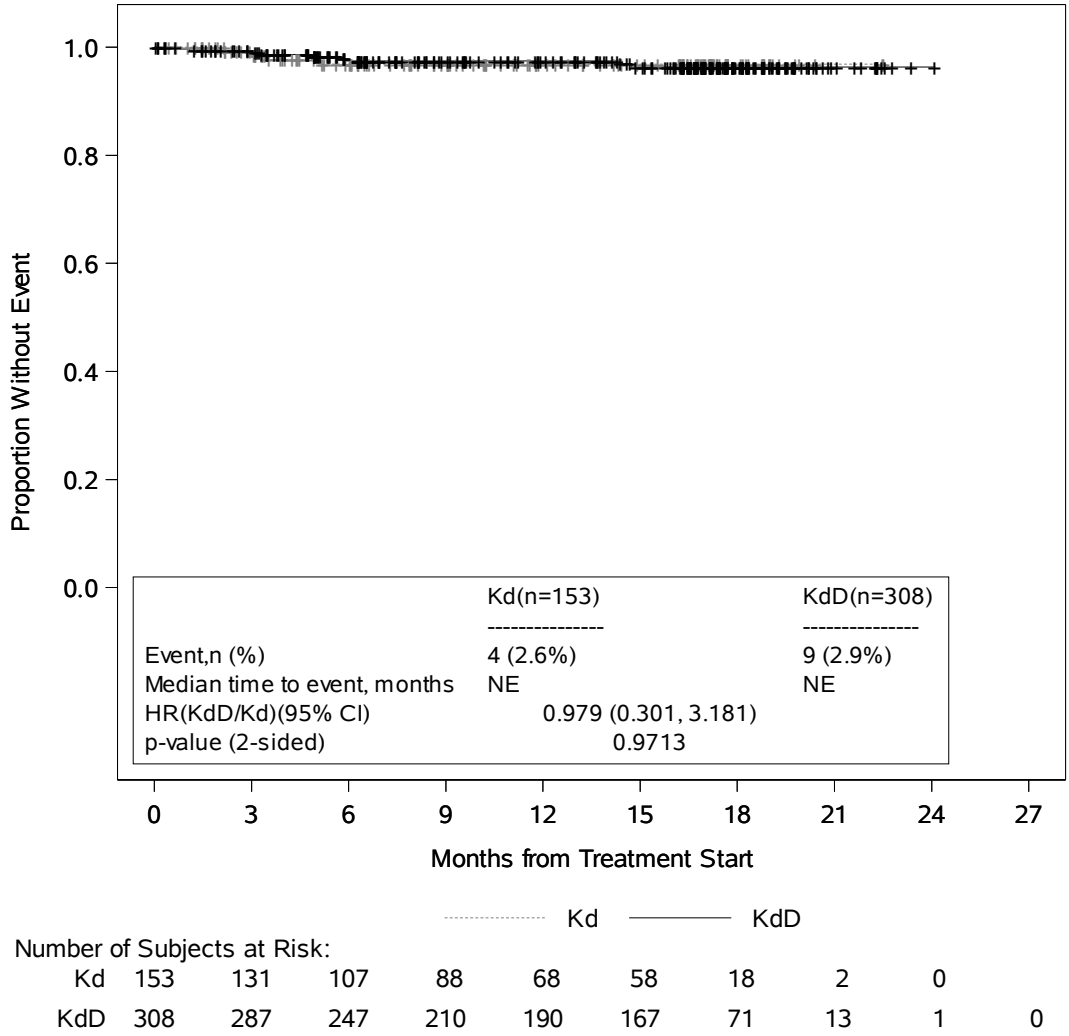


Number of Subjects at Risk:

Kd	153	132	108	88	68	58	18	2	0	
KdD	308	287	252	213	192	171	75	14	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-cfz-sub.sas.
Output: f14-06-001-579-ae-cox-tumor-cfz-grd345.rtf (Date Generated: 27MAY20:04:38:40).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.557. KM Curves of Grade ≥3 Adverse Events of Interest for Carfilzomib - Cardiac Arrhythmias (SMQ) - Narrow <Safety Population>

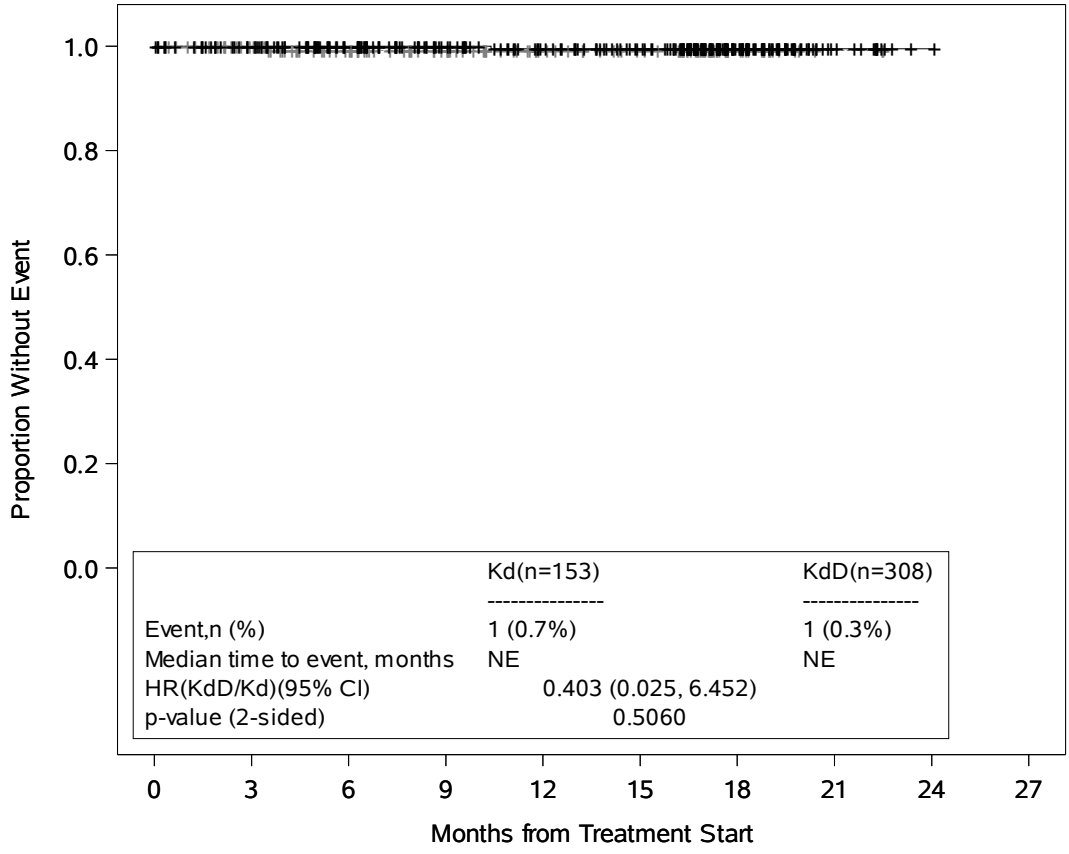


Number of Subjects at Risk:

Kd	153	131	107	88	68	58	18	2	0	
KdD	308	287	247	210	190	167	71	13	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-cfz-sub.sas.
Output: f14-06-001-557-ae-cox-cardarr-cfz-grd345.rtf (Date Generated: 27MAY20:04:38:02).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.559. KM Curves of Grade ≥3 Adverse Events of Interest for Carfilzomib - Cardiomyopathy (SMQ) - Narrow
<Safety Population>

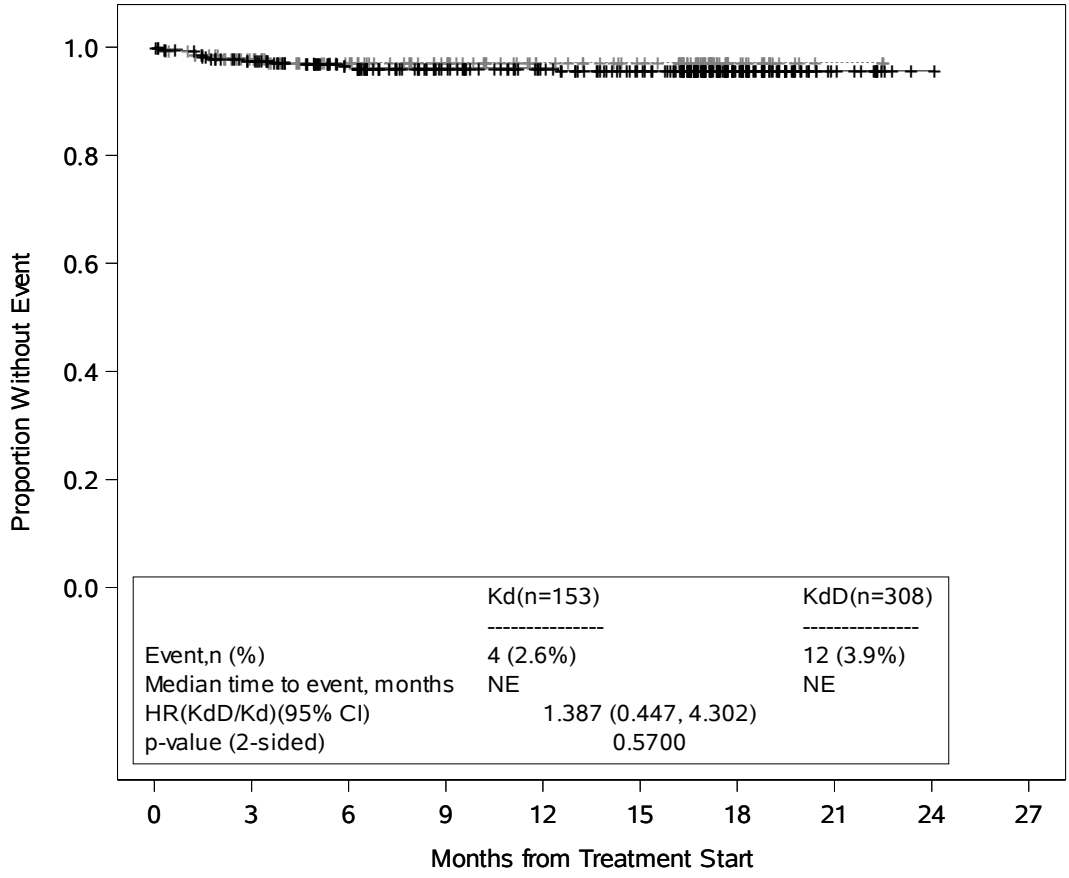


Number of Subjects at Risk:

Kd	153	132	108	88	68	58	18	2	0	
KdD	308	289	253	214	192	171	75	14	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-cfz-sub.sas.
Output: f14-06-001-559-ae-cox-cardmyo-cfz-grd345.rtf (Date Generated: 27MAY20:04:38:07).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.560. KM Curves of Grade ≥3 Adverse Events of Interest for Carfilzomib - Dyspnoeas (HLT)
<Safety Population>

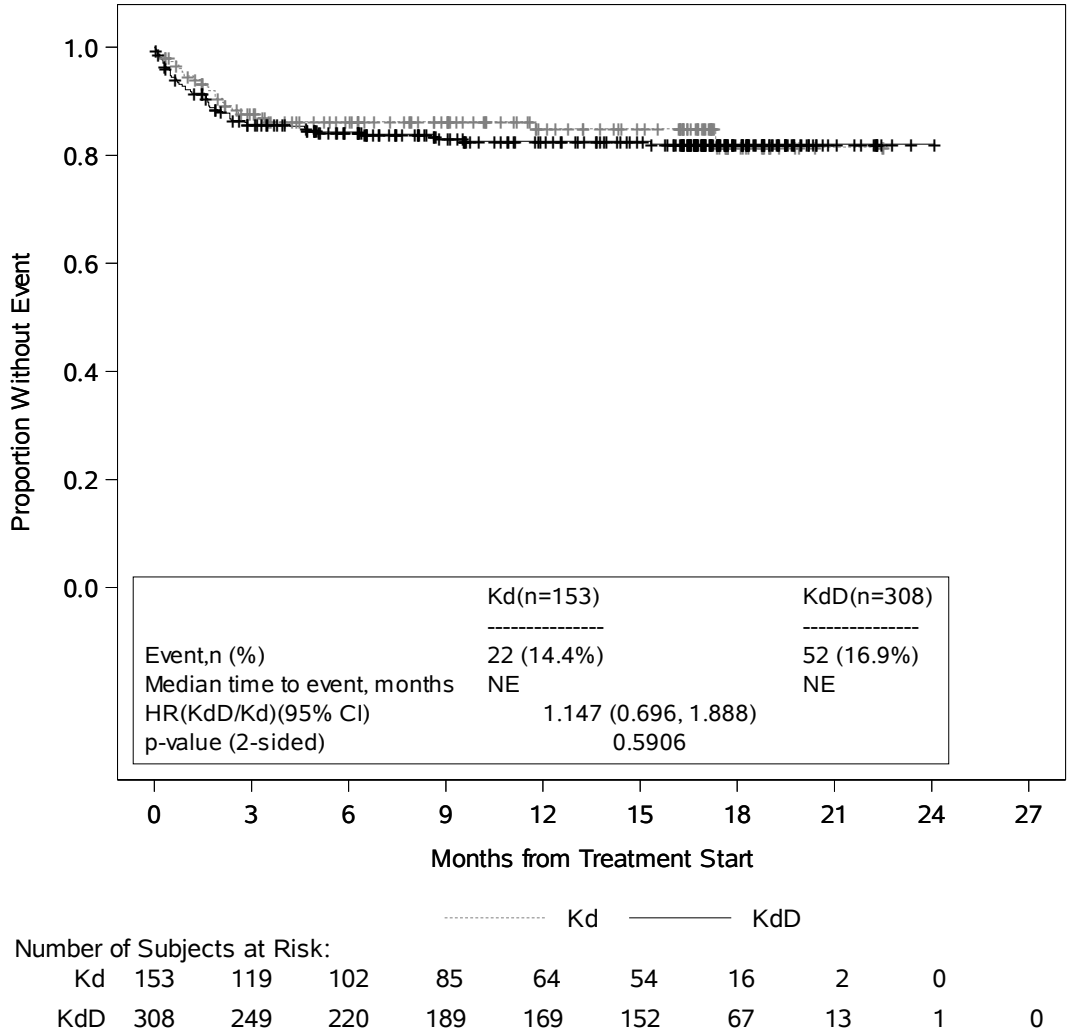


Number of Subjects at Risk:

Kd	153	130	106	86	67	58	18	2	0	
KdD	308	282	247	208	187	166	71	14	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-cfz-sub.sas.
Output: f14-06-001-560-ae-cox-dysp-cfz-grd345.rtf (Date Generated: 27MAY20:04:38:09).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.562. KM Curves of Grade ≥3 Adverse Events of Interest for Carfilzomib - Haematopoietic Erythropenia (SMQ) - Broad <Safety Population>

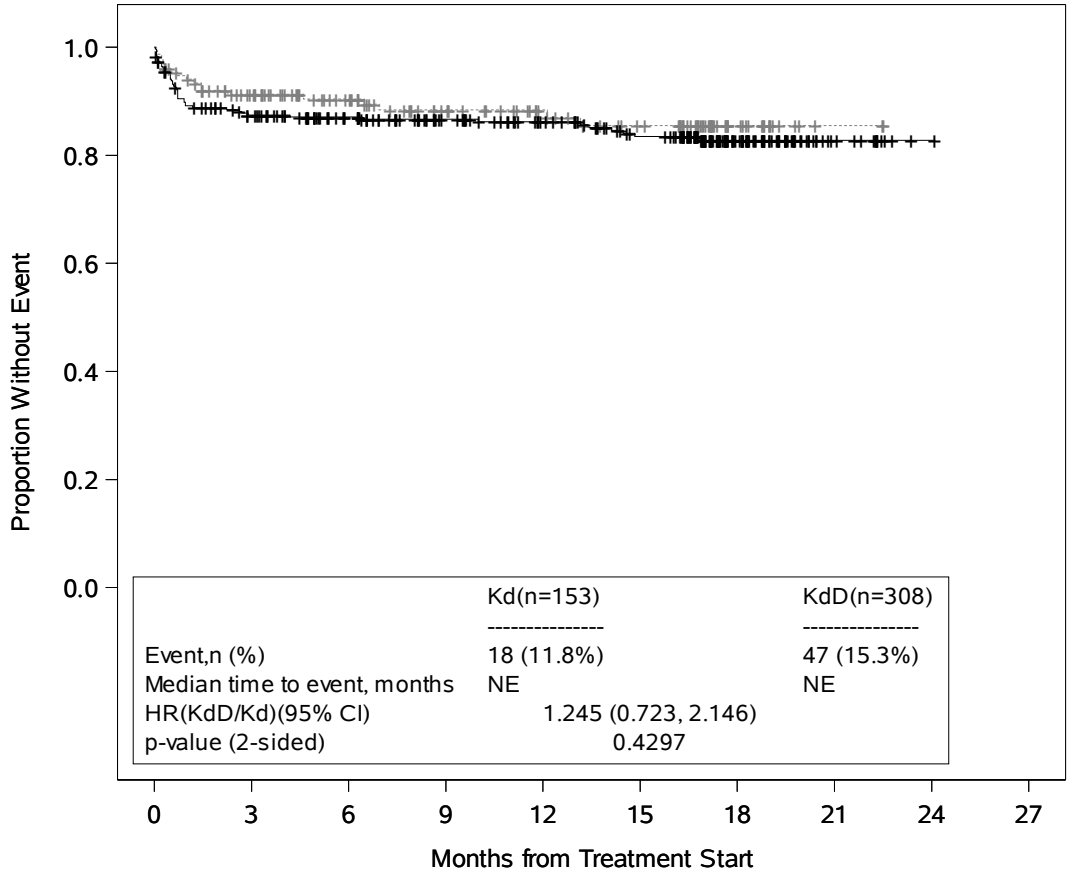


Number of Subjects at Risk:

Kd	153	119	102	85	64	54	16	2	0	
KdD	308	249	220	189	169	152	67	13	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-cfz-sub.sas.
Output: f14-06-001-562-ae-cox-haeery-cfz-grd345.rtf (Date Generated: 27MAY20:04:38:13).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.563. KM Curves of Grade ≥3 Adverse Events of Interest for Carfilzomib - Haematopoietic Leukopenia (SMQ) - Narrow <Safety Population>

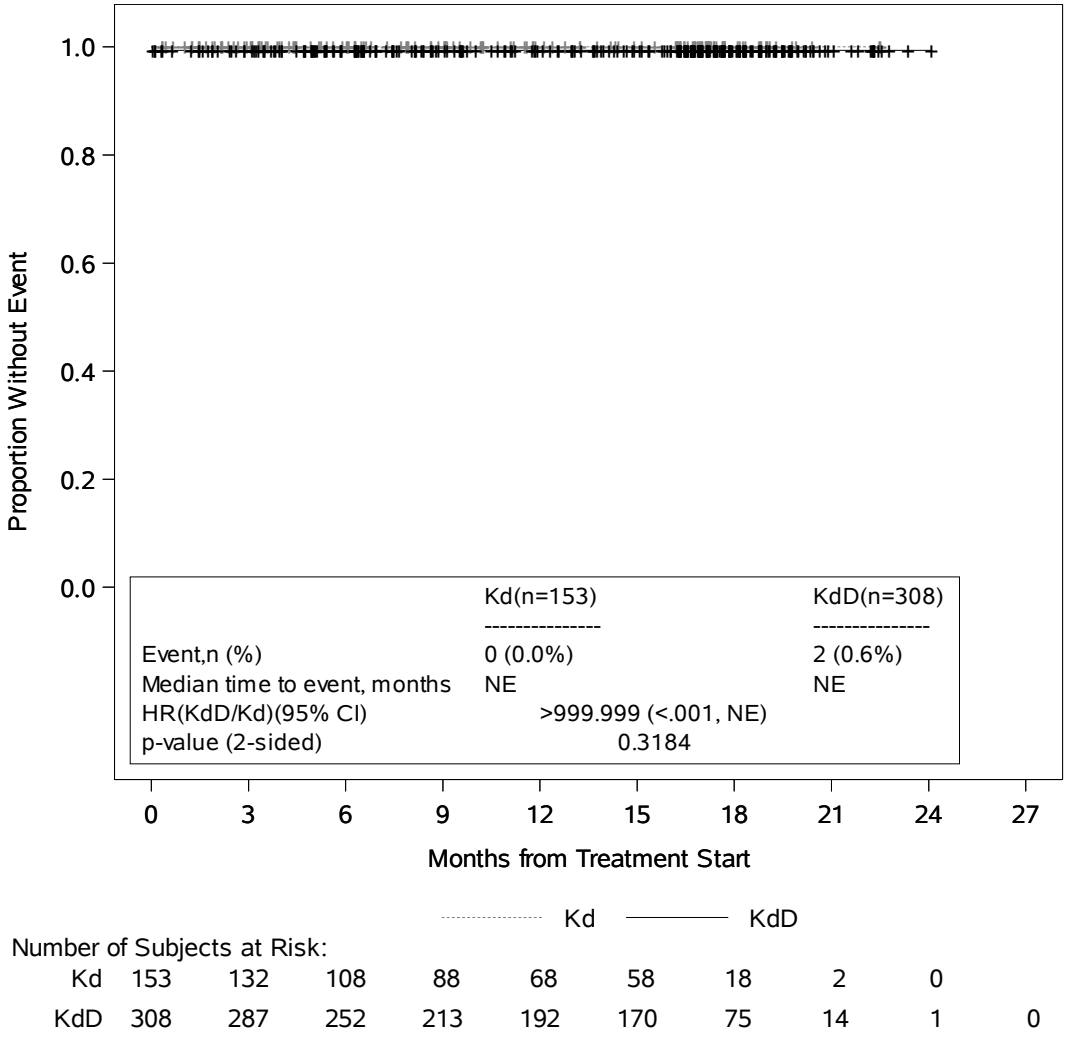


Number of Subjects at Risk:

Kd	153	122	98	76	62	51	18	2	0	
KdD	308	253	221	191	171	149	71	14	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-cfz-sub.sas.
Output: f14-06-001-563-ae-cox-haeleu-cfz-grd345.rtf (Date Generated: 27MAY20:04:38:15).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.592. KM Curves of Serious Adverse Events of Interest for Carfilzomib - Infusion Reaction (AMQ) - Narrow (Event on Same Date of First Carfilzomib Dosing)
<Safety Population>

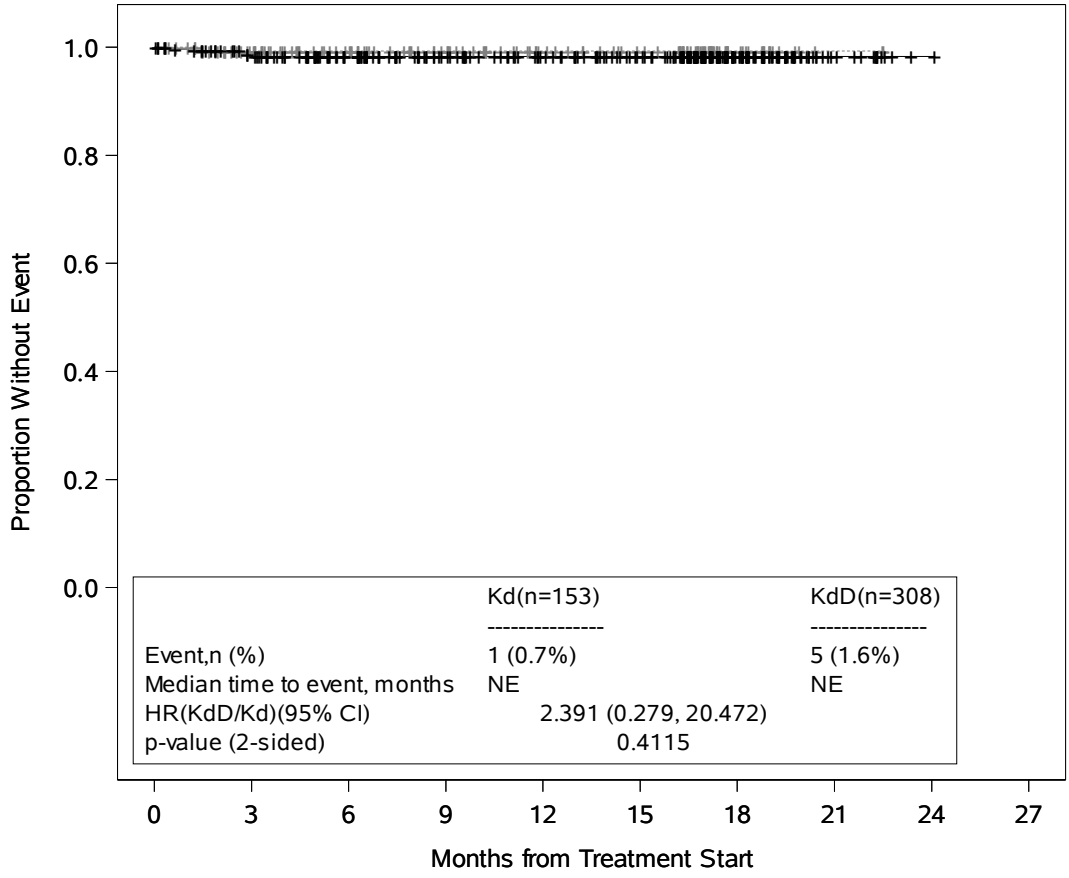


Number of Subjects at Risk:

Kd	153	132	108	88	68	58	18	2	0	
KdD	308	287	252	213	192	170	75	14	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-cfz-sub.sas.
Output: f14-06-001-592-sae-cox-infst-cfz.rtf (Date Generated: 27MAY20:04:39:00).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.593. KM Curves of Serious Adverse Events of Interest for Carfilzomib - Interstitial Lung Disease (SMQ) - Narrow <Safety Population>

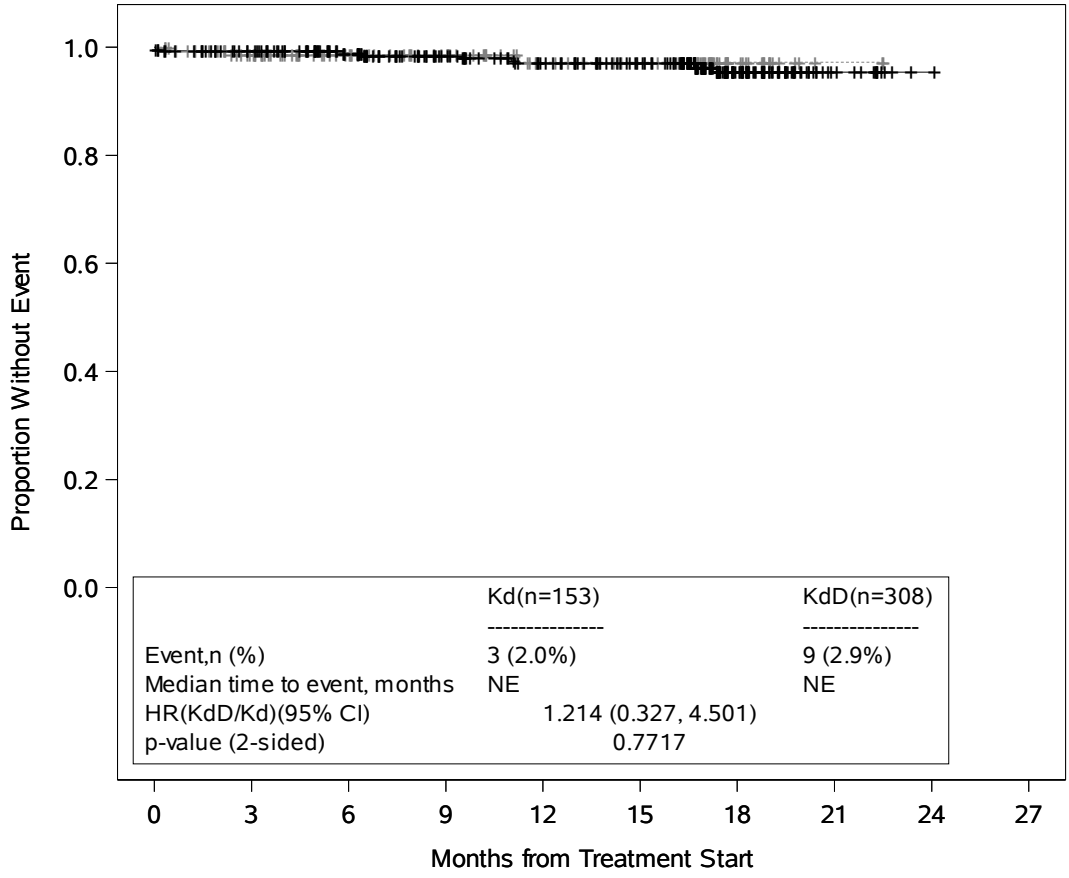


Number of Subjects at Risk:

Kd	153	131	107	87	68	58	18	2	0	
KdD	308	284	249	212	191	169	74	14	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-cfz-sub.sas.
Output: f14-06-001-593-sae-cox-lung-cfz.rtf (Date Generated: 27MAY20:04:39:02).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.594. KM Curves of Serious Adverse Events of Interest for Carfilzomib - Ischaemic Heart Disease (SMQ) - Narrow <Safety Population>

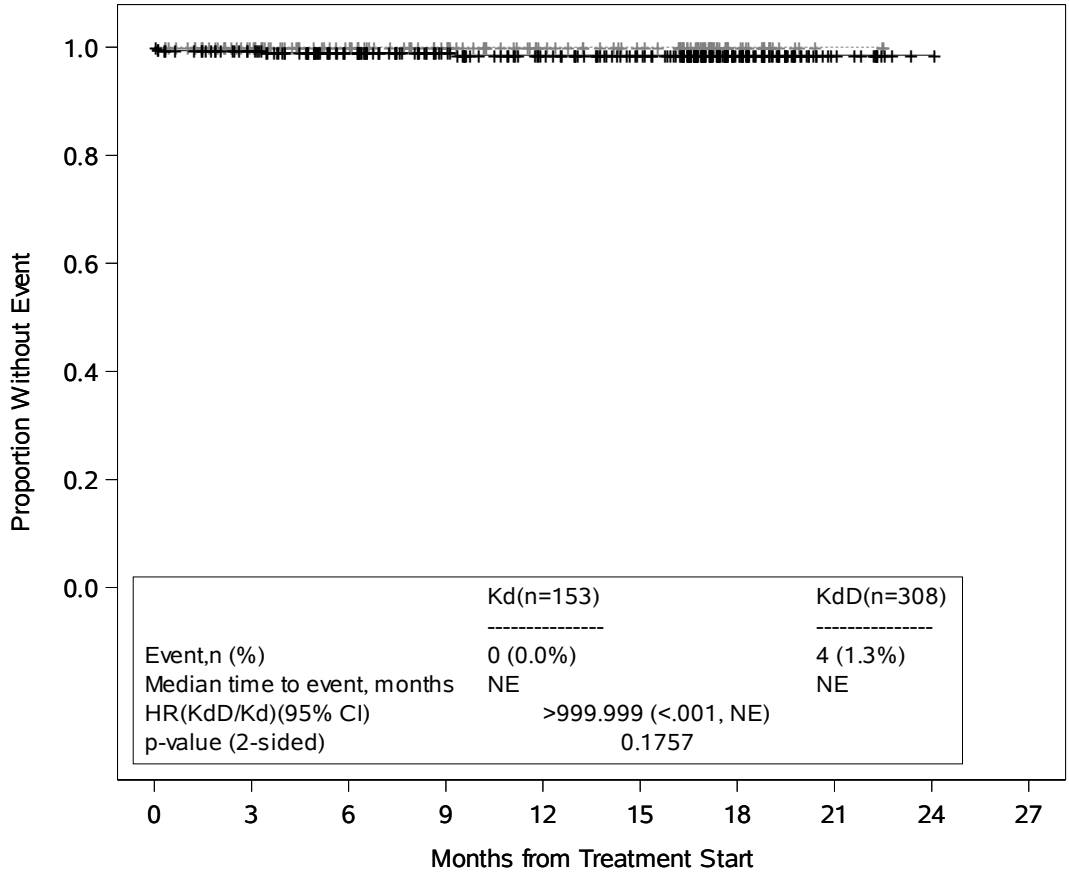


Number of Subjects at Risk:

Kd	153	130	106	86	66	57	18	2	0	
KdD	308	287	251	212	189	168	74	14	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-cfz-sub.sas.
Output: f14-06-001-594-sae-cox-heart-cfz.rtf (Date Generated: 27MAY20:04:39:03).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.595. KM Curves of Serious Adverse Events of Interest for Carfilzomib - Liver Related Investigations, Signs and Symptoms (SMQ) - Narrow <Safety Population>

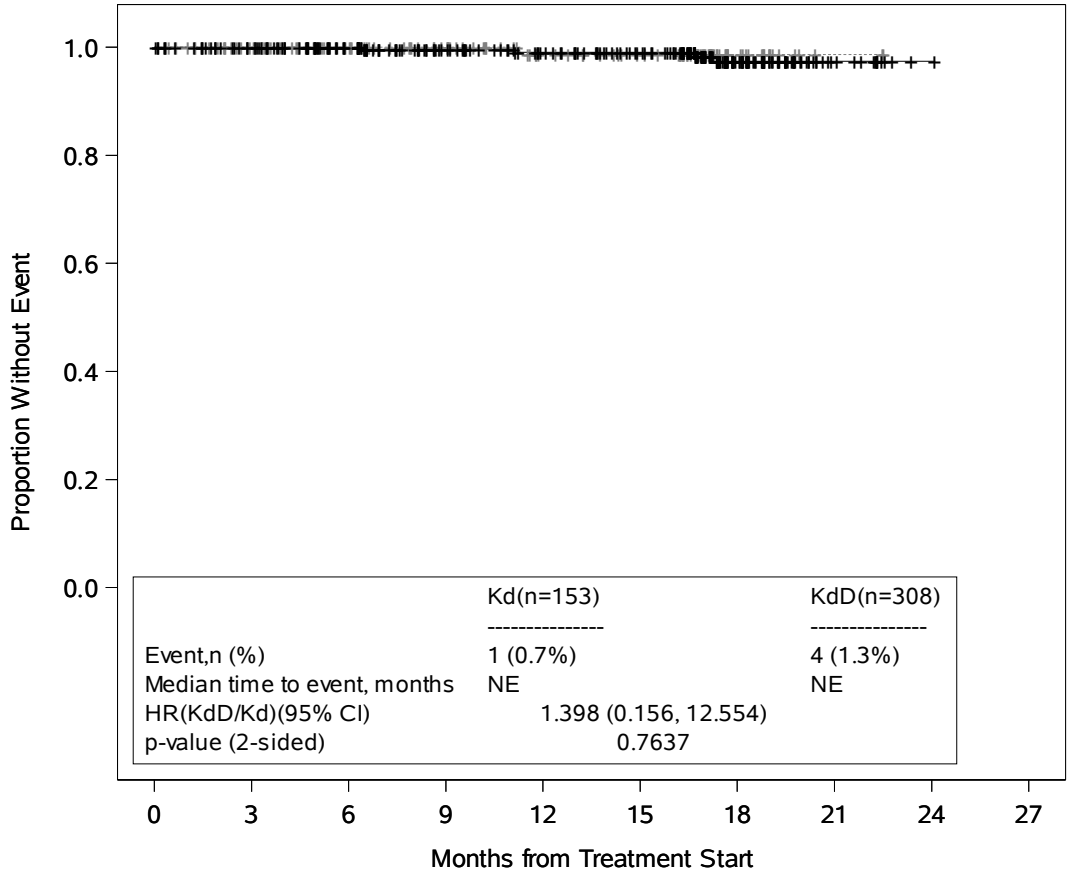


Number of Subjects at Risk:

Kd	153	132	108	88	68	58	18	2	0	
KdD	308	287	251	212	190	168	74	14	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-cfz-sub.sas.
Output: f14-06-001-595-sae-cox-liverel-cfz.rtf (Date Generated: 27MAY20:04:39:05).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.596. KM Curves of Serious Adverse Events of Interest for Carfilzomib - Myocardial Infarction (SMQ) - Narrow <Safety Population>

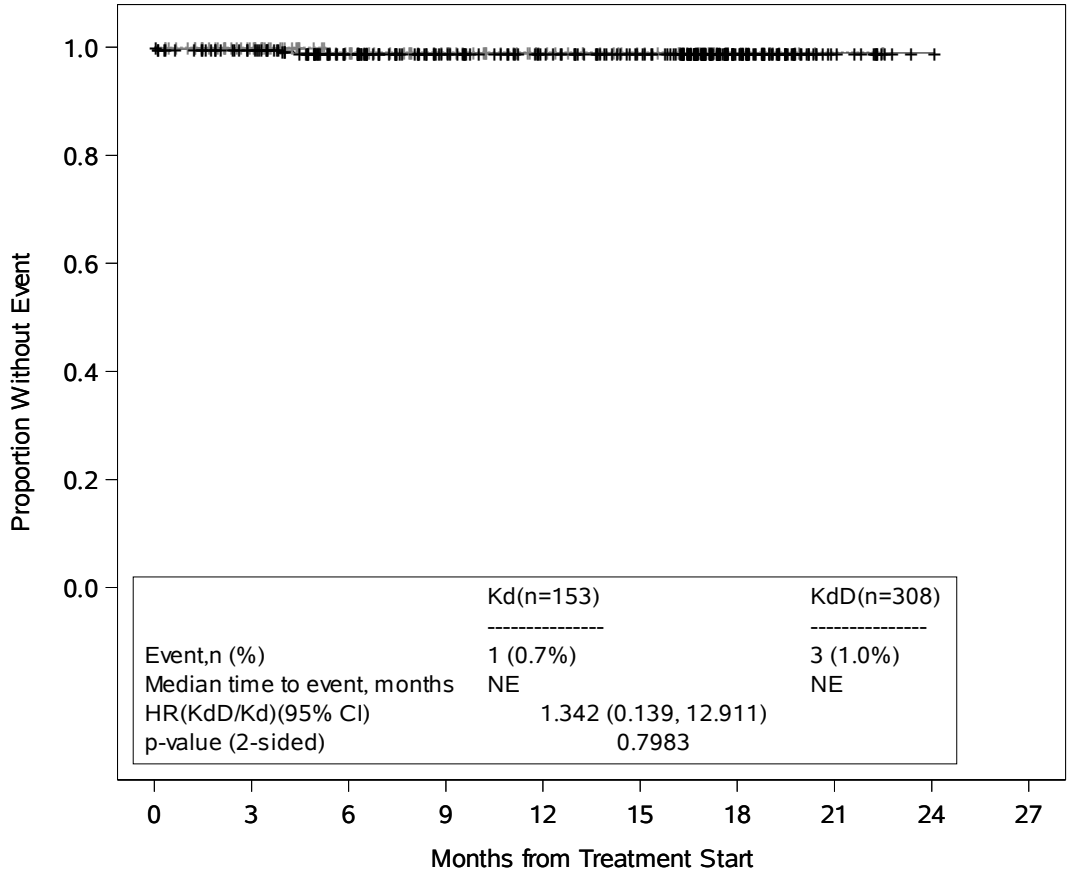


Number of Subjects at Risk:

Kd	153	132	108	88	67	58	18	2	0	
KdD	308	289	253	214	192	170	74	14	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-cfz-sub.sas.
Output: f14-06-001-596-sae-cox-myo-cfz.rtf (Date Generated: 27MAY20:04:39:07).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.597. KM Curves of Serious Adverse Events of Interest for Carfilzomib - Pulmonary Hypertension (SMQ) - Narrow <Safety Population>

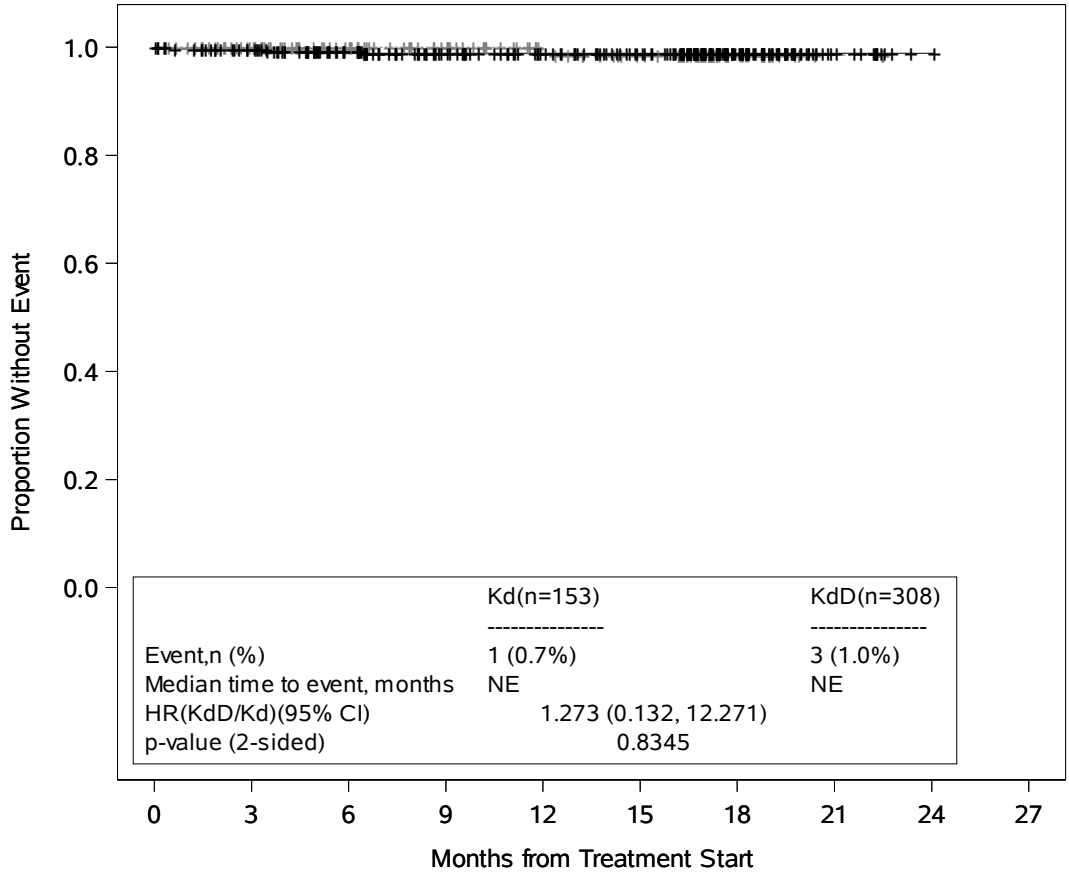


Number of Subjects at Risk:

Kd	153	132	107	87	67	57	17	2	0	
KdD	308	288	251	212	191	169	74	13	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-cfz-sub.sas.
Output: f14-06-001-597-sae-cox-pulhyp-cfz.rtf (Date Generated: 27MAY20:04:39:08).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.598. KM Curves of Serious Adverse Events of Interest for Carfilzomib - Respiratory Failure (SMQ) - Narrow <Safety Population>

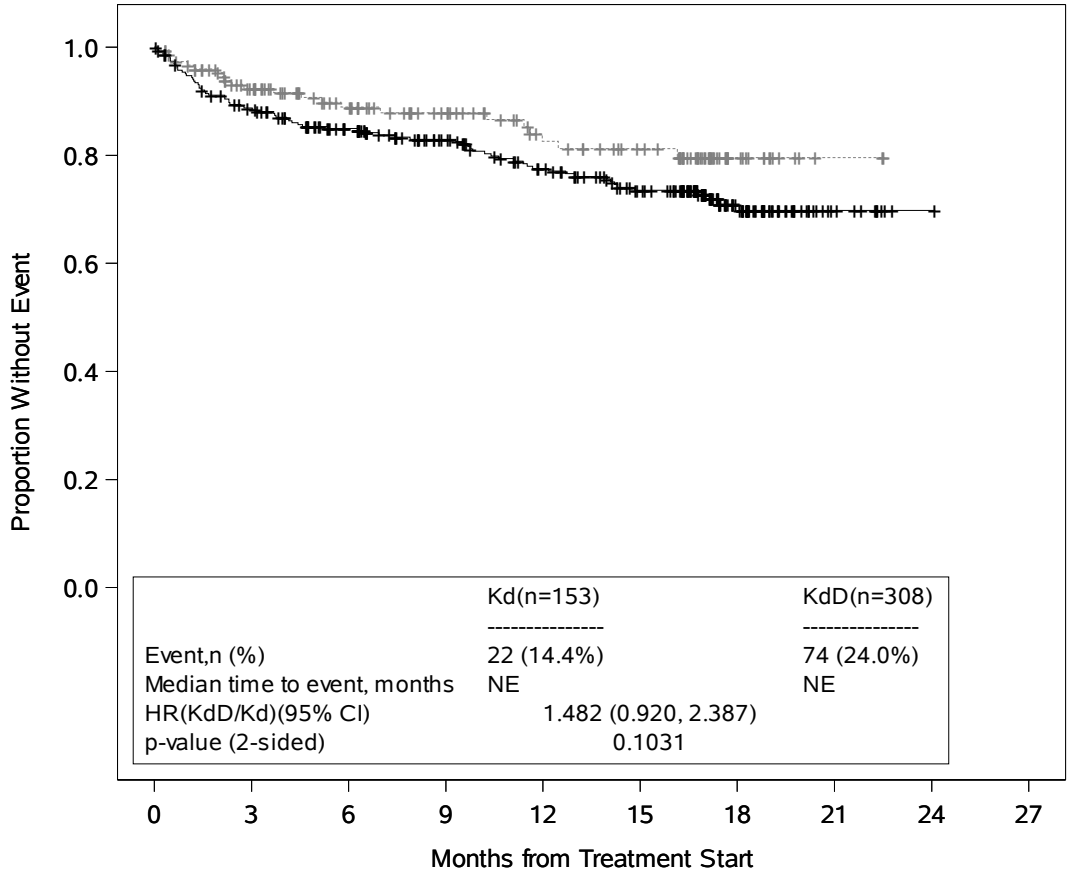


Number of Subjects at Risk:

Kd	153	132	108	88	67	58	18	2	0	
KdD	308	288	252	214	193	171	75	14	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-cfz-sub.sas.
Output: f14-06-001-598-sae-cox-resfai-cfz.rtf (Date Generated: 27MAY20:04:39:10).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.599. KM Curves of Serious Adverse Events of Interest for Carfilzomib - Respiratory Tract Infections (HLGT)
<Safety Population>

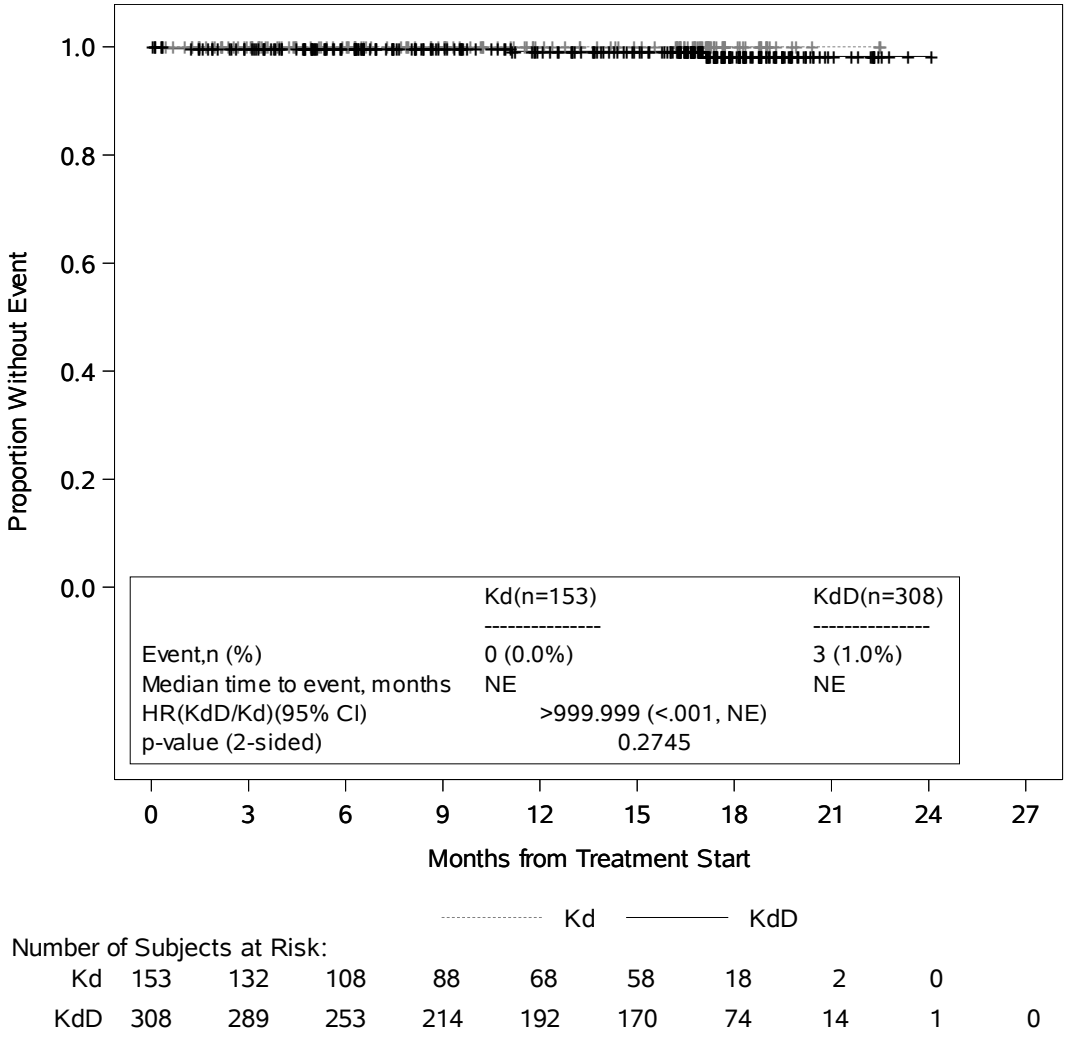


Number of Subjects at Risk:

Kd	153	122	97	78	60	51	15	2	0	
KdD	308	263	227	192	165	138	60	11	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-cfz-sub.sas.
Output: f14-06-001-599-sae-cox-restra-cfz.rtf (Date Generated: 27MAY20:04:39:11).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.600. KM Curves of Serious Adverse Events of Interest for Carfilzomib - Reversible Posterior Leukoencephalopathy Syndrome (AMQ) - Narrow
<Safety Population>

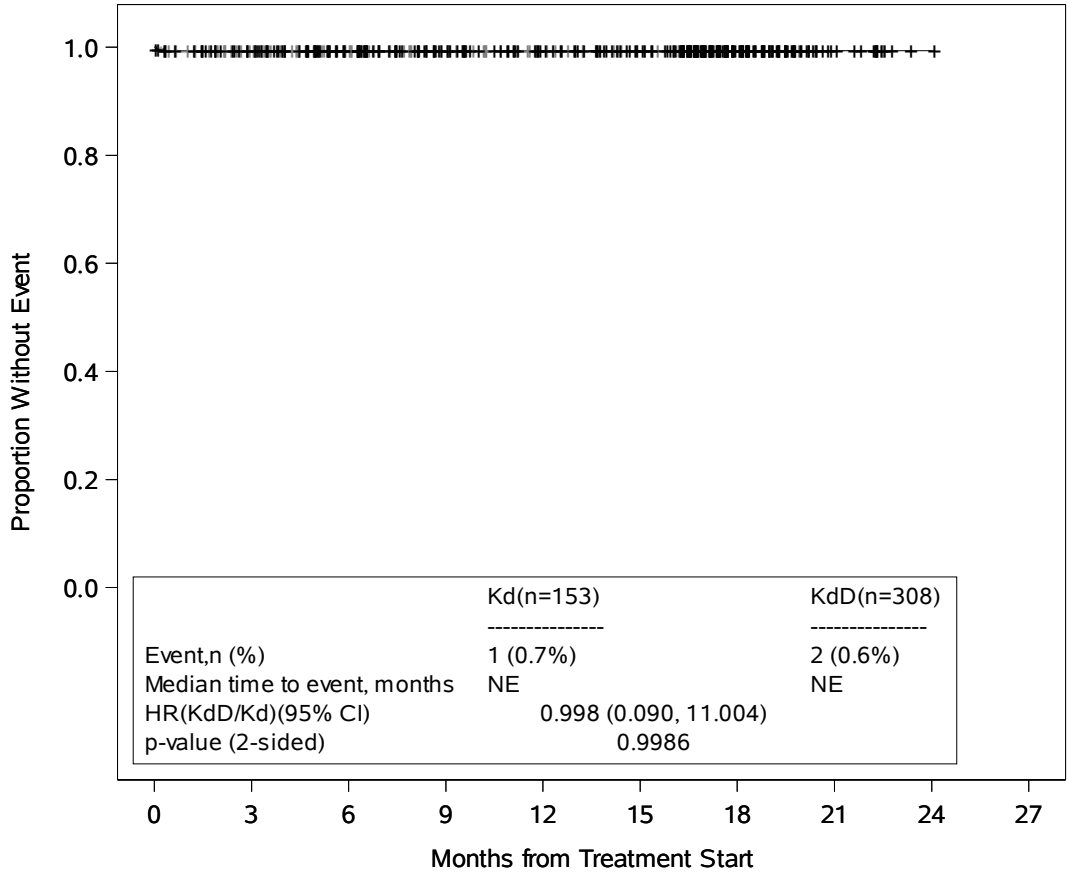


Number of Subjects at Risk:

Kd	153	132	108	88	68	58	18	2	0	
KdD	308	289	253	214	192	170	74	14	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-cfz-sub.sas.
Output: f14-06-001-600-sae-cox-leusyn-cfz.rtf (Date Generated: 27MAY20:04:39:13).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.601. KM Curves of Serious Adverse Events of Interest for Carfilzomib - Tumour Lysis Syndrome (SMQ) - Narrow <Safety Population>

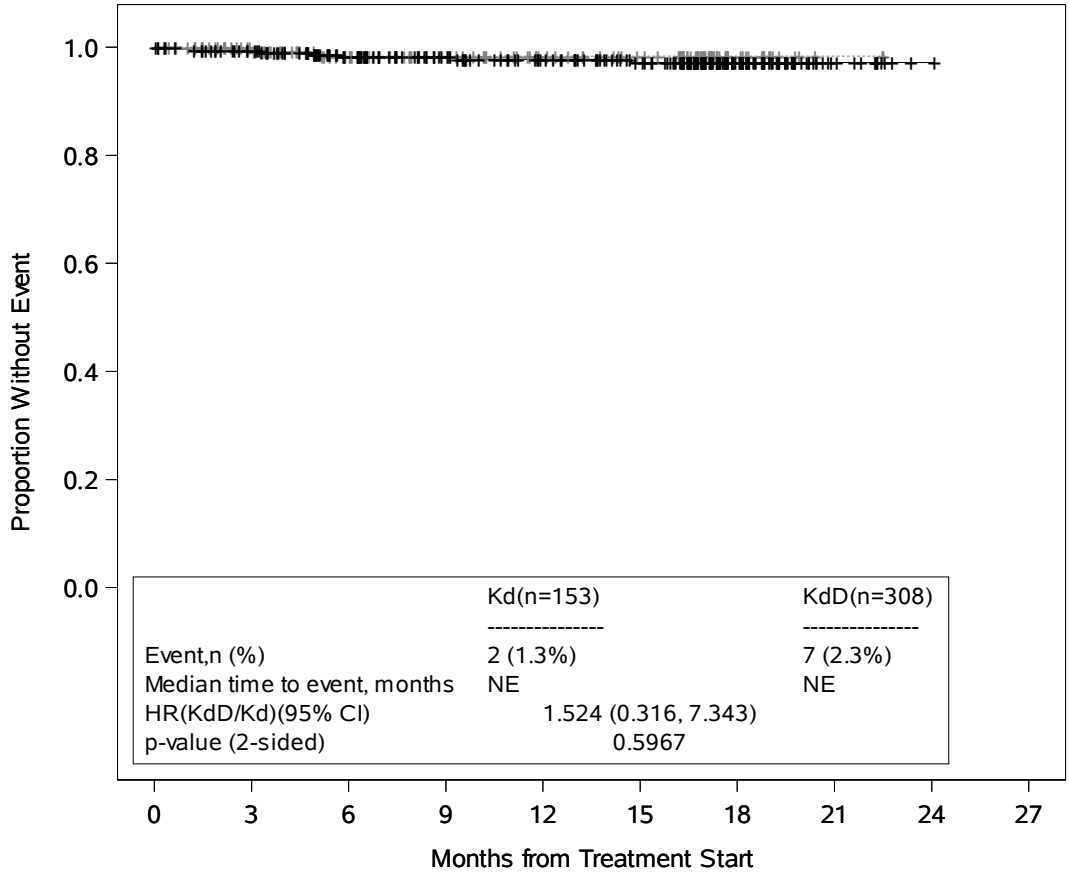


Number of Subjects at Risk:

Kd	153	132	108	88	68	58	18	2	0	
KdD	308	288	252	213	192	171	75	14	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-cfz-sub.sas.
Output: f14-06-001-601-sae-cox-tumor-cfz.rtf (Date Generated: 27MAY20:04:39:14).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.581. KM Curves of Serious Adverse Events of Interest for Carfilzomib - Cardiac Arrhythmias (SMQ) - Narrow <Safety Population>

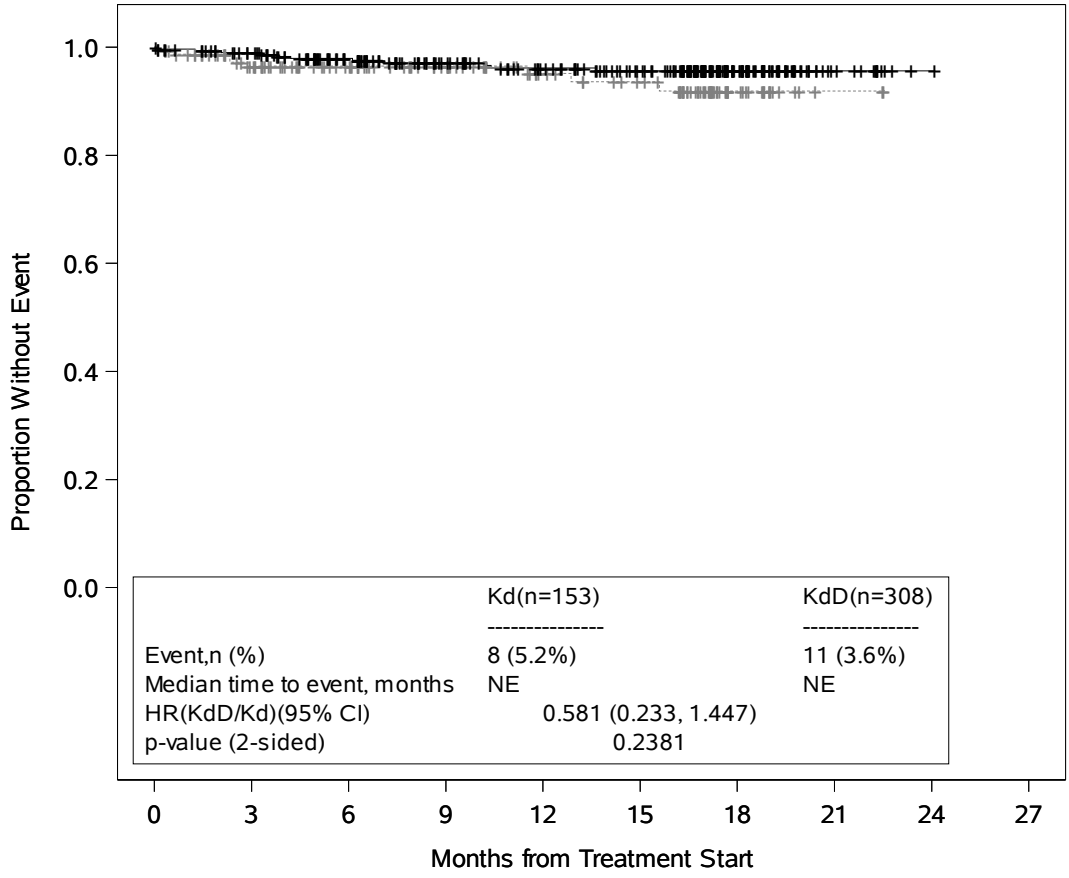


Number of Subjects at Risk:

Kd	153	132	107	88	68	58	18	2	0	
KdD	308	287	248	211	190	168	72	13	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-cfz-sub.sas.
Output: f14-06-001-581-sae-cox-cardarr-cfz.rtf (Date Generated: 27MAY20:04:38:43).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.582. KM Curves of Serious Adverse Events of Interest for Carfilzomib - Cardiac Failure (SMQ) - Narrow
<Safety Population>

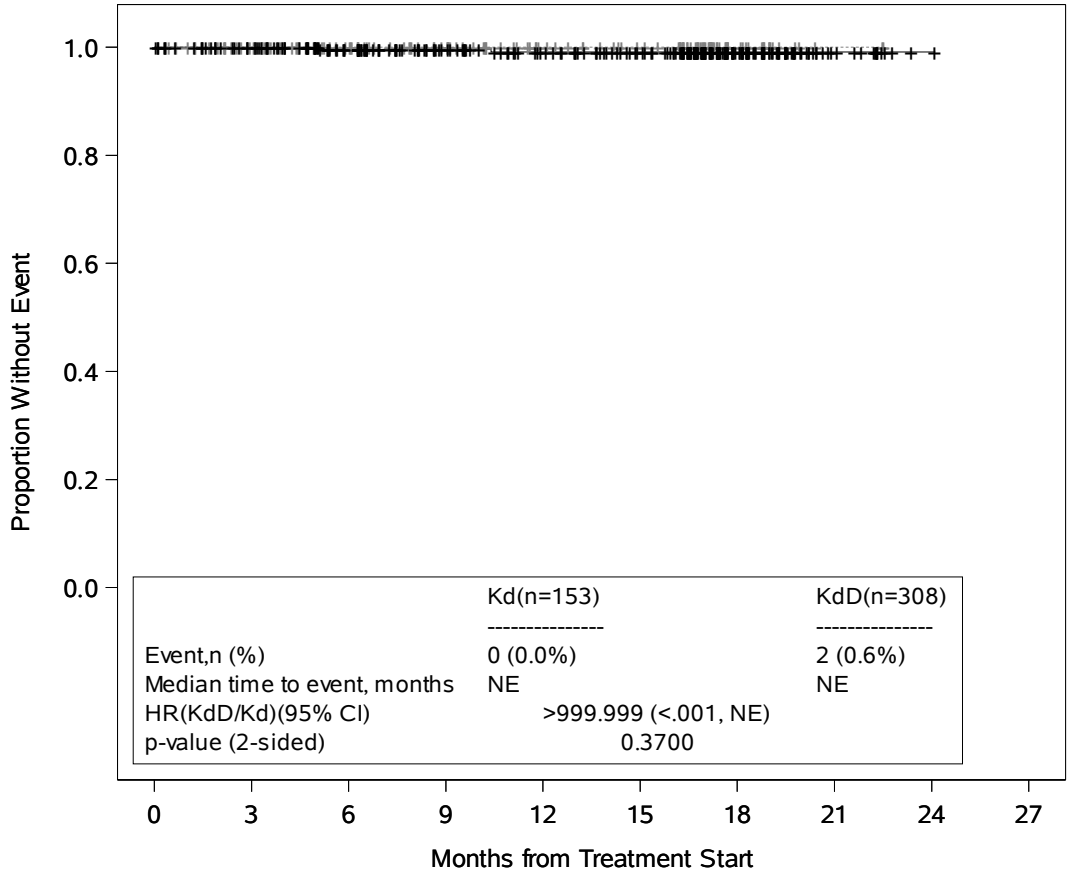


Number of Subjects at Risk:

Kd	153	129	106	86	65	57	18	2	0	
KdD	308	288	251	210	189	167	73	14	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-cfz-sub.sas.
Output: f14-06-001-582-sae-cox-cardfai-cfz.rtf (Date Generated: 27MAY20:04:38:45).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.583. KM Curves of Serious Adverse Events of Interest for Carfilzomib - Cardiomyopathy (SMQ) - Narrow
<Safety Population>

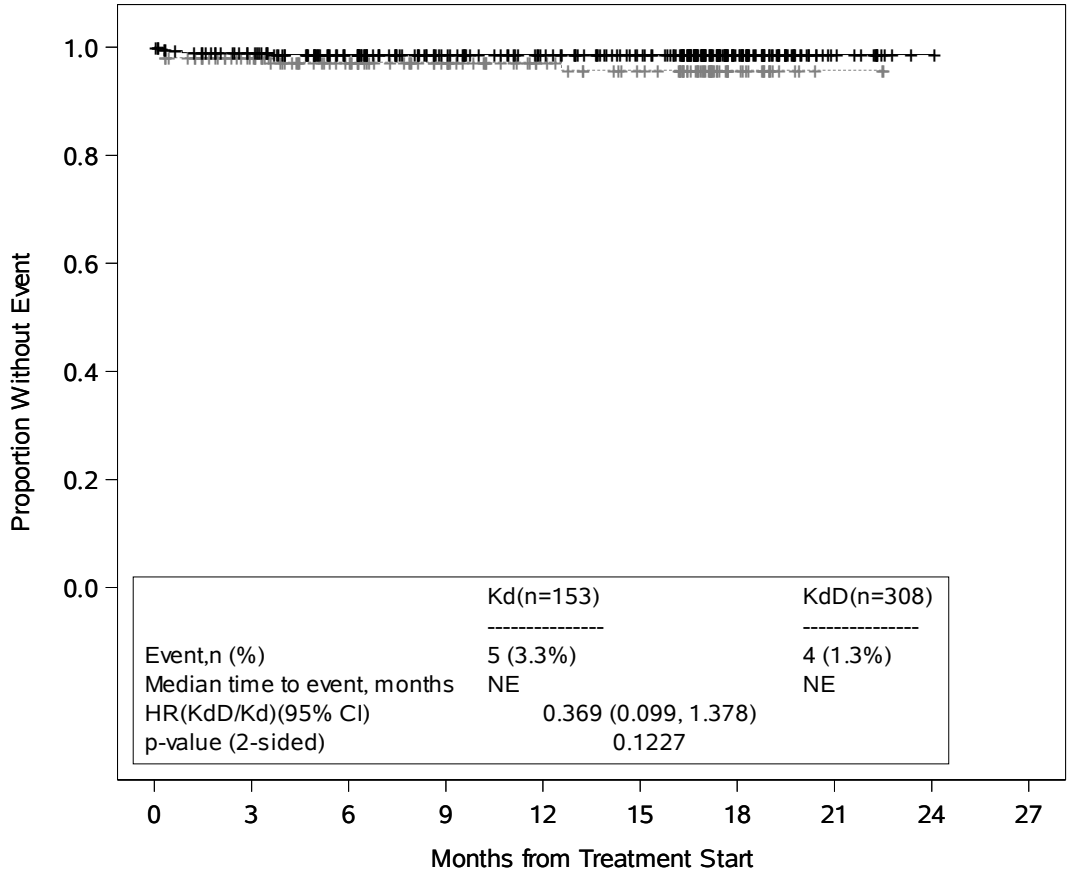


Number of Subjects at Risk:

Kd	153	132	108	88	68	58	18	2	0	
KdD	308	289	252	213	192	171	75	14	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-cfz-sub.sas.
Output: f14-06-001-583-sae-cox-cardmyo-cfz.rtf (Date Generated: 27MAY20:04:38:46).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.584. KM Curves of Serious Adverse Events of Interest for Carfilzomib - Dyspnoeas (HLT)
<Safety Population>

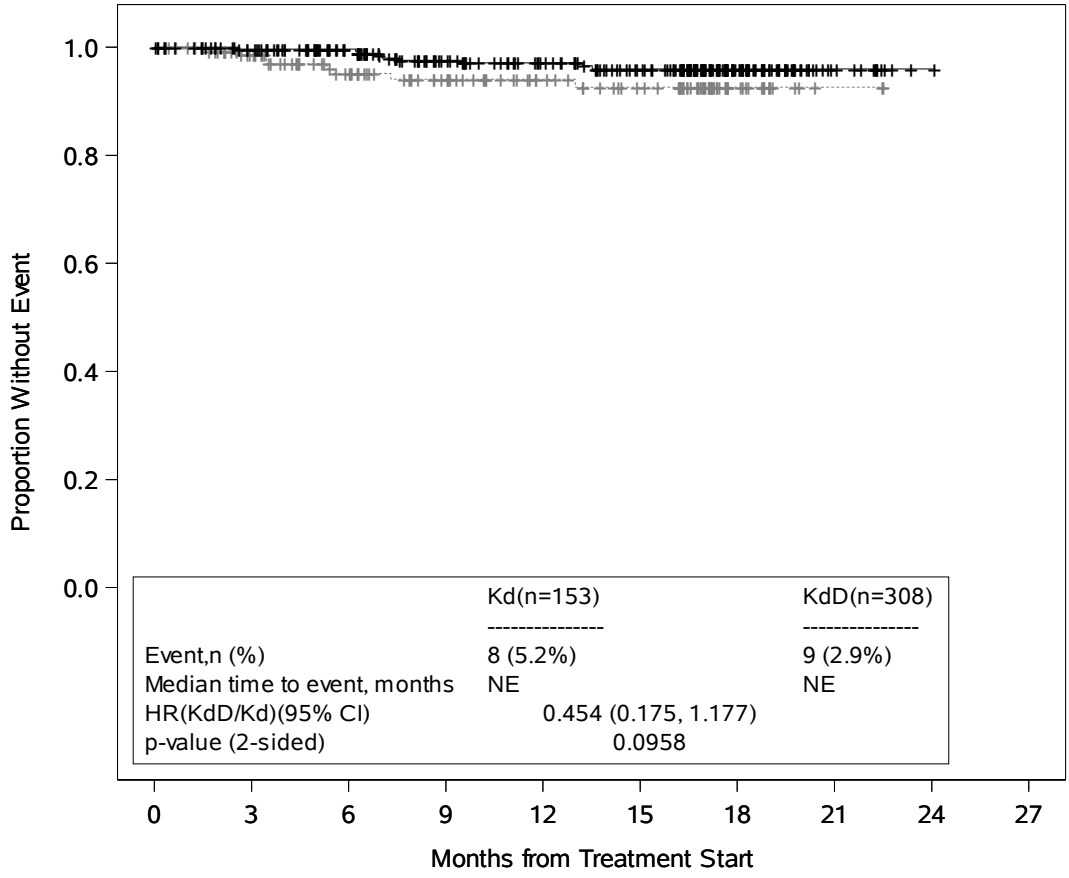


Number of Subjects at Risk:

Kd	153	131	106	86	67	57	18	2	0	
KdD	308	286	251	212	191	169	74	14	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-cfz-sub.sas.
Output: f14-06-001-584-sae-cox-dysp-cfz.rtf (Date Generated: 27MAY20:04:38:48).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.585. KM Curves of Serious Adverse Events of Interest for Carfilzomib - Embolic and Thrombotic Events, Venous (SMQ) - Narrow <Safety Population>

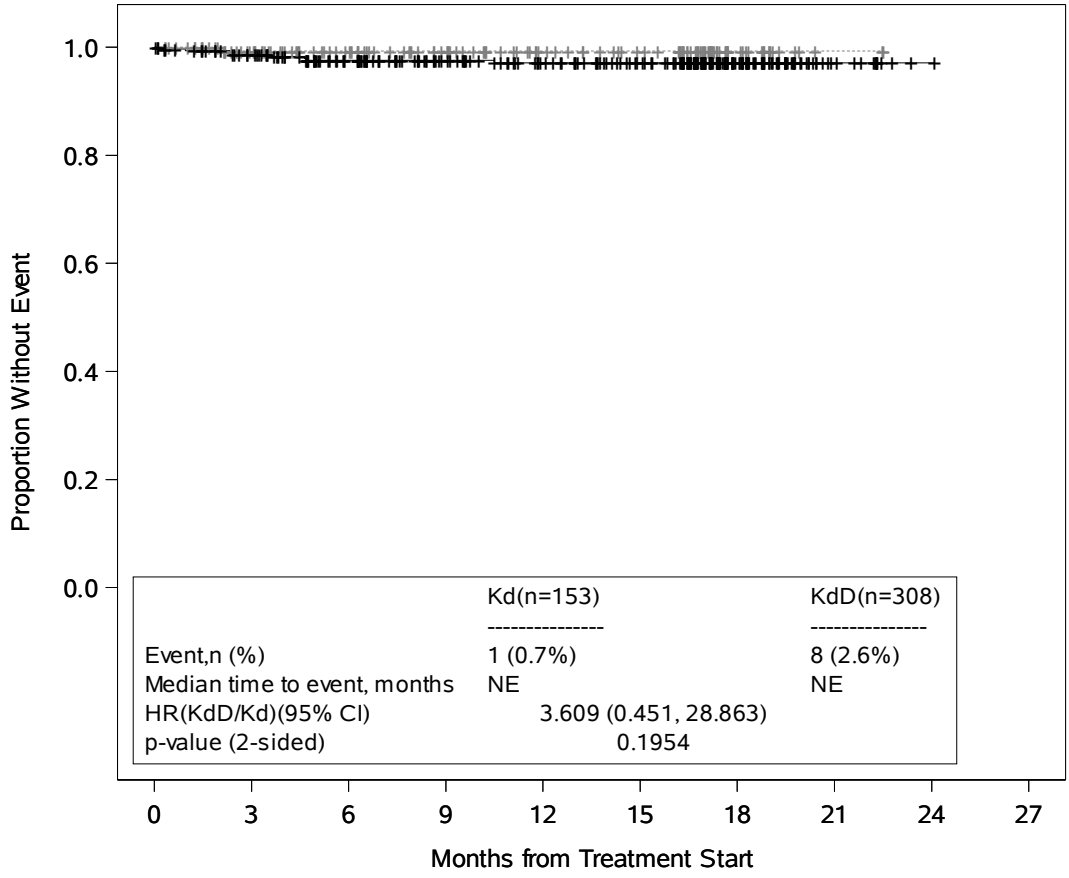


Number of Subjects at Risk:

Kd	153	130	103	83	65	54	17	2	0	
KdD	308	288	252	208	186	162	72	13	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-cfz-sub.sas.
Output: f14-06-001-585-sae-cox-emb-cfz.rtf (Date Generated: 27MAY20:04:38:49).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.586. KM Curves of Serious Adverse Events of Interest for Carfilzomib - Haematopoietic Erythropenia (SMQ) - Broad <Safety Population>

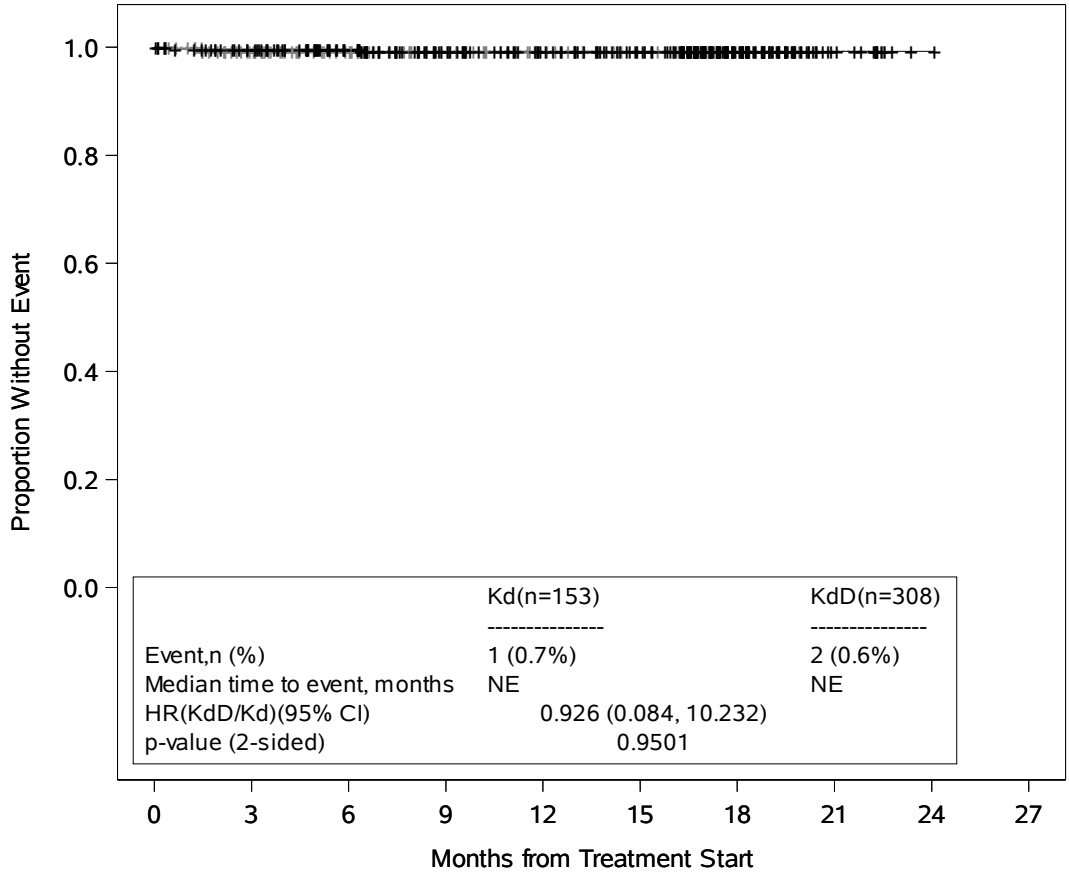


Number of Subjects at Risk:

Kd	153	131	108	88	68	58	18	2	0	
KdD	308	286	250	211	189	167	73	13	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-cfz-sub.sas.
Output: f14-06-001-586-sae-cox-haeery-cfz.rtf (Date Generated: 27MAY20:04:38:51).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.587. KM Curves of Serious Adverse Events of Interest for Carfilzomib - Haematopoietic Leukopenia (SMQ) - Narrow <Safety Population>

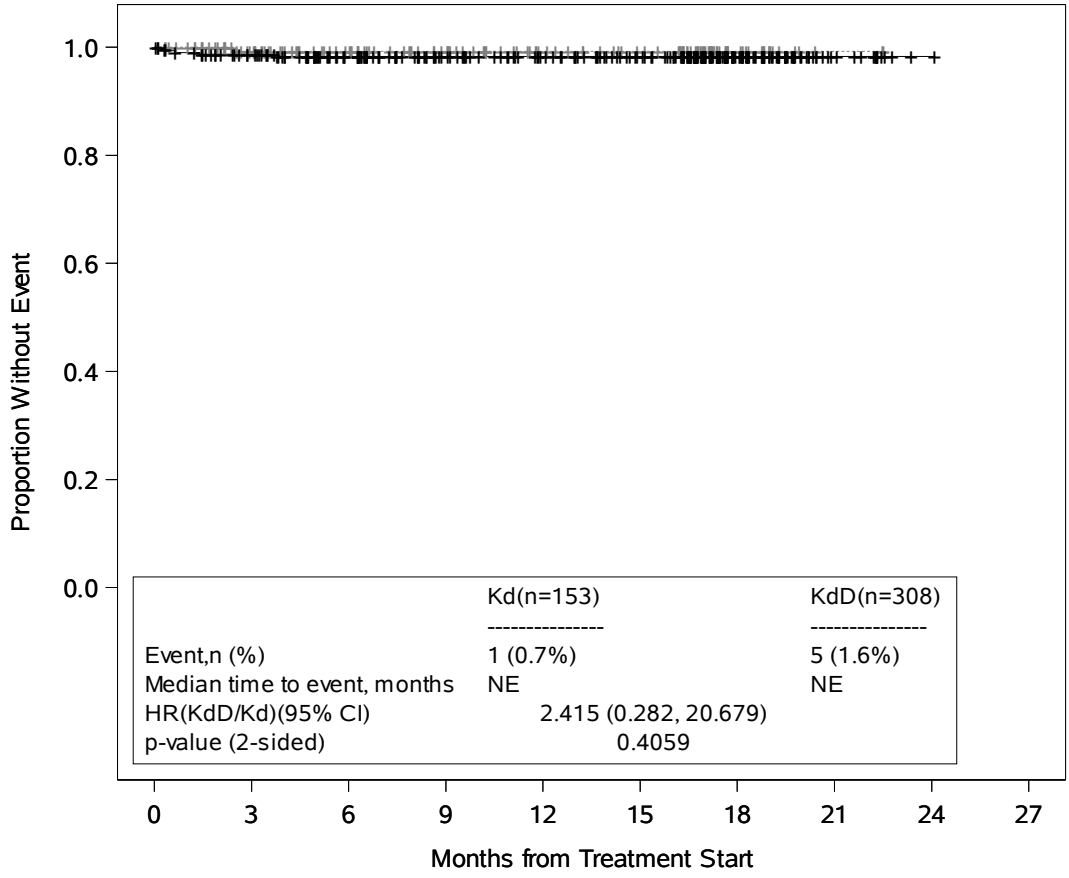


Number of Subjects at Risk:

Kd	153	132	108	88	68	58	18	2	0	
KdD	308	289	253	214	193	171	75	14	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-cfz-sub.sas.
Output: f14-06-001-587-sae-cox-haeleu-cfz.rtf (Date Generated: 27MAY20:04:38:52).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.588. KM Curves of Serious Adverse Events of Interest for Carfilzomib - Haematopoietic Thrombocytopenia (SMQ) - Narrow <Safety Population>

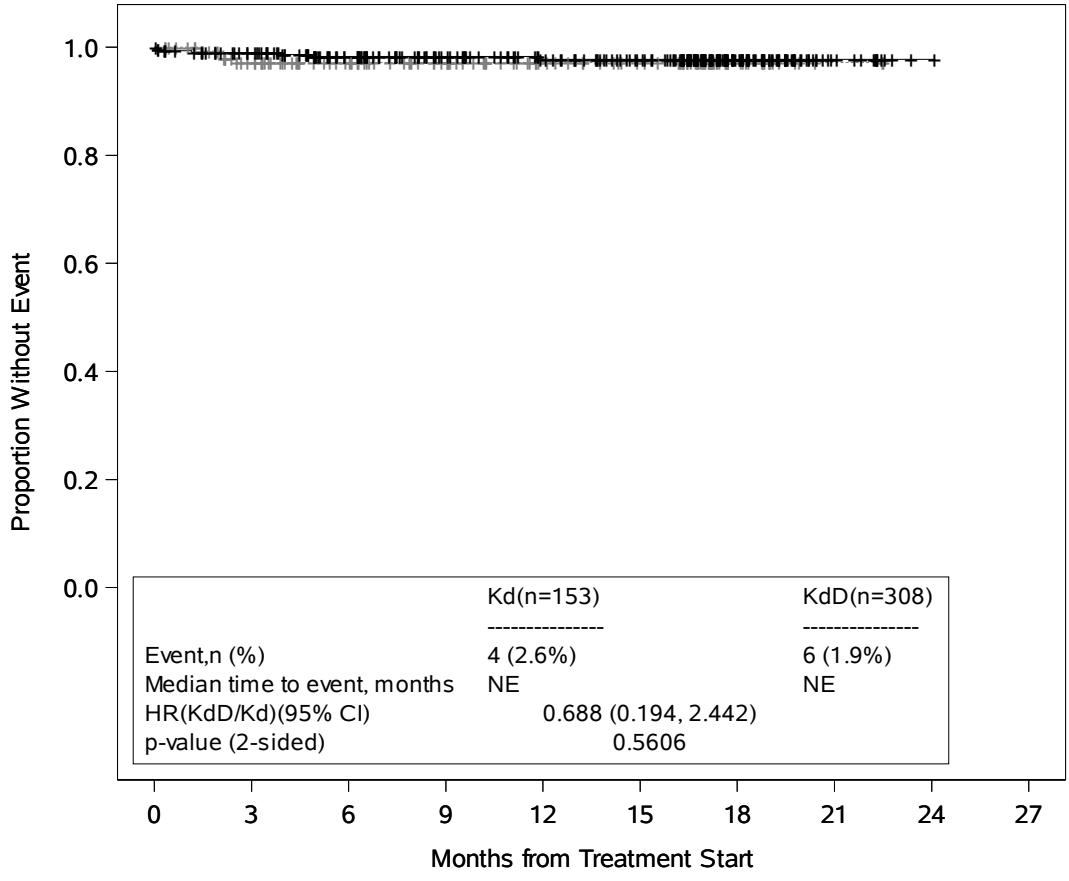


Number of Subjects at Risk:

Kd	153	131	108	88	68	58	18	2	0	
KdD	308	285	249	211	191	169	75	14	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-cfz-sub.sas.
Output: f14-06-001-588-sae-cox-haethr-cfz.rtf (Date Generated: 27MAY20:04:38:54).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.589. KM Curves of Serious Adverse Events of Interest for Carfilzomib - Haemorrhage Terms (Excl Laboratory Terms) (SMQ) - Narrow <Safety Population>

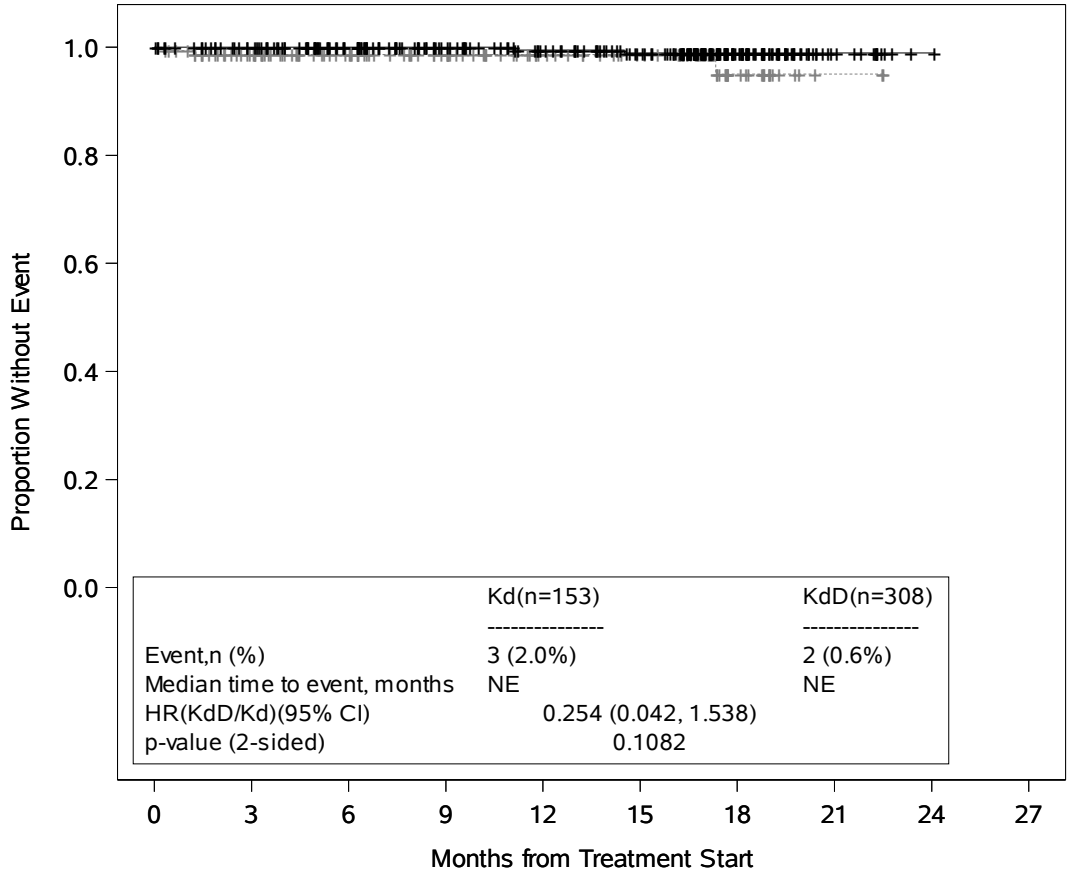


Number of Subjects at Risk:

Kd	153	129	108	88	68	58	18	2	0	
KdD	308	287	251	213	191	170	74	14	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-cfz-sub.sas.
Output: f14-06-001-589-sae-cox-haeterm-cfz.rtf (Date Generated: 27MAY20:04:38:56).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.590. KM Curves of Serious Adverse Events of Interest for Carfilzomib - Hypertension (SMQ) - Narrow
<Safety Population>

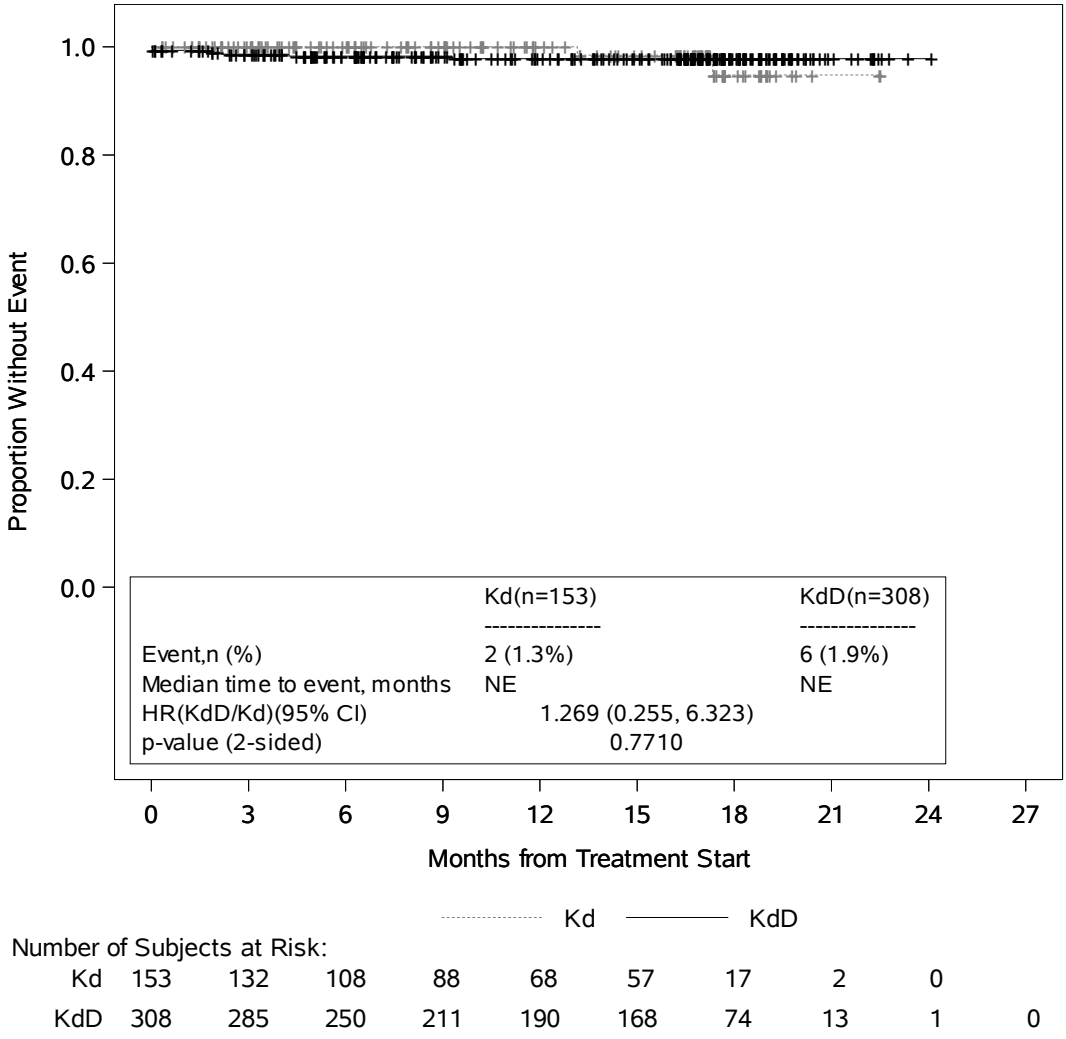


Number of Subjects at Risk:

Kd	153	132	108	88	68	58	17	2	0	
KdD	308	289	253	214	192	169	74	14	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-cfz-sub.sas.
Output: f14-06-001-590-sae-cox-hyper-cfz.rtf (Date Generated: 27MAY20:04:38:57).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.591. KM Curves of Serious Adverse Events of Interest for Carfilzomib - Infusion Reaction (AMQ) - Narrow (Event on Same Date of any Carfilzomib Dosing)
<Safety Population>

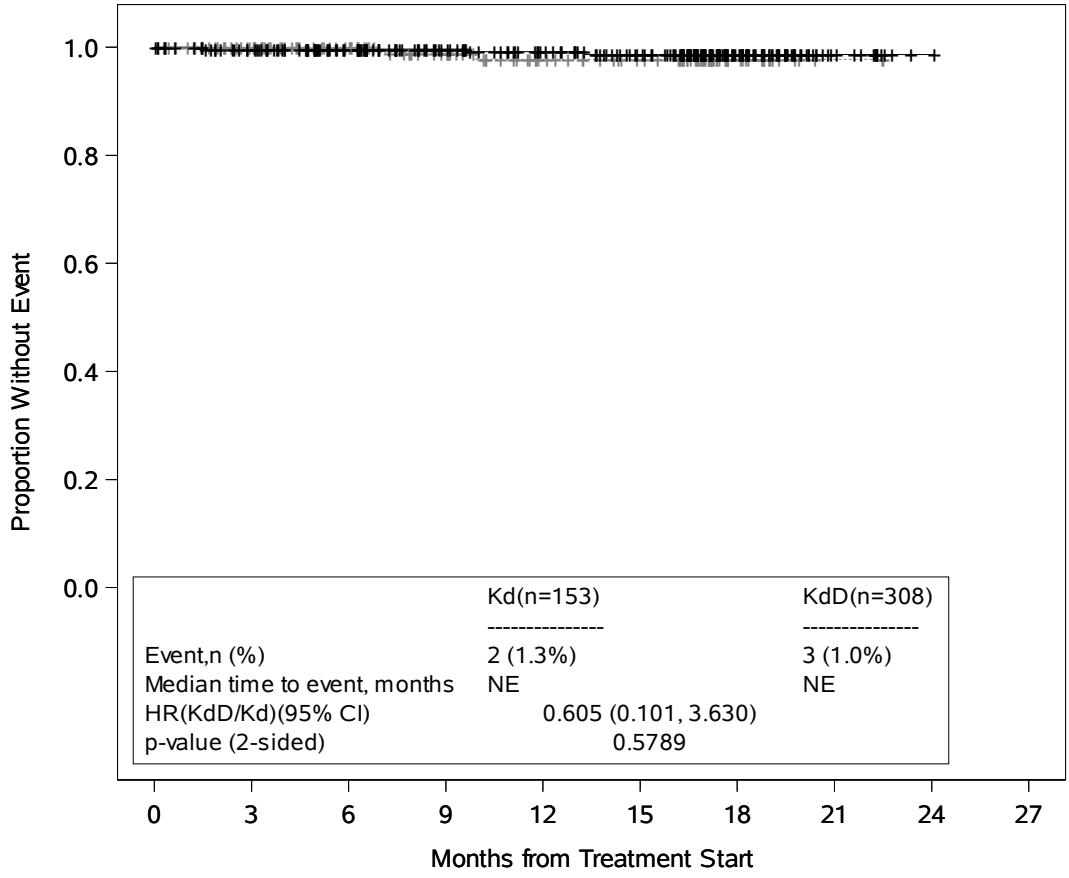


Number of Subjects at Risk:

Kd	153	132	108	88	68	57	17	2	0	
KdD	308	285	250	211	190	168	74	13	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-cfz-sub.sas.
Output: f14-06-001-591-sae-cox-infany-cfz.rtf (Date Generated: 27MAY20:04:38:59).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.607. KM Curves of Adverse Events of Interest for Daratumumab - Second Primary Malignancies: Malignant Tumours (SMQ) - Narrow <Safety Population>

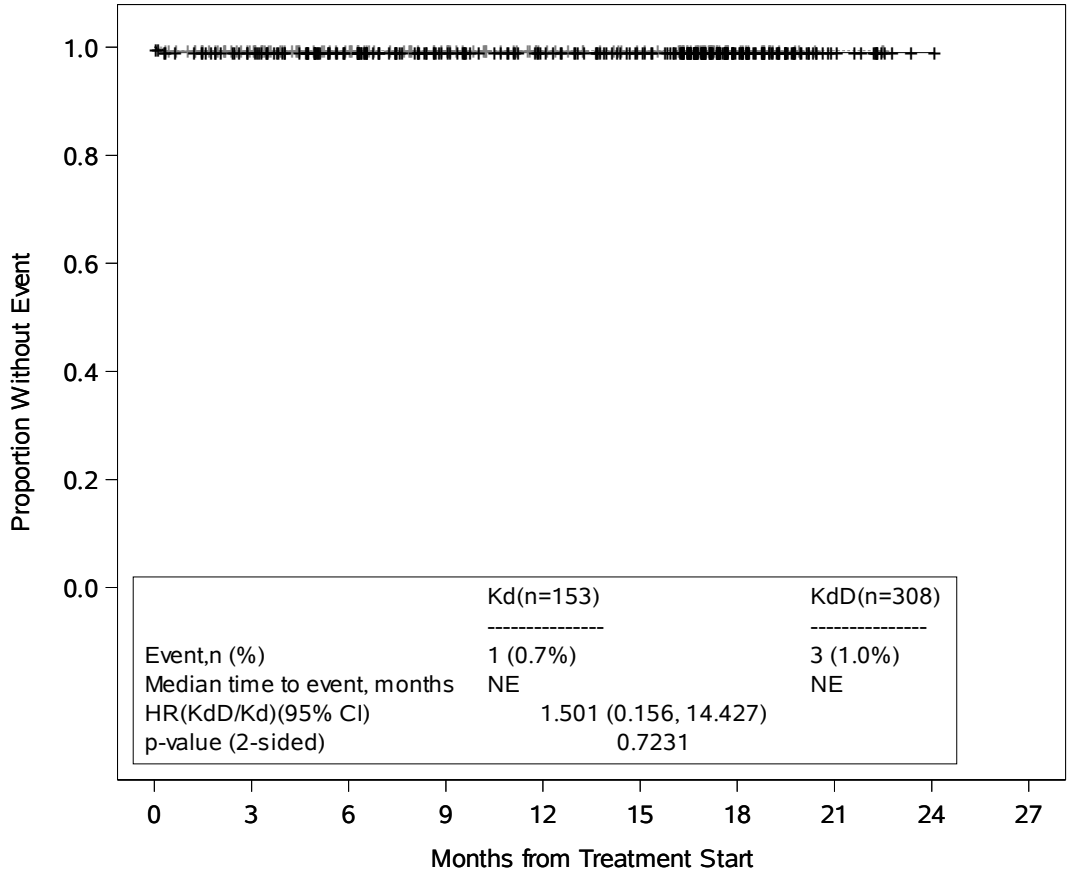


Number of Subjects at Risk:

Kd	153	132	108	88	68	58	18	2	0	
KdD	308	288	252	213	191	169	74	14	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-dar.sas.
Output: f14-06-001-607-ae-cox-mali-dar.rtf (Date Generated: 27MAY20:22:33:24).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.608. KM Curves of Adverse Events of Interest for Daratumumab - Tumour Lysis Syndrome (SMQ) - Narrow
<Safety Population>

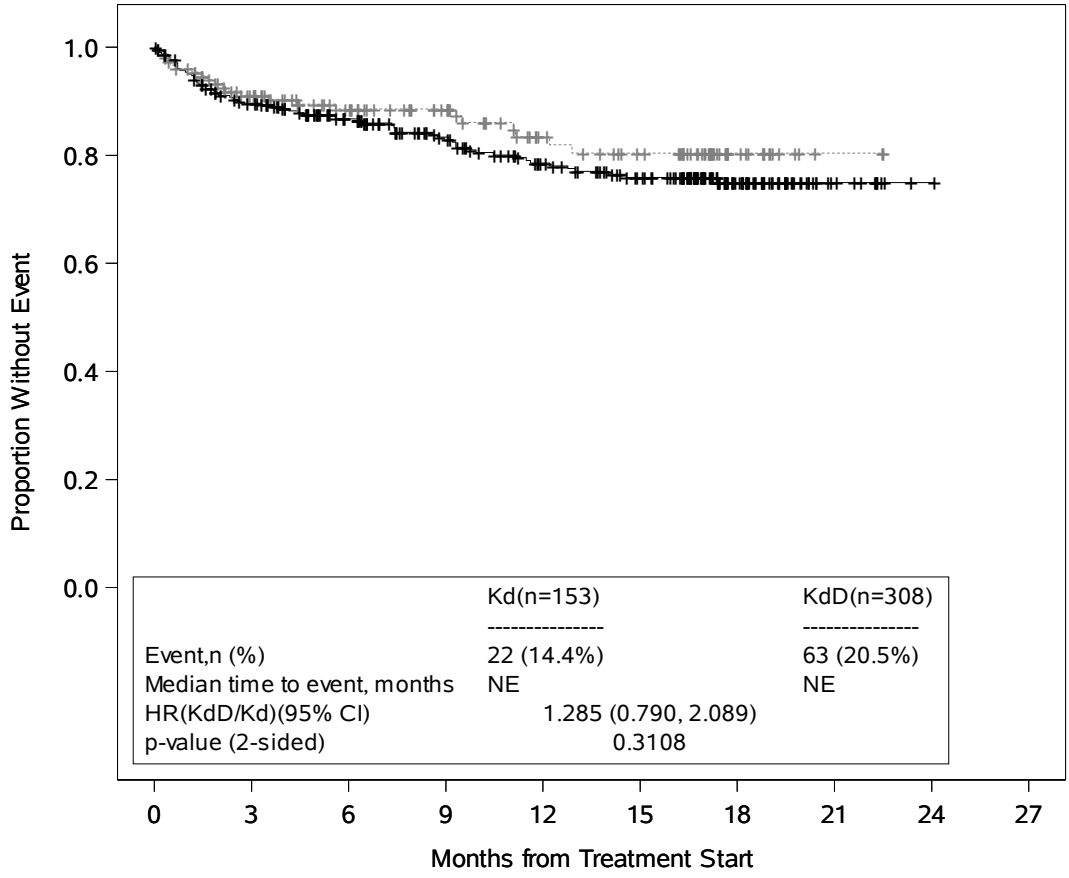


Number of Subjects at Risk:

Kd	153	132	108	88	68	58	18	2	0	
KdD	308	287	252	213	192	171	75	14	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-dar.sas.
Output: f14-06-001-608-ae-cox-lysis-dar.rtf (Date Generated: 27MAY20:22:33:26).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.609. KM Curves of Adverse Events of Interest for Daratumumab - Viral Infection (JMQ)
<Safety Population>

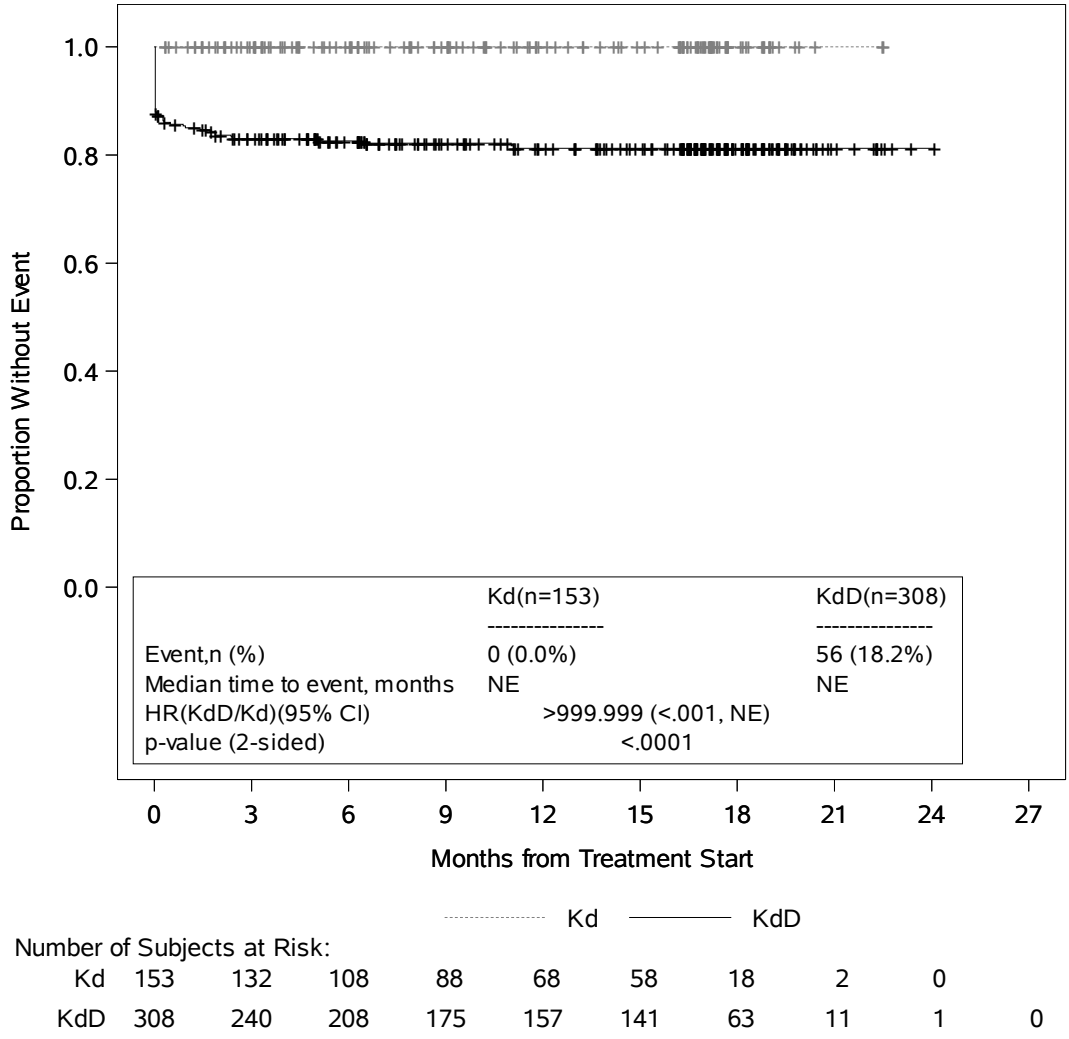


Number of Subjects at Risk:

Kd	153	120	95	78	56	47	15	2	0	
KdD	308	260	221	182	154	133	59	12	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-dar.sas.
Output: f14-06-001-609-ae-cox-viral-dar.rtf (Date Generated: 27MAY20:22:33:28).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.602. KM Curves of Adverse Events of Interest for Daratumumab - Daratumumab-related Infusion Reaction (AMQ) - Narrow (Event on Same Date or Next Date of Any Daratumumab Dosing)
<Safety Population>

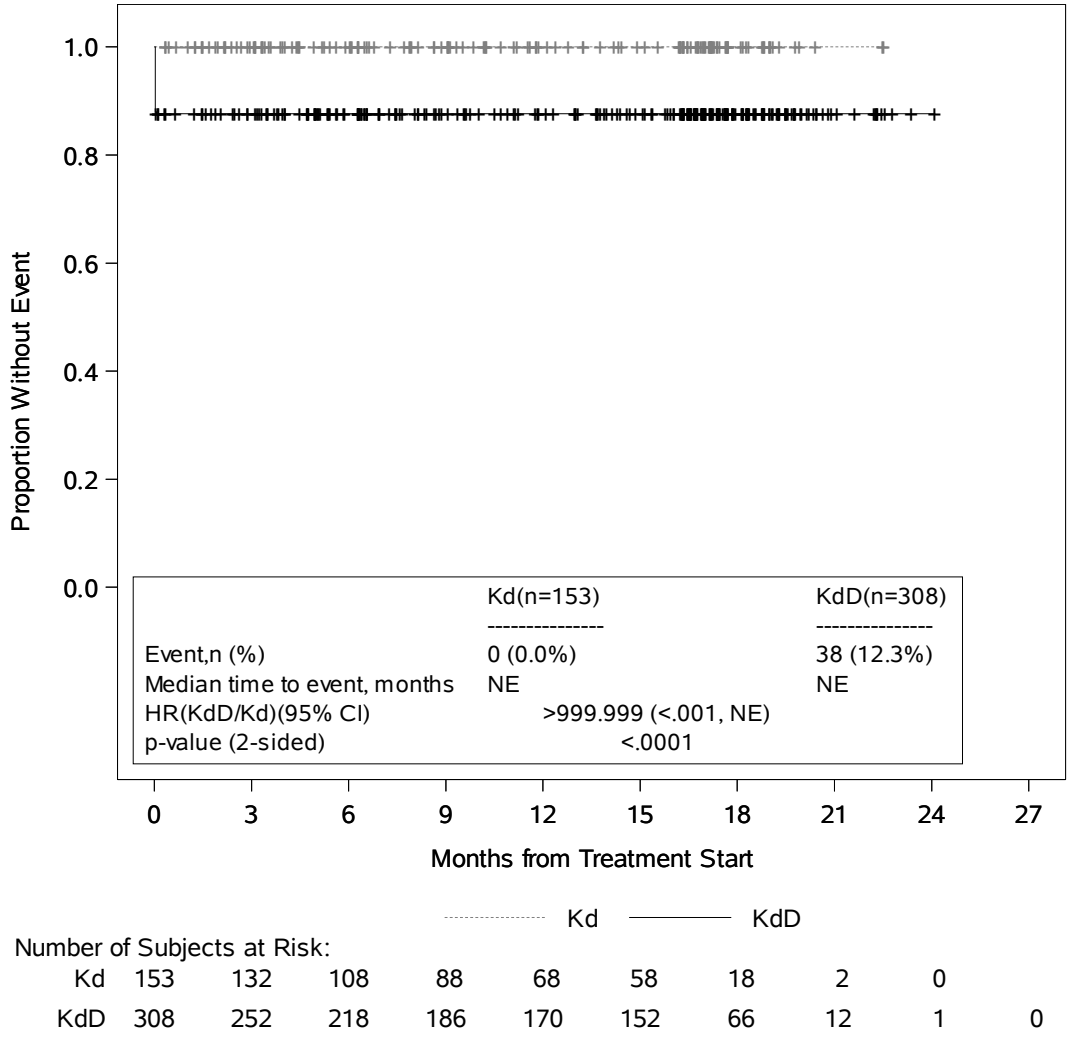


Number of Subjects at Risk:

Kd	153	132	108	88	68	58	18	2	0	
KdD	308	240	208	175	157	141	63	11	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-dar.sas.
Output: f14-06-001-602-ae-cox-infany-dar.rtf (Date Generated: 27MAY20:22:33:06).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.603. KM Curves of Adverse Events of Interest for Daratumumab - Daratumumab-related Infusion Reaction (AMQ) - Narrow (Event on Same Date or Next Date of First Daratumumab Dosing)
<Safety Population>

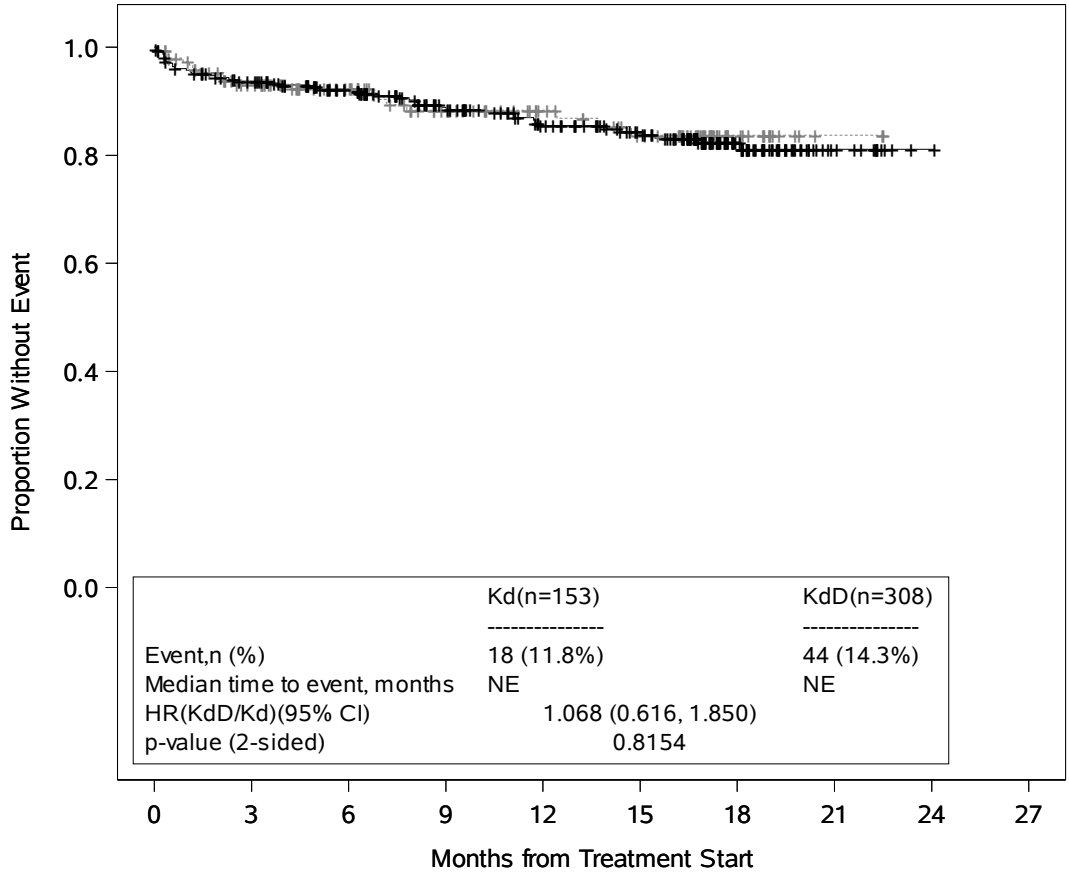


Number of Subjects at Risk:

Kd	153	132	108	88	68	58	18	2	0	
KdD	308	252	218	186	170	152	66	12	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-dar.sas.
Output: f14-06-001-603-ae-cox-infst-dar.rtf (Date Generated: 27MAY20:22:33:08).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.604. KM Curves of Adverse Events of Interest for Daratumumab - Haemorrhage Terms (Excl Laboratory Terms) (SMQ) - Narrow <Safety Population>

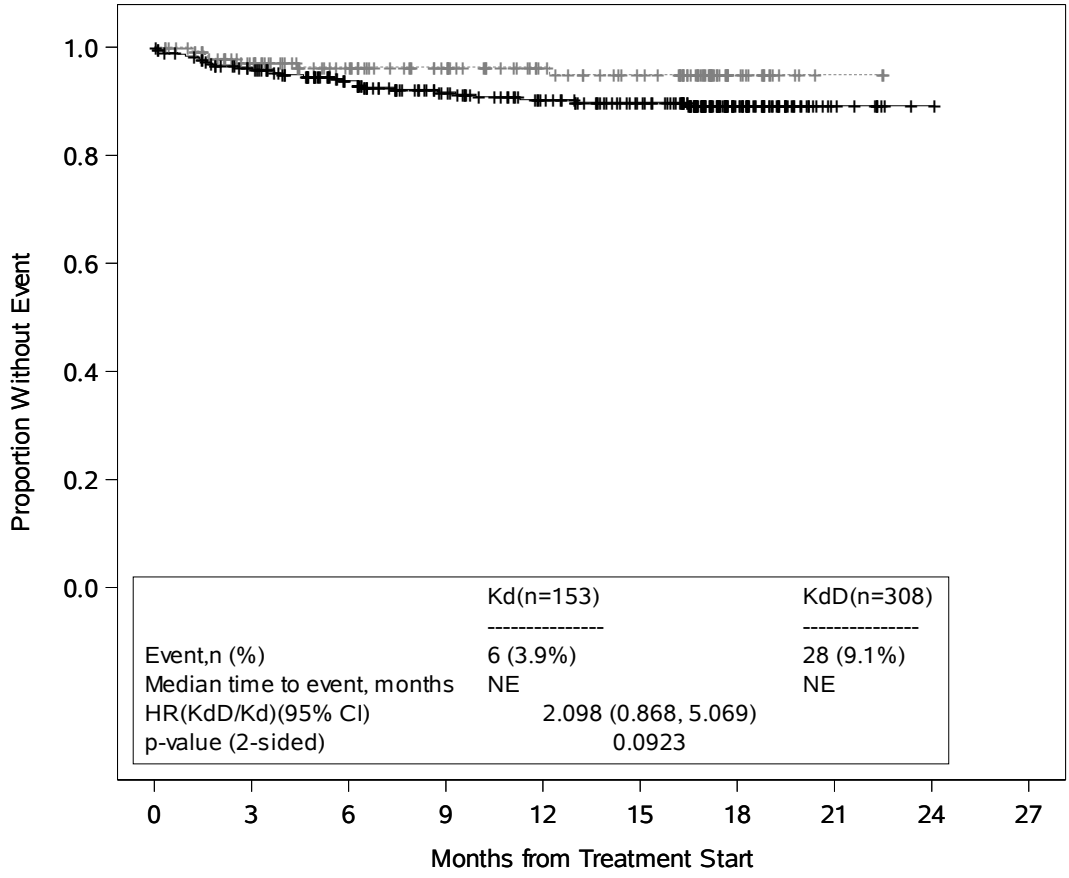


Number of Subjects at Risk:

Kd	153	124	103	80	62	51	16	2	0	
KdD	308	273	239	196	168	146	64	14	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-dar.sas.
Output: f14-06-001-604-ae-cox-haeterm-dar.rtf (Date Generated: 27MAY20:22:33:12).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.606. KM Curves of Adverse Events of Interest for Daratumumab - Opportunistic Infections (JMQ)
<Safety Population>

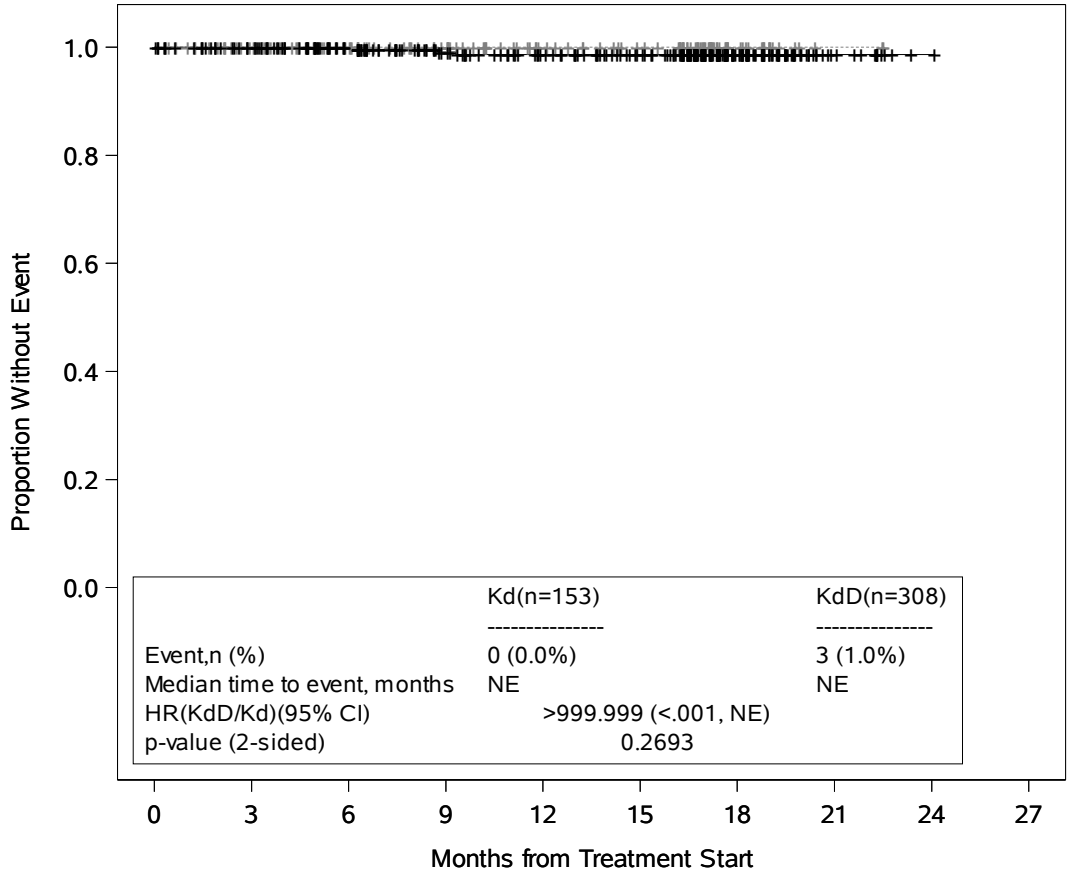


Number of Subjects at Risk:

Kd	153	129	105	87	68	57	17	2	0	
KdD	308	279	239	202	179	156	65	10	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-dar.sas.
Output: f14-06-001-606-ae-cox-oppor-dar.rtf (Date Generated: 27MAY20:22:33:21).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.614. KM Curves of Grade ≥3 Adverse Events of Interest for Daratumumab - Opportunistic Infections (JMQ)
<Safety Population>

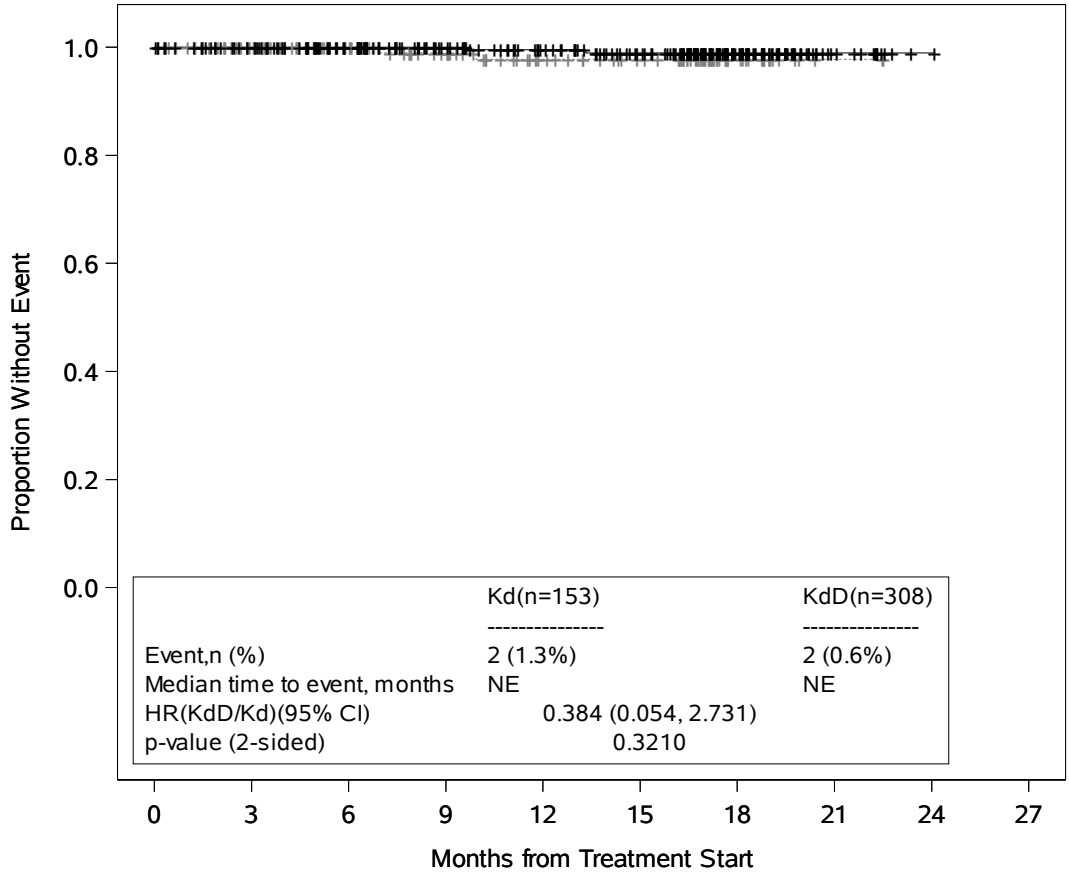


Number of Subjects at Risk:

Kd	153	132	108	88	68	58	18	2	0	
KdD	308	289	253	213	192	170	74	13	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-dar.sas.
Output: f14-06-001-614-ae-cox-oppor-dar-grd345.rtf (Date Generated: 27MAY20:22:33:37).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.615. KM Curves of Grade ≥3 Adverse Events of Interest for Daratumumab - Second Primary Malignancies: Malignant Tumours (SMQ) - Narrow <Safety Population>

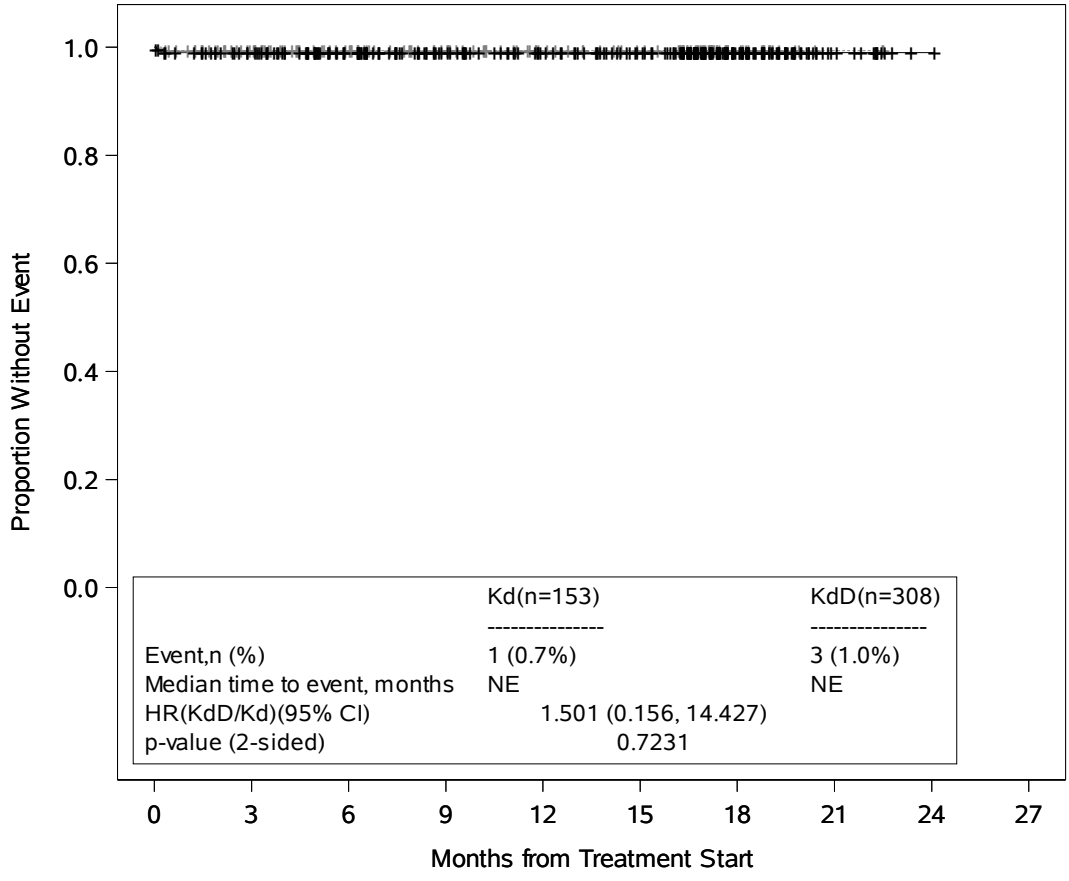


Number of Subjects at Risk:

Kd	153	132	108	88	68	58	18	2	0	
KdD	308	289	253	214	192	170	74	14	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-dar.sas.
Output: f14-06-001-615-ae-cox-mali-dar-grd345.rtf (Date Generated: 27MAY20:22:33:38).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.616. KM Curves of Grade ≥3 Adverse Events of Interest for Daratumumab - Tumour Lysis Syndrome (SMQ) - Narrow <Safety Population>

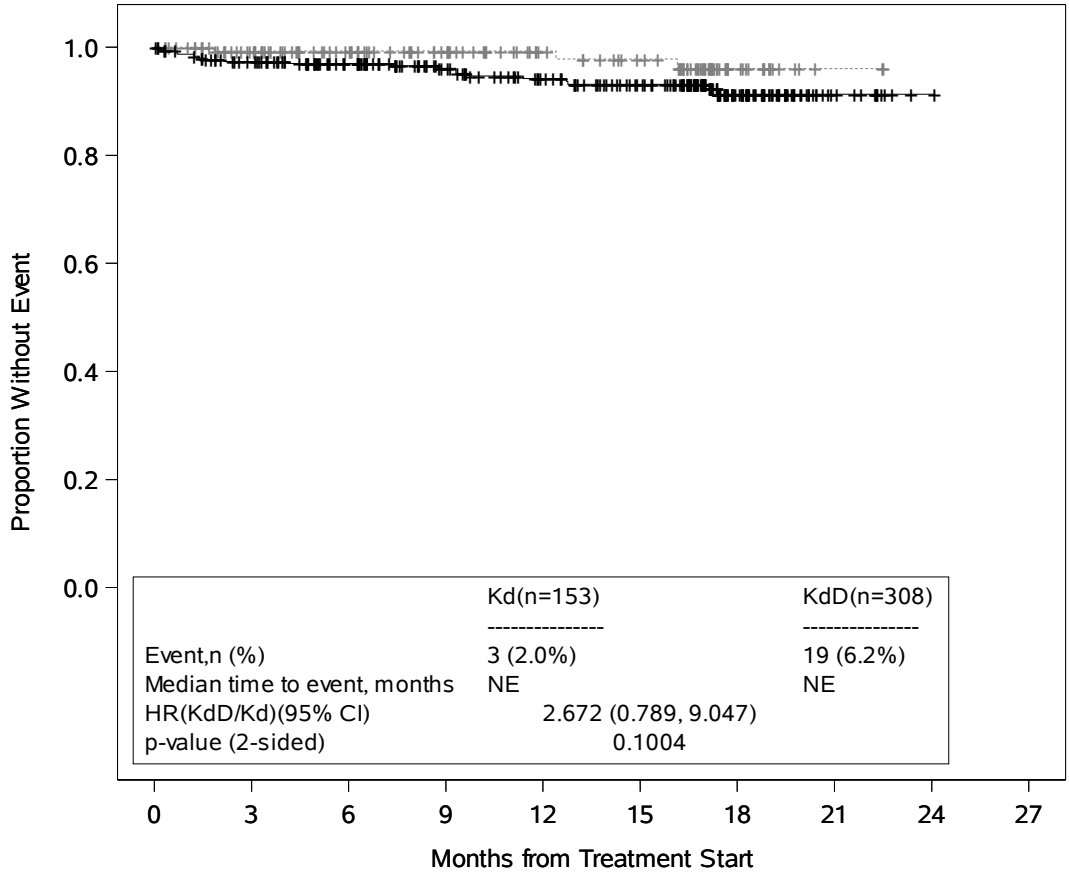


Number of Subjects at Risk:

Kd	153	132	108	88	68	58	18	2	0	
KdD	308	287	252	213	192	171	75	14	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-dar.sas.
Output: f14-06-001-616-ae-cox-lysis-dar-grd345.rtf (Date Generated: 27MAY20:22:33:40).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.617. KM Curves of Grade ≥3 Adverse Events of Interest for Daratumumab - Viral Infection (JMQ)
<Safety Population>

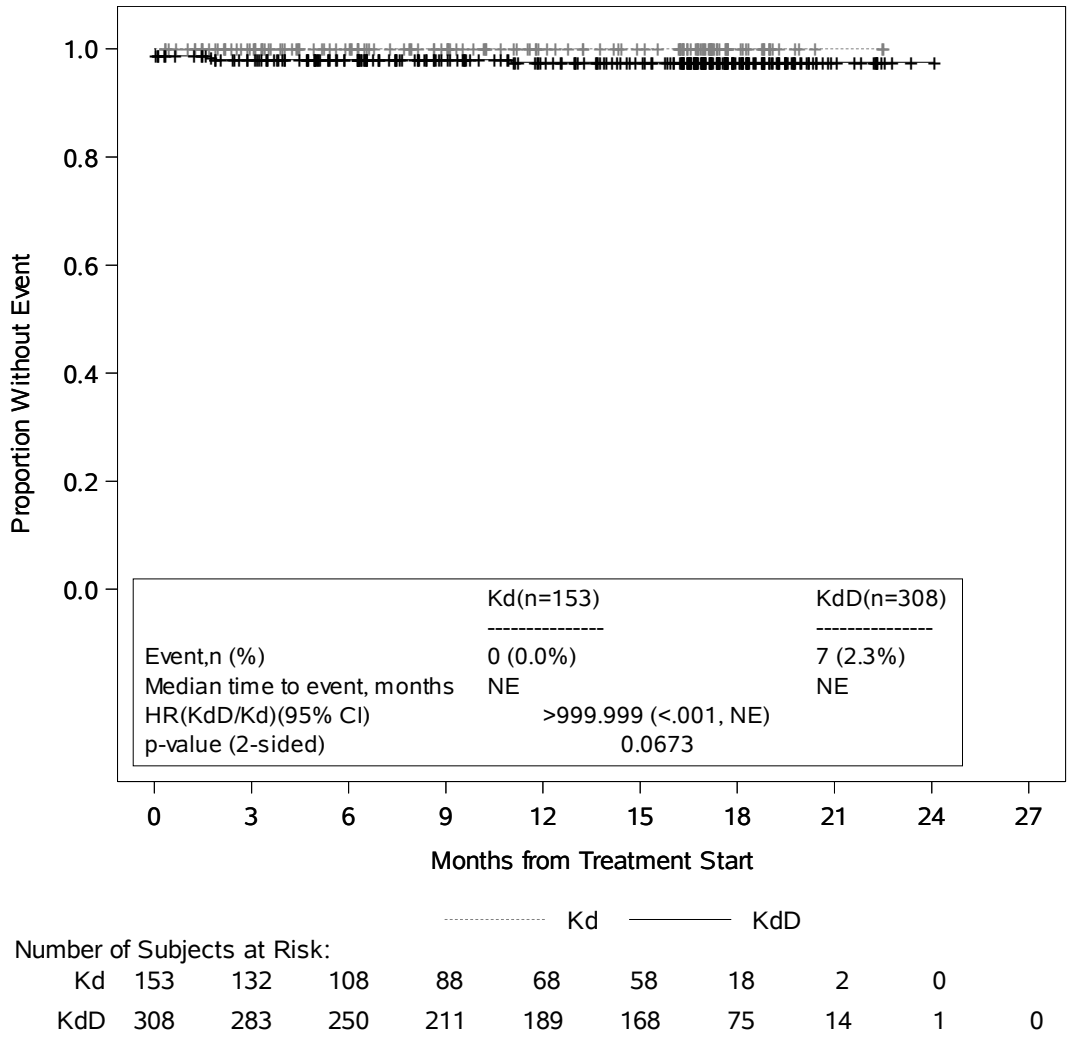


Number of Subjects at Risk:

Kd	153	131	107	87	67	58	17	2	0	
KdD	308	282	248	209	186	163	70	13	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-dar.sas.
Output: f14-06-001-617-ae-cox-viral-dar-grd345.rtf (Date Generated: 27MAY20:22:33:41).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.610. KM Curves of Grade ≥3 Adverse Events of Interest for Daratumumab - Daratumumab-related Infusion Reaction (AMQ) - Narrow (Event on Same Date or Next Date of any Daratumumab Dosing)
<Safety Population>

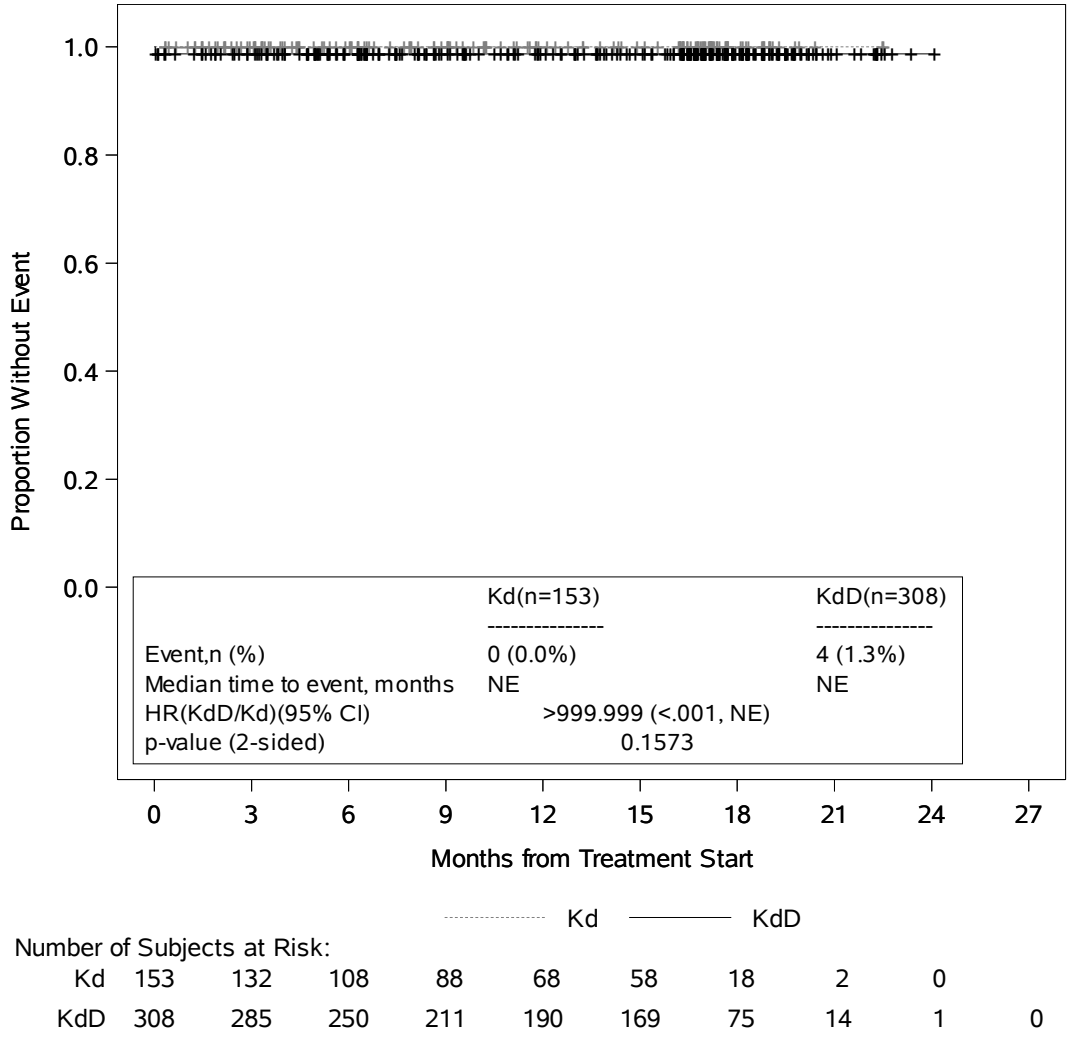


Number of Subjects at Risk:

Kd	153	132	108	88	68	58	18	2	0	
KdD	308	283	250	211	189	168	75	14	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-dar.sas.
Output: f14-06-001-610-ae-cox-infany-dar-grd345.rtf (Date Generated: 27MAY20:22:33:30).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.611. KM Curves of Grade ≥3 Adverse Events of Interest for Daratumumab - Daratumumab-related Infusion Reaction (AMQ) - Narrow (Event on Same Date or Next Date of First Daratumumab Dosing)
<Safety Population>

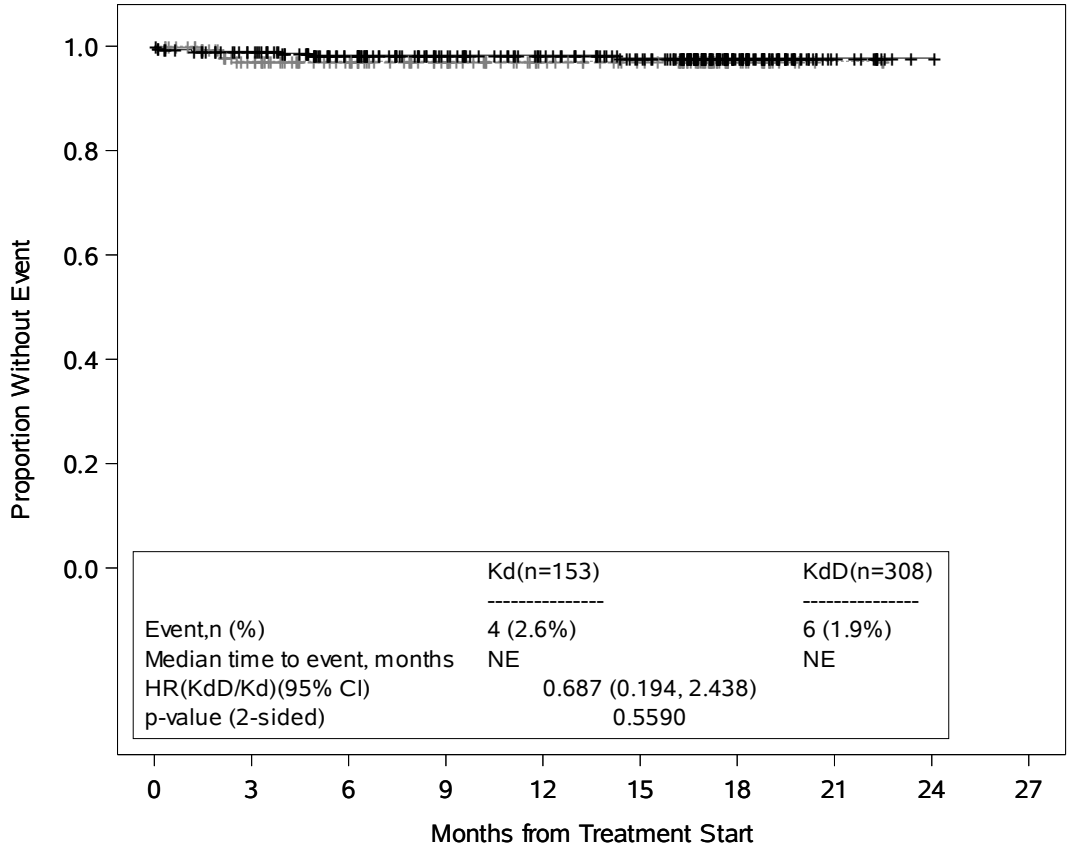


Number of Subjects at Risk:

Kd	153	132	108	88	68	58	18	2	0	
KdD	308	285	250	211	190	169	75	14	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-dar.sas.
Output: f14-06-001-611-ae-cox-infst-dar-grd345.rtf (Date Generated: 27MAY20:22:33:32).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.612. KM Curves of Grade ≥3 Adverse Events of Interest for Daratumumab - Haemorrhage Terms (Excl Laboratory Terms) (SMQ) - Narrow <Safety Population>

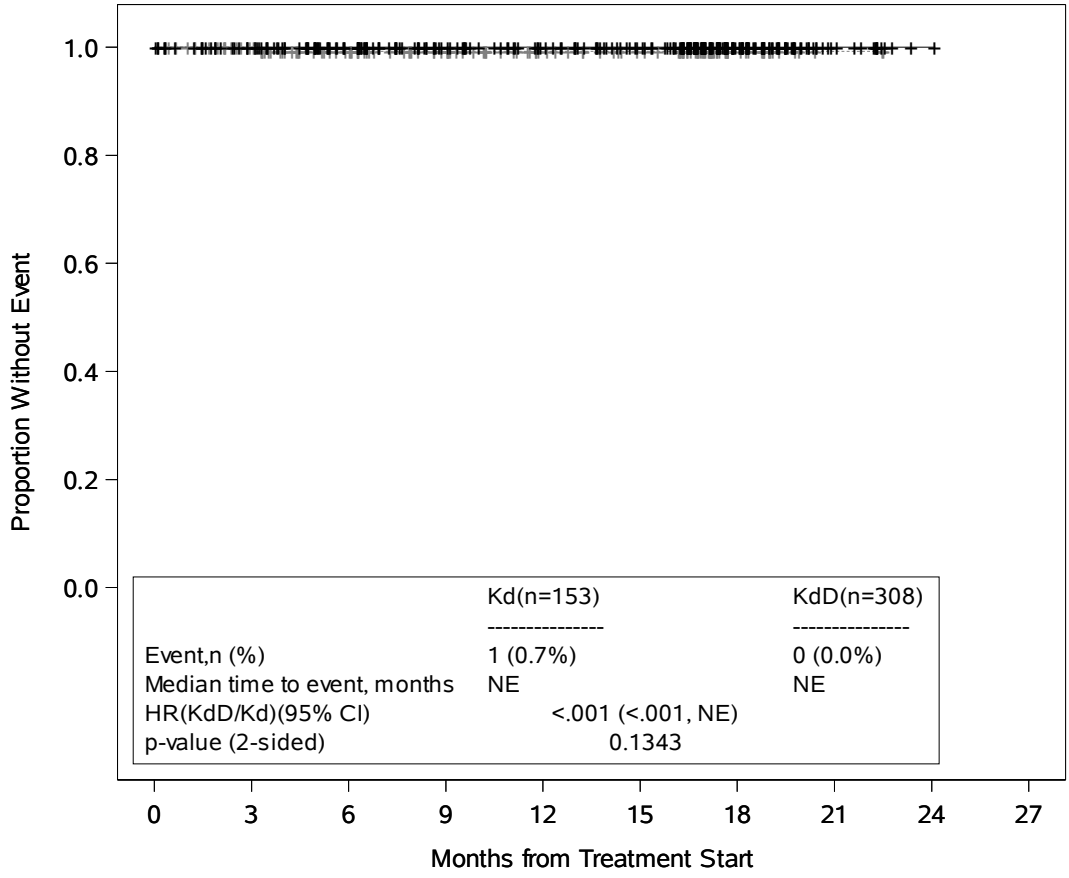


Number of Subjects at Risk:

Kd	153	129	108	88	68	58	18	2	0	
KdD	308	287	251	213	192	170	75	14	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-dar.sas.
Output: f14-06-001-612-ae-cox-haeterm-dar-grd345.rtf (Date Generated: 27MAY20:22:33:34).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.613. KM Curves of Grade ≥3 Adverse Events of Interest for Daratumumab - Intravascular Hemolysis (JMQ)
<Safety Population>

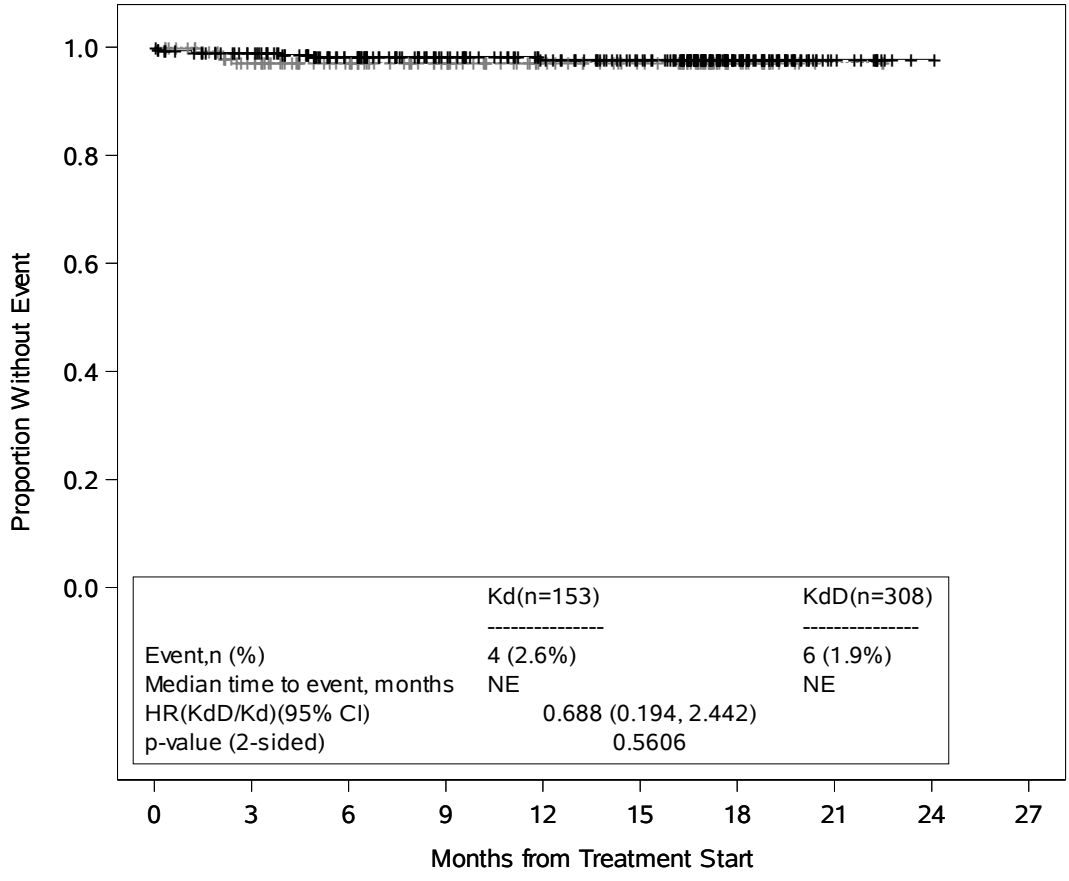


Number of Subjects at Risk:

Kd	153	132	107	87	67	57	17	2	0	
KdD	308	289	253	214	193	171	75	14	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-dar.sas.
Output: f14-06-001-613-ae-cox-intra-dar-grd345.rtf (Date Generated: 27MAY20:22:33:35).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.620. KM Curves of Serious Adverse Events of Interest for Daratumumab - Haemorrhage Terms (Excl Laboratory Terms) (SMQ) - Narrow <Safety Population>

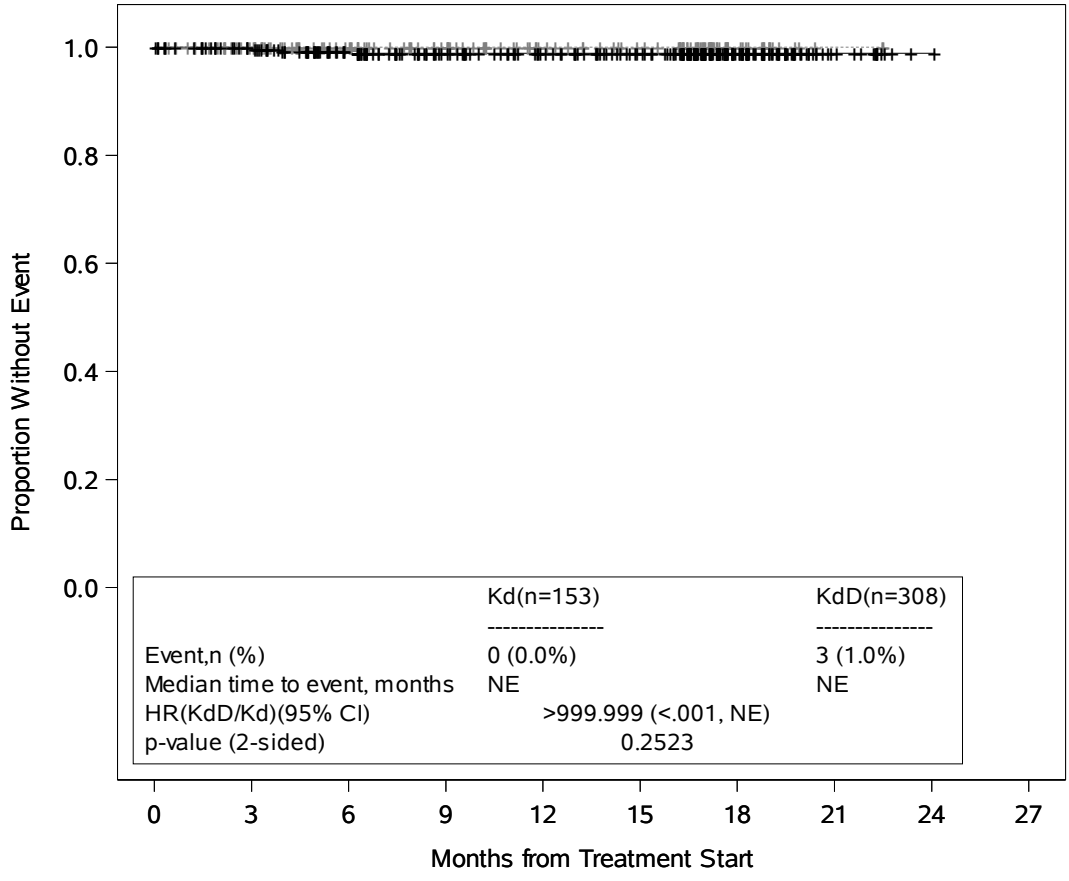


Number of Subjects at Risk:

Kd	153	129	108	88	68	58	18	2	0	
KdD	308	287	251	213	191	170	74	14	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-dar.sas.
Output: f14-06-001-620-sae-cox-haeterm-dar.rtf (Date Generated: 27MAY20:22:33:46).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.621. KM Curves of Serious Adverse Events of Interest for Daratumumab - Opportunistic Infections (JMQ)
<Safety Population>

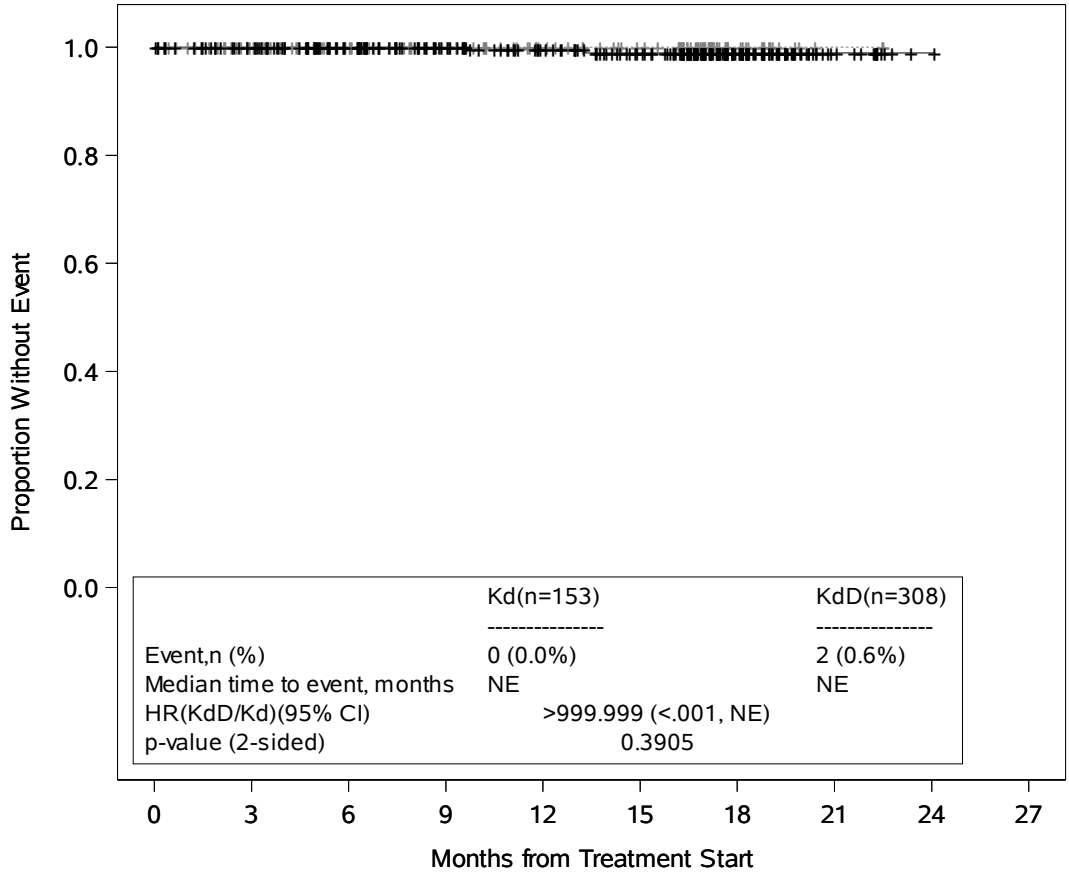


Number of Subjects at Risk:

Kd	153	132	108	88	68	58	18	2	0	
KdD	308	289	252	214	193	171	75	14	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-dar.sas.
Output: f14-06-001-621-sae-cox-oppor-dar.rtf (Date Generated: 27MAY20:22:33:48).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.622. KM Curves of Serious Adverse Events of Interest for Daratumumab - Second Primary Malignancies: Malignant Tumours (SMQ) - Narrow <Safety Population>

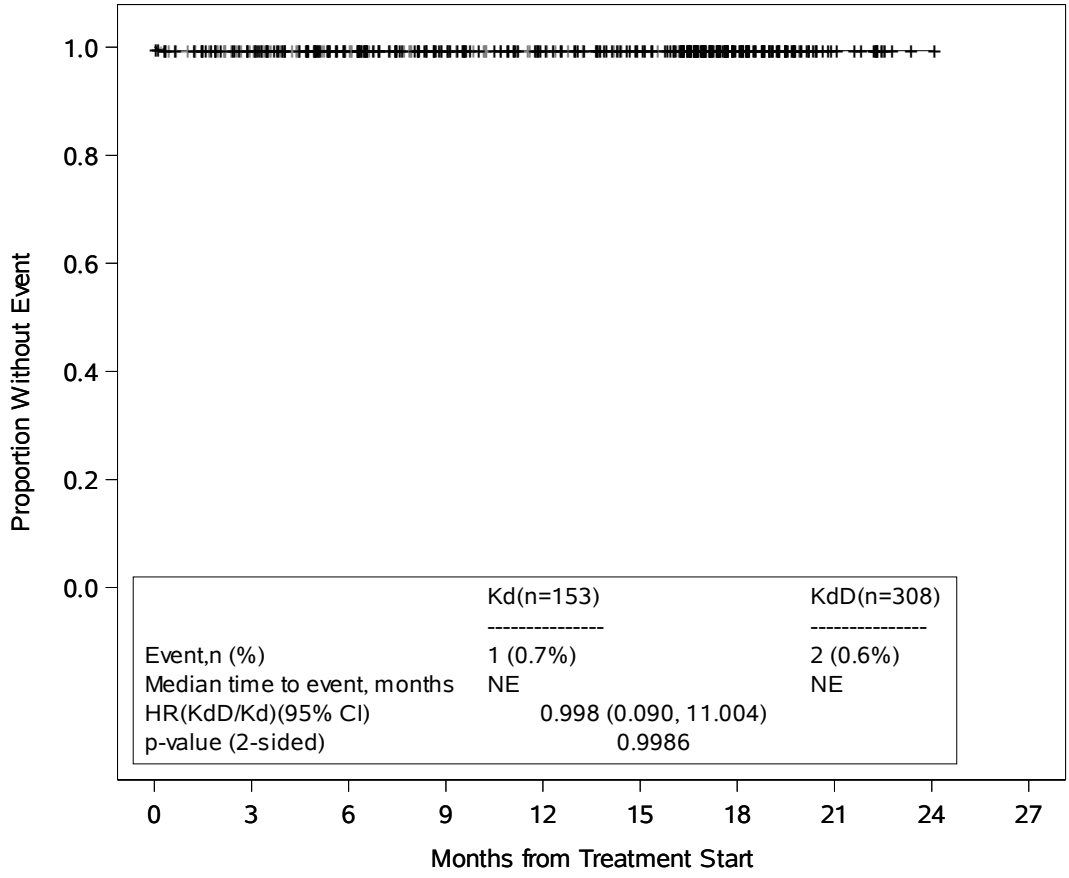


Number of Subjects at Risk:

Kd	153	132	108	88	68	58	18	2	0	
KdD	308	289	253	214	192	170	74	14	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-dar.sas.
Output: f14-06-001-622-sae-cox-mali-dar.rtf (Date Generated: 27MAY20:22:33:49).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.623. KM Curves of Serious Adverse Events of Interest for Daratumumab - Tumour Lysis Syndrome (SMQ) - Narrow <Safety Population>

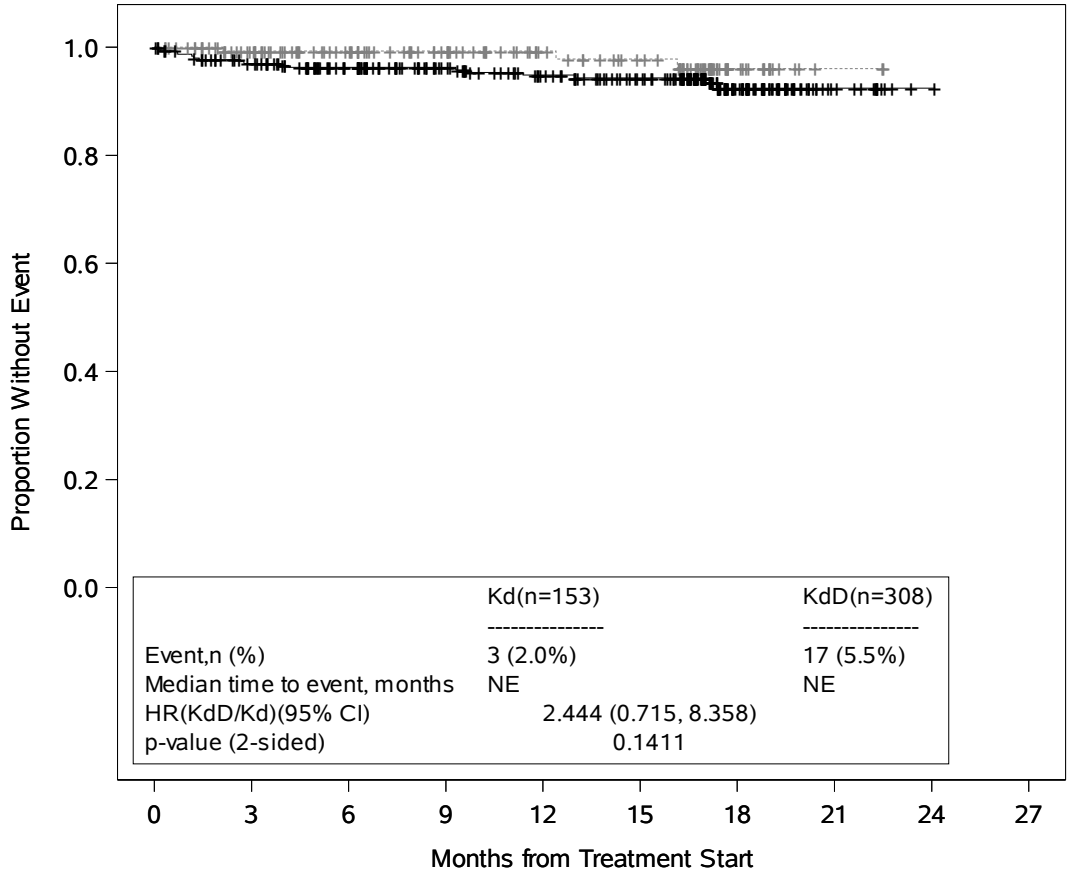


Number of Subjects at Risk:

Kd	153	132	108	88	68	58	18	2	0	
KdD	308	288	252	213	192	171	75	14	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-dar.sas.
Output: f14-06-001-623-sae-cox-lysis-dar.rtf (Date Generated: 27MAY20:22:33:51).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.624. KM Curves of Serious Adverse Events of Interest for Daratumumab - Viral Infection (JMQ)
<Safety Population>

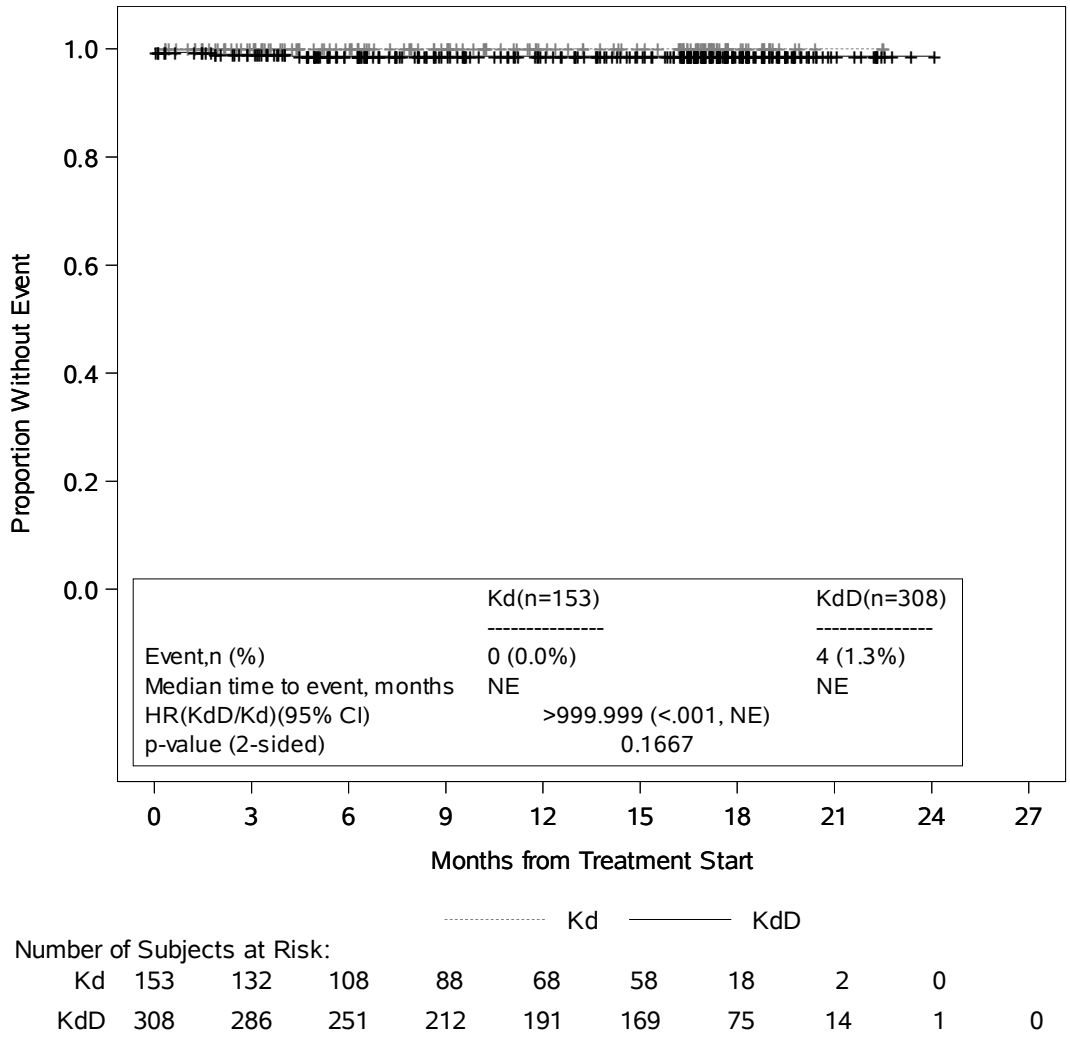


Number of Subjects at Risk:

Kd	153	131	108	88	68	58	17	2	0	
KdD	308	281	247	209	186	164	71	14	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-dar.sas.
Output: f14-06-001-624-sae-cox-viral-dar.rtf (Date Generated: 27MAY20:22:33:53).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.618. KM Curves of Serious Adverse Events of Interest for Daratumumab - Daratumumab-related Infusion Reaction (AMQ) - Narrow (Event on Same Date or Next Date of any Daratumumab Dosing) <Safety Population>

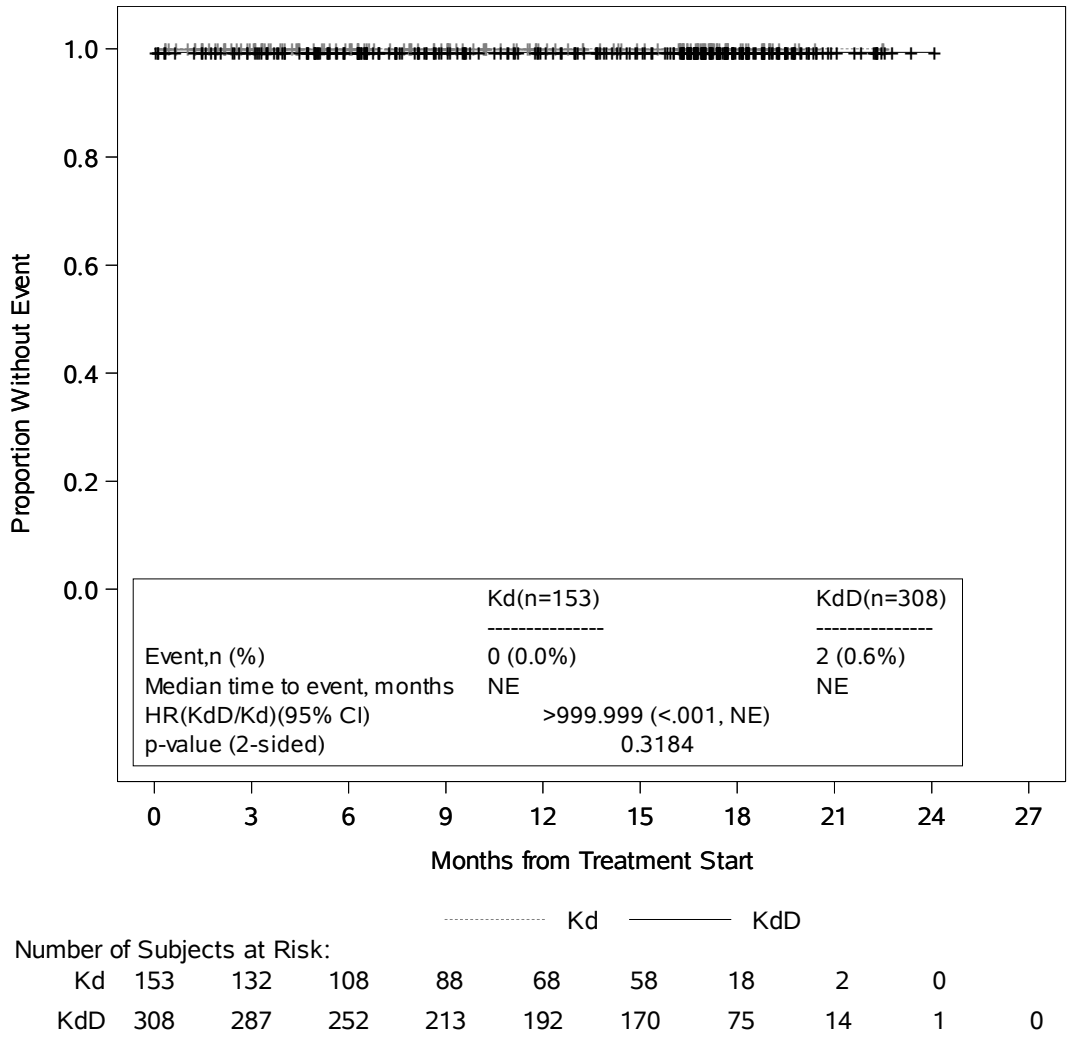


Number of Subjects at Risk:

Kd	153	132	108	88	68	58	18	2	0	
KdD	308	286	251	212	191	169	75	14	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-dar.sas.
Output: f14-06-001-618-sae-cox-infany-dar.rtf (Date Generated: 27MAY20:22:33:43).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.1.619. KM Curves of Serious Adverse Events of Interest for Daratumumab - Daratumumab-related Infusion Reaction (AMQ) - Narrow (Event on Same Date or Next Date of First Daratumumab Dosing)
<Safety Population>

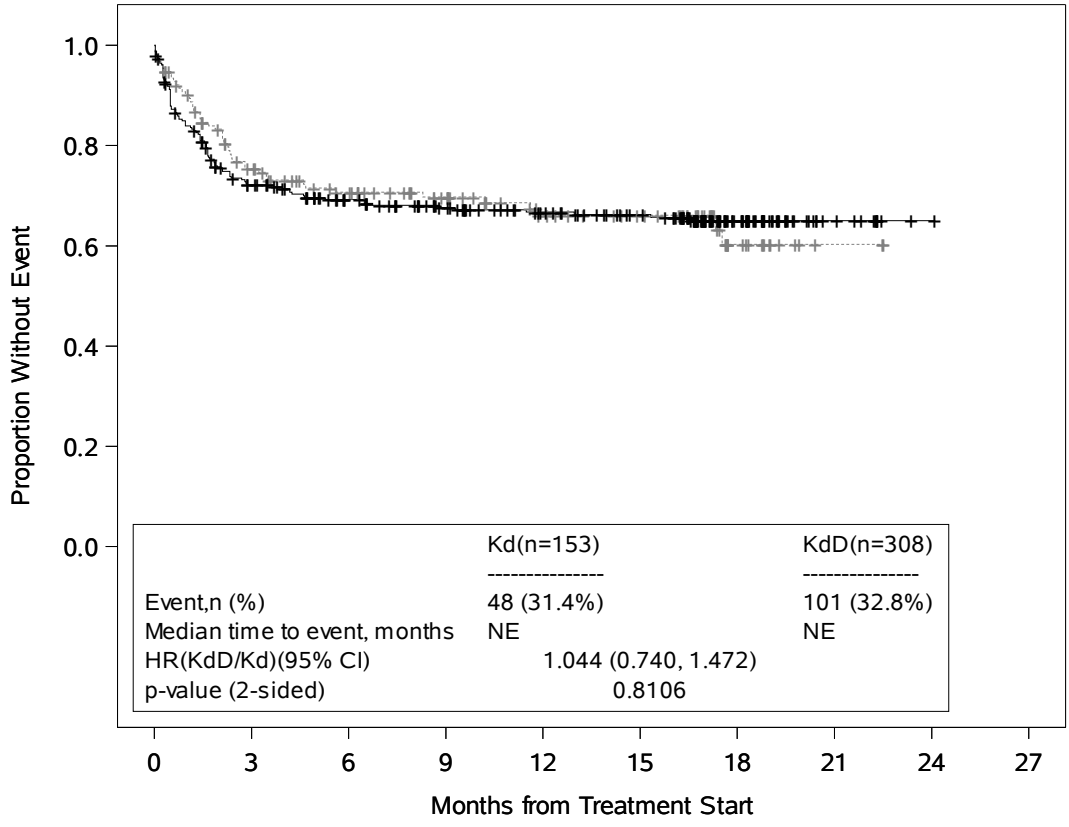


Number of Subjects at Risk:

Kd	153	132	108	88	68	58	18	2	0	
KdD	308	287	252	213	192	170	75	14	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-eoi-dar.sas.
Output: f14-06-001-619-sae-cox-infst-dar.rtf (Date Generated: 27MAY20:22:33:45).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.500. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Blood and Lymphatic System Disorders) and PT (Anaemia) <Safety Population>

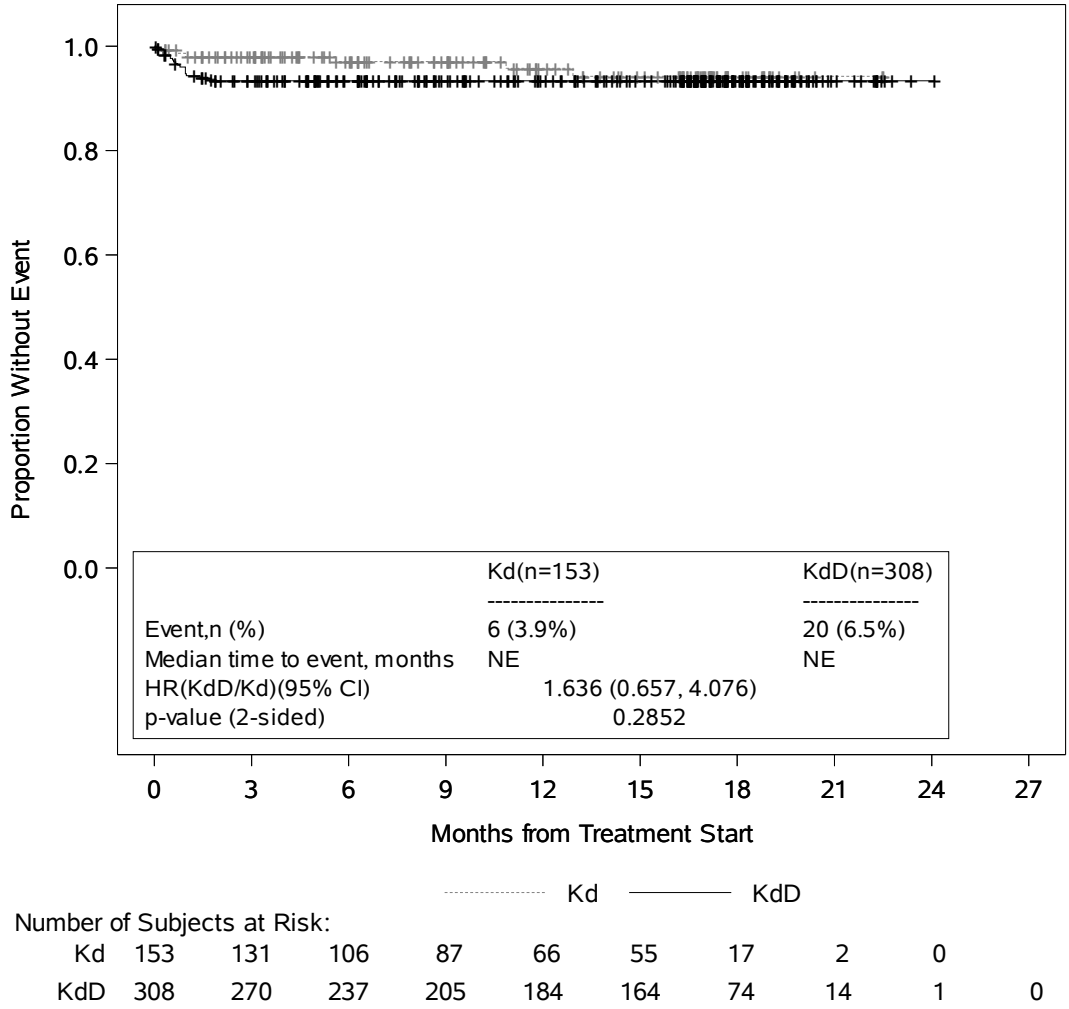


Number of Subjects at Risk:

Kd	153	103	85	68	51	44	14	2	0	
KdD	308	208	178	156	136	121	55	12	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-500-ae-cox-blolym-anaemia-ge10.rtf (Date Generated: 27MAY20:22:27:53).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.501. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Blood and Lymphatic System Disorders) and PT (Leukopenia) <Safety Population>

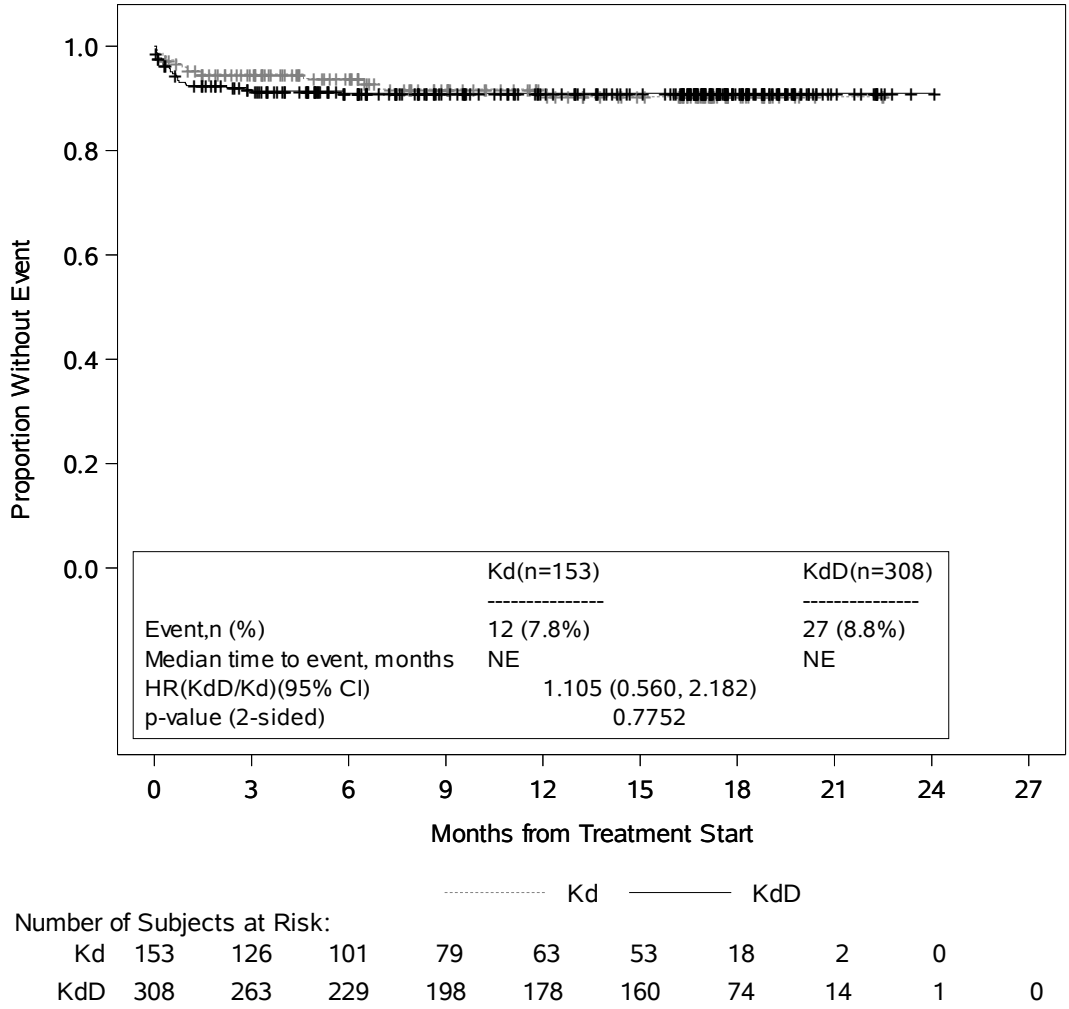


Number of Subjects at Risk:

Kd	153	131	106	87	66	55	17	2	0	
KdD	308	270	237	205	184	164	74	14	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-501-ae-cox-blolym-leuk-ge10.rtf (Date Generated: 27MAY20:22:27:55).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.502. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Blood and Lymphatic System Disorders) and PT (Lymphopenia) <Safety Population>

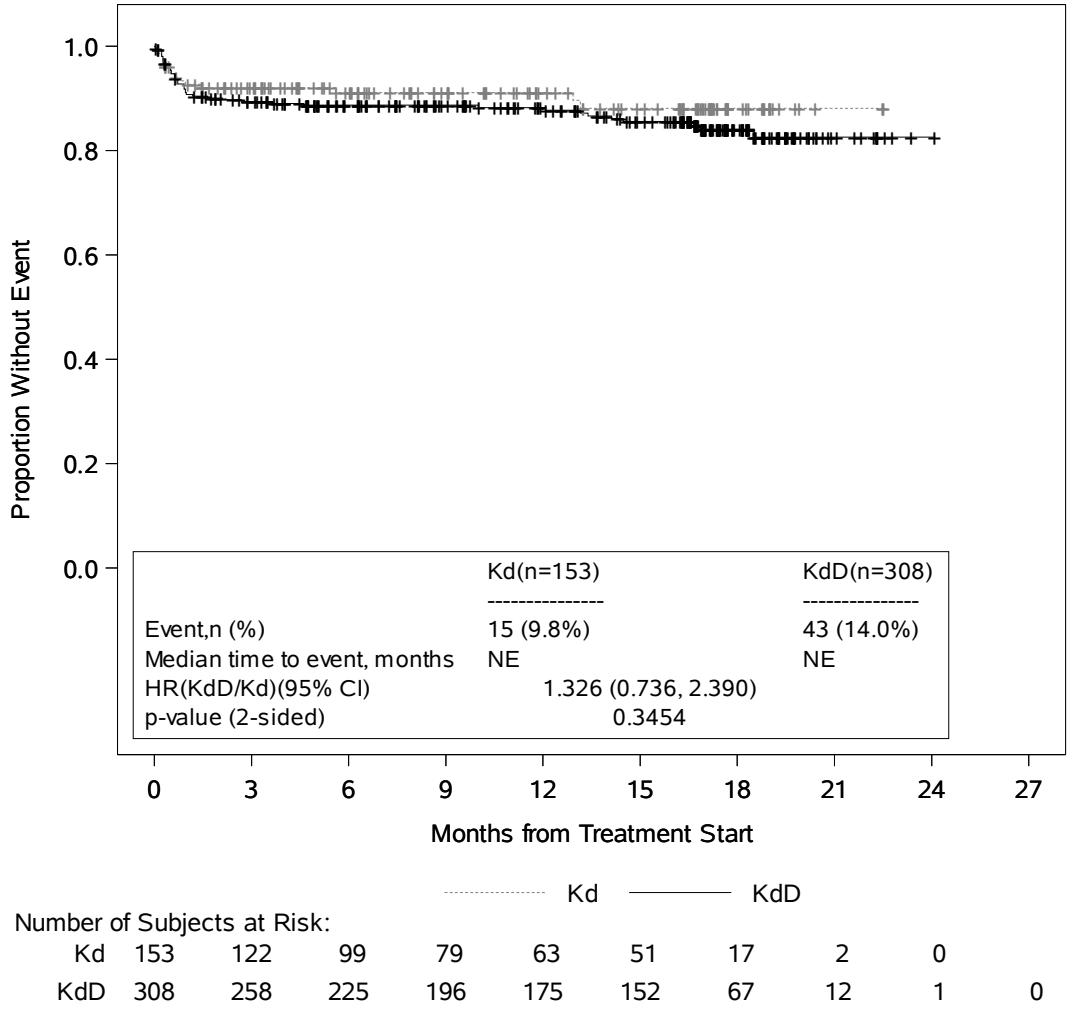


Number of Subjects at Risk:

Kd	153	126	101	79	63	53	18	2	0	
KdD	308	263	229	198	178	160	74	14	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-502-ae-cox-blolym-lym-ge10.rtf (Date Generated: 27MAY20:22:27:57).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.503. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Blood and Lymphatic System Disorders) and PT (Neutropenia) <Safety Population>

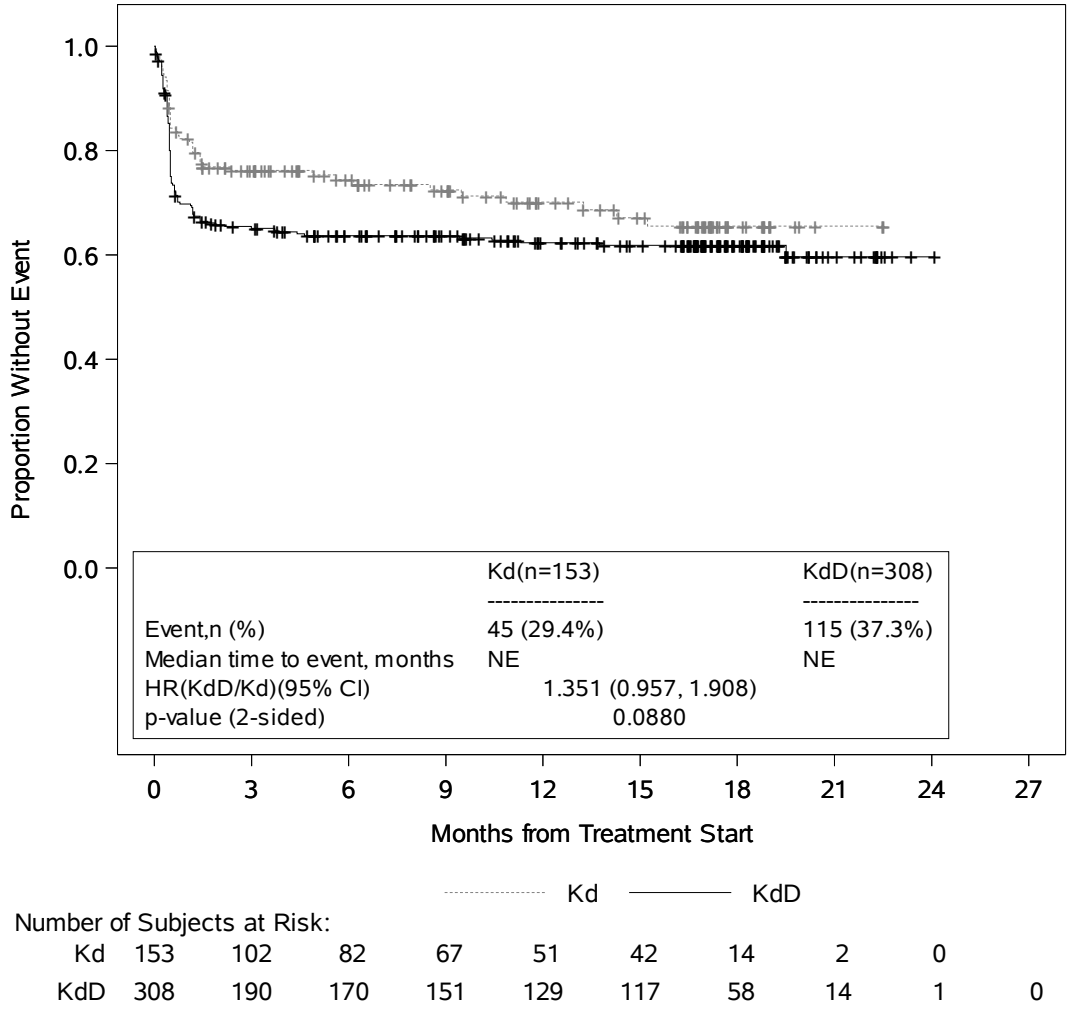


Number of Subjects at Risk:

Kd	153	122	99	79	63	51	17	2	0	
KdD	308	258	225	196	175	152	67	12	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-503-ae-cox-blolym-neu-ge10.rtf (Date Generated: 27MAY20:22:27:58).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.504. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Blood and Lymphatic System Disorders) and PT (Thrombocytopenia) <Safety Population>

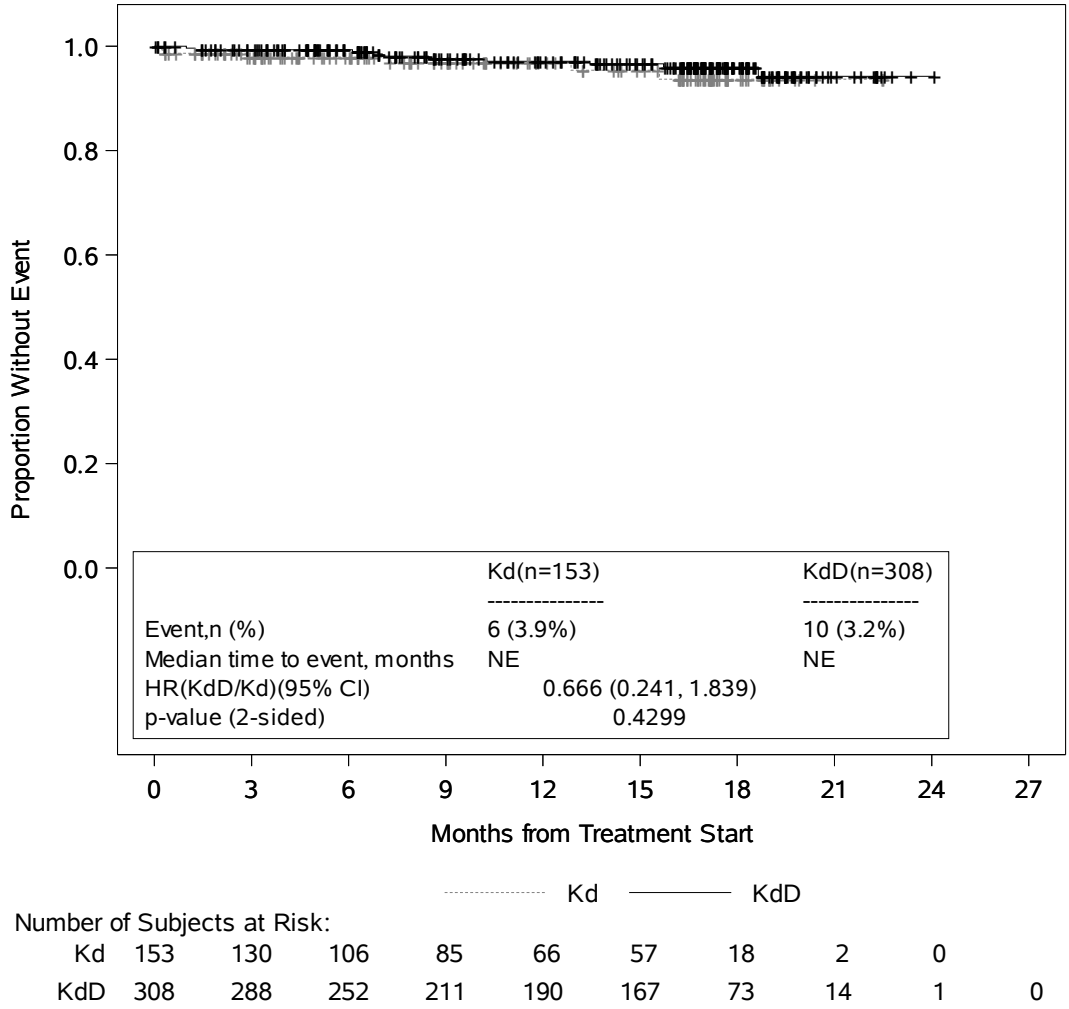


Number of Subjects at Risk:

Kd	153	102	82	67	51	42	14	2	0	
KdD	308	190	170	151	129	117	58	14	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-504-ae-cox-blolym-throm-ge10.rtf (Date Generated: 27MAY20:22:28:00).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.505. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Cardiac Disorders) and PT (Cardiac Failure)
<Safety Population>

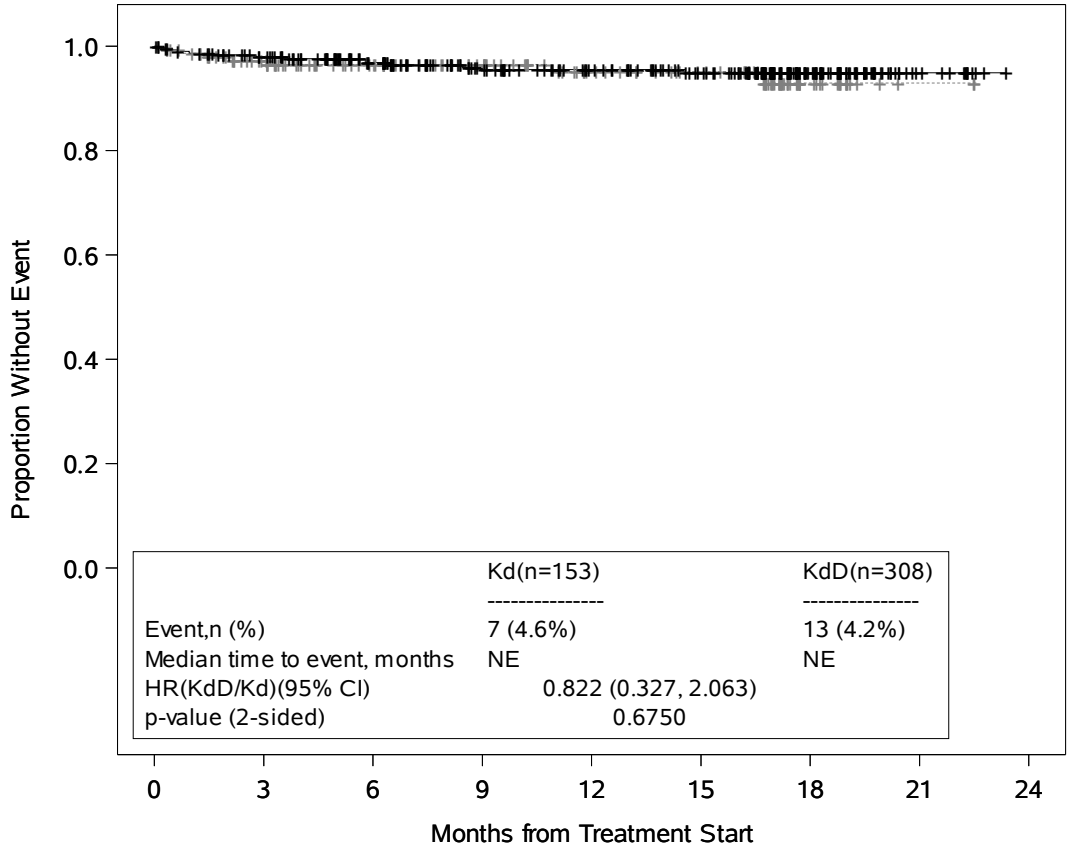


Number of Subjects at Risk:

Kd	153	130	106	85	66	57	18	2	0	
KdD	308	288	252	211	190	167	73	14	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-505-ae-cox-card-fail-ge10.rtf (Date Generated: 27MAY20:22:28:02).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.506. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Cardiac Disorders) and PT (Tachycardia) <Safety Population>

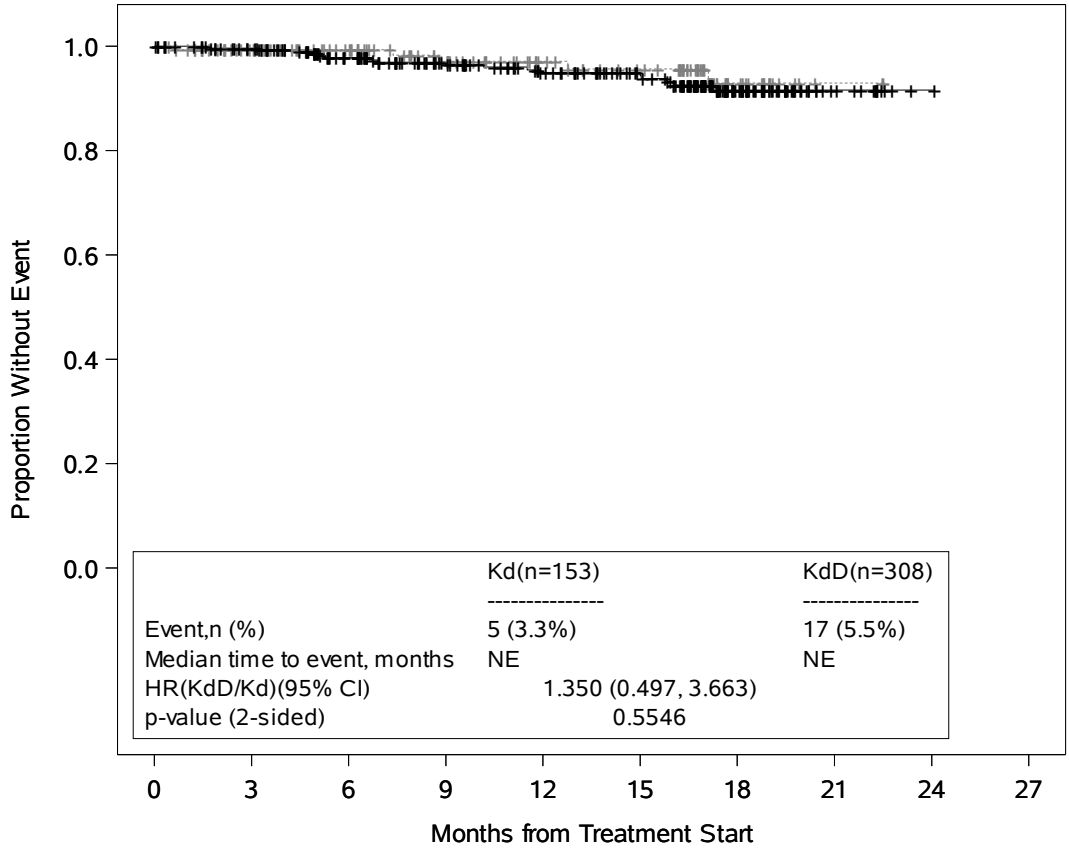


Number of Subjects at Risk:

Kd	153	128	104	86	65	55	17	2	0
KdD	308	283	244	203	182	159	70	13	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-506-ae-cox-card-tach-ge10.rtf (Date Generated: 27MAY20:22:28:05).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.507. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Eye Disorders) and PT (Cataract)
<Safety Population>

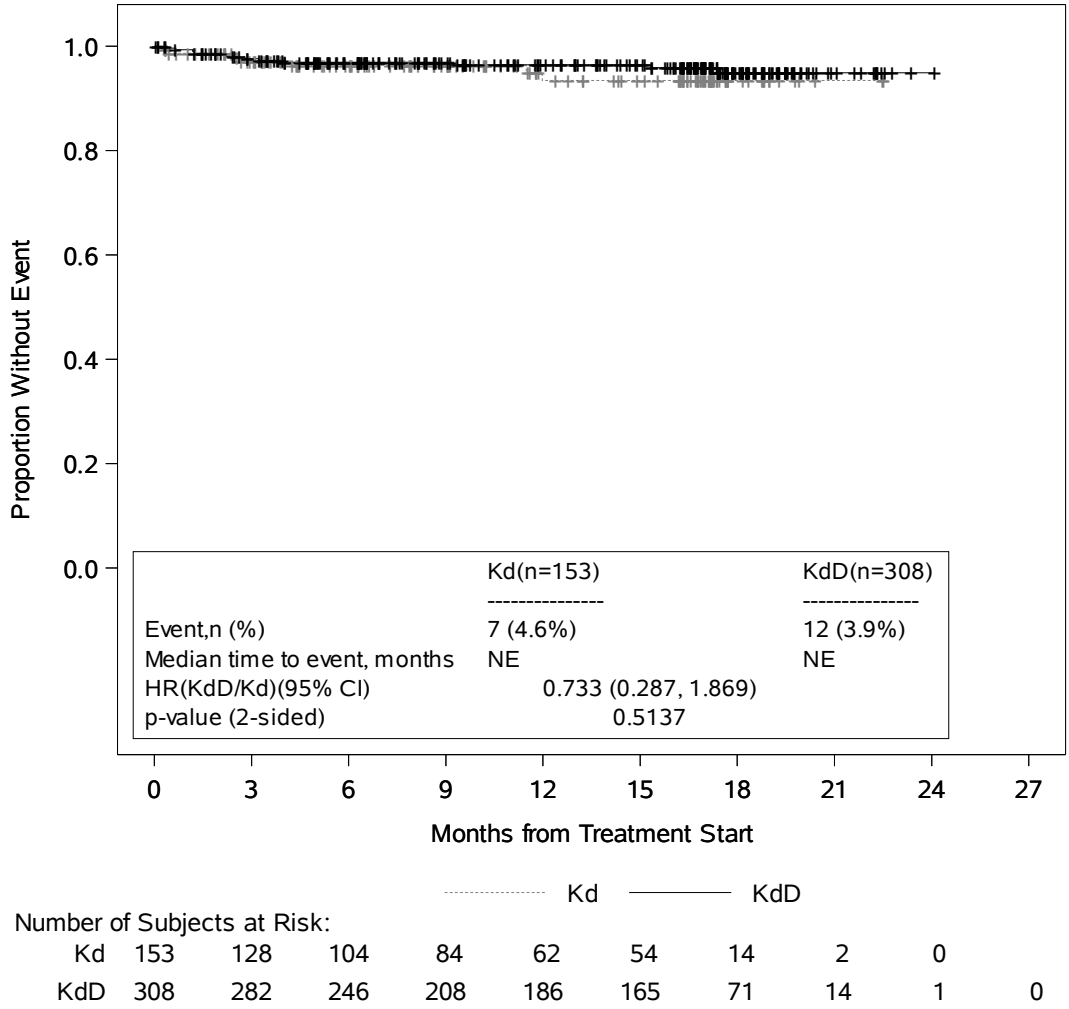


Number of Subjects at Risk:

Kd	153	131	107	85	66	57	18	2	0	
KdD	308	288	248	206	182	160	69	14	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-507-ae-cox-eye-cont-ge10.rtf (Date Generated: 27MAY20:22:28:06).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.508. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Gastrointestinal Disorders) and PT (Abdominal Pain) <Safety Population>

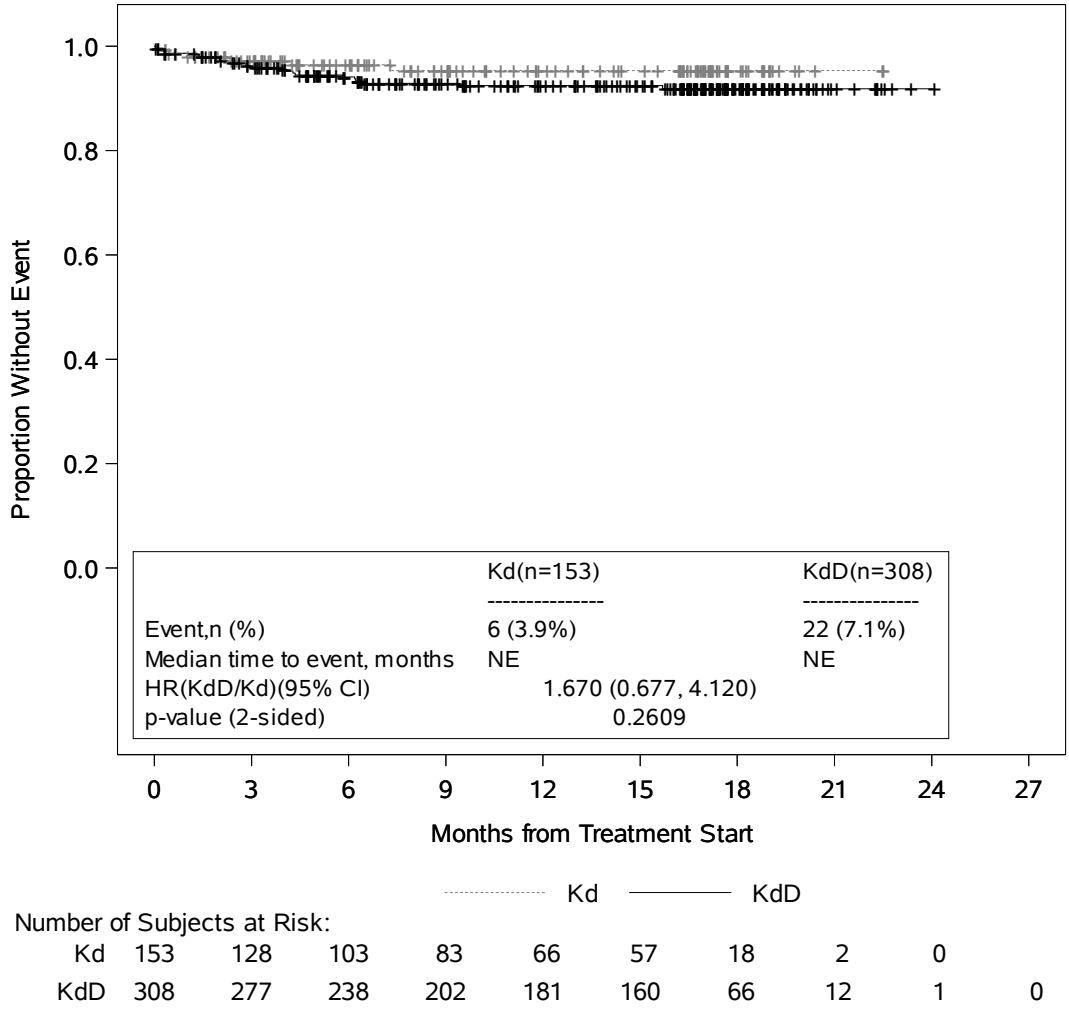


Number of Subjects at Risk:

Kd	153	128	104	84	62	54	14	2	0	
KdD	308	282	246	208	186	165	71	14	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-508-ae-cox-gas-abdo-ge10.rtf (Date Generated: 27MAY20:22:28:08).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.509. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Gastrointestinal Disorders) and PT (Constipation) <Safety Population>

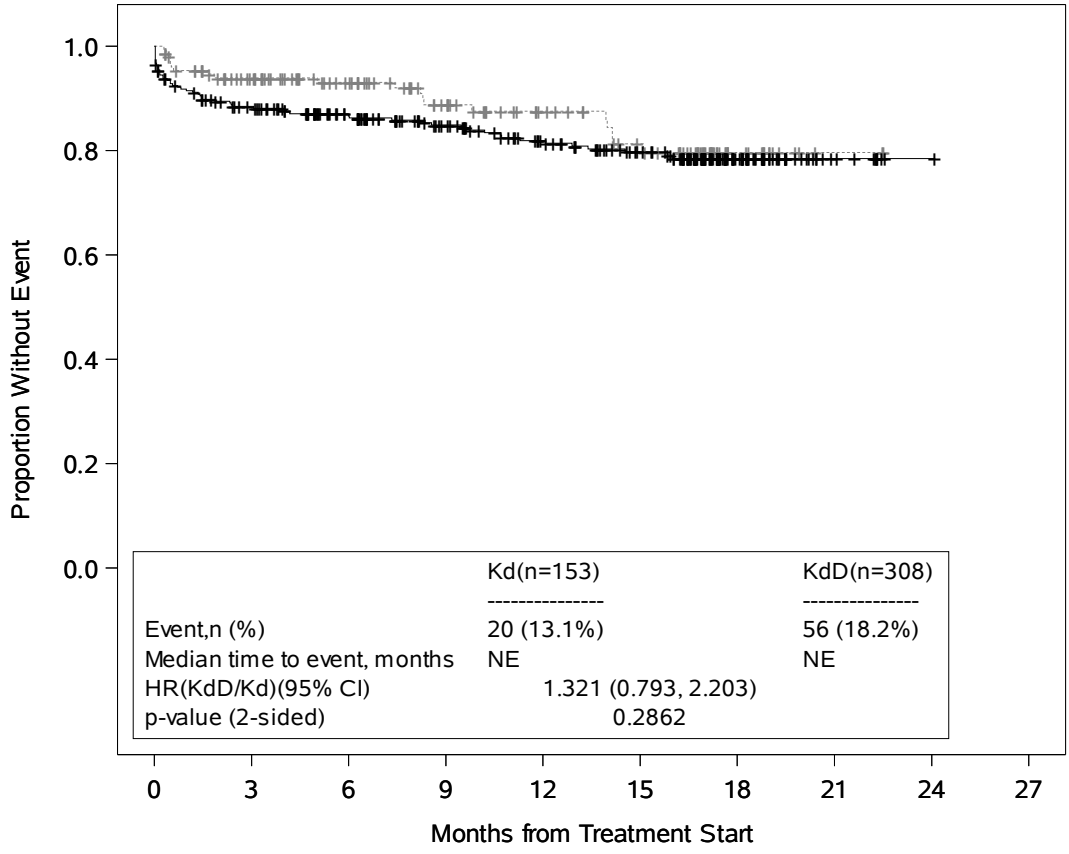


Number of Subjects at Risk:

Kd	153	128	103	83	66	57	18	2	0	
KdD	308	277	238	202	181	160	66	12	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-509-ae-cox-gas-con-ge10.rtf (Date Generated: 27MAY20:22:28:10).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.511. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Gastrointestinal Disorders) and PT (Nausea)
<Safety Population>

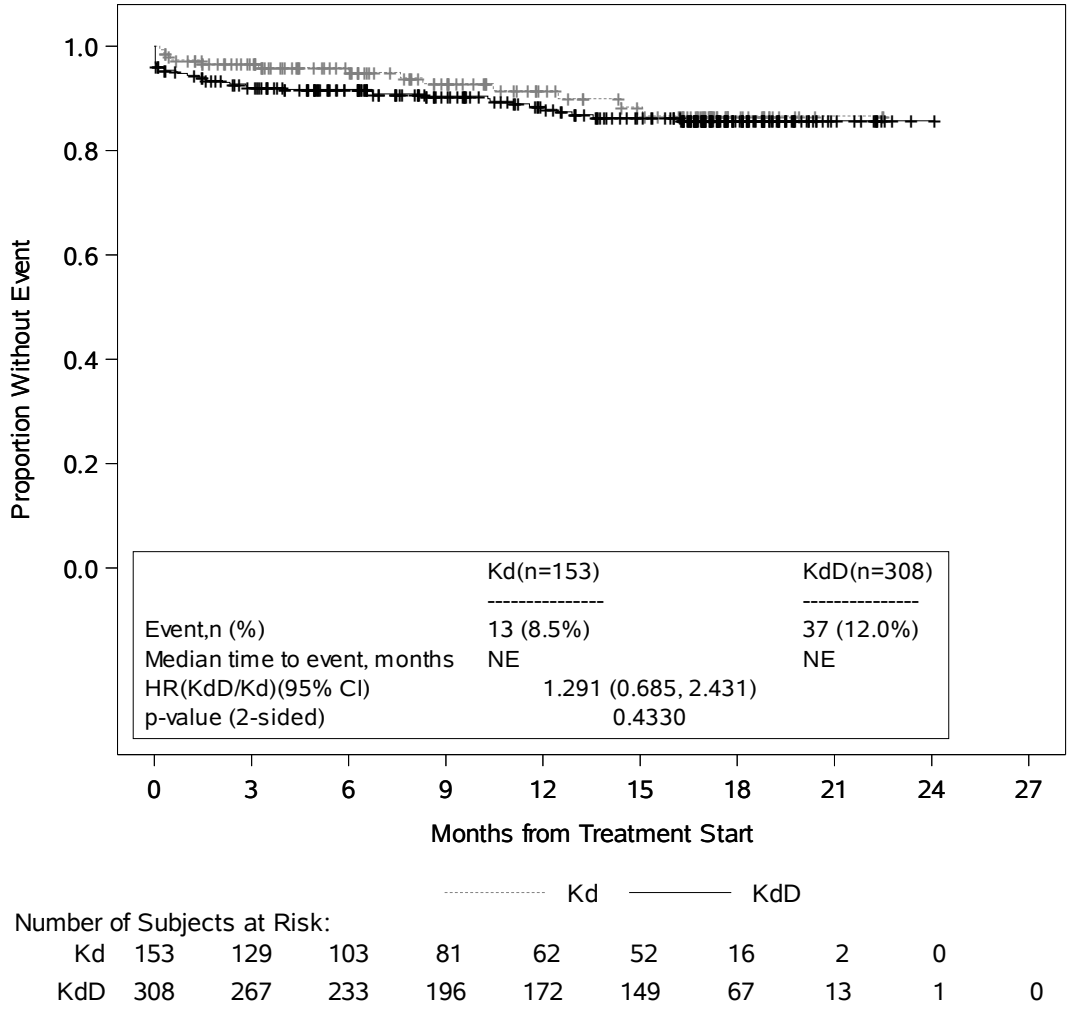


Number of Subjects at Risk:

Kd	153	125	101	78	61	49	15	2	0	
KdD	308	256	219	182	156	133	54	10	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-511-ae-cox-gas-nau-ge10.rtf (Date Generated: 27MAY20:22:28:13).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.512. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Gastrointestinal Disorders) and PT (Vomiting) <Safety Population>

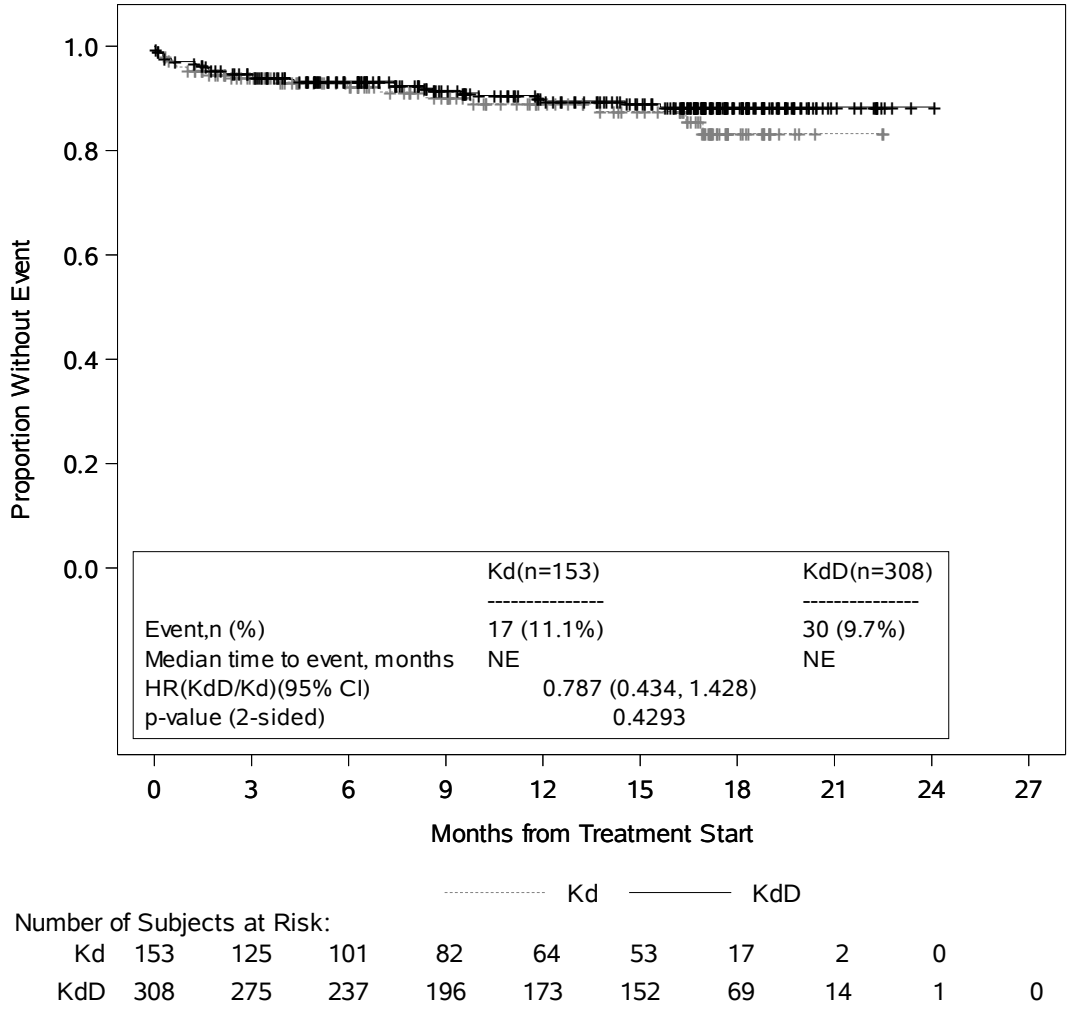


Number of Subjects at Risk:

Kd	153	129	103	81	62	52	16	2	0	
KdD	308	267	233	196	172	149	67	13	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-512-ae-cox-gas-vom-ge10.rtf (Date Generated: 27MAY20:22:28:15).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.513. KM Curves of Most Frequent Adverse Events by MedDRA SOC (General Disorders and Administration Site Conditions) and PT (Asthenia) <Safety Population>

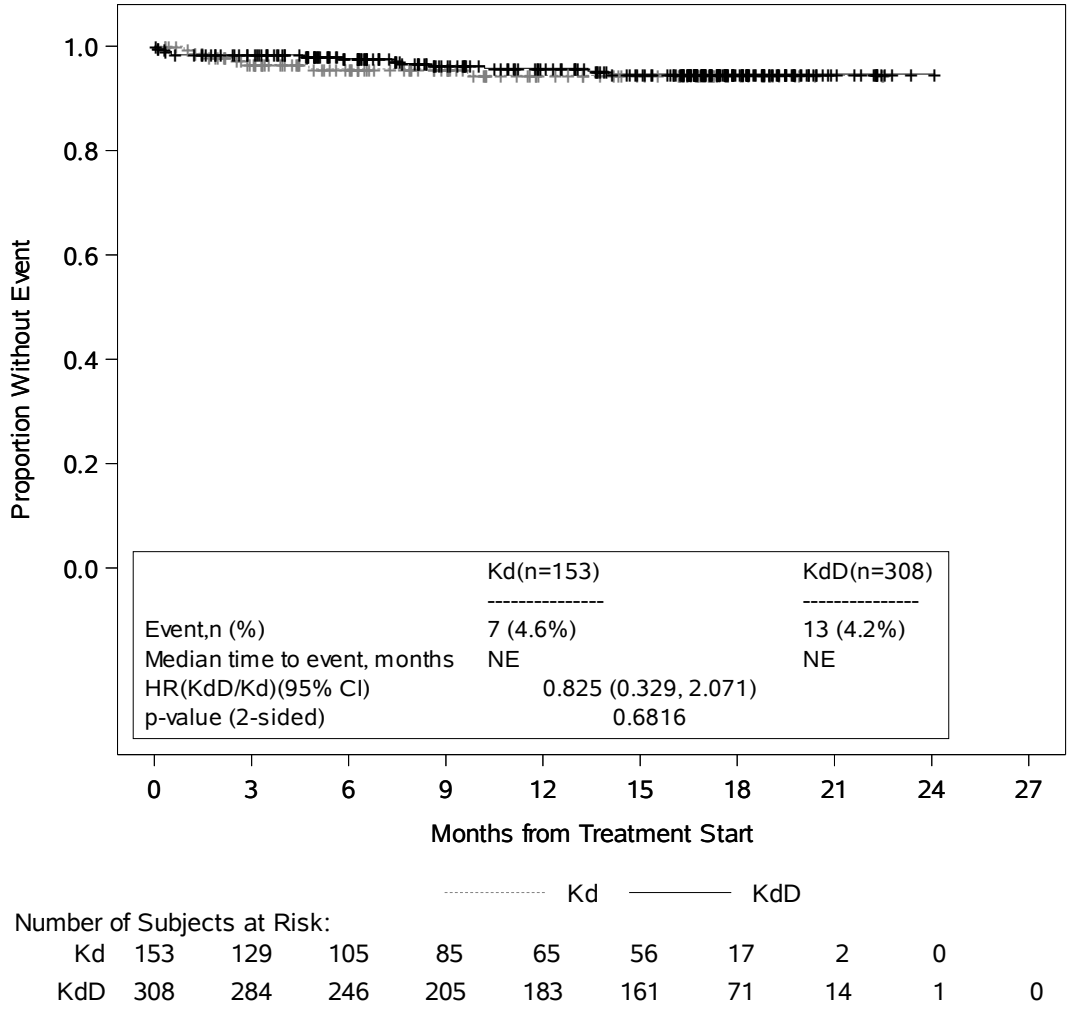


Number of Subjects at Risk:

Kd	153	125	101	82	64	53	17	2	0	
KdD	308	275	237	196	173	152	69	14	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-513-ae-cox-gen-asth-ge10.rtf (Date Generated: 27MAY20:22:28:16).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.514. KM Curves of Most Frequent Adverse Events by MedDRA SOC (General Disorders and Administration Site Conditions) and PT (Chest Pain) <Safety Population>

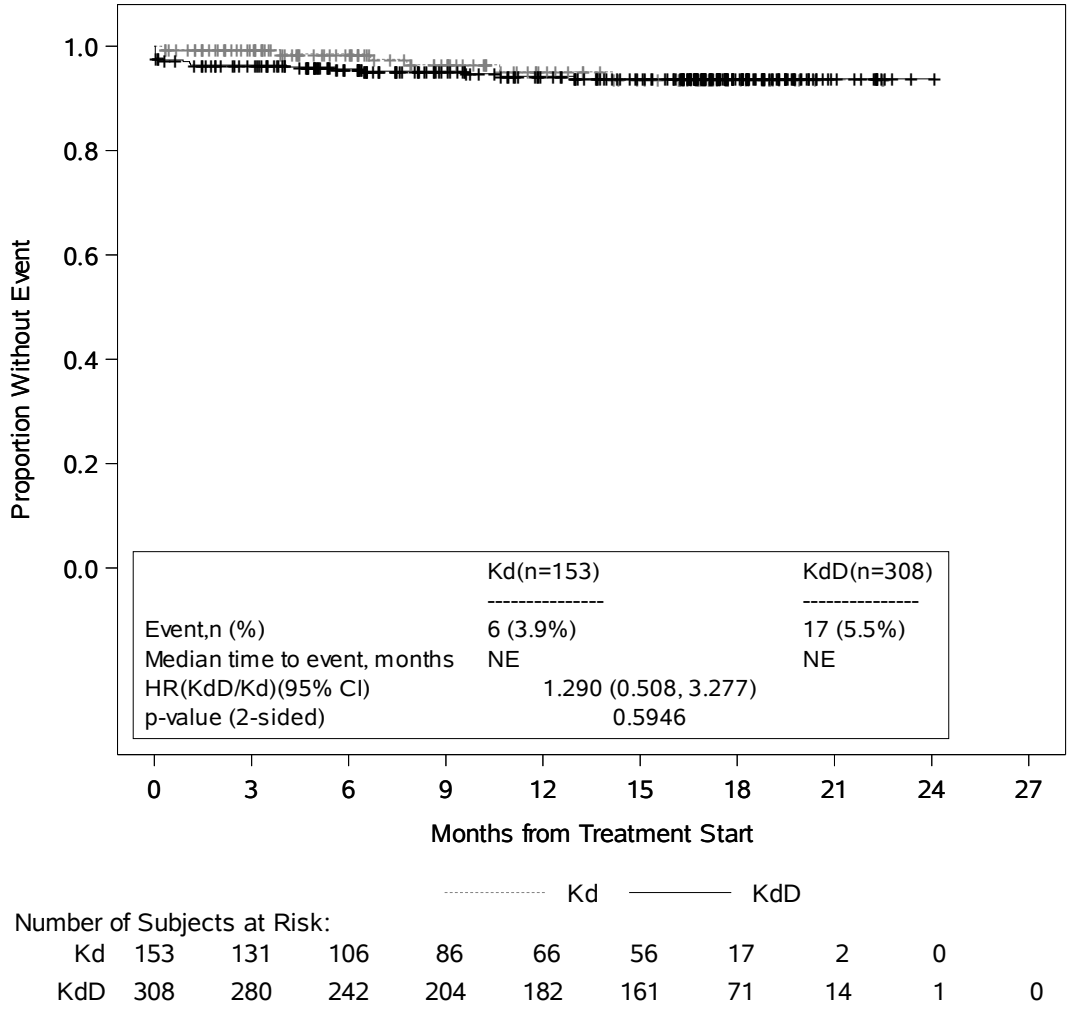


Number of Subjects at Risk:

Kd	153	129	105	85	65	56	17	2	0	
KdD	308	284	246	205	183	161	71	14	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-514-ae-cox-gen-chest-ge10.rtf (Date Generated: 27MAY20:22:28:18).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.515. KM Curves of Most Frequent Adverse Events by MedDRA SOC (General Disorders and Administration Site Conditions) and PT (Chills) <Safety Population>

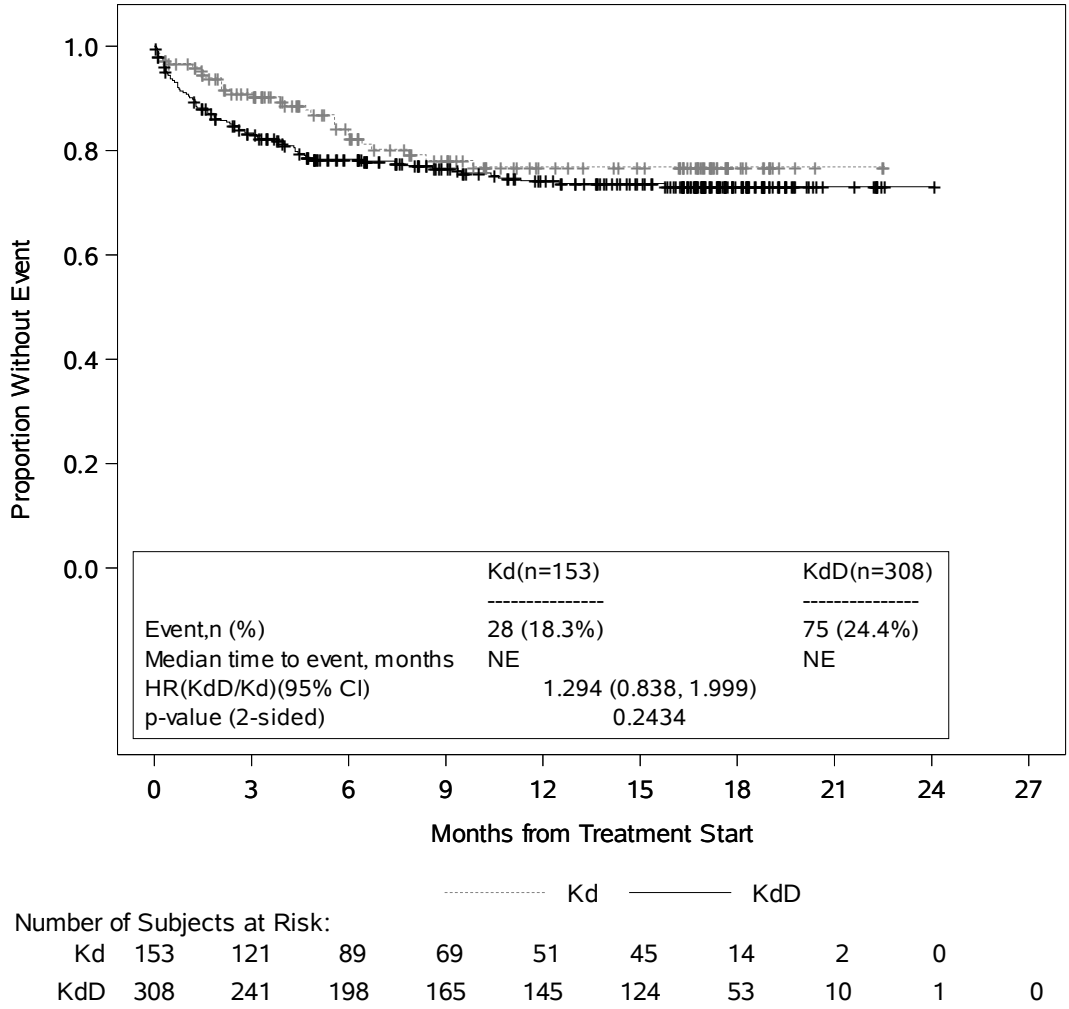


Number of Subjects at Risk:

Kd	153	131	106	86	66	56	17	2	0	
KdD	308	280	242	204	182	161	71	14	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-515-ae-cox-gen-chil-ge10.rtf (Date Generated: 27MAY20:22:28:20).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.516. KM Curves of Most Frequent Adverse Events by MedDRA SOC (General Disorders and Administration Site Conditions) and PT (Fatigue) <Safety Population>

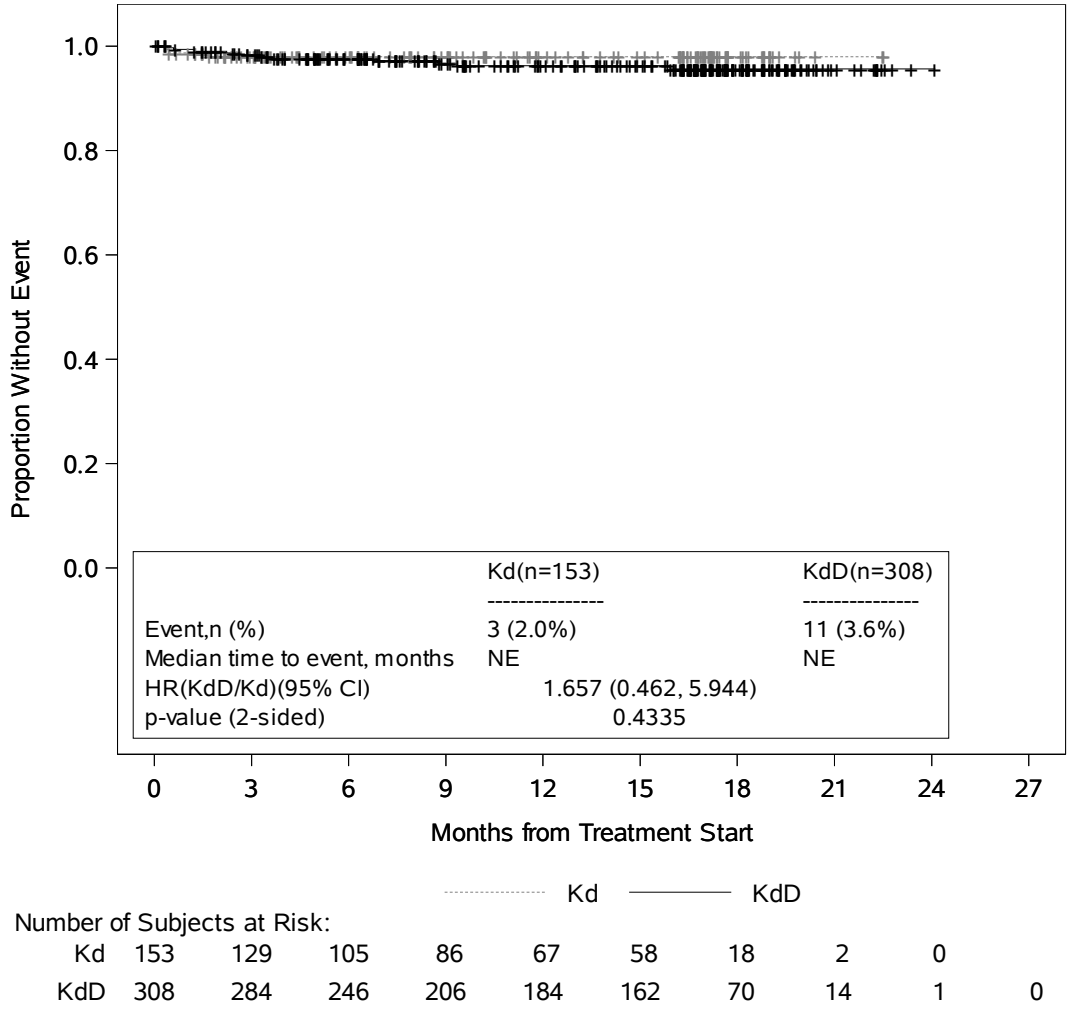


Number of Subjects at Risk:

Kd	153	121	89	69	51	45	14	2	0	
KdD	308	241	198	165	145	124	53	10	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-516-ae-cox-gen-fati-ge10.rtf (Date Generated: 27MAY20:22:28:22).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.517. KM Curves of Most Frequent Adverse Events by MedDRA SOC (General Disorders and Administration Site Conditions) and PT (Influenza Like Illness)
<Safety Population>

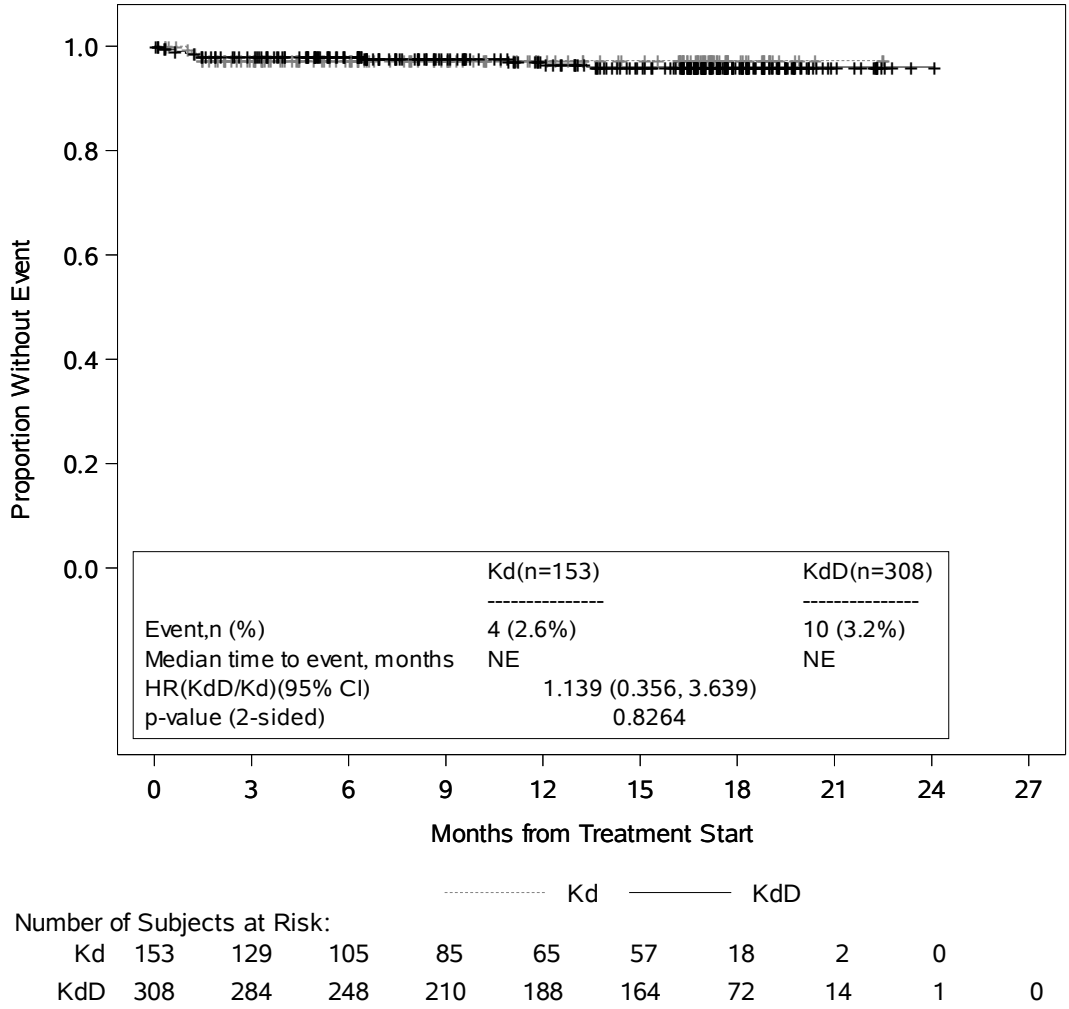


Number of Subjects at Risk:

Kd	153	129	105	86	67	58	18	2	0	
KdD	308	284	246	206	184	162	70	14	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-517-ae-cox-gen-inf-ge10.rtf (Date Generated: 27MAY20:22:28:23).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.518. KM Curves of Most Frequent Adverse Events by MedDRA SOC (General Disorders and Administration Site Conditions) and PT (Malaise) <Safety Population>

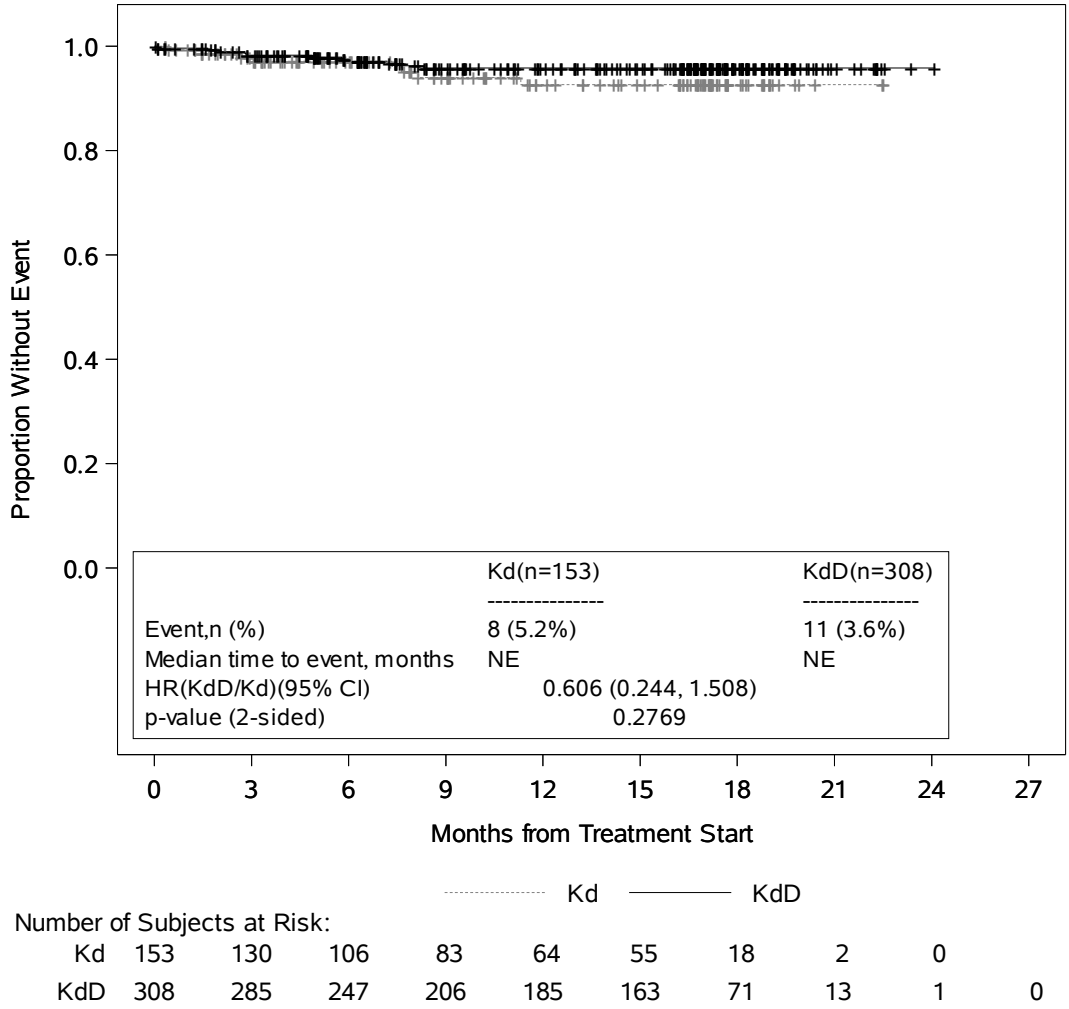


Number of Subjects at Risk:

Kd	153	129	105	85	65	57	18	2	0	
KdD	308	284	248	210	188	164	72	14	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-518-ae-cox-gen-mal-ge10.rtf (Date Generated: 27MAY20:22:28:25).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.519. KM Curves of Most Frequent Adverse Events by MedDRA SOC (General Disorders and Administration Site Conditions) and PT (Oedema) <Safety Population>

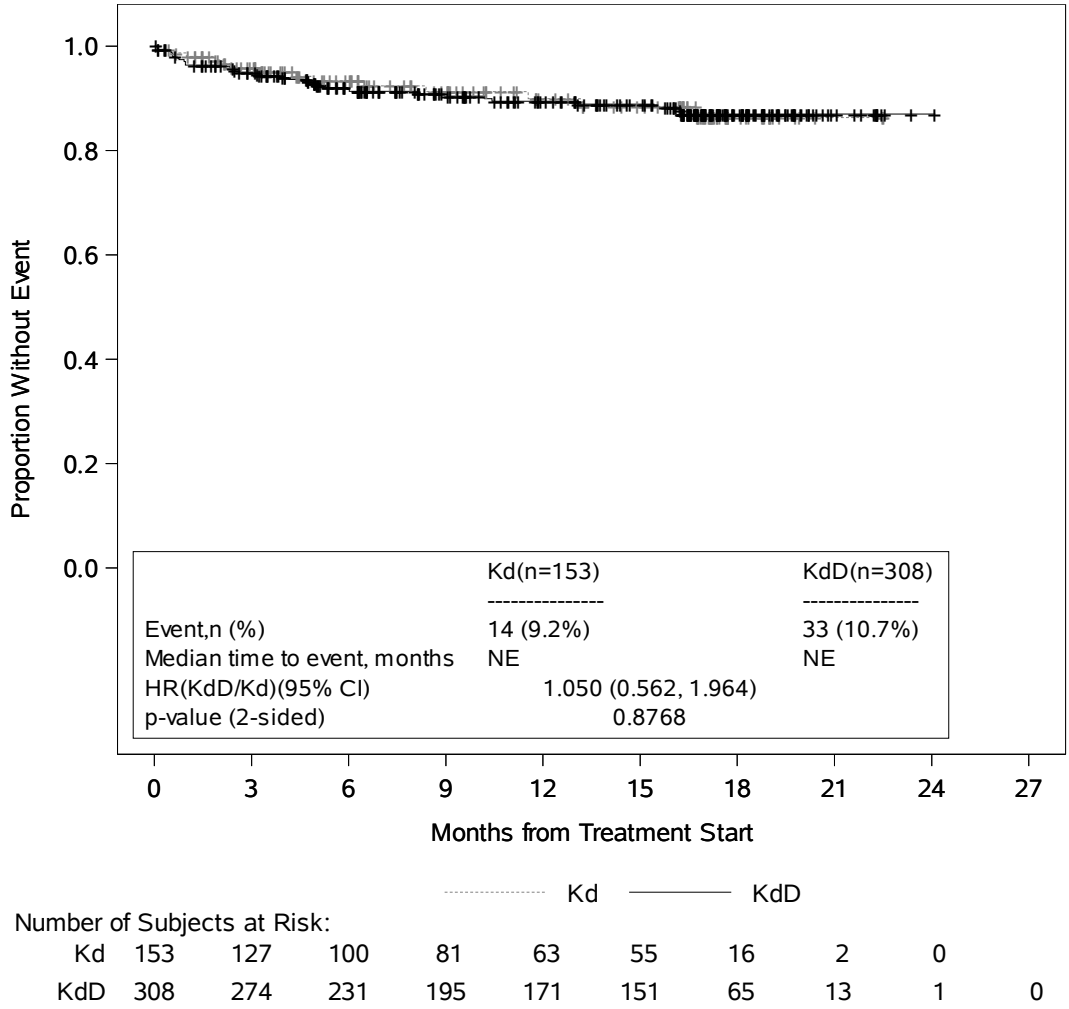


Number of Subjects at Risk:

Kd	153	130	106	83	64	55	18	2	0	
KdD	308	285	247	206	185	163	71	13	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-519-ae-cox-gen-oede-ge10.rtf (Date Generated: 27MAY20:22:28:27).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.520. KM Curves of Most Frequent Adverse Events by MedDRA SOC (General Disorders and Administration Site Conditions) and PT (Oedema Peripheral)
<Safety Population>

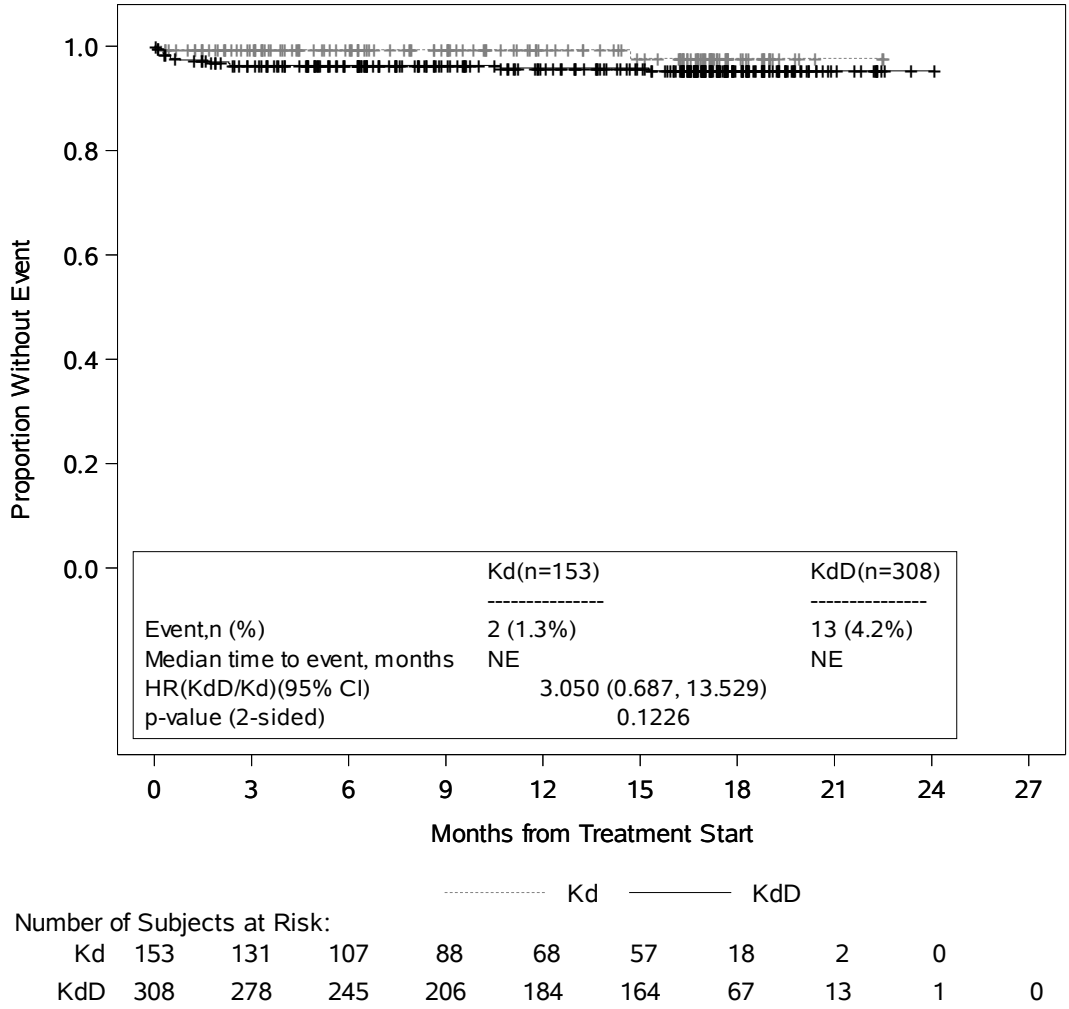


Number of Subjects at Risk:

Kd	153	127	100	81	63	55	16	2	0	
KdD	308	274	231	195	171	151	65	13	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-520-ae-cox-gen-oedper-ge10.rtf (Date Generated: 27MAY20:22:28:29).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.521. KM Curves of Most Frequent Adverse Events by MedDRA SOC (General Disorders and Administration Site Conditions) and PT (Pain) <Safety Population>

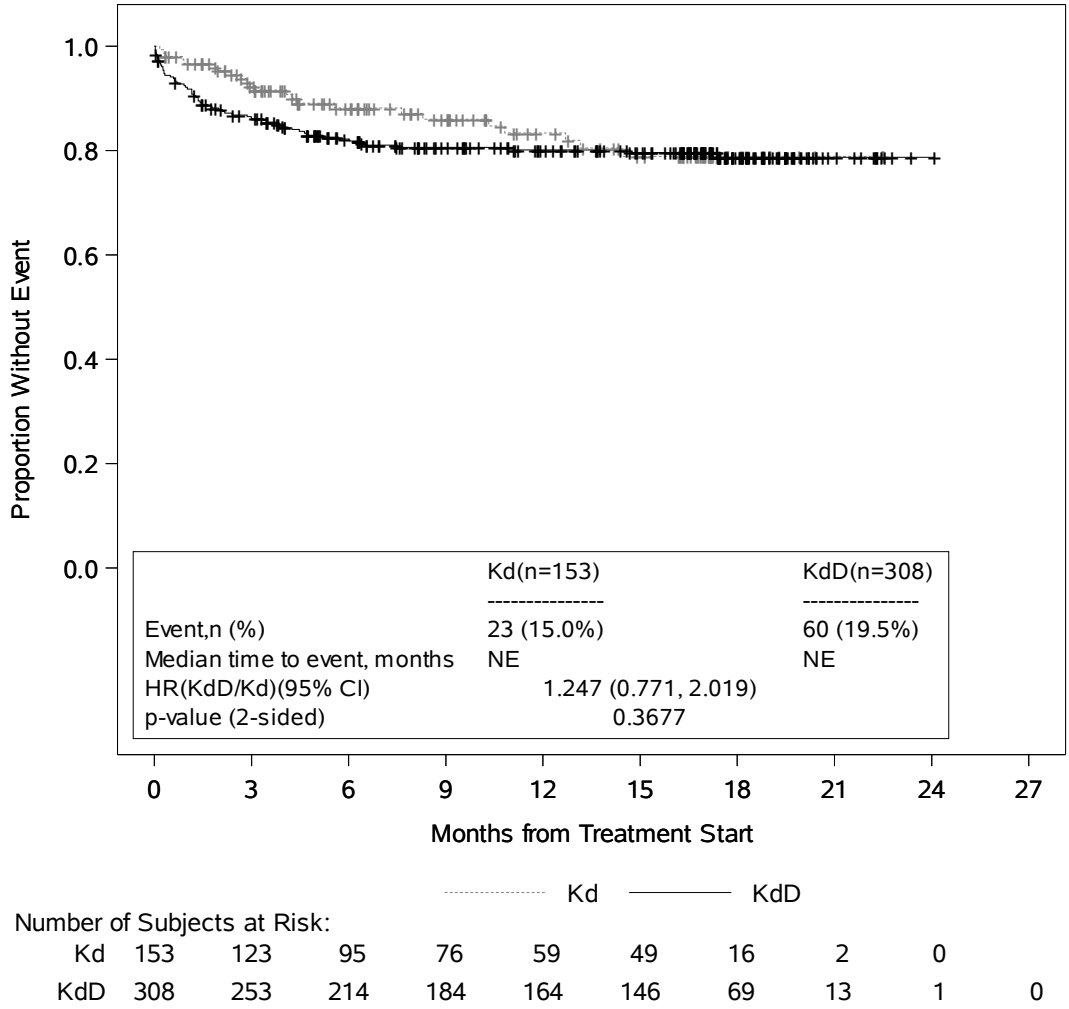


Number of Subjects at Risk:

Kd	153	131	107	88	68	57	18	2	0	
KdD	308	278	245	206	184	164	67	13	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-521-ae-cox-gen-pain-ge10.rtf (Date Generated: 27MAY20:22:28:31).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.522. KM Curves of Most Frequent Adverse Events by MedDRA SOC (General Disorders and Administration Site Conditions) and PT (Pyrexia) <Safety Population>

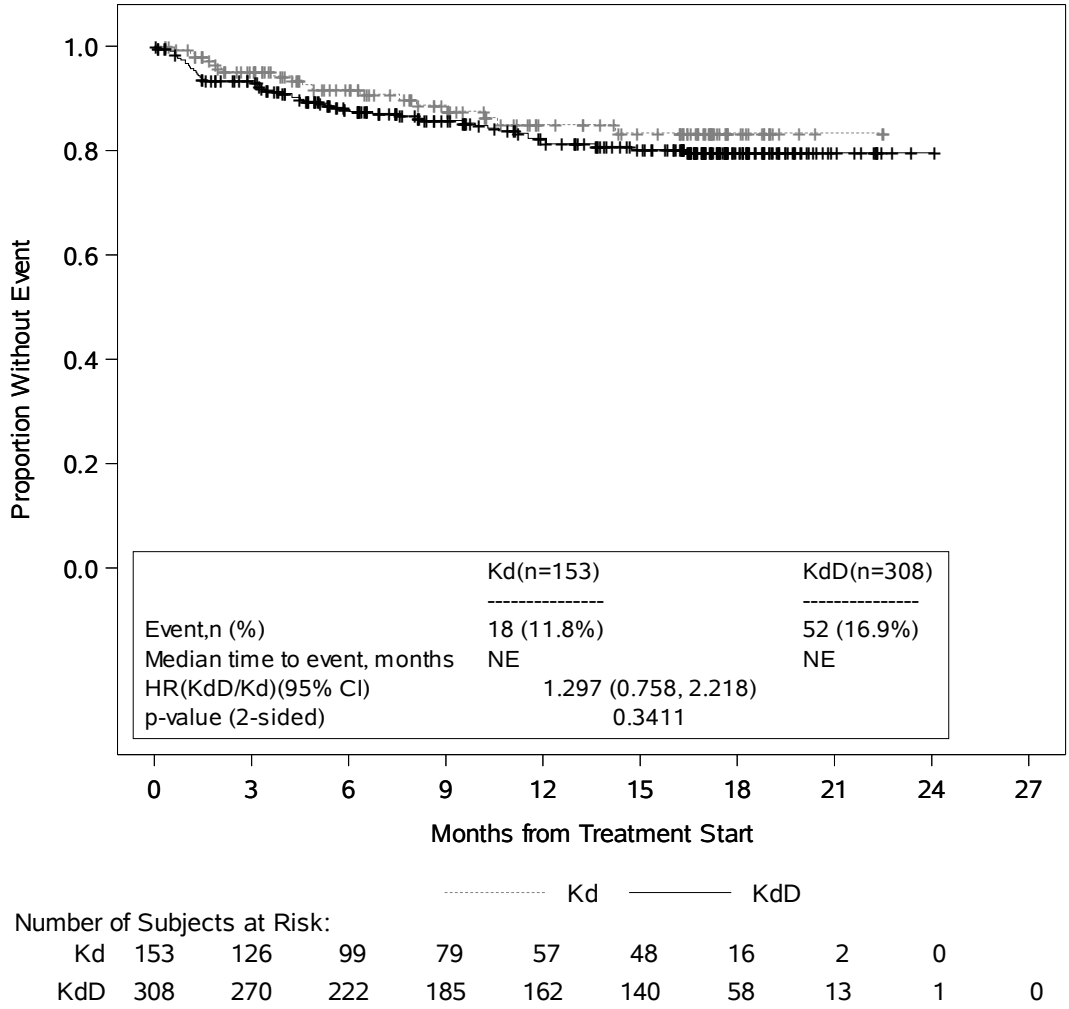


Number of Subjects at Risk:

Kd	153	123	95	76	59	49	16	2	0	
KdD	308	253	214	184	164	146	69	13	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-522-ae-cox-gen-pyr-ge10.rtf (Date Generated: 27MAY20:22:28:32).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.523. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Infections and Infestations) and PT (Bronchitis)
<Safety Population>

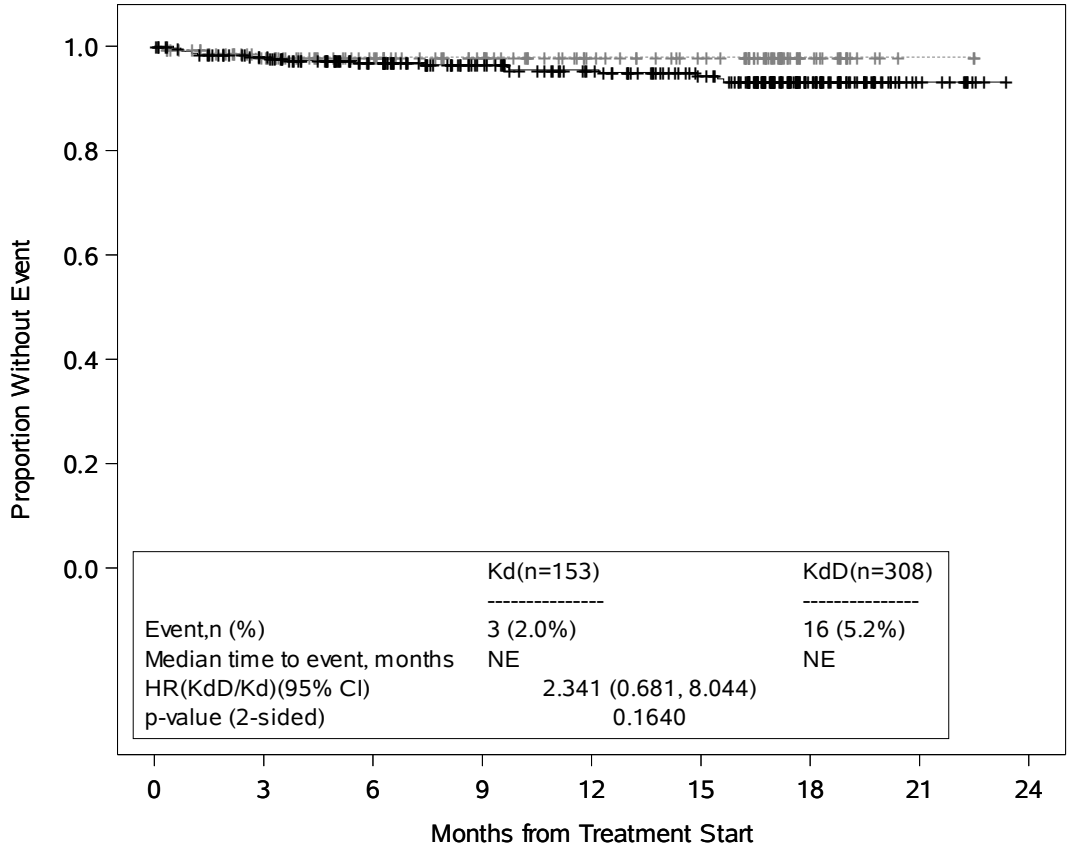


Number of Subjects at Risk:

Kd	153	126	99	79	57	48	16	2	0	
KdD	308	270	222	185	162	140	58	13	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-523-ae-cox-infe-bro-ge10.rtf (Date Generated: 27MAY20:22:28:34).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.524. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Infections and Infestations) and PT (Conjunctivitis) <Safety Population>

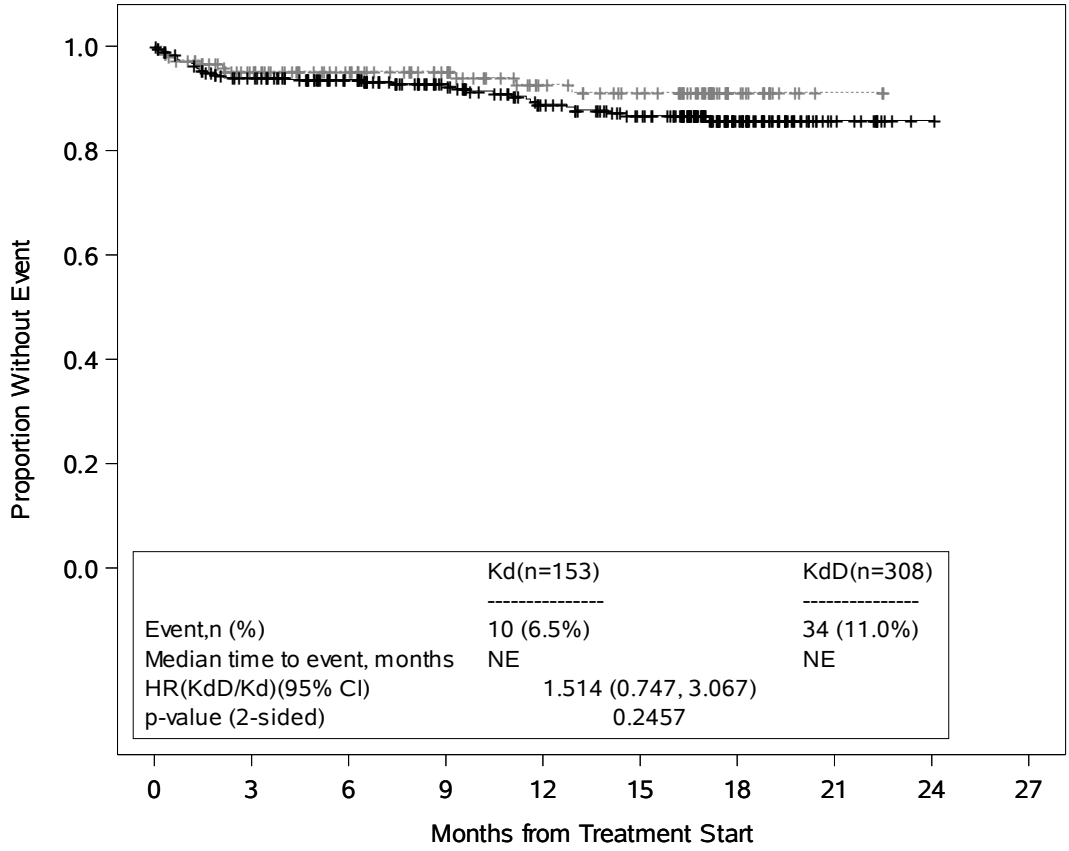


Number of Subjects at Risk:

Kd	153	129	105	87	67	57	18	2	0
KdD	308	283	245	205	183	159	67	12	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-524-ae-cox-infe-conj-ge10.rtf (Date Generated: 27MAY20:22:28:35).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.525. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Infections and Infestations) and PT (Influenza)
<Safety Population>

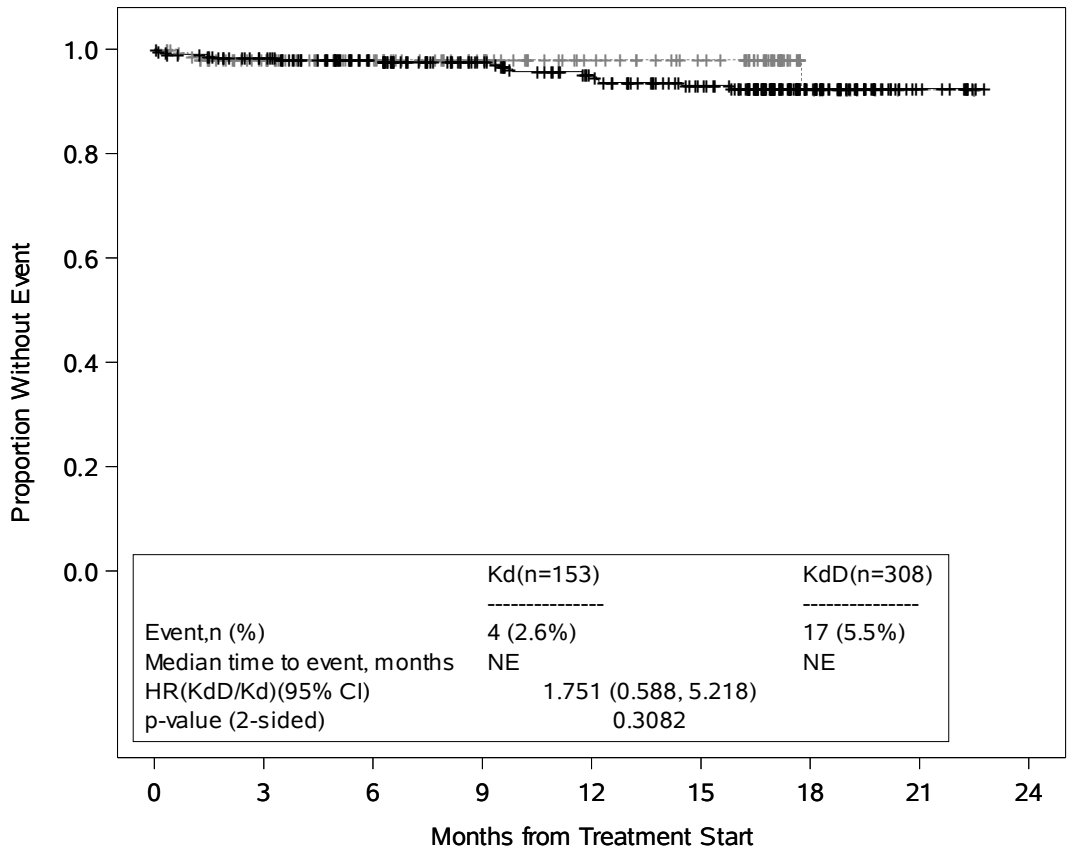


Number of Subjects at Risk:

Kd	153	125	103	84	63	53	17	2	0	
KdD	308	272	239	200	171	150	67	14	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-525-ae-cox-infe-infl-ge10.rtf (Date Generated: 27MAY20:22:28:37).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.526. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Infections and Infestations) and PT (Lower Respiratory Tract Infection) <Safety Population>

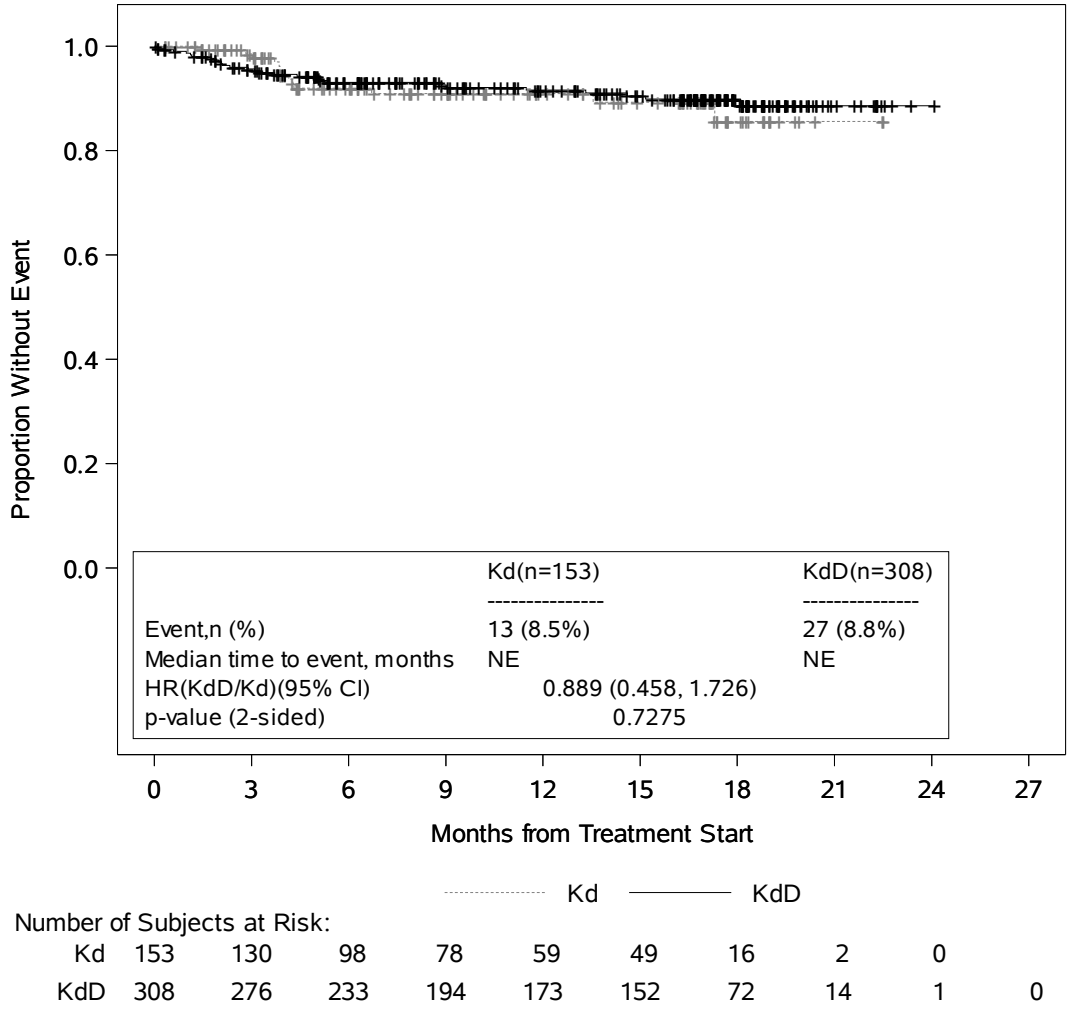


Number of Subjects at Risk:

Kd	153	129	105	85	67	57	16	2	0
KdD	308	285	249	210	186	161	70	12	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-526-ae-cox-infe-loresp-ge10.rtf (Date Generated: 27MAY20:22:28:39).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.527. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Infections and Infestations) and PT (Nasopharyngitis) <Safety Population>

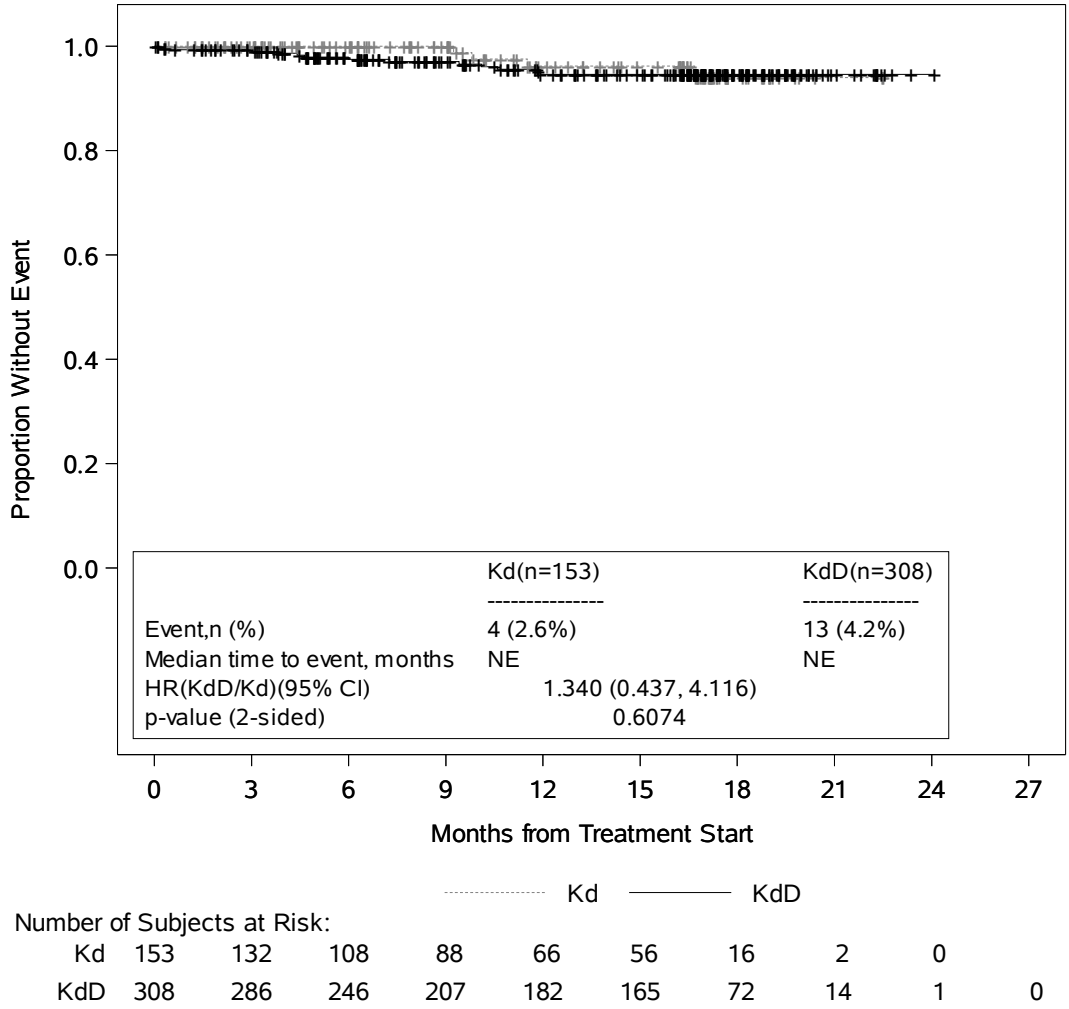


Number of Subjects at Risk:

Kd	153	130	98	78	59	49	16	2	0	
KdD	308	276	233	194	173	152	72	14	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-527-ae-cox-infe-nas-ge10.rtf (Date Generated: 27MAY20:22:28:40).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.528. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Infections and Infestations) and PT (Pharyngitis) <Safety Population>

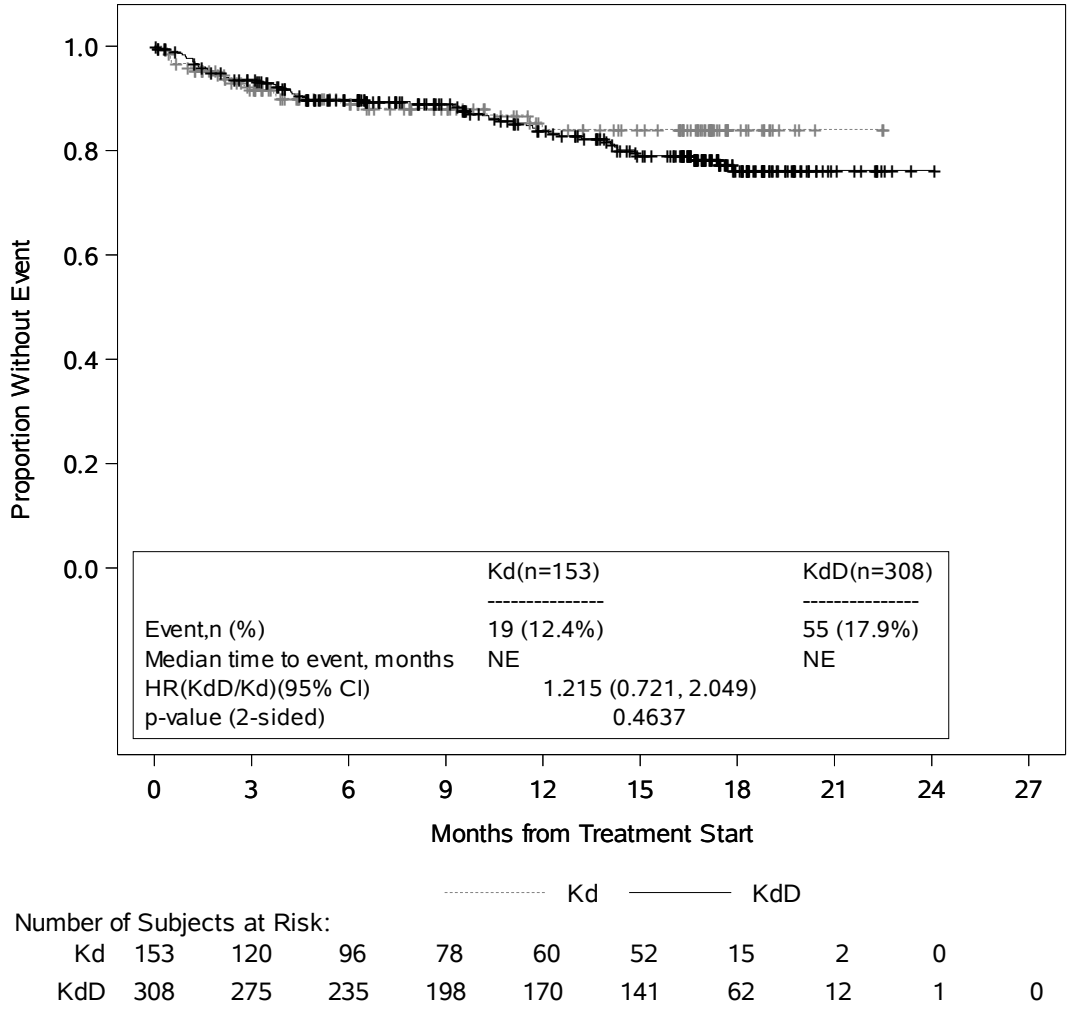


Number of Subjects at Risk:

Kd	153	132	108	88	66	56	16	2	0	
KdD	308	286	246	207	182	165	72	14	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-528-ae-cox-infe-phar-ge10.rtf (Date Generated: 27MAY20:22:28:42).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.529. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Infections and Infestations) and PT (Pneumonia) <Safety Population>

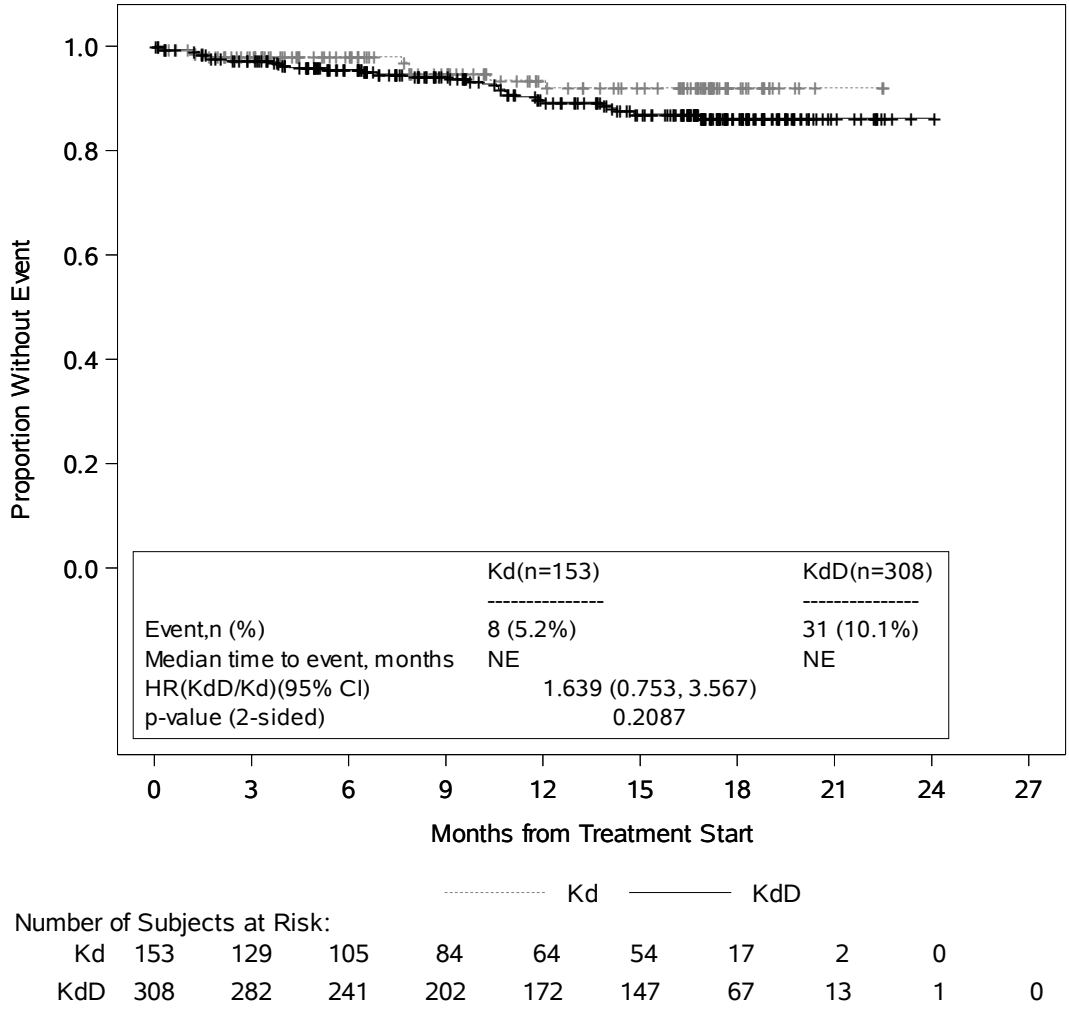


Number of Subjects at Risk:

Kd	153	120	96	78	60	52	15	2	0	
KdD	308	275	235	198	170	141	62	12	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-529-ae-cox-infe-pneu-ge10.rtf (Date Generated: 27MAY20:22:28:43).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.530. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Infections and Infestations) and PT (Respiratory Tract Infection) <Safety Population>

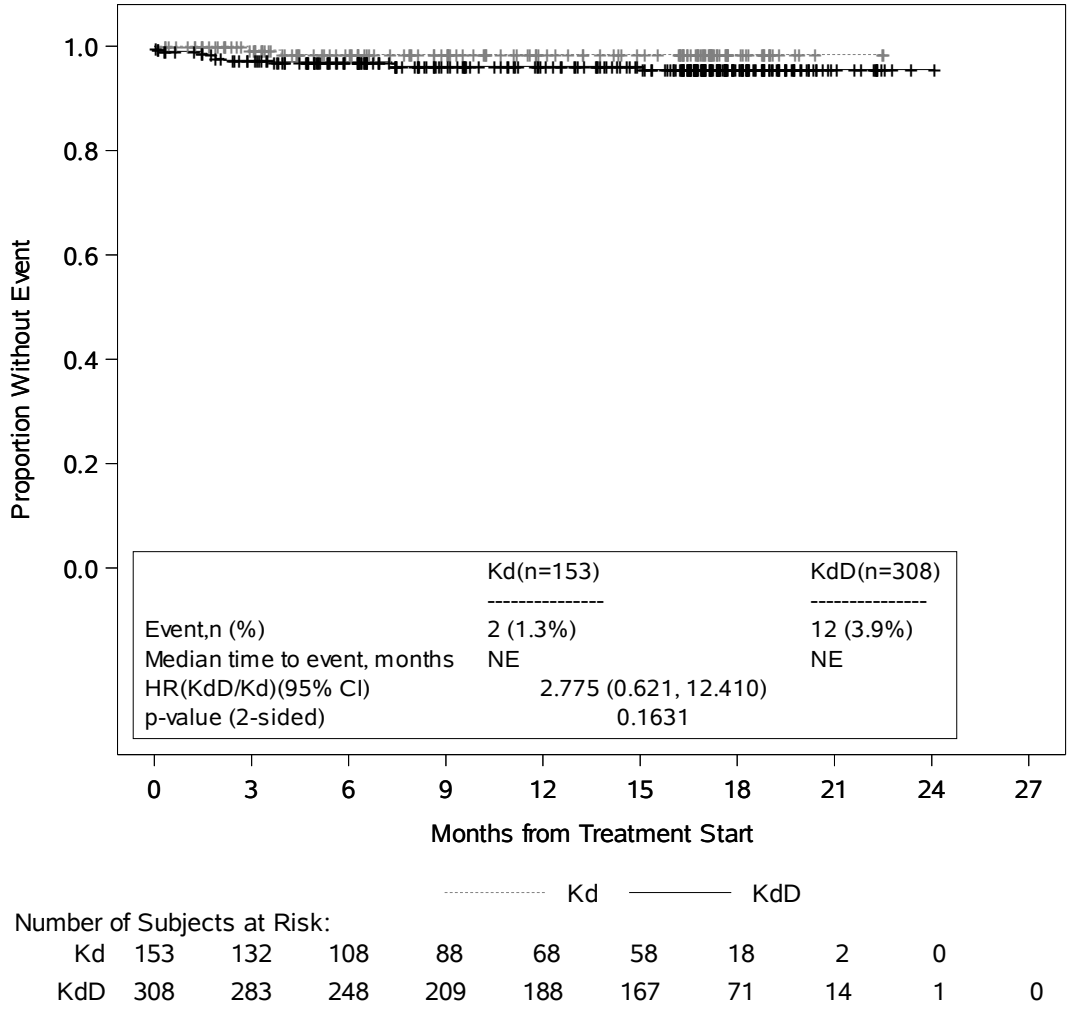


Number of Subjects at Risk:

Kd	153	129	105	84	64	54	17	2	0	
KdD	308	282	241	202	172	147	67	13	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-530-ae-cox-infe-resp-ge10.rtf (Date Generated: 27MAY20:22:28:45).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.531. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Infections and Infestations) and PT (Sepsis)
<Safety Population>

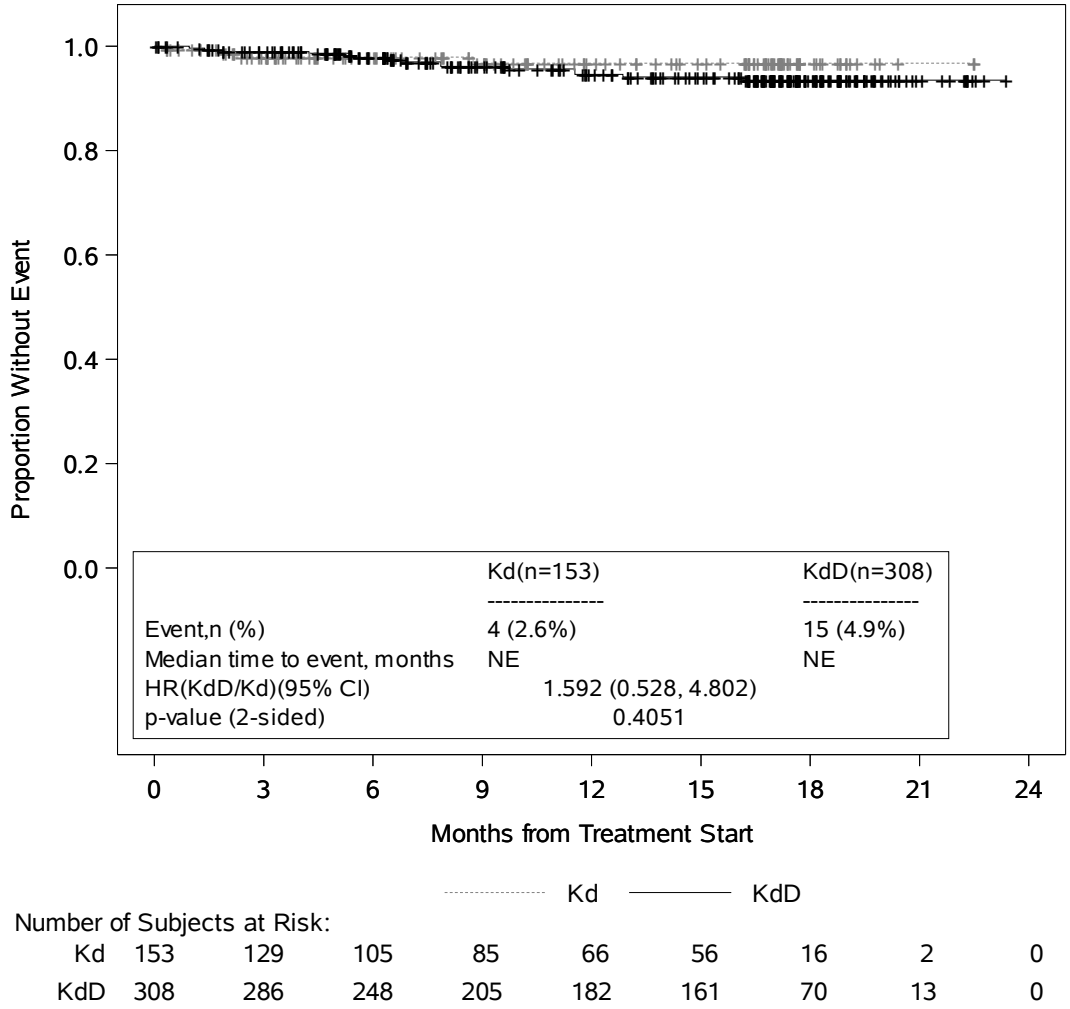


Number of Subjects at Risk:

Kd	153	132	108	88	68	58	18	2	0	
KdD	308	283	248	209	188	167	71	14	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-531-ae-cox-infe-seps-ge10.rtf (Date Generated: 27MAY20:22:28:47).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.532. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Infections and Infestations) and PT (Sinusitis) <Safety Population>

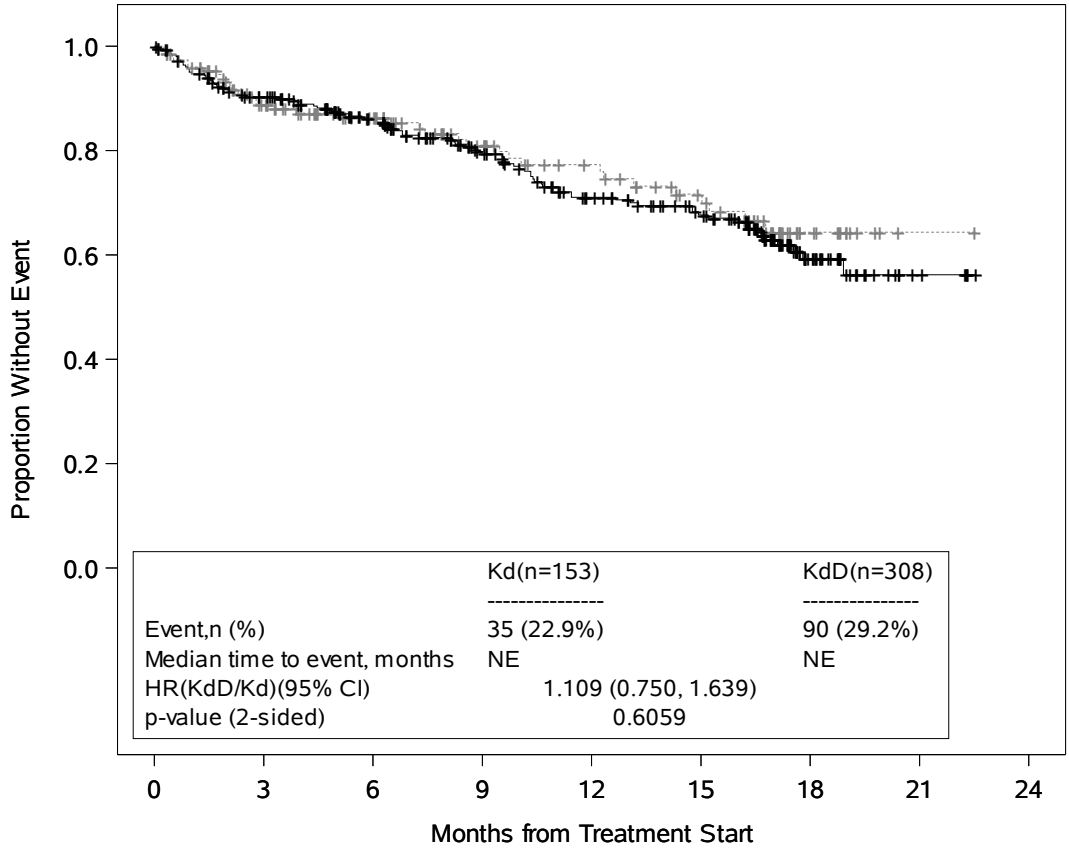


Number of Subjects at Risk:

Kd	153	129	105	85	66	56	16	2	0
KdD	308	286	248	205	182	161	70	13	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-532-ae-cox-infe-sinu-ge10.rtf (Date Generated: 27MAY20:22:28:48).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.533. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Infections and Infestations) and PT (Upper Respiratory Tract Infection) <Safety Population>

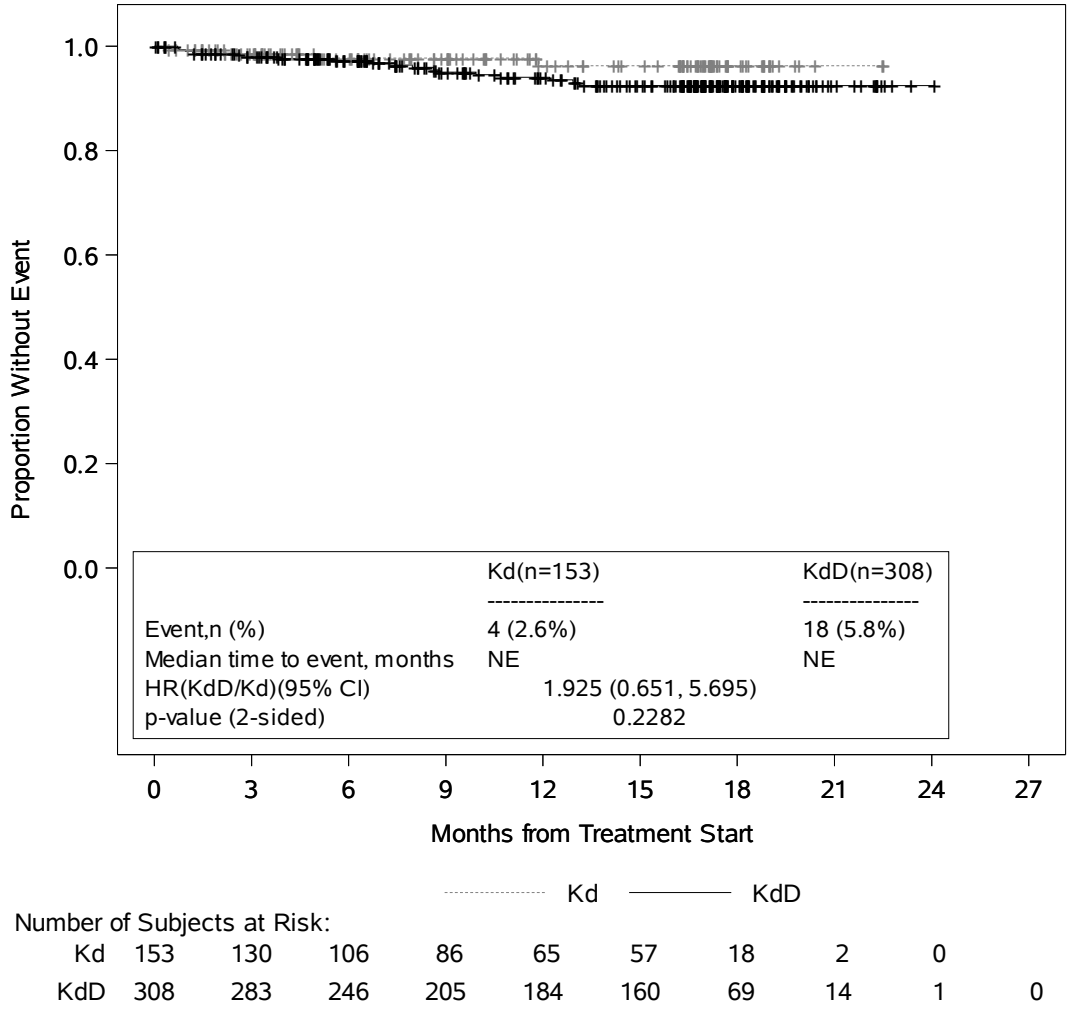


Number of Subjects at Risk:

Kd	153	117	94	70	57	44	13	1	0
KdD	308	260	217	172	136	115	36	6	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-533-ae-cox-infe-upresp-ge10.rtf (Date Generated: 27MAY20:22:28:50).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.534. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Infections and Infestations) and PT (Urinary Tract Infection) <Safety Population>

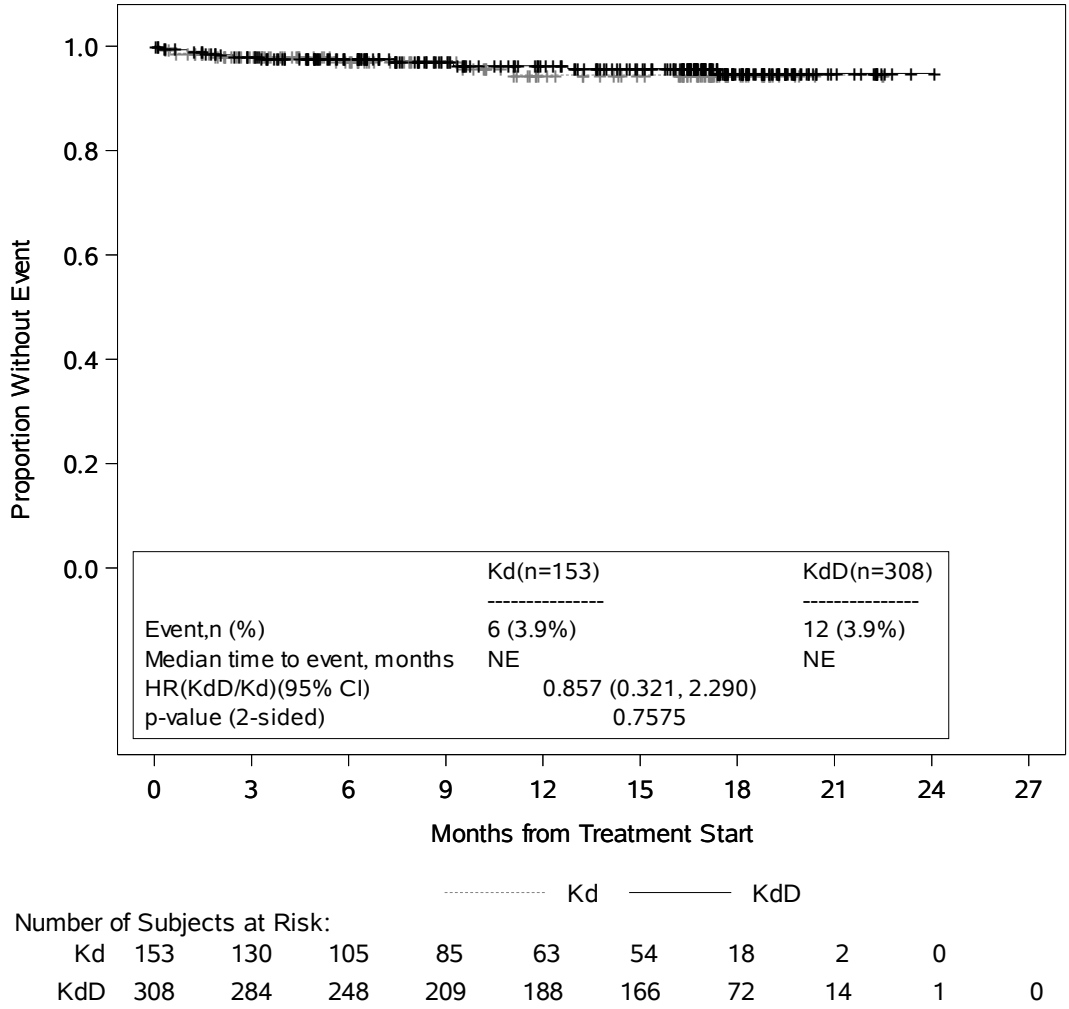


Number of Subjects at Risk:

Kd	153	130	106	86	65	57	18	2	0	
KdD	308	283	246	205	184	160	69	14	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-534-ae-cox-infe-uri-ge10.rtf (Date Generated: 27MAY20:22:28:51).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.535. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Infections and Infestations) and PT (Viral Infection) <Safety Population>

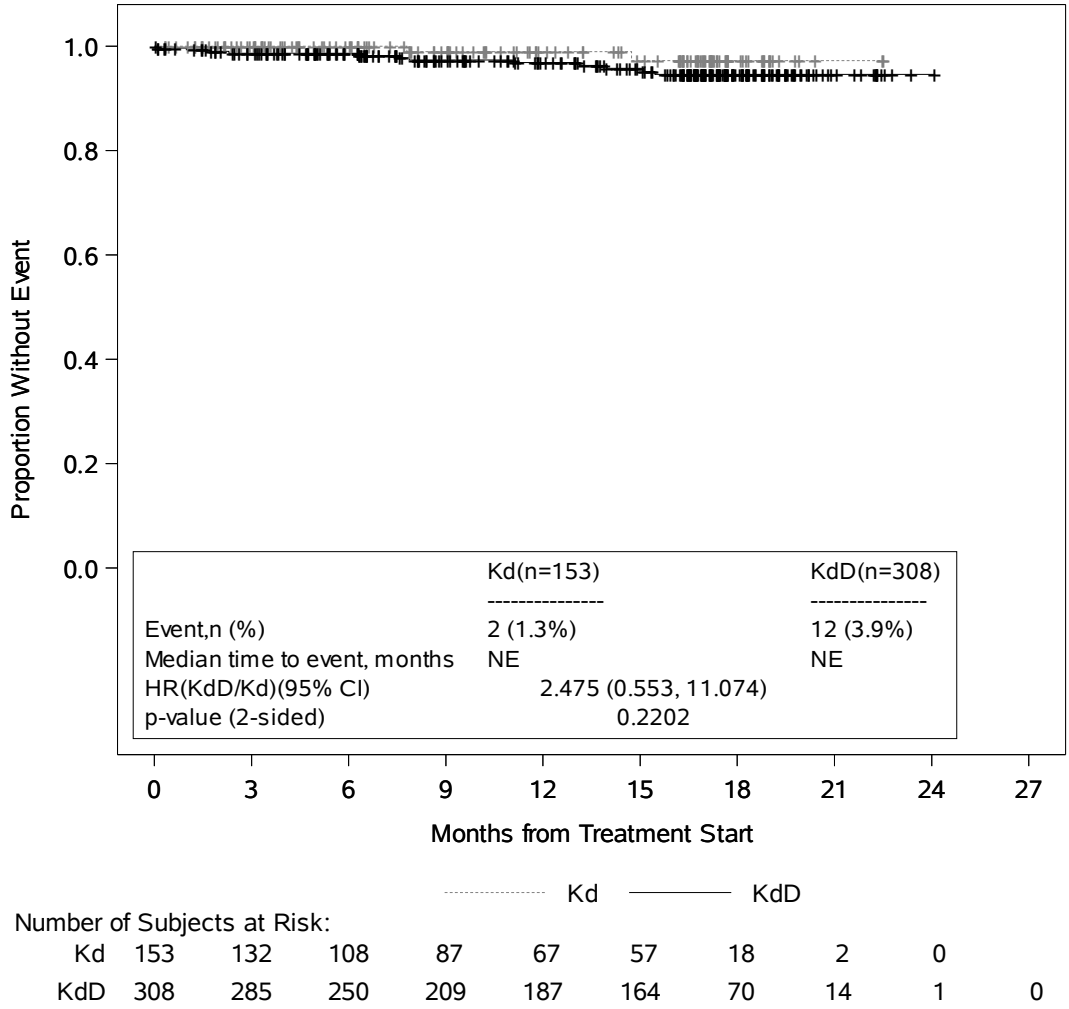


Number of Subjects at Risk:

Kd	153	130	105	85	63	54	18	2	0	
KdD	308	284	248	209	188	166	72	14	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-535-ae-cox-infe-viral-ge10.rtf (Date Generated: 27MAY20:22:28:53).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.536. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Injury, Poisoning and Procedural Complications) and PT (Contusion) <Safety Population>

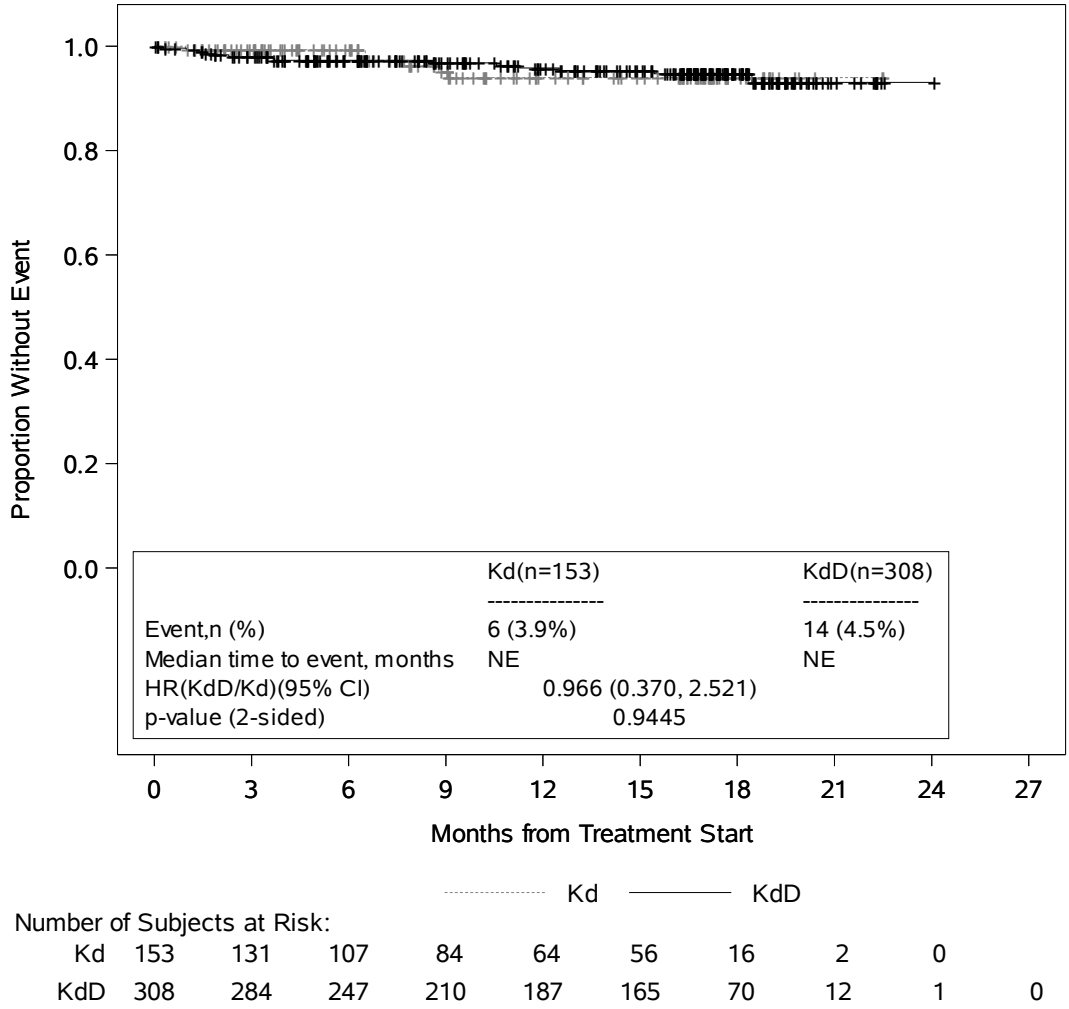


Number of Subjects at Risk:

Kd	153	132	108	87	67	57	18	2	0	
KdD	308	285	250	209	187	164	70	14	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-536-ae-cox-inju-cont-ge10.rtf (Date Generated: 27MAY20:22:28:54).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.537. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Injury, Poisoning and Procedural Complications) and PT (Fall) <Safety Population>

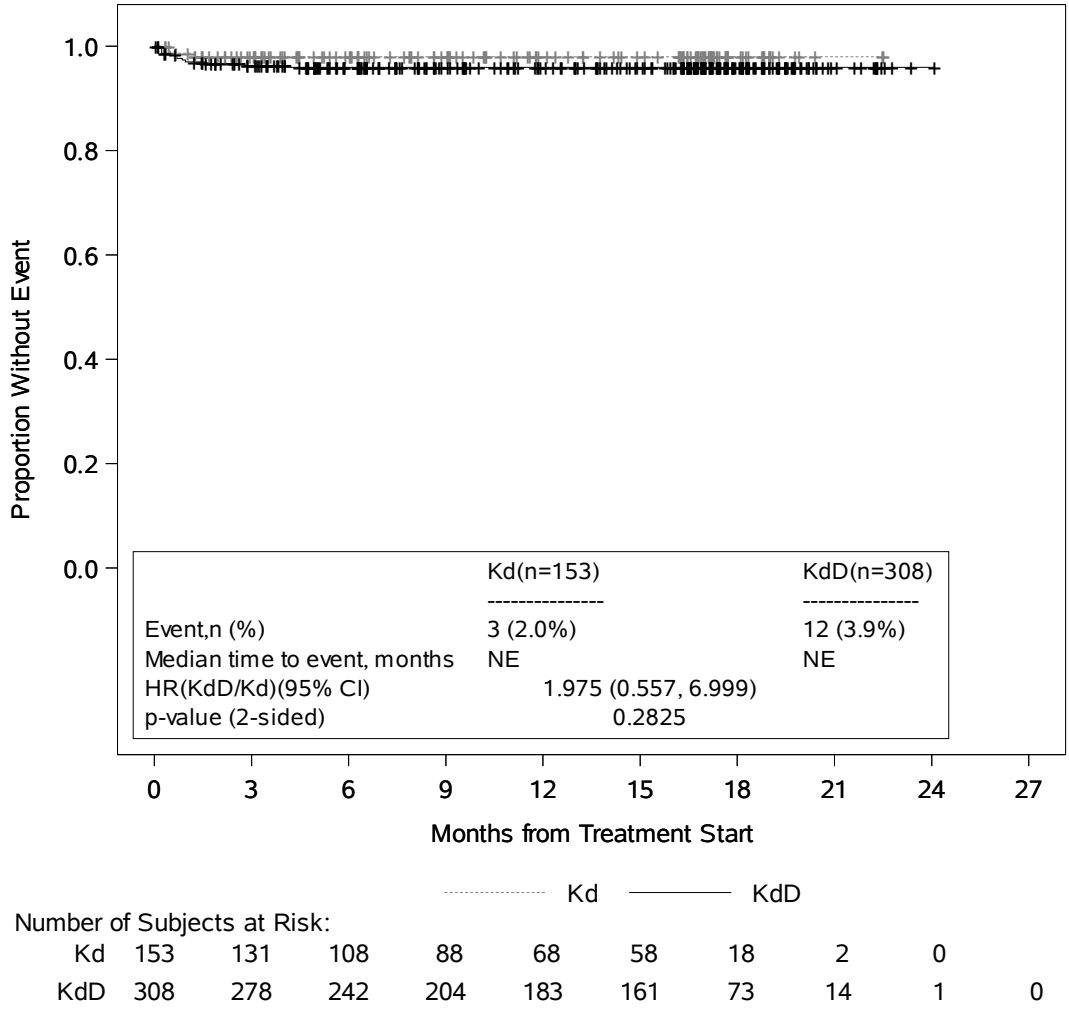


Number of Subjects at Risk:

Kd	153	131	107	84	64	56	16	2	0	
KdD	308	284	247	210	187	165	70	12	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-537-ae-cox-inju-fall-ge10.rtf (Date Generated: 27MAY20:22:28:56).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.539. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Investigations) and PT (Alanine Aminotransferase Increased) <Safety Population>

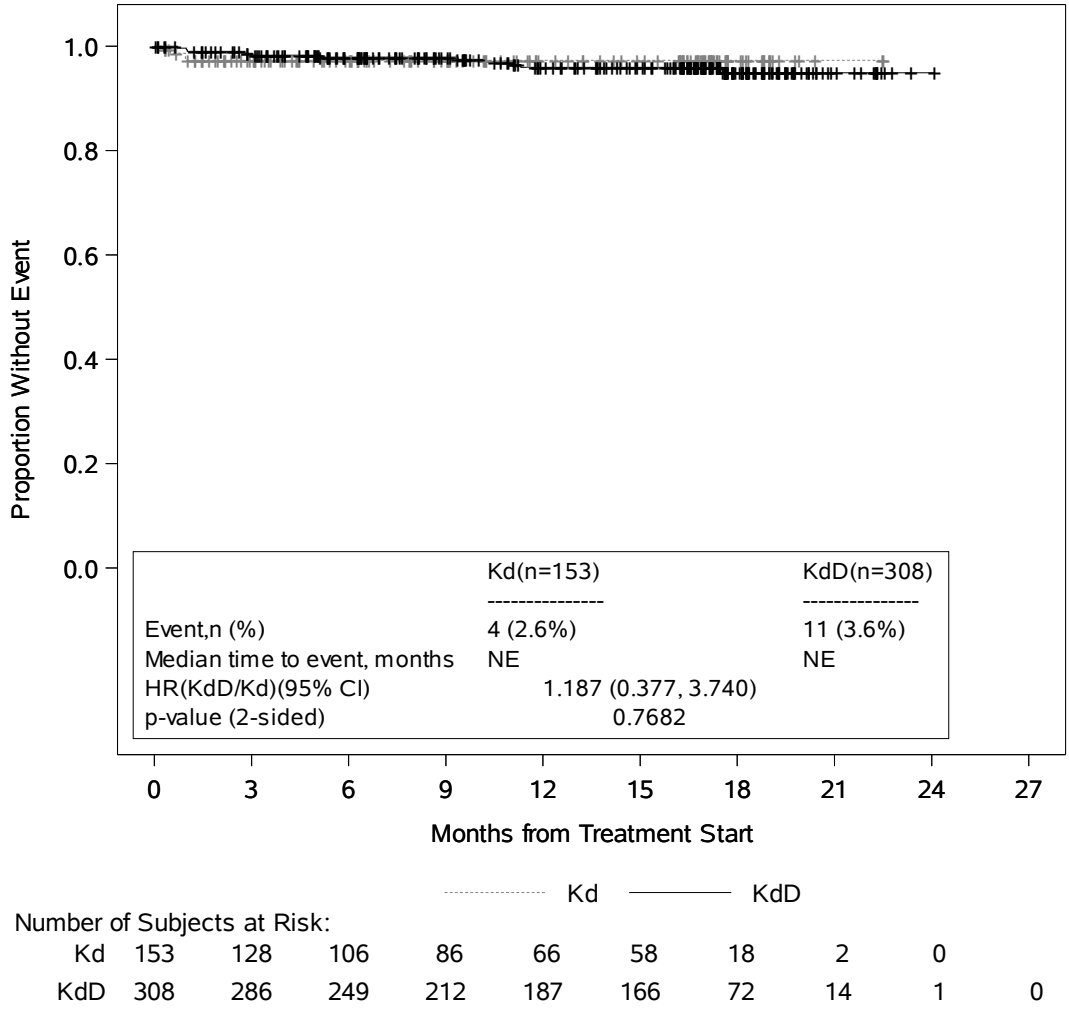


Number of Subjects at Risk:

Kd	153	131	108	88	68	58	18	2	0	
KdD	308	278	242	204	183	161	73	14	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-539-ae-cox-inve-alan-ge10.rtf (Date Generated: 27MAY20:22:28:59).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.540. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Investigations) and PT (Weight Decreased) <Safety Population>

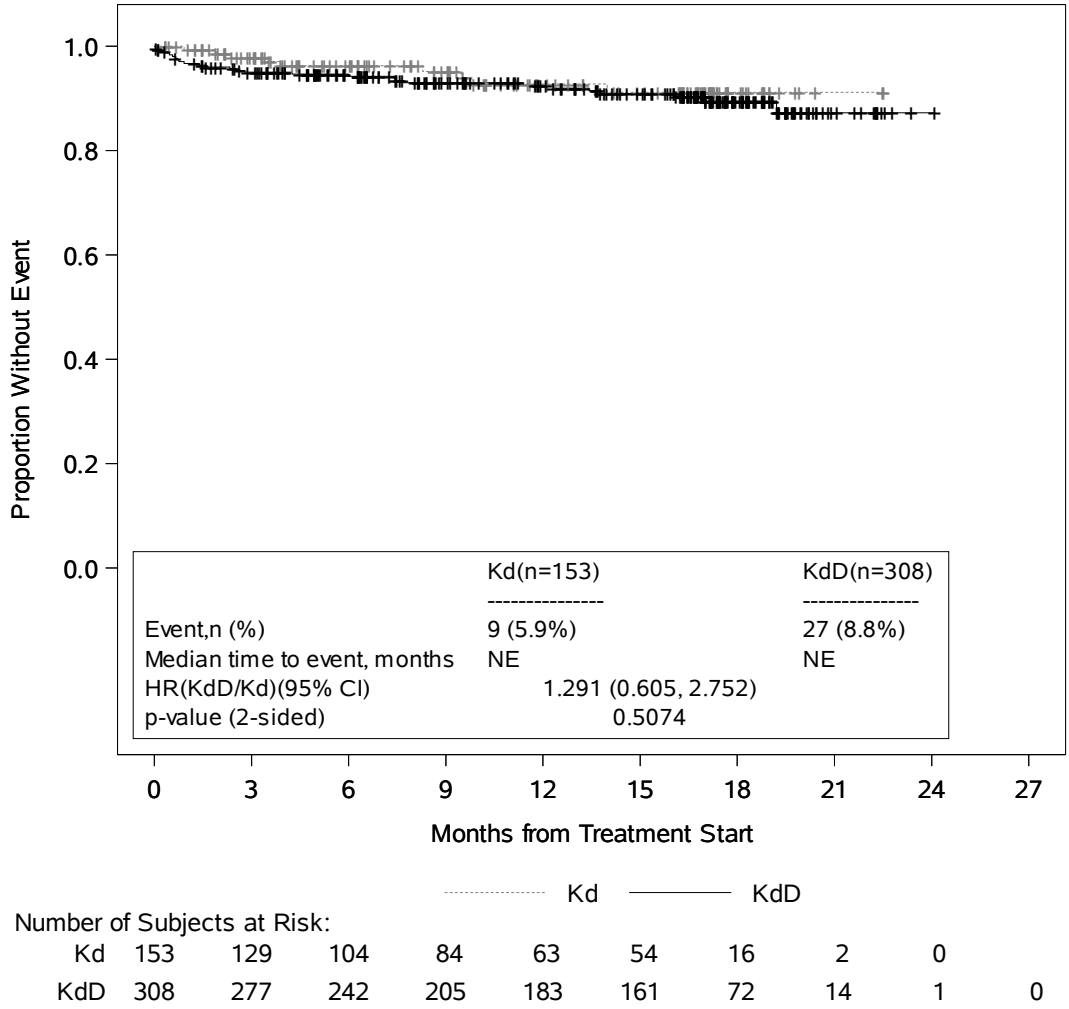


Number of Subjects at Risk:

Kd	153	128	106	86	66	58	18	2	0	
KdD	308	286	249	212	187	166	72	14	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-540-ae-cox-inve-wei-ge10.rtf (Date Generated: 27MAY20:22:29:01).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.541. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Metabolism and Nutrition Disorders) and PT (Decreased Appetite) <Safety Population>

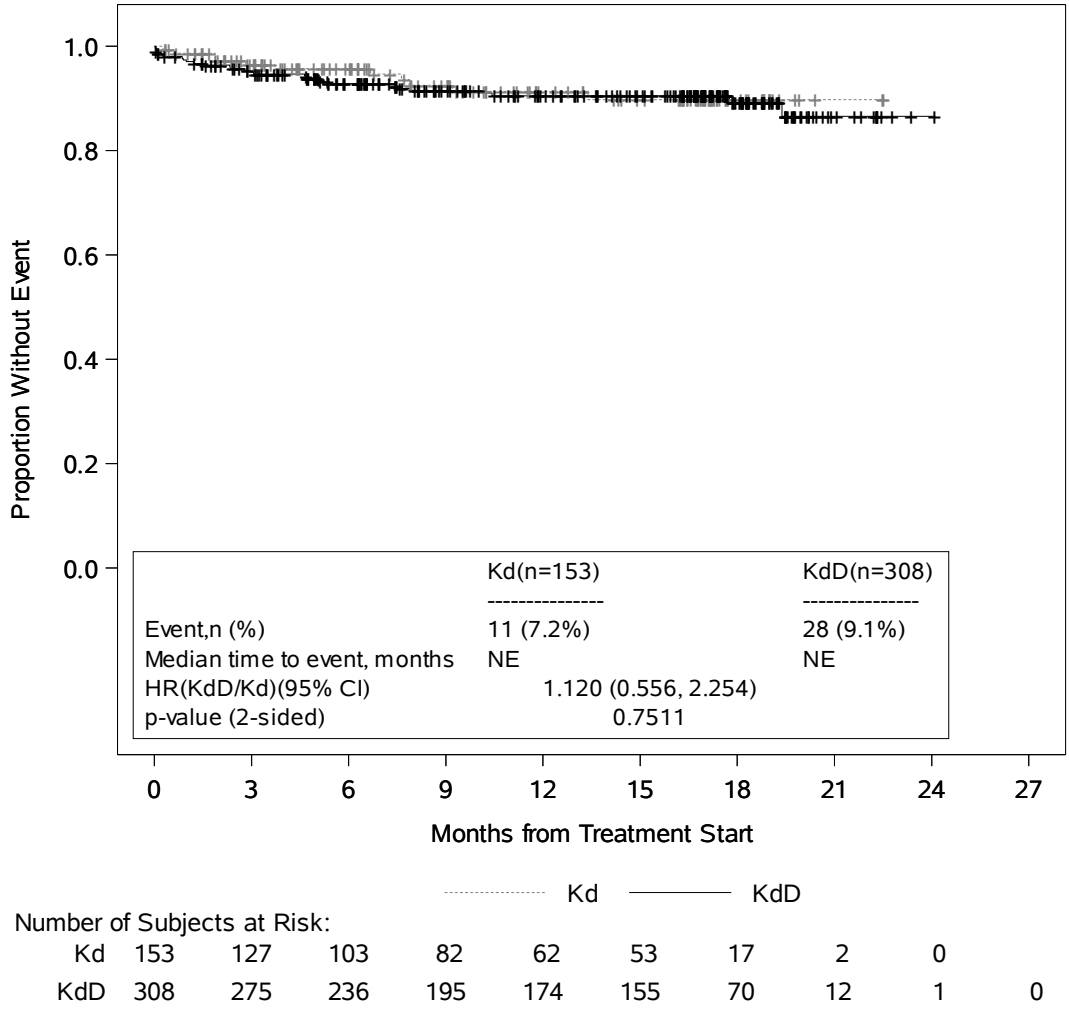


Number of Subjects at Risk:

Kd	153	129	104	84	63	54	16	2	0	
KdD	308	277	242	205	183	161	72	14	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-541-ae-cox-meta-decapp-ge10.rtf (Date Generated: 27MAY20:22:29:02).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.542. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Metabolism and Nutrition Disorders) and PT (Hyperglycaemia) <Safety Population>

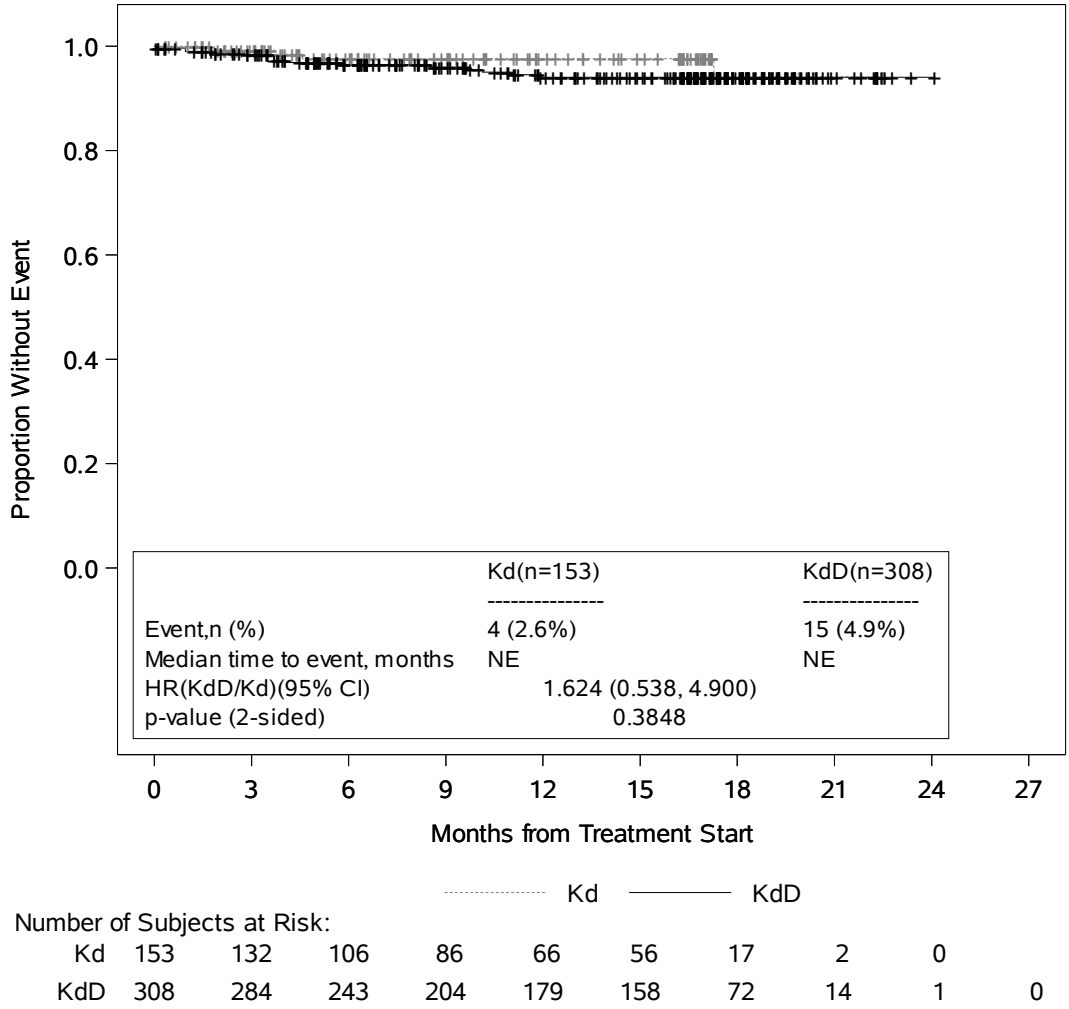


Number of Subjects at Risk:

Kd	153	127	103	82	62	53	17	2	0	
KdD	308	275	236	195	174	155	70	12	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-542-ae-cox-meta-hygly-ge10.rtf (Date Generated: 27MAY20:22:29:04).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.543. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Metabolism and Nutrition Disorders) and PT (Hypocalcaemia) <Safety Population>

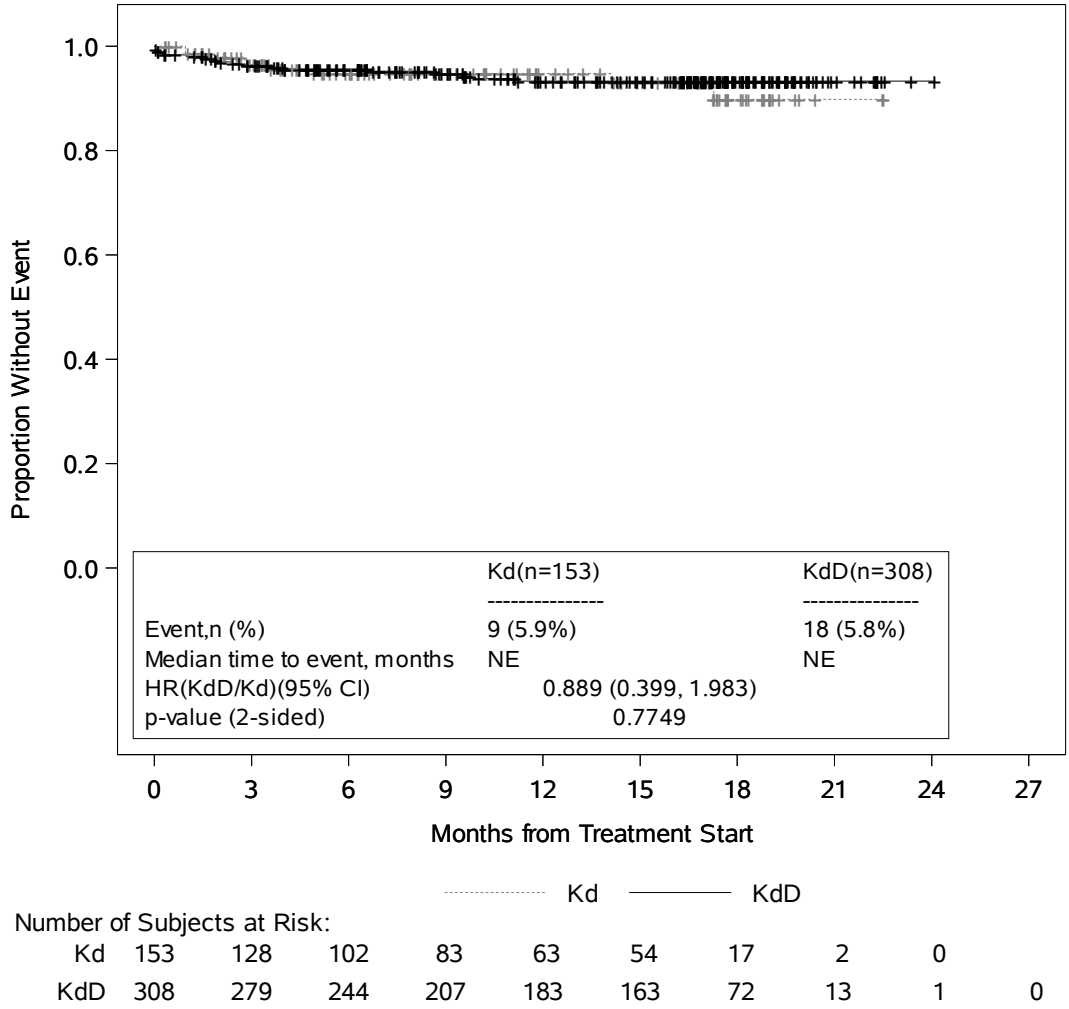


Number of Subjects at Risk:

Kd	153	132	106	86	66	56	17	2	0	
KdD	308	284	243	204	179	158	72	14	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-543-ae-cox-meta-hycal-ge10.rtf (Date Generated: 27MAY20:22:29:06).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.544. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Metabolism and Nutrition Disorders) and PT (Hypokalaemia) <Safety Population>

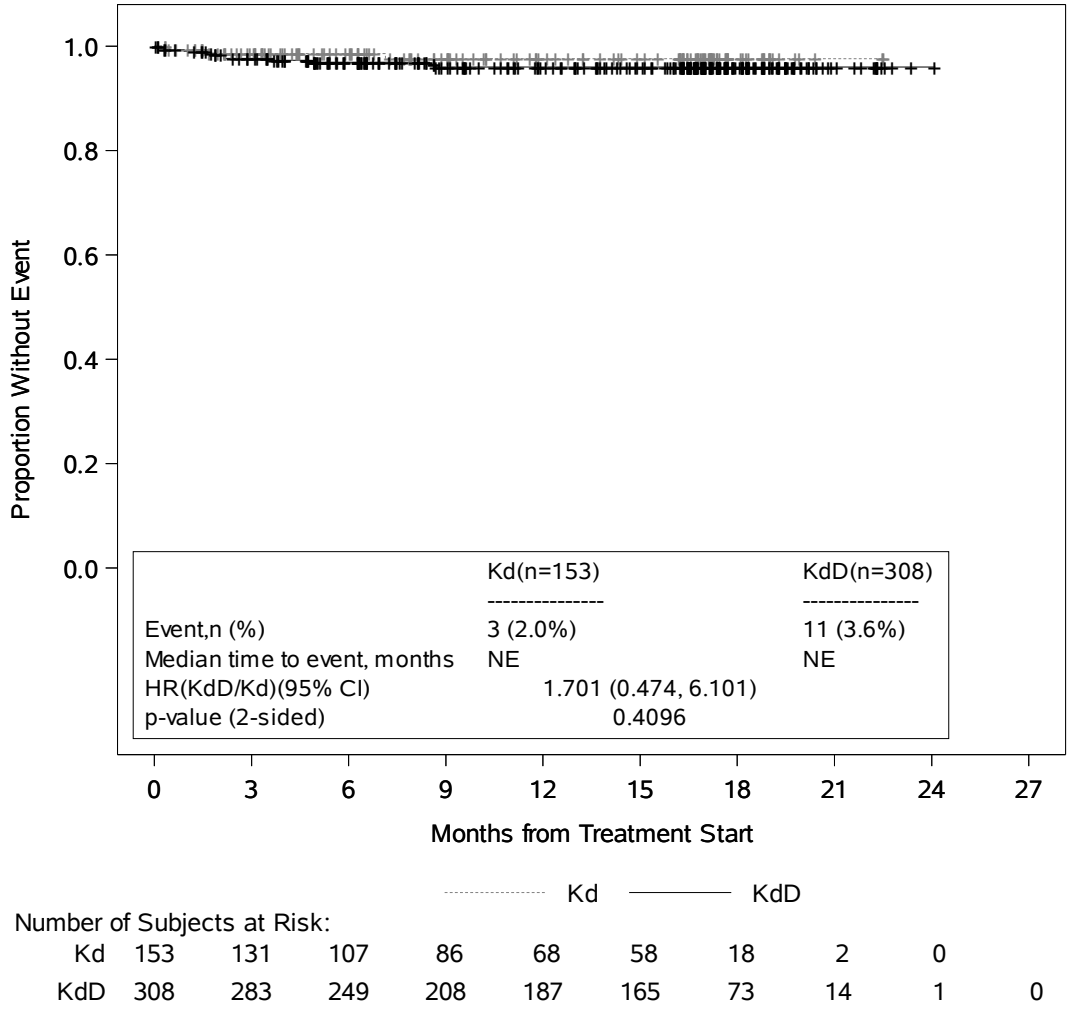


Number of Subjects at Risk:

Kd	153	128	102	83	63	54	17	2	0	
KdD	308	279	244	207	183	163	72	13	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-544-ae-cox-meta-hykal-ge10.rtf (Date Generated: 27MAY20:22:29:08).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.545. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Metabolism and Nutrition Disorders) and PT (Hypomagnesaemia) <Safety Population>

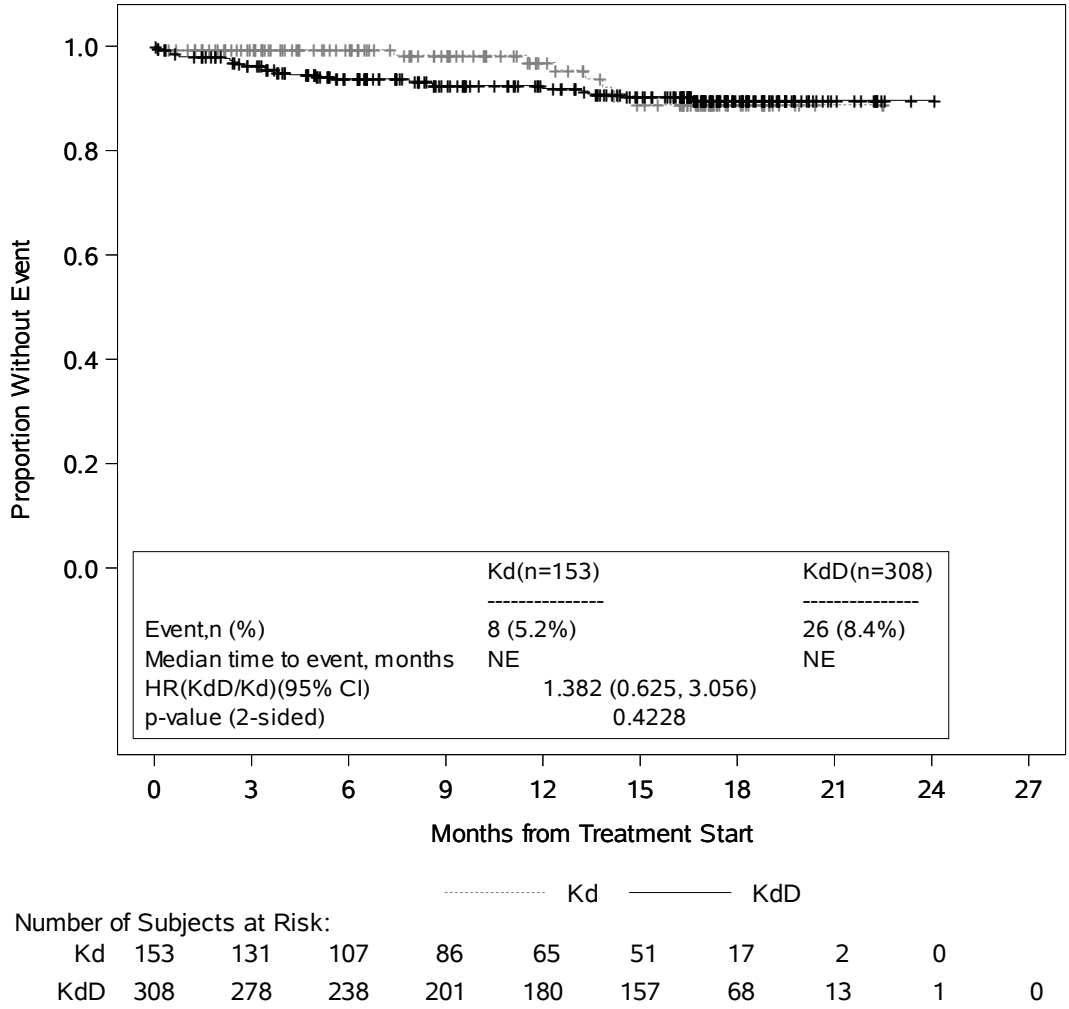


Number of Subjects at Risk:

Kd	153	131	107	86	68	58	18	2	0	
KdD	308	283	249	208	187	165	73	14	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-545-ae-cox-meta-hymag-ge10.rtf (Date Generated: 27MAY20:22:29:09).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.546. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Musculoskeletal and Connective Tissue Disorders) and PT (Arthralgia) <Safety Population>

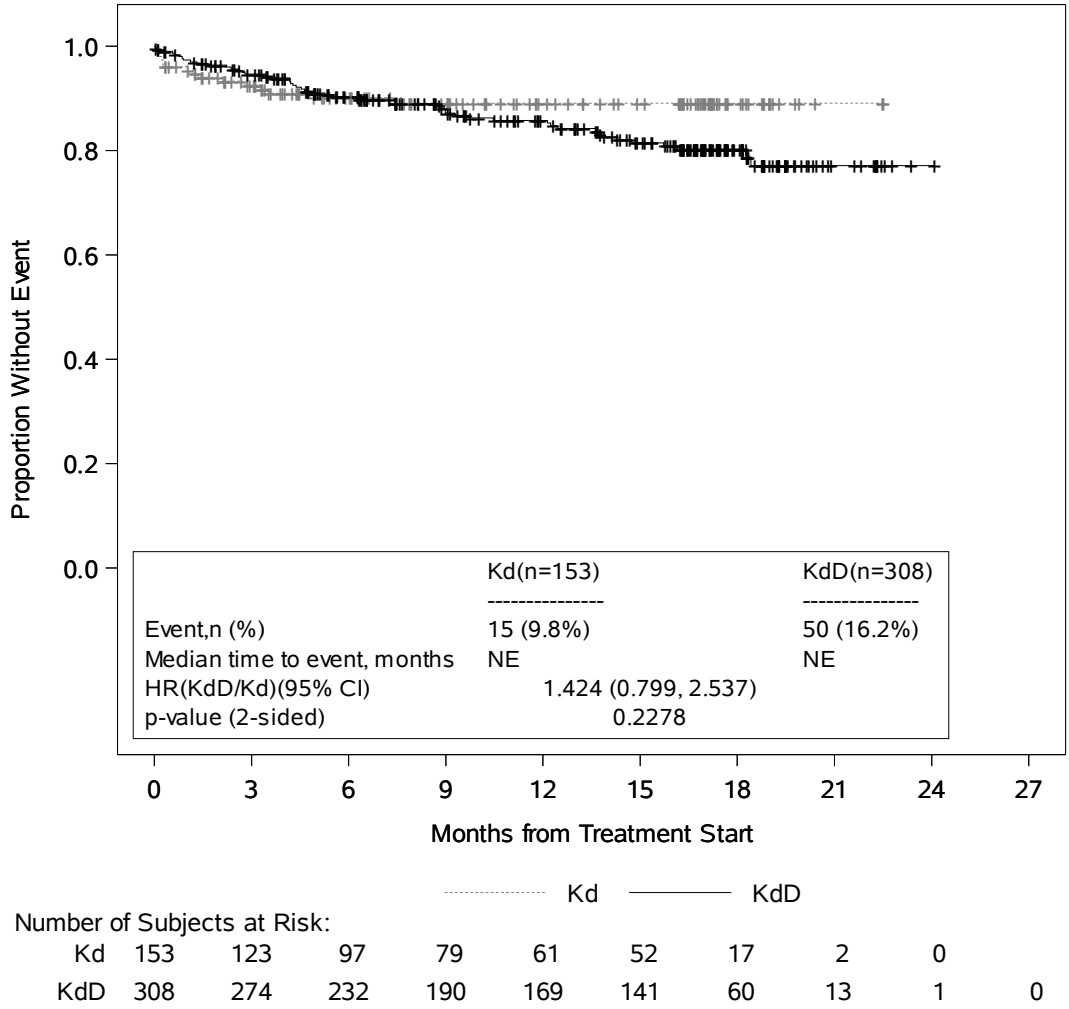


Number of Subjects at Risk:

Kd	153	131	107	86	65	51	17	2	0	
KdD	308	278	238	201	180	157	68	13	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-546-ae-cox-mus-art-ge10.rtf (Date Generated: 27MAY20:22:29:11).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.547. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Musculoskeletal and Connective Tissue Disorders) and PT (Back Pain) <Safety Population>

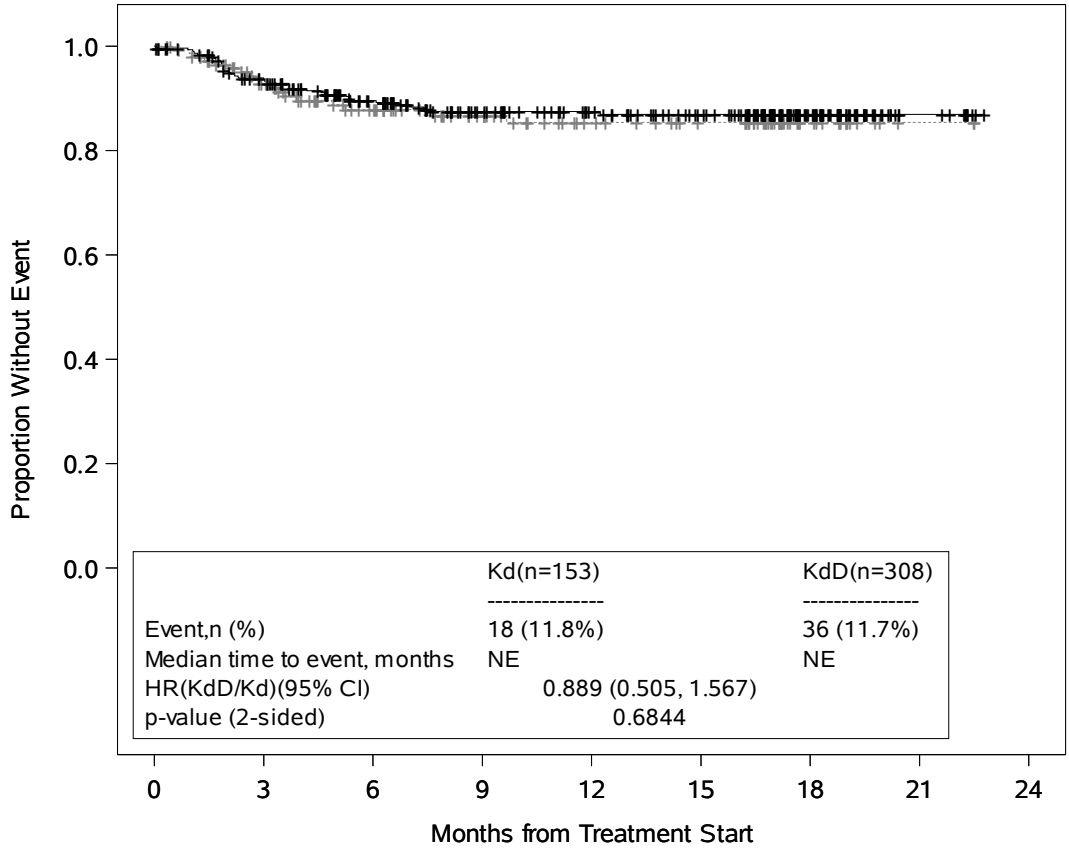


Number of Subjects at Risk:

Kd	153	123	97	79	61	52	17	2	0	
KdD	308	274	232	190	169	141	60	13	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-547-ae-cox-mus-back-ge10.rtf (Date Generated: 27MAY20:22:29:12).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.548. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Musculoskeletal and Connective Tissue Disorders) and PT (Muscle Spasms) <Safety Population>

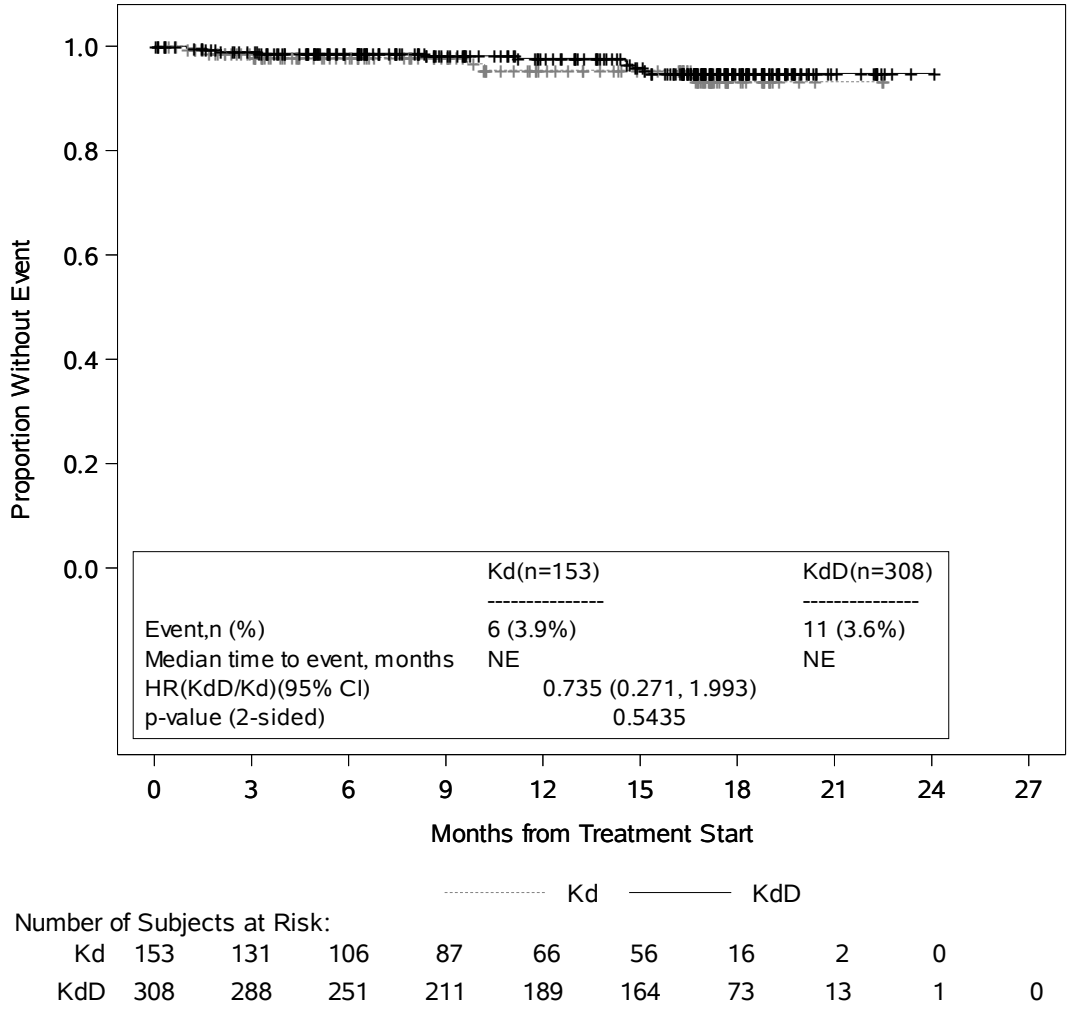


Number of Subjects at Risk:

Kd	153	122	92	71	55	47	16	2	0
KdD	308	271	226	184	164	144	65	11	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-548-ae-cox-mus-spas-ge10.rtf (Date Generated: 27MAY20:22:29:14).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.549. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Musculoskeletal and Connective Tissue Disorders) and PT (Muscular Weakness) <Safety Population>

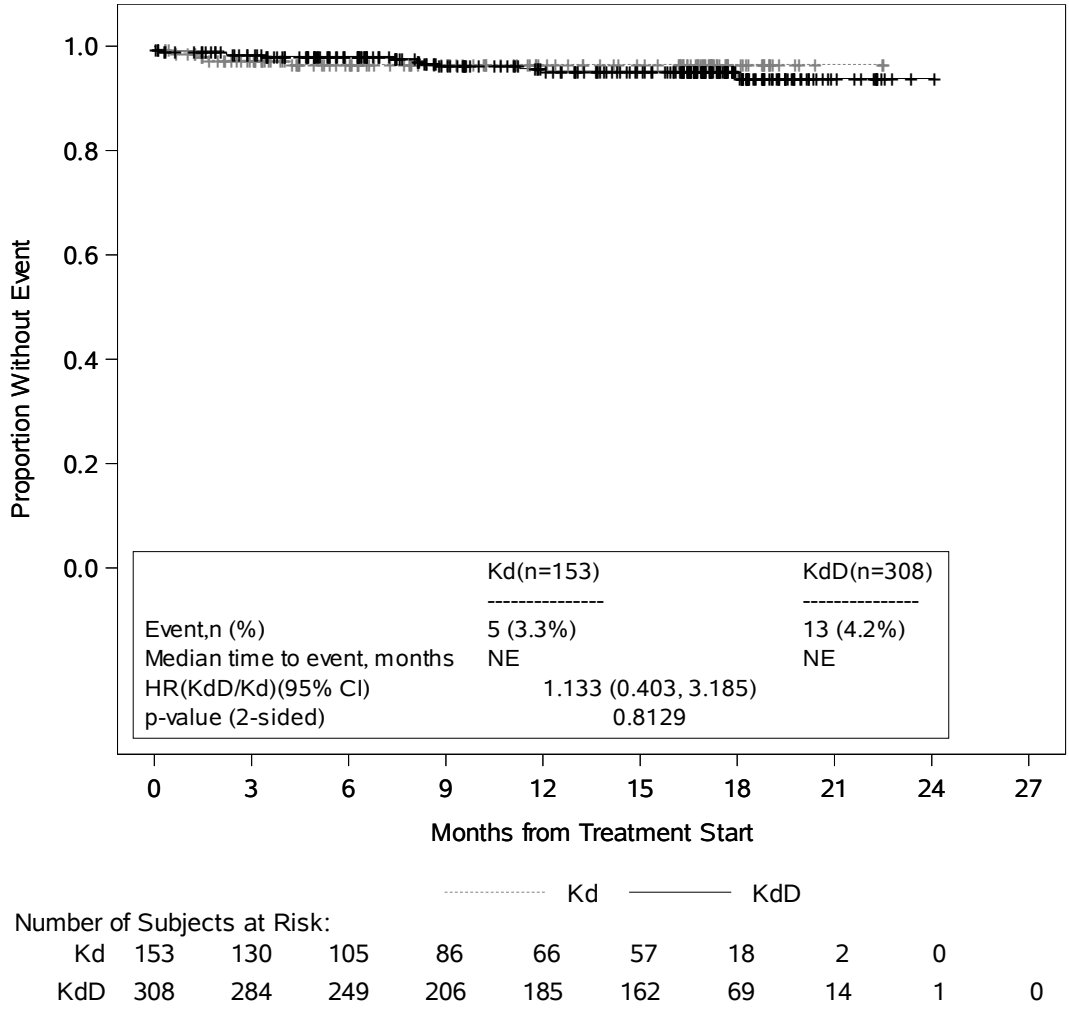


Number of Subjects at Risk:

Kd	153	131	106	87	66	56	16	2	0	
KdD	308	288	251	211	189	164	73	13	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-549-ae-cox-mus-weak-ge10.rtf (Date Generated: 27MAY20:22:29:15).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.550. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Musculoskeletal and Connective Tissue Disorders) and PT (Musculoskeletal Chest Pain)
<Safety Population>

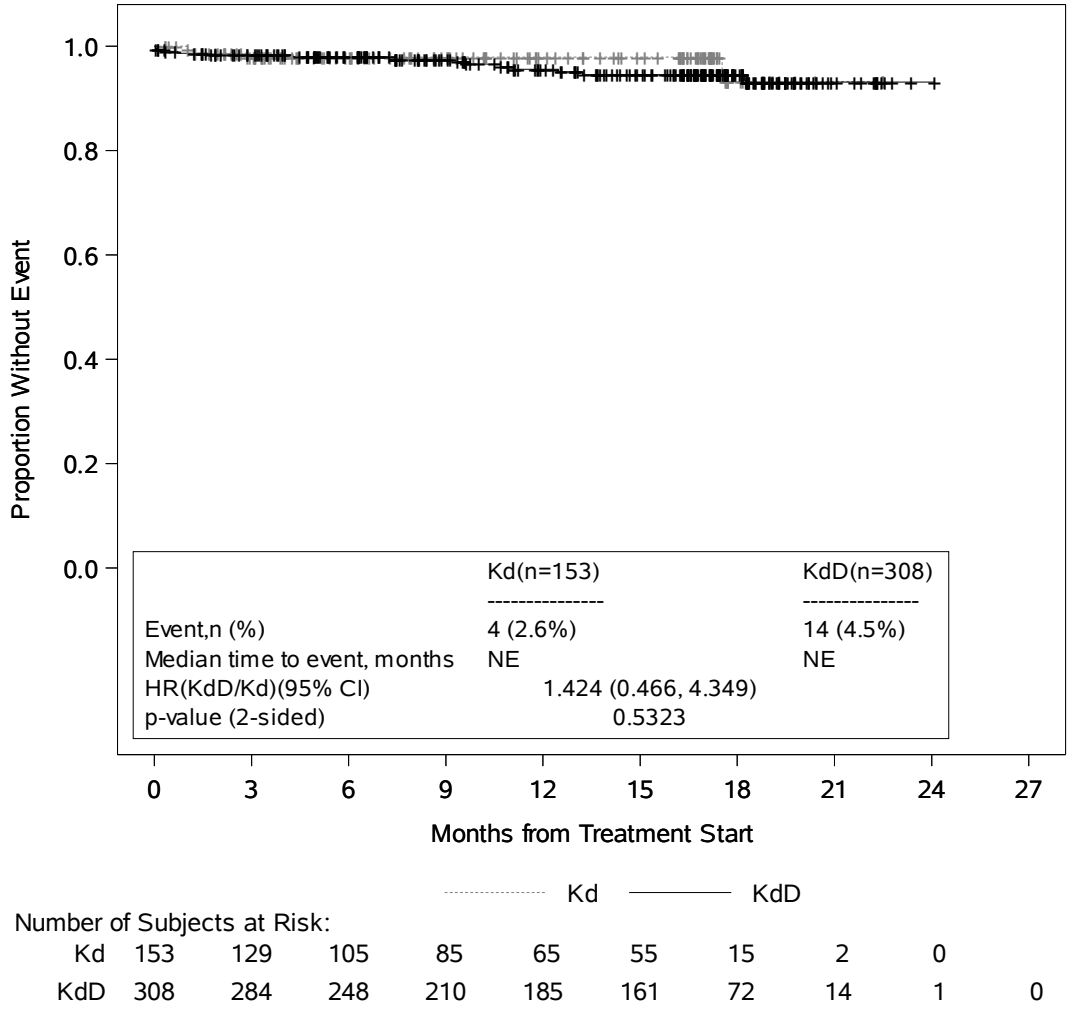


Number of Subjects at Risk:

Kd	153	130	105	86	66	57	18	2	0	
KdD	308	284	249	206	185	162	69	14	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-550-ae-cox-mus-chest-ge10.rtf (Date Generated: 27MAY20:22:29:17).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.551. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Musculoskeletal and Connective Tissue Disorders) and PT (Myalgia) <Safety Population>

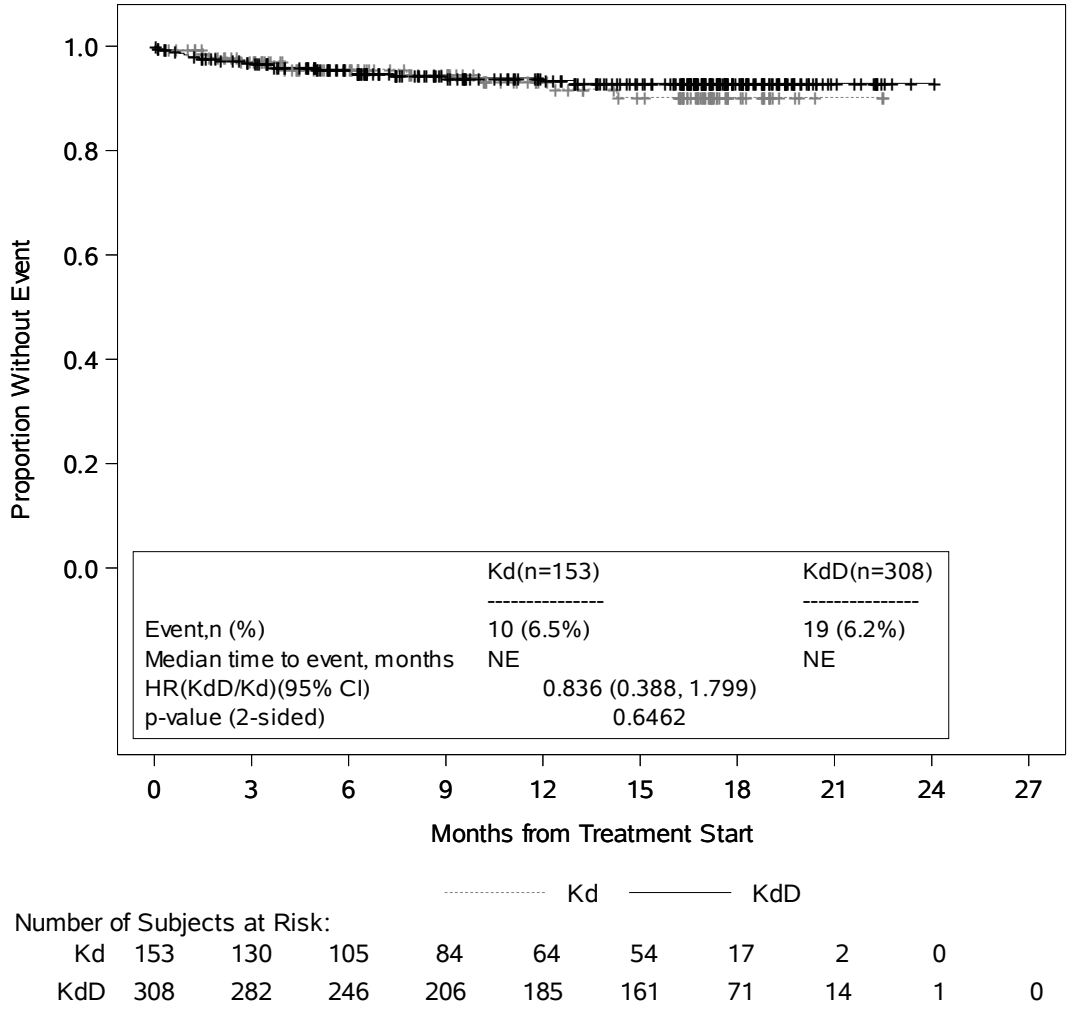


Number of Subjects at Risk:

Kd	153	129	105	85	65	55	15	2	0	
KdD	308	284	248	210	185	161	72	14	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-551-ae-cox-mus-myalgia-ge10.rtf (Date Generated: 27MAY20:22:29:19).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.552. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Musculoskeletal and Connective Tissue Disorders) and PT (Pain in Extremity) <Safety Population>

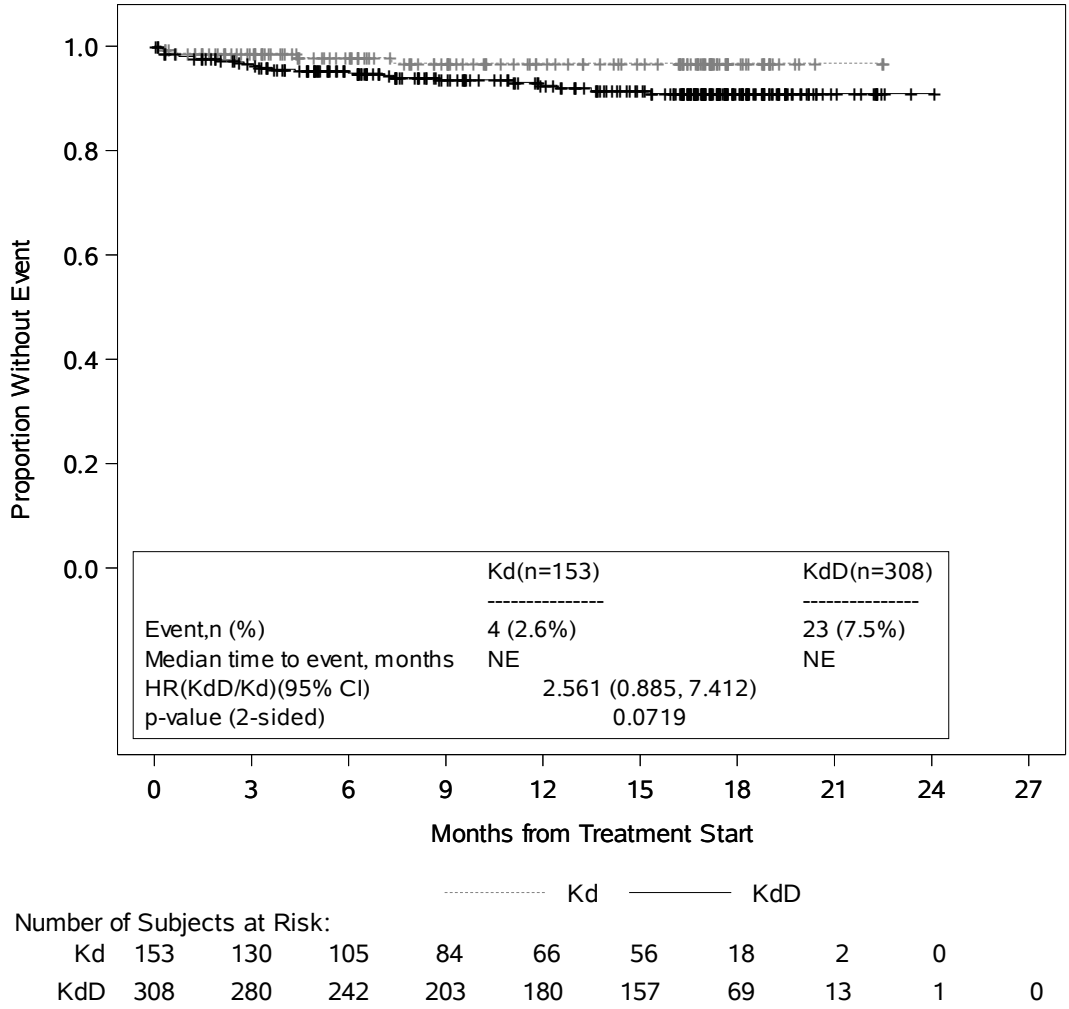


Number of Subjects at Risk:

Kd	153	130	105	84	64	54	17	2	0	
KdD	308	282	246	206	185	161	71	14	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-552-ae-cox-mus-pain-ge10.rtf (Date Generated: 27MAY20:22:29:20).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.553. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Nervous System Disorders) and PT (Dizziness) <Safety Population>

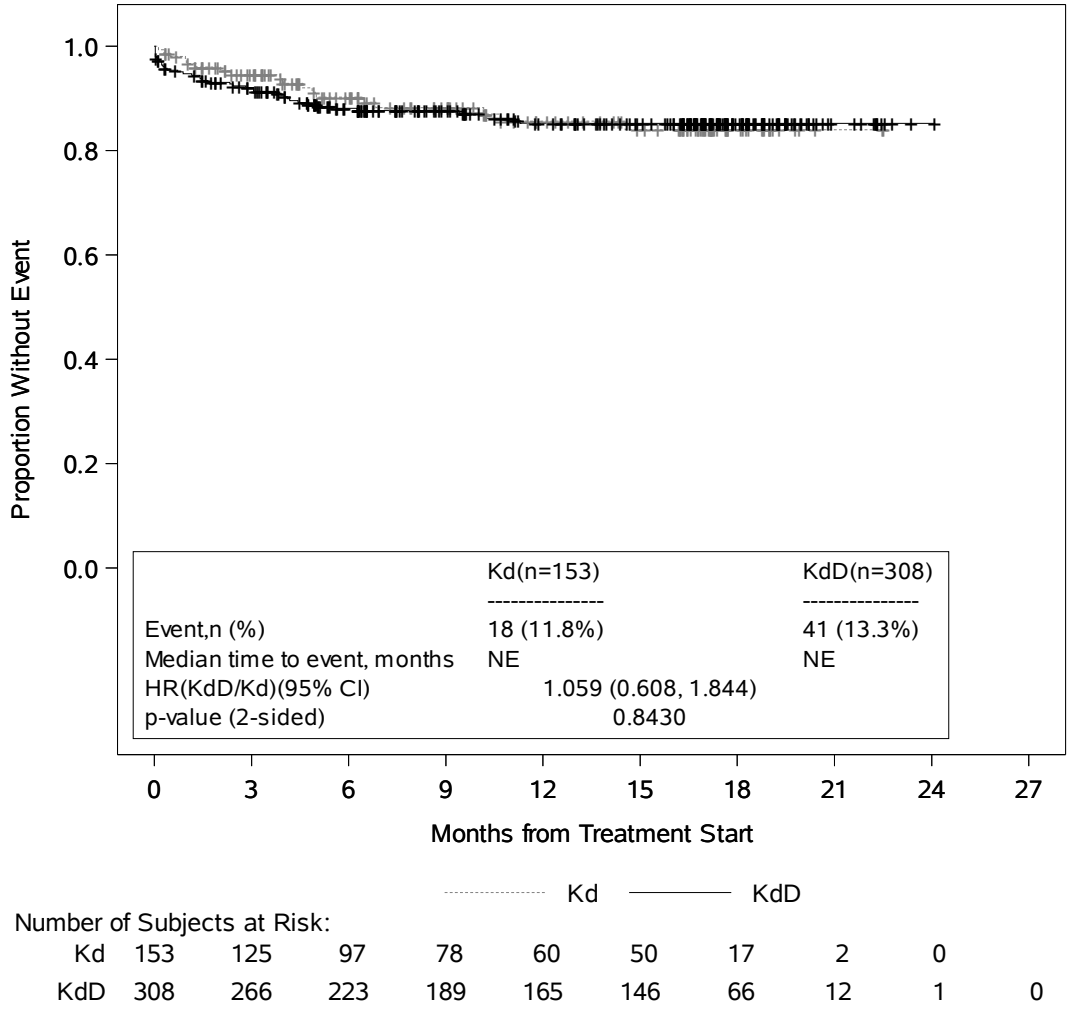


Number of Subjects at Risk:

Kd	153	130	105	84	66	56	18	2	0	
KdD	308	280	242	203	180	157	69	13	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-553-ae-cox-ner-diz-ge10.rtf (Date Generated: 27MAY20:22:29:22).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.554. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Nervous System Disorders) and PT (Headache)
<Safety Population>

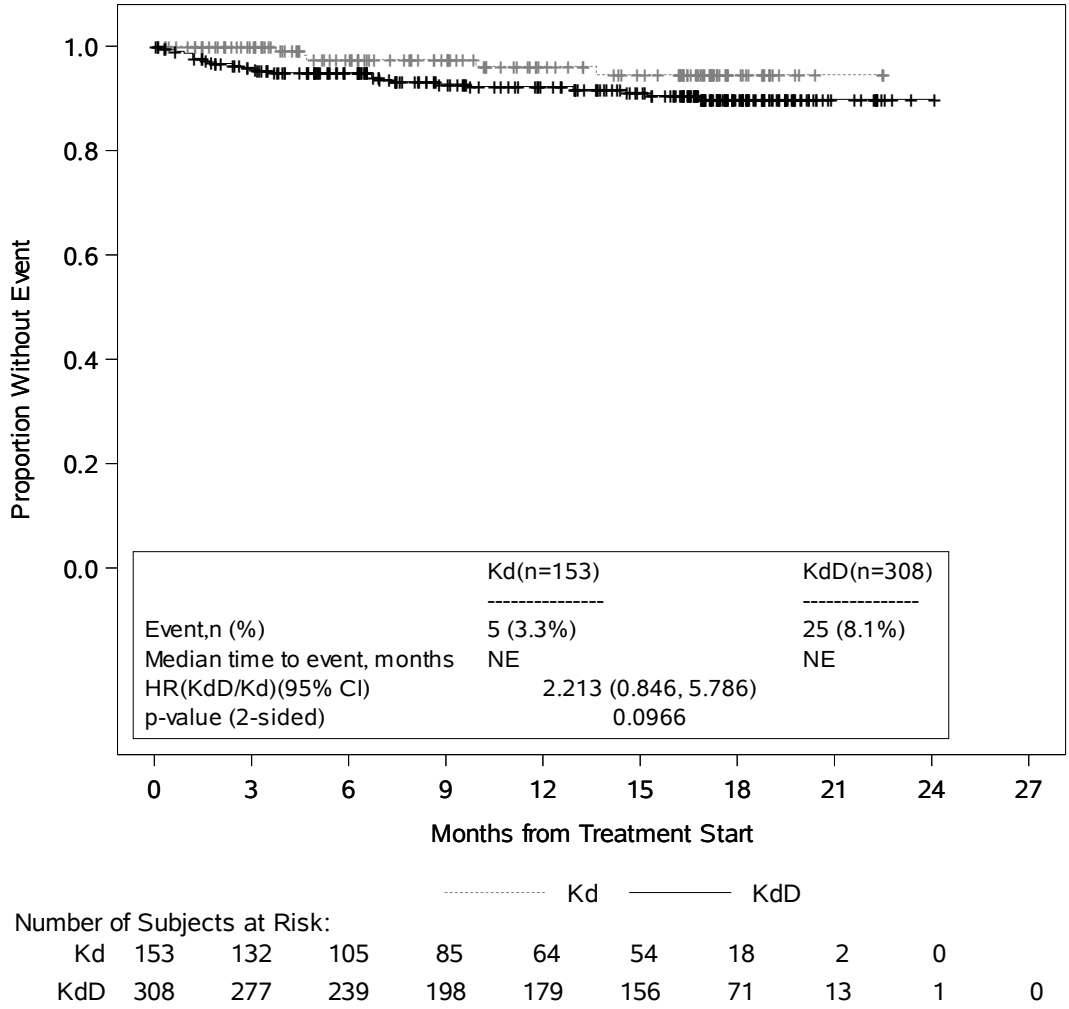


Number of Subjects at Risk:

Kd	153	125	97	78	60	50	17	2	0	
KdD	308	266	223	189	165	146	66	12	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-554-ae-cox-ner-head-ge10.rtf (Date Generated: 27MAY20:22:29:23).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.555. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Nervous System Disorders) and PT (Neuropathy Peripheral) <Safety Population>

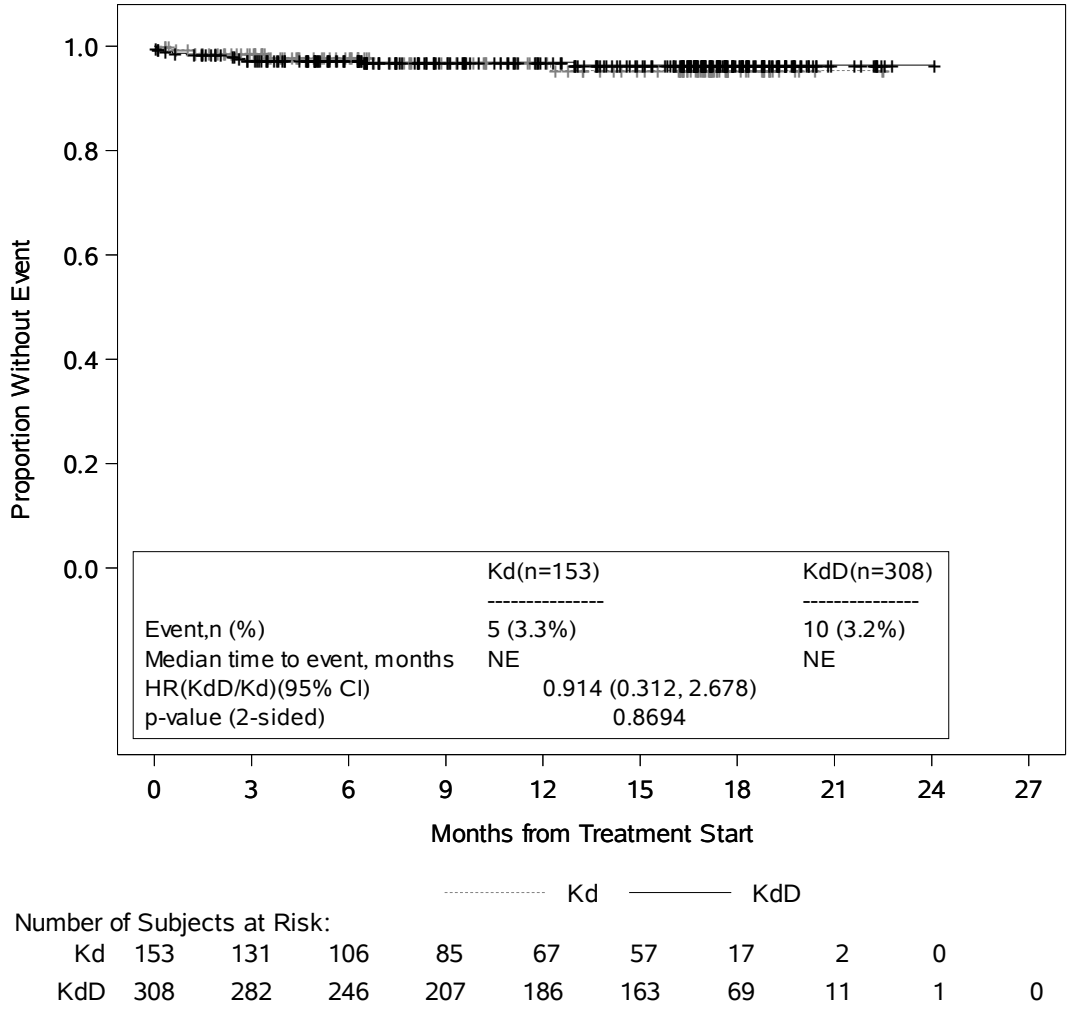


Number of Subjects at Risk:

Kd	153	132	105	85	64	54	18	2	0	
KdD	308	277	239	198	179	156	71	13	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-555-ae-cox-ner-neu-ge10.rtf (Date Generated: 27MAY20:22:29:25).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.557. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Psychiatric Disorders) and PT (Agitation) <Safety Population>

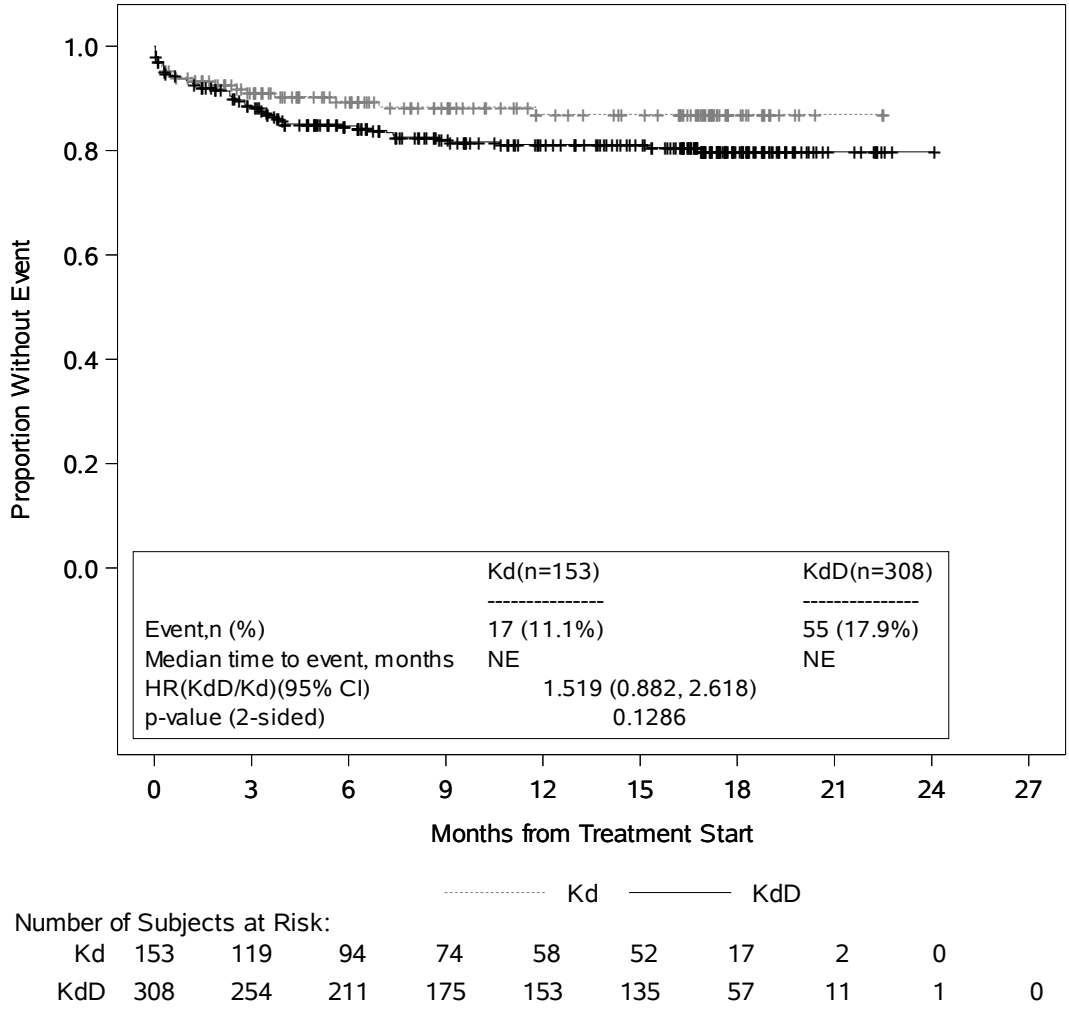


Number of Subjects at Risk:

Kd	153	131	106	85	67	57	17	2	0	
KdD	308	282	246	207	186	163	69	11	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-557-ae-cox-psy-agi-ge10.rtf (Date Generated: 27MAY20:22:29:28).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.558. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Psychiatric Disorders) and PT (Insomnia)
<Safety Population>

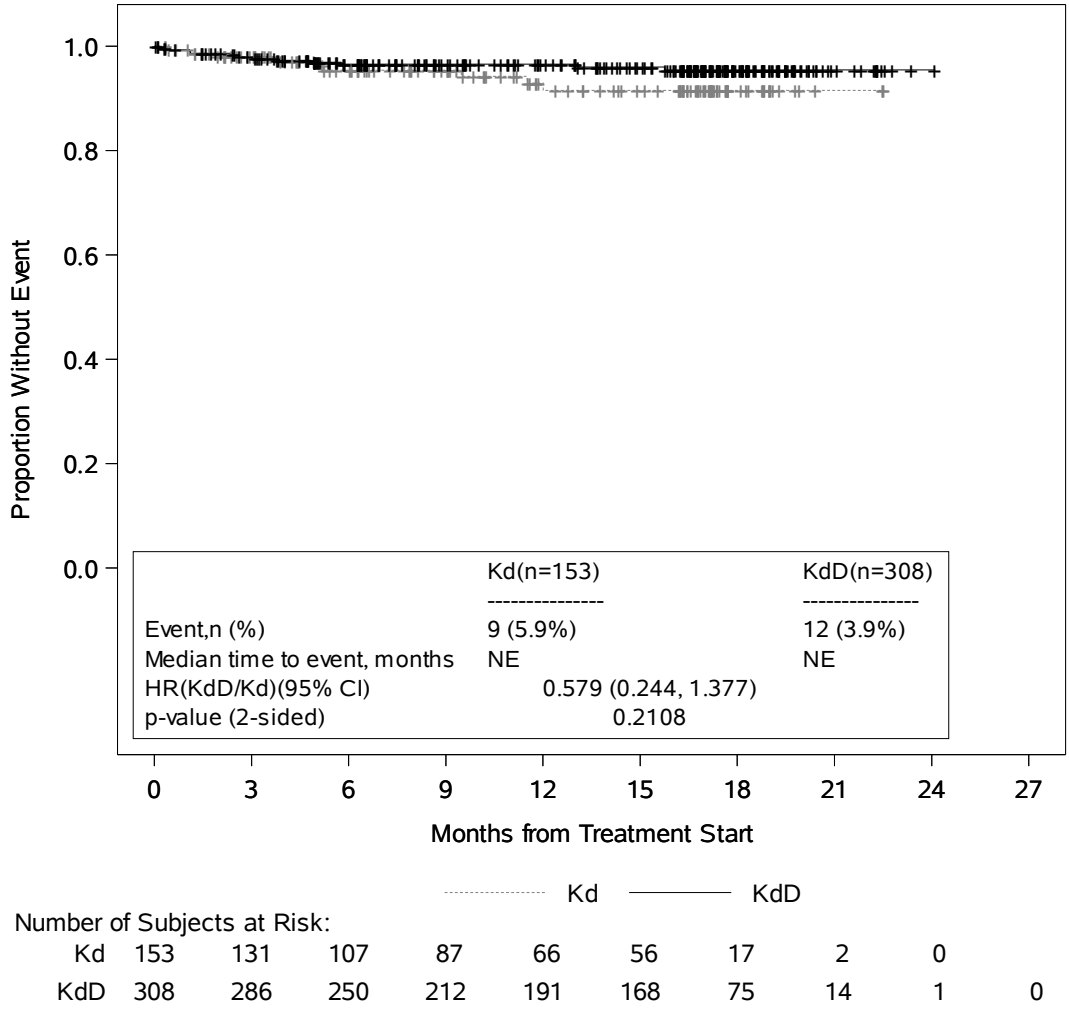


Number of Subjects at Risk:

Kd	153	119	94	74	58	52	17	2	0	
KdD	308	254	211	175	153	135	57	11	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-558-ae-cox-psy-ins-ge10.rtf (Date Generated: 27MAY20:22:29:30).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.559. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Renal and Urinary Disorders) and PT (Acute Kidney Injury) <Safety Population>

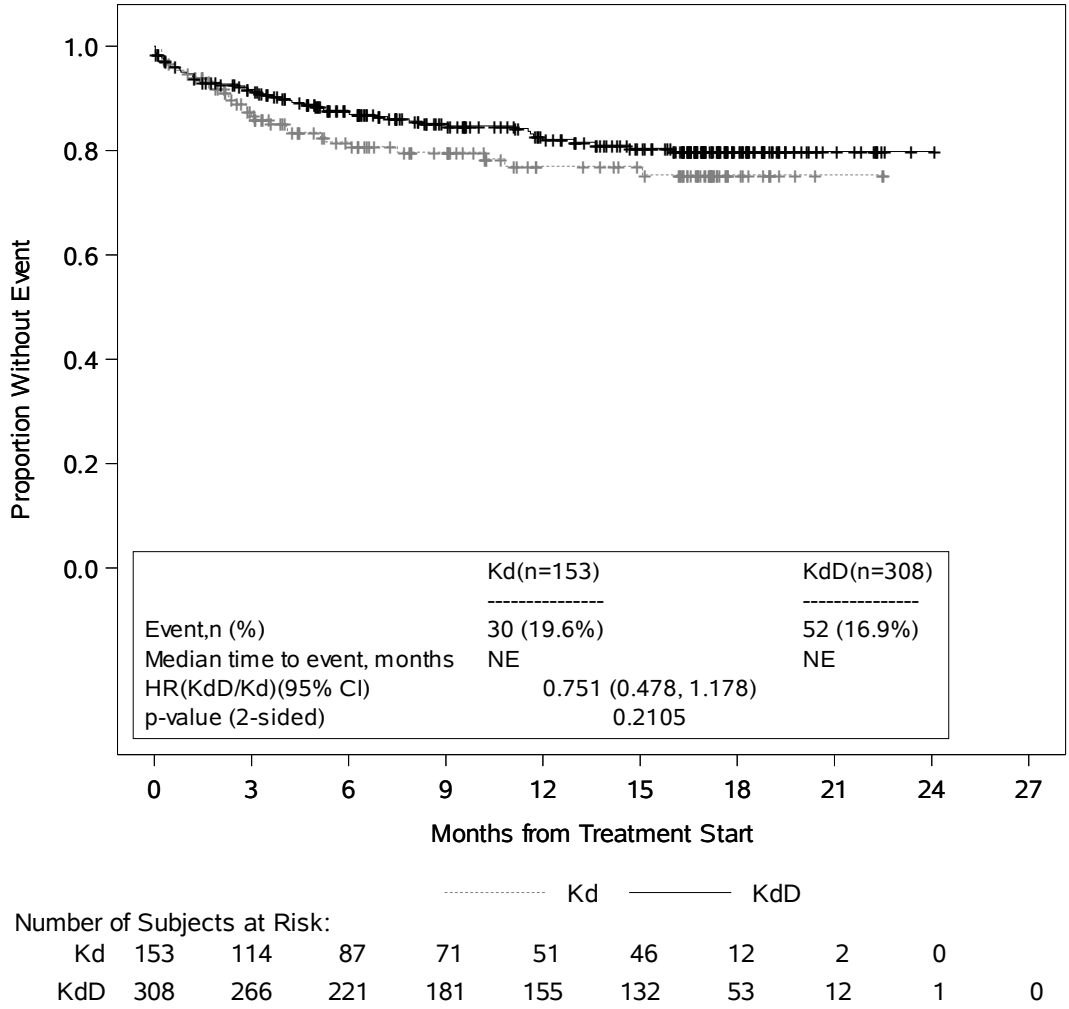


Number of Subjects at Risk:

Kd	153	131	107	87	66	56	17	2	0	
KdD	308	286	250	212	191	168	75	14	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-559-ae-cox-ren-acute-ge10.rtf (Date Generated: 27MAY20:22:29:31).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.560. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Respiratory, Thoracic and Mediastinal Disorders) and PT (Cough) <Safety Population>

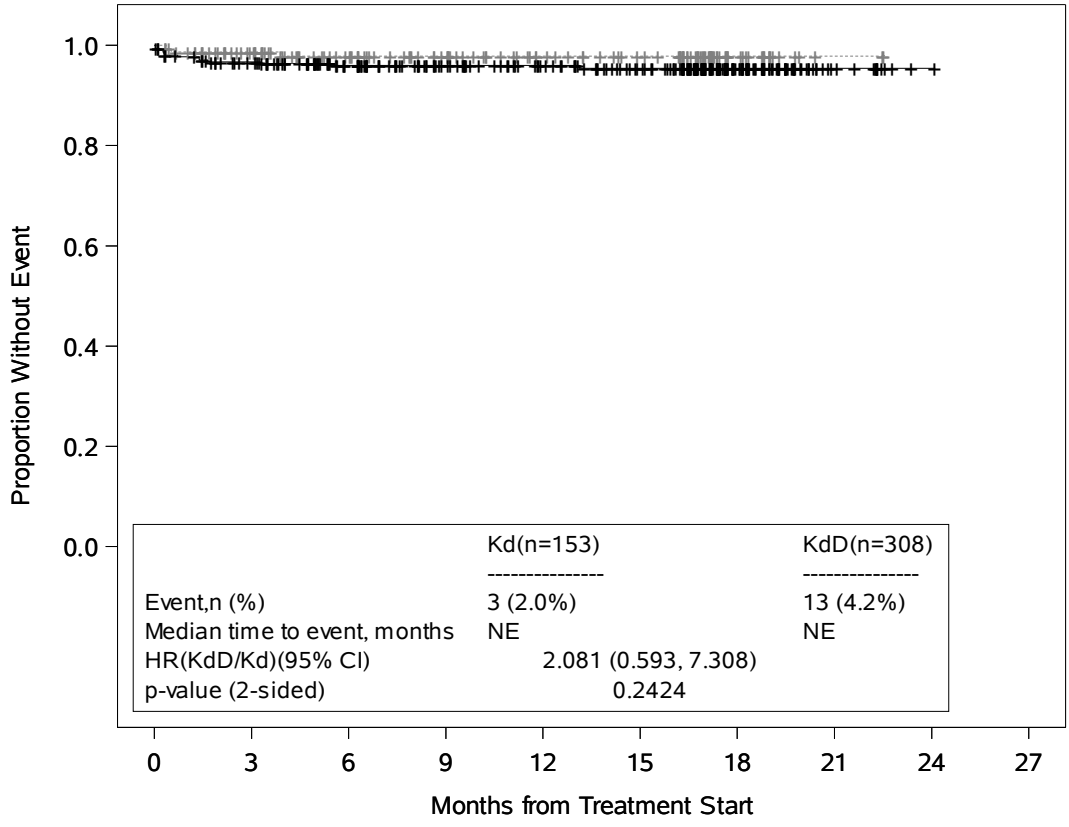


Number of Subjects at Risk:

Kd	153	114	87	71	51	46	12	2	0	
KdD	308	266	221	181	155	132	53	12	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-560-ae-cox-resp-cough-ge10.rtf (Date Generated: 27MAY20:22:29:33).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.561. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Respiratory, Thoracic and Mediastinal Disorders) and PT (Dysphonia) <Safety Population>

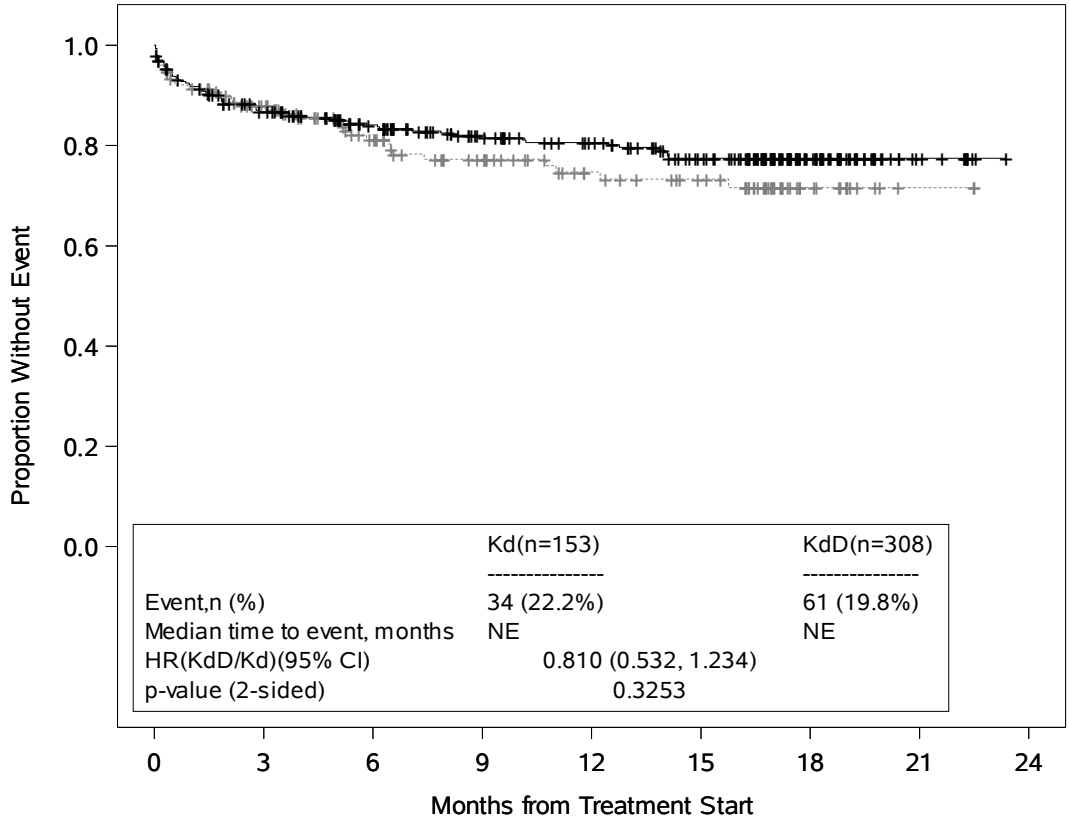


Number of Subjects at Risk:

Kd	153	130	105	85	67	57	18	2	0	
KdD	308	280	243	208	187	165	74	13	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-561-ae-cox-resp-dysphonia-ge10.rtf (Date Generated: 27MAY20:22:29:34).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.562. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Respiratory, Thoracic and Mediastinal Disorders) and PT (Dyspnoea) <Safety Population>

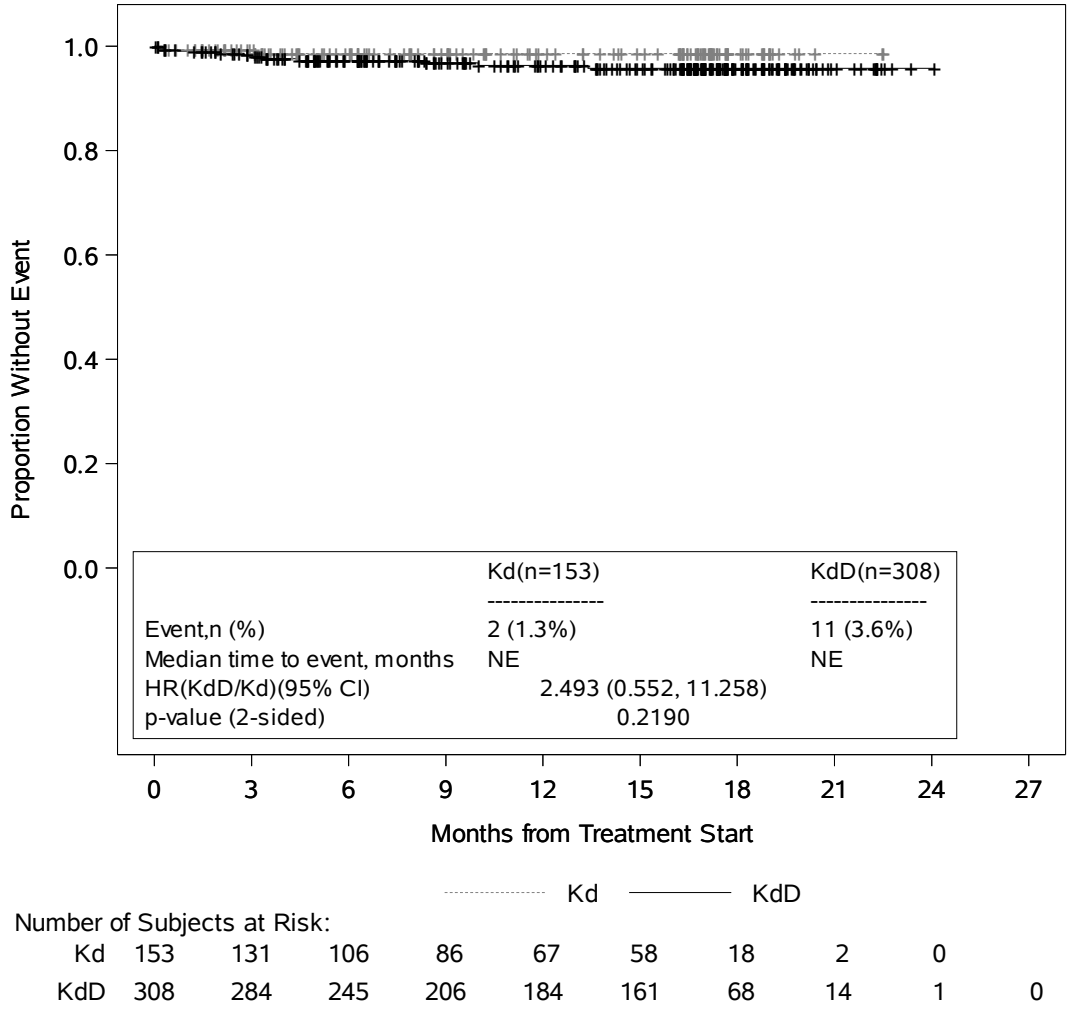


Number of Subjects at Risk:

Kd	153	119	90	70	53	45	14	2	0
KdD	308	250	215	180	162	136	58	11	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-562-ae-cox-resp-dyspnoea-ge10.rtf (Date Generated: 27MAY20:22:29:36).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.563. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Respiratory, Thoracic and Mediastinal Disorders) and PT (Dyspnoea Exertional) <Safety Population>

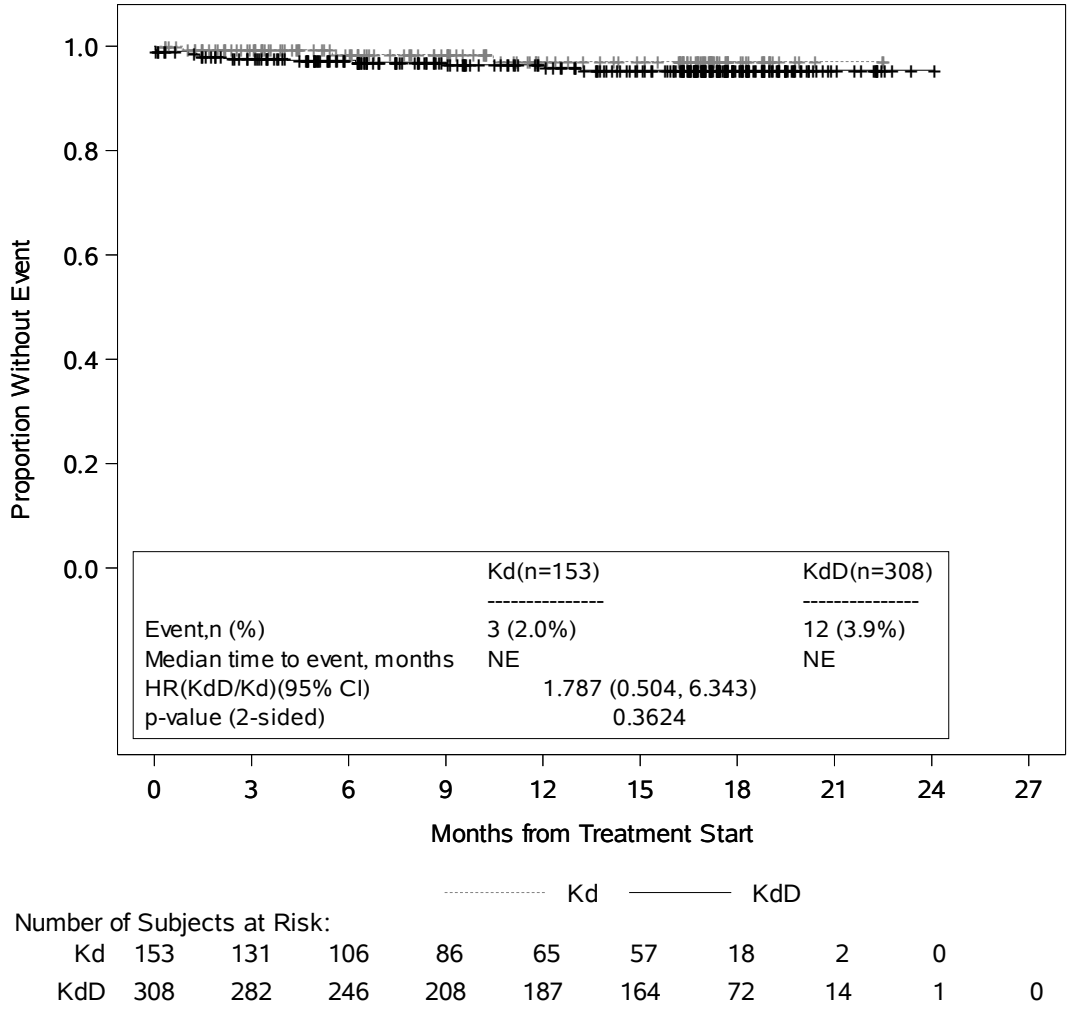


Number of Subjects at Risk:

Kd	153	131	106	86	67	58	18	2	0	
KdD	308	284	245	206	184	161	68	14	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-563-ae-cox-resp-dysexe-ge10.rtf (Date Generated: 27MAY20:22:29:37).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.564. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Respiratory, Thoracic and Mediastinal Disorders) and PT (Oropharyngeal Pain) <Safety Population>

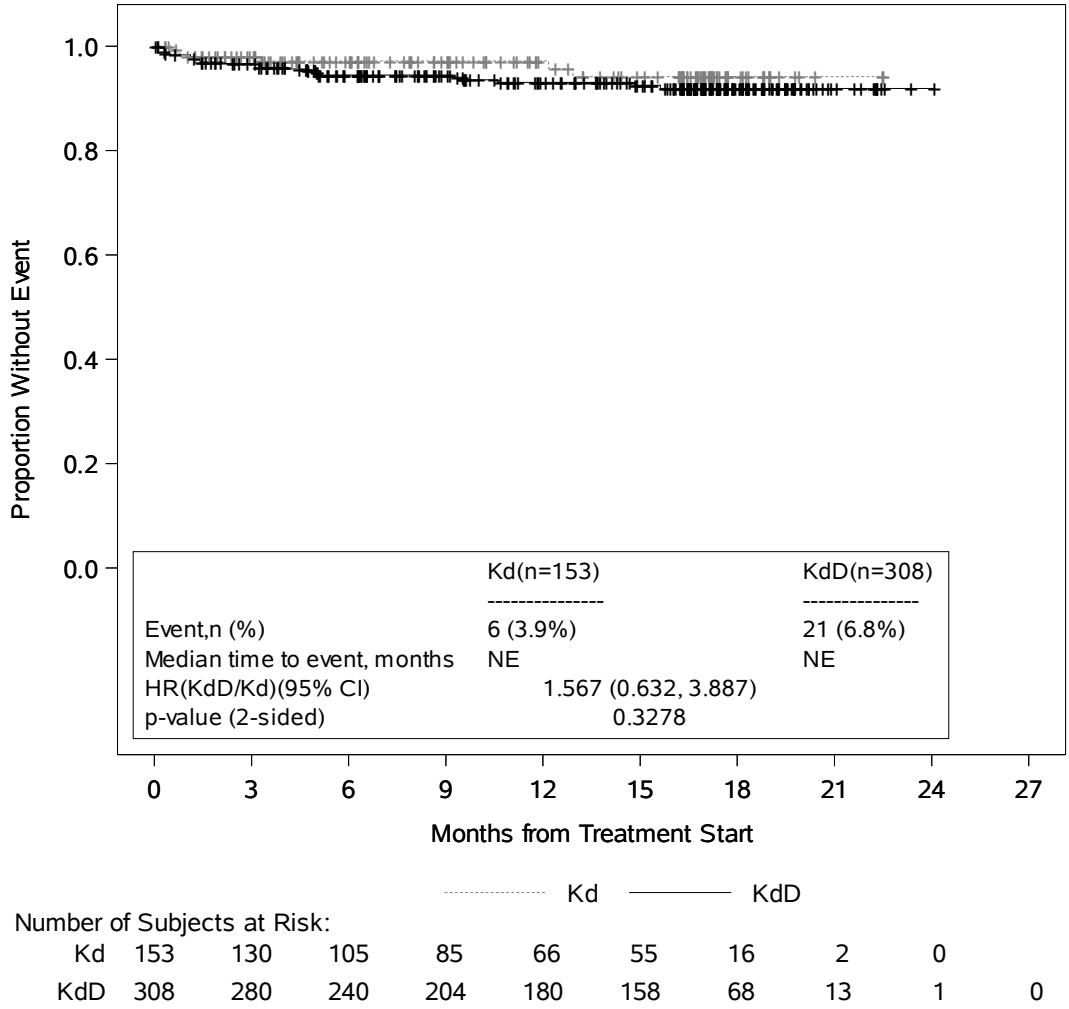


Number of Subjects at Risk:

Kd	153	131	106	86	65	57	18	2	0	
KdD	308	282	246	208	187	164	72	14	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-564-ae-cox-resp-orop-ge10.rtf (Date Generated: 27MAY20:22:29:39).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.565. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Respiratory, Thoracic and Mediastinal Disorders) and PT (Productive Cough) <Safety Population>

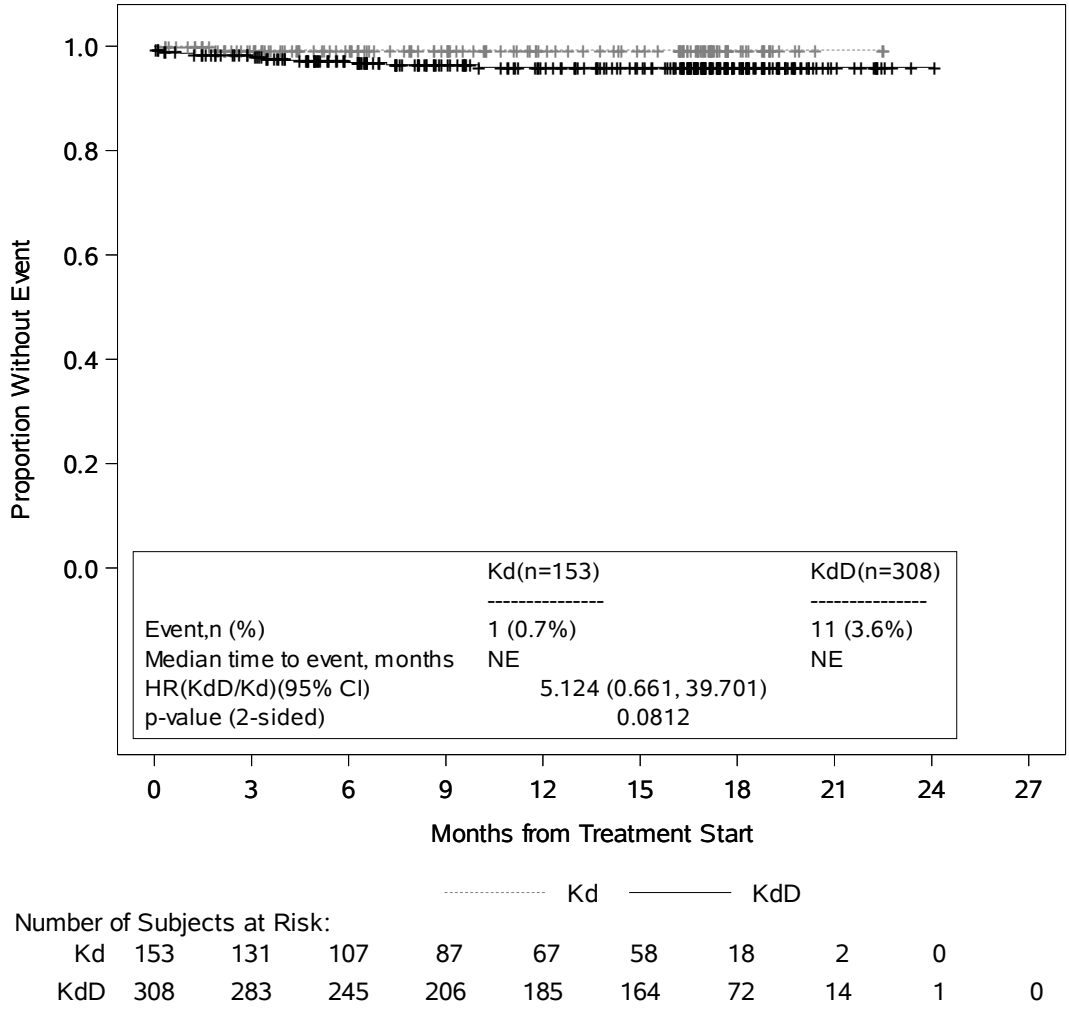


Number of Subjects at Risk:

Kd	153	130	105	85	66	55	16	2	0	
KdD	308	280	240	204	180	158	68	13	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-565-ae-cox-resp-procog-ge10.rtf (Date Generated: 27MAY20:22:29:41).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.566. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Respiratory, Thoracic and Mediastinal Disorders) and PT (Rhinorrhoea) <Safety Population>

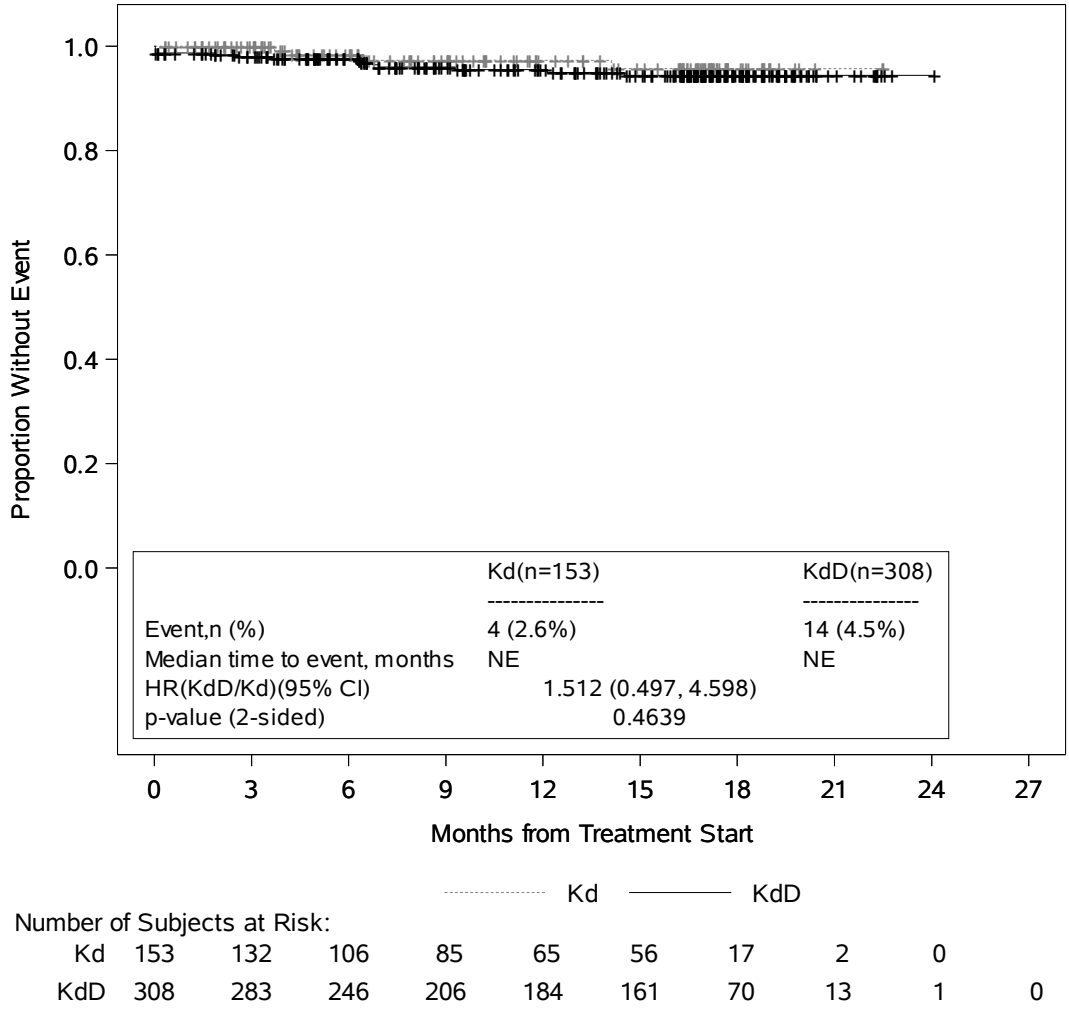


Number of Subjects at Risk:

Kd	153	131	107	87	67	58	18	2	0	
KdD	308	283	245	206	185	164	72	14	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-566-ae-cox-resp-rhi-ge10.rtf (Date Generated: 27MAY20:22:29:42).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.567. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Skin and Subcutaneous Tissue Disorders) and PT (Pruritus) <Safety Population>

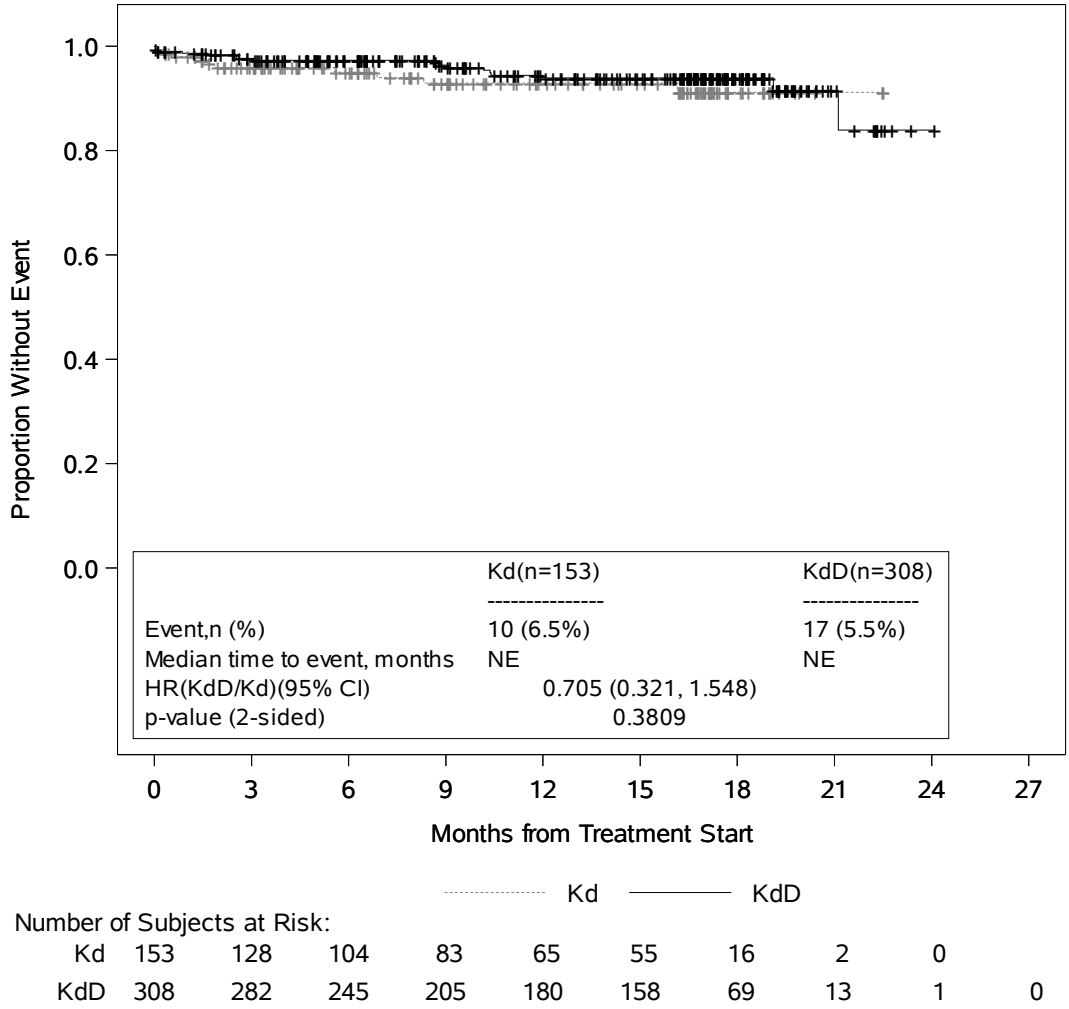


Number of Subjects at Risk:

Kd	153	132	106	85	65	56	17	2	0	
KdD	308	283	246	206	184	161	70	13	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-567-ae-cox-skin-pru-ge10.rtf (Date Generated: 27MAY20:22:29:44).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.568. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Skin and Subcutaneous Tissue Disorders) and PT (Rash) <Safety Population>

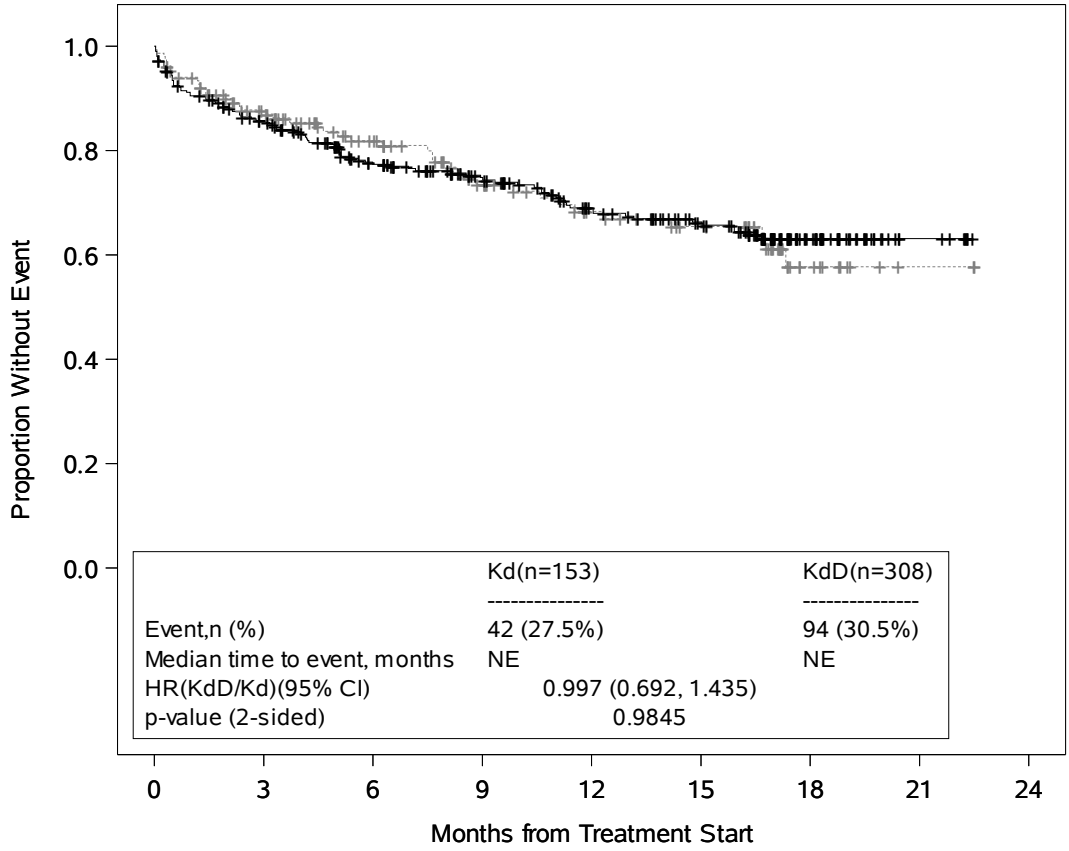


Number of Subjects at Risk:

Kd	153	128	104	83	65	55	16	2	0	
KdD	308	282	245	205	180	158	69	13	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-568-ae-cox-skin-rash-ge10.rtf (Date Generated: 27MAY20:22:29:46).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.569. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Vascular Disorders) and PT (Hypertension) <Safety Population>

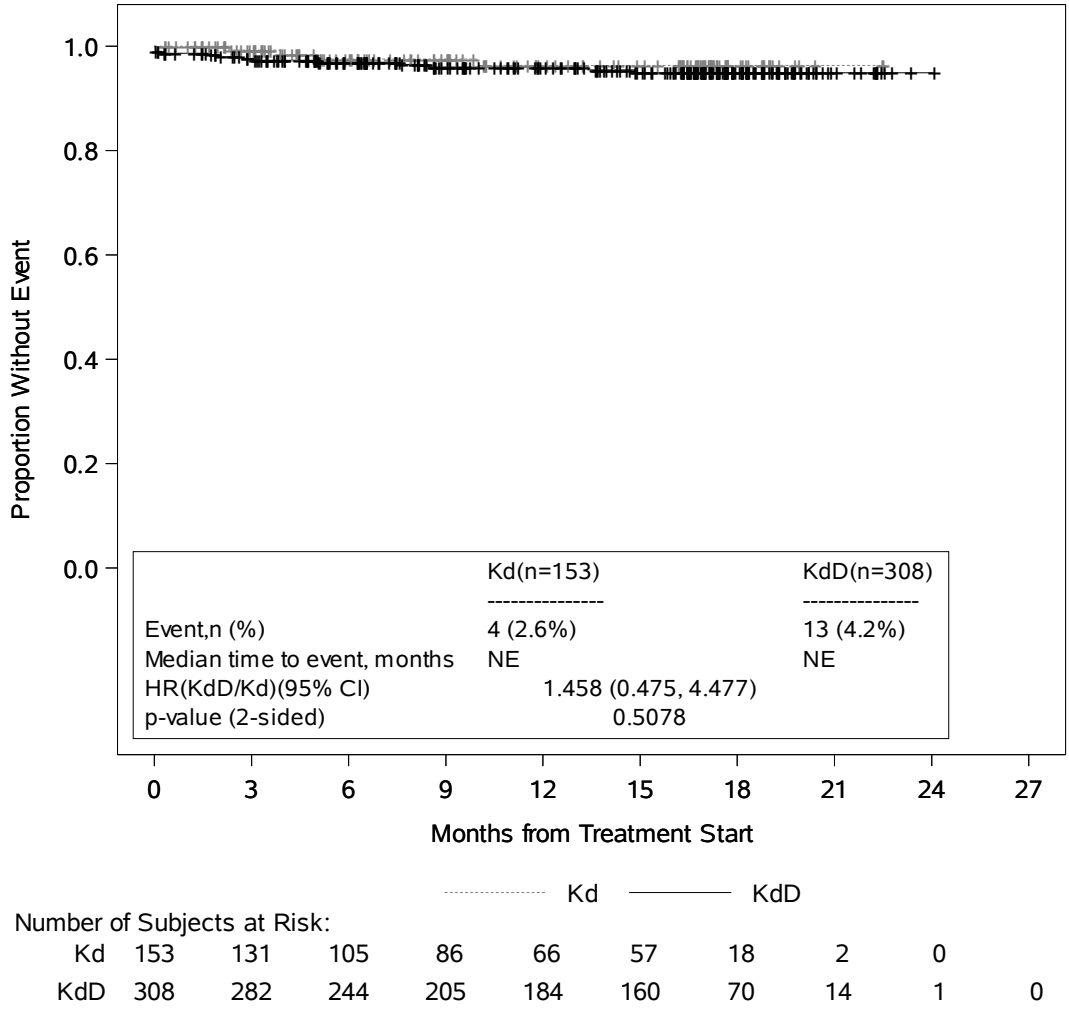


Number of Subjects at Risk:

Kd	153	116	88	64	49	41	11	2	0
KdD	308	249	199	165	133	111	46	8	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-569-ae-cox-vas-hyper-ge10.rtf (Date Generated: 27MAY20:22:29:47).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.570. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Vascular Disorders) and PT (Hypotension) <Safety Population>

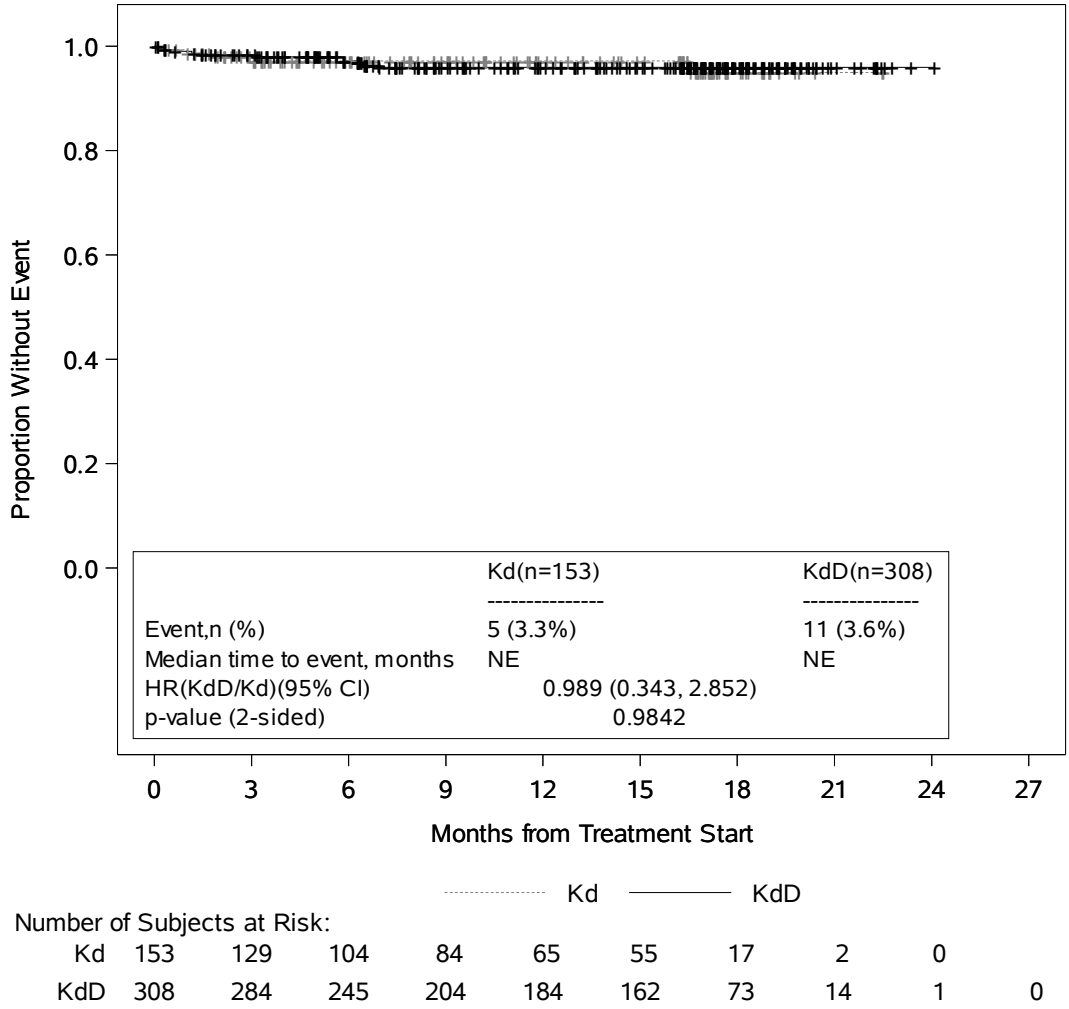


Number of Subjects at Risk:

Kd	153	131	105	86	66	57	18	2	0	
KdD	308	282	244	205	184	160	70	14	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-570-ae-cox-vas-hypo-ge10.rtf (Date Generated: 27MAY20:22:29:49).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.571. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Vascular Disorders) and PT (Phlebitis)
<Safety Population>

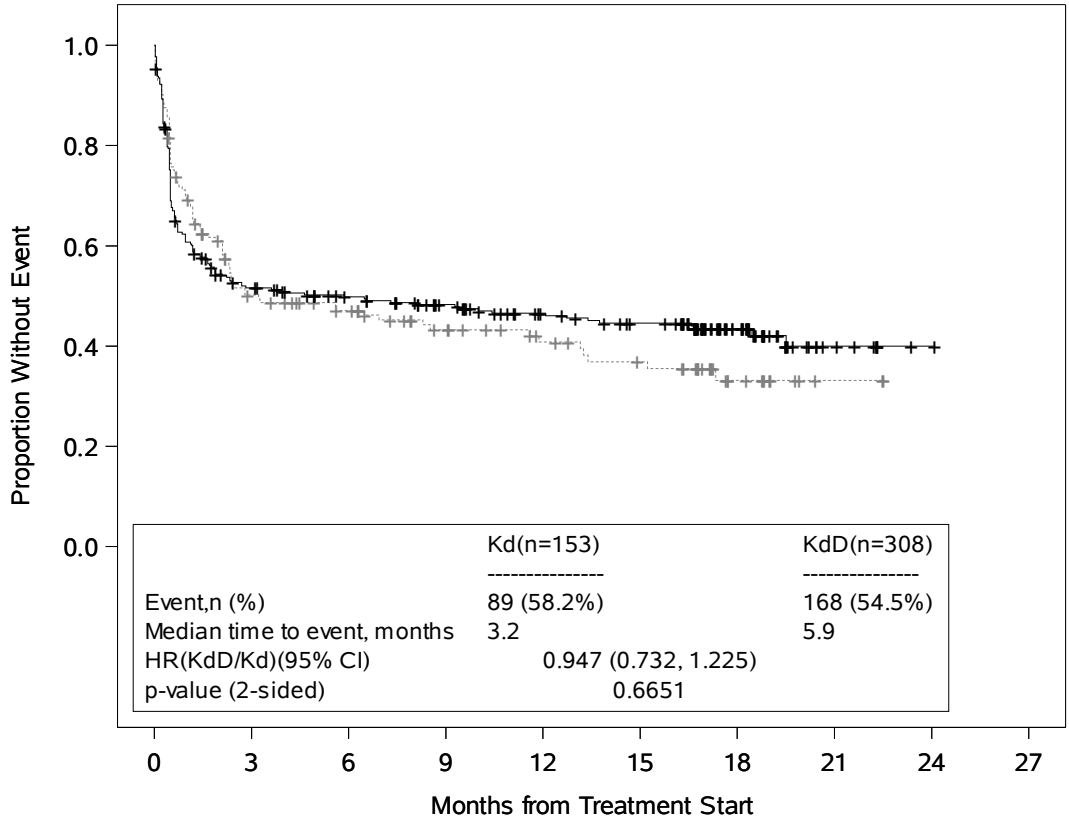


Number of Subjects at Risk:

Kd	153	129	104	84	65	55	17	2	0	
KdD	308	284	245	204	184	162	73	14	1	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-002-571-ae-cox-vas-phi-ge10.rtf (Date Generated: 27MAY20:22:29:50).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.572. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Blood and Lymphatic System Disorders)
<Safety Population>

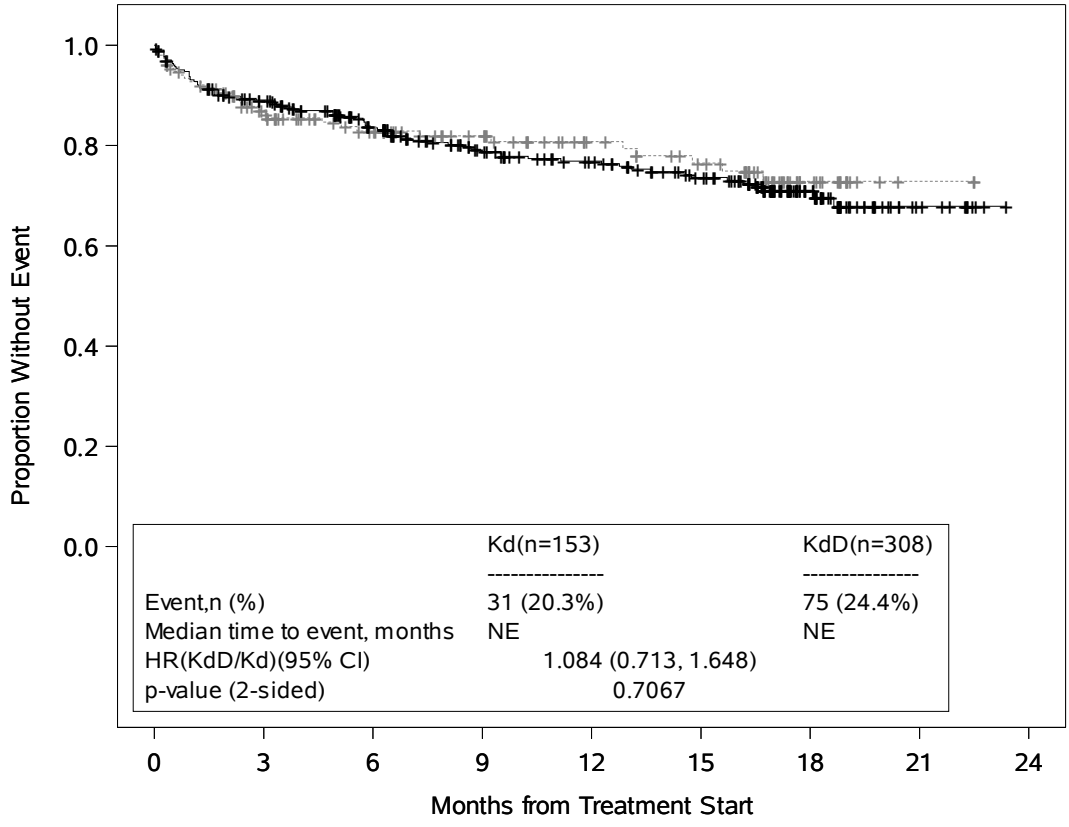


Number of Subjects at Risk:

Kd	153	68	57	42	33	27	11	2	0	
KdD	308	150	132	115	96	86	43	9	1	0

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-ge10.sas.
Output: f14-06-002-572-ae-cox-blolym-ge10.rtf (Date Generated: 27MAY20:04:04:49).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.573. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Cardiac Disorders)
<Safety Population>

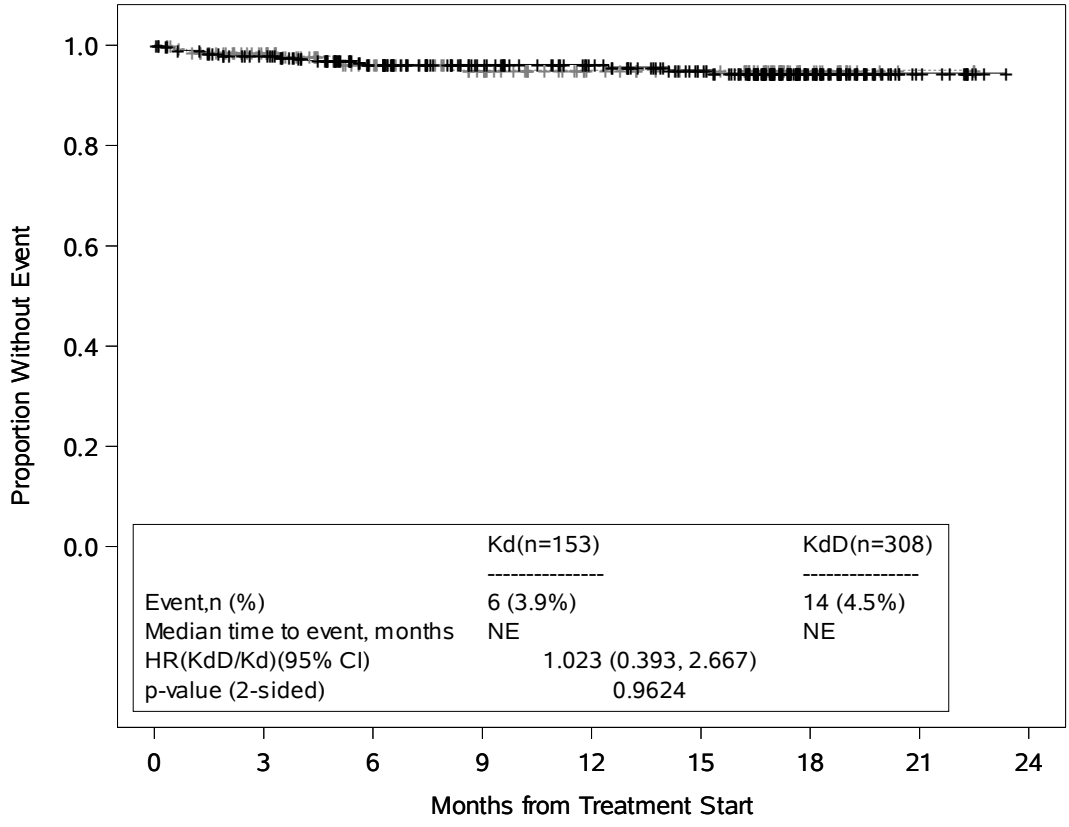


Number of Subjects at Risk:

Kd	153	115	92	76	59	50	17	2	0
KdD	308	258	213	171	151	129	54	11	0

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-ge10.sas.
Output: f14-06-002-573-ae-cox-card-ge10.rtf (Date Generated: 27MAY20:04:04:51).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.574. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Ear and Labyrinth Disorders)
<Safety Population>

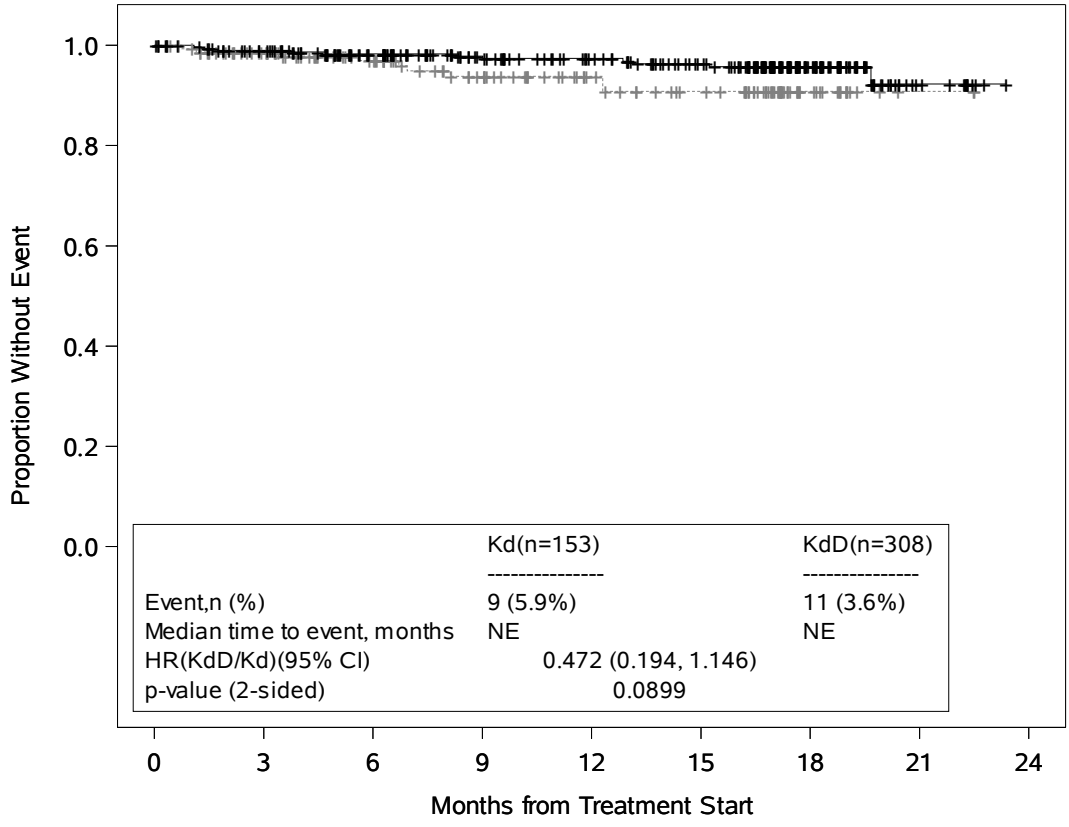


Number of Subjects at Risk:

Kd	153	130	104	83	63	55	17	2	0
KdD	308	284	243	205	185	162	68	13	0

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-ge10.sas.
Output: f14-06-002-574-ae-cox-earlab-ge10.rtf (Date Generated: 27MAY20:04:04:53).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.575. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Endocrine Disorders)
<Safety Population>

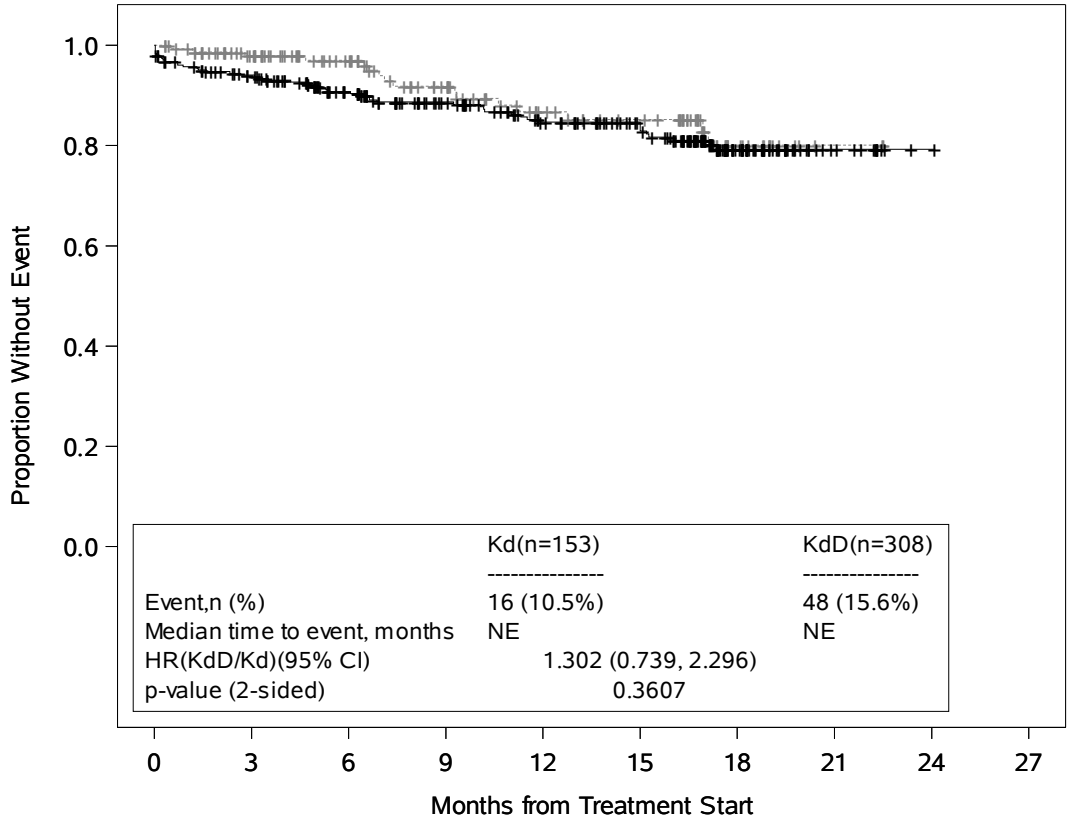


Number of Subjects at Risk:

Kd	153	130	105	83	64	53	17	2	0
KdD	308	286	249	210	189	165	72	12	0

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-ge10.sas.
Output: f14-06-002-575-ae-cox-endo-ge10.rtf (Date Generated: 27MAY20:04:04:56).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.576. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Eye Disorders)
<Safety Population>

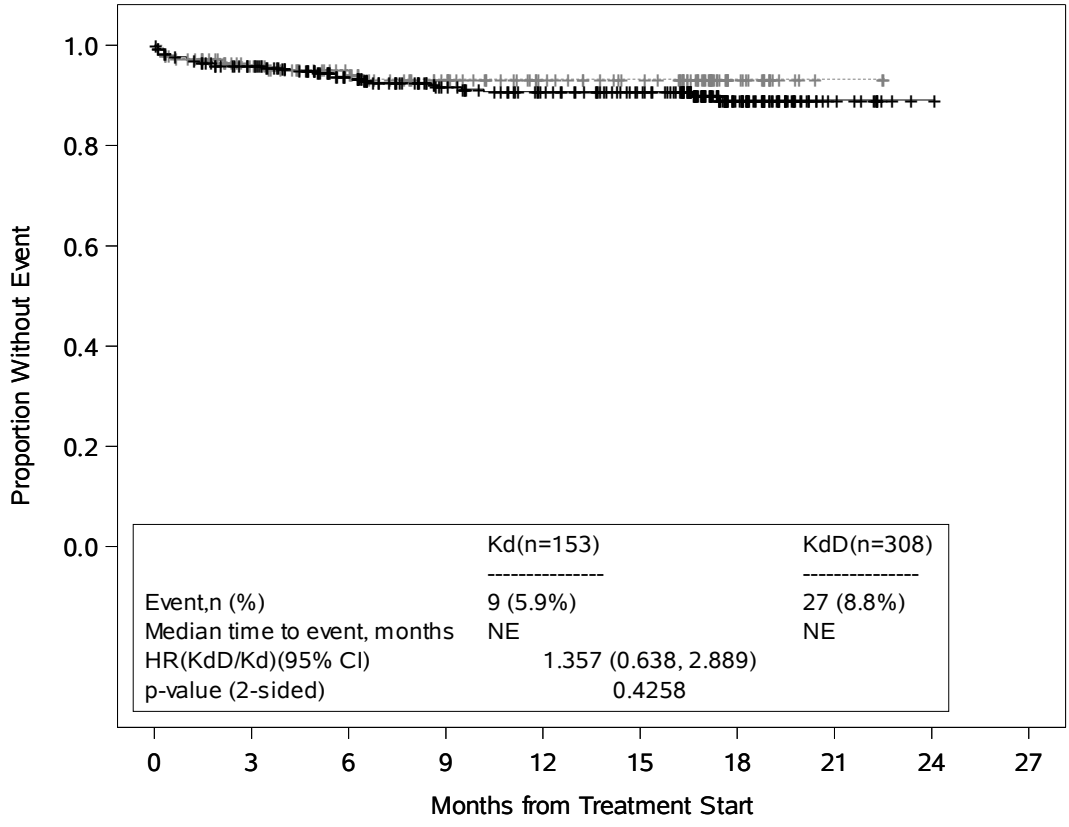


Number of Subjects at Risk:

Kd	153	129	104	80	59	51	15	2	0	
KdD	308	272	229	190	162	141	59	13	1	0

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-ge10.sas.
Output: f14-06-002-576-ae-cox-eye-ge10.rtf (Date Generated: 27MAY20:04:04:58).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.579. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Hepatobiliary Disorders)
<Safety Population>

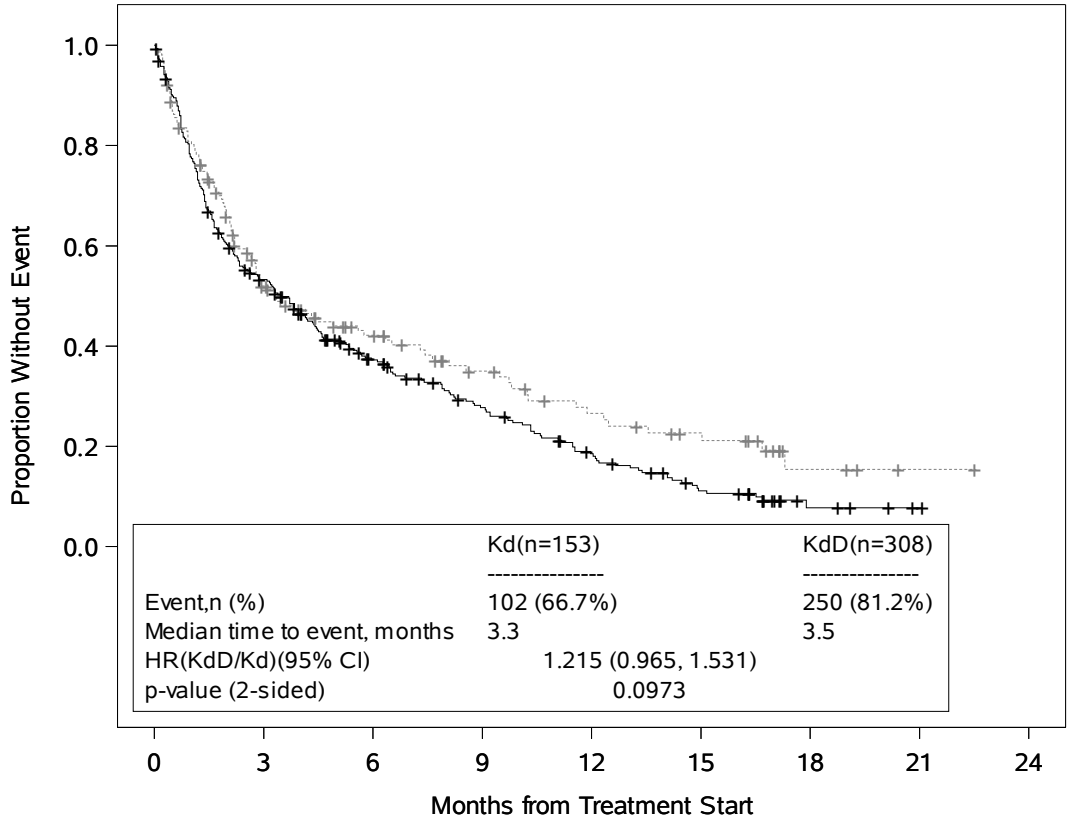


Number of Subjects at Risk:

Kd	153	127	105	84	65	56	18	2	0	
KdD	308	277	239	199	179	159	69	12	1	0

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-ge10.sas.
Output: f14-06-002-579-ae-cox-hepa-ge10.rtf (Date Generated: 27MAY20:04:05:05).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.581. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Infections and Infestations)
<Safety Population>

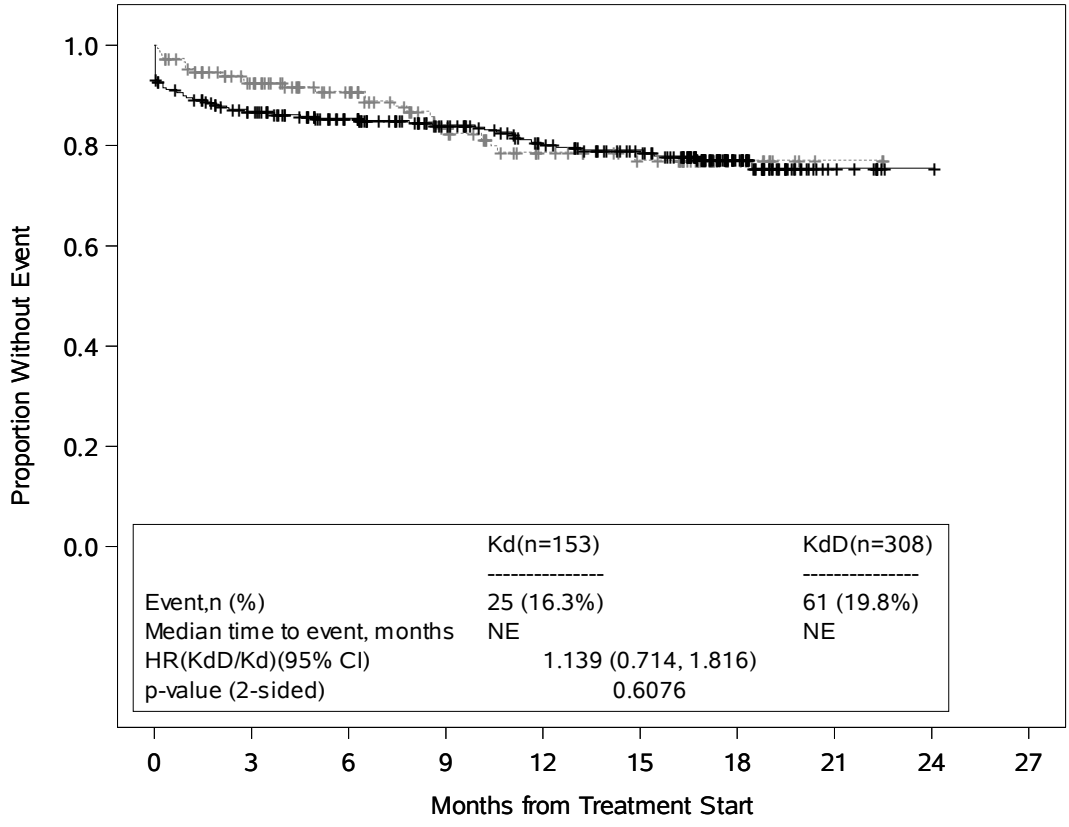


Number of Subjects at Risk:

Kd	153	69	46	31	21	15	4	1	0
KdD	308	157	95	65	40	21	5	1	0

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-ge10.sas.
Output: f14-06-002-581-ae-cox-infe-ge10.rtf (Date Generated: 27MAY20:04:05:09).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.582. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Injury, Poisoning and Procedural Complications) <Safety Population>

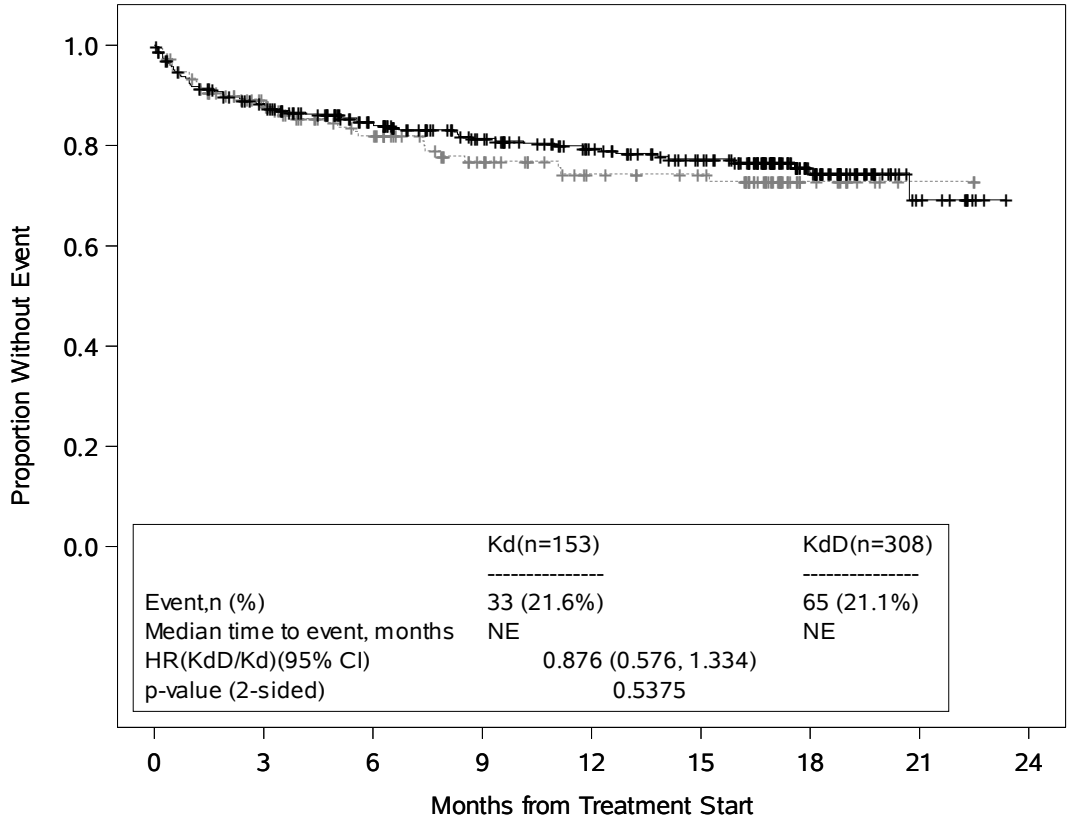


Number of Subjects at Risk:

Kd	153	124	101	75	55	47	13	2	0	
KdD	308	252	216	182	156	137	58	10	1	0

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-ge10.sas.
Output: f14-06-002-582-ae-cox-inju-ge10.rtf (Date Generated: 27MAY20:04:05:11).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.583. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Investigations)
<Safety Population>

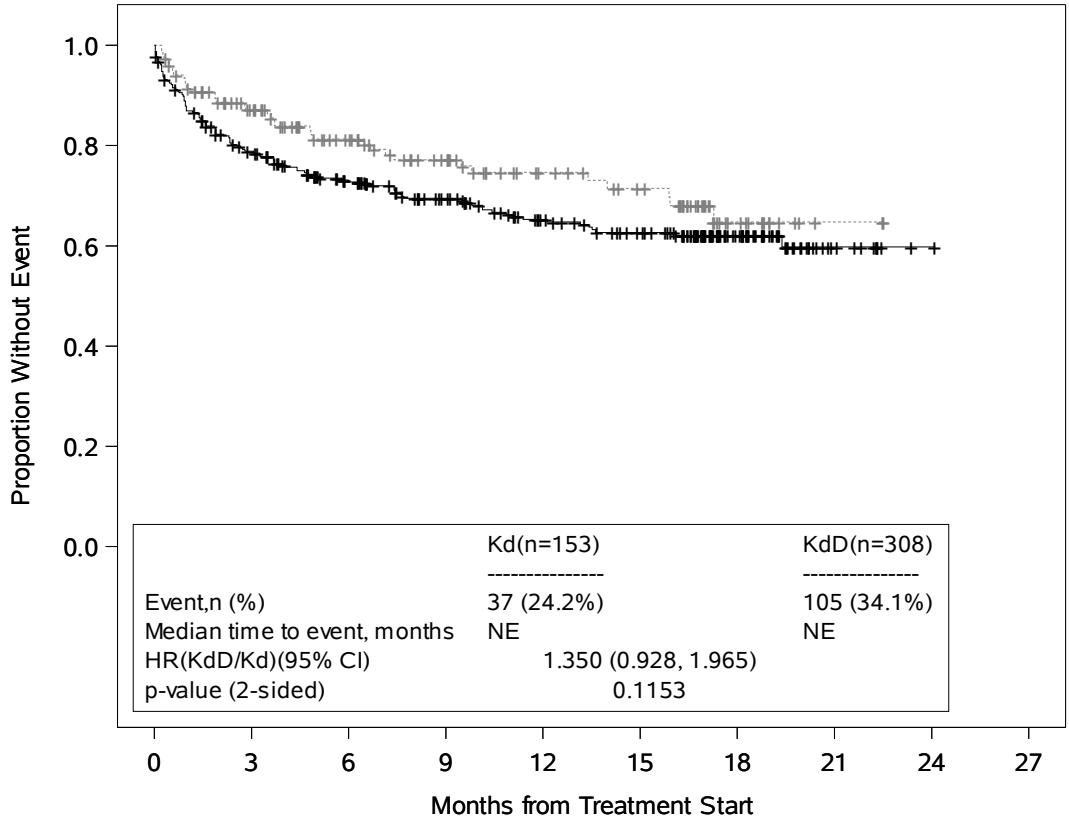


Number of Subjects at Risk:

Kd	153	118	94	70	55	50	13	2	0
KdD	308	257	216	180	155	134	61	11	0

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-ge10.sas.
Output: f14-06-002-583-ae-cox-inve-ge10.rtf (Date Generated: 27MAY20:04:05:13).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.584. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Metabolism and Nutrition Disorders)
<Safety Population>

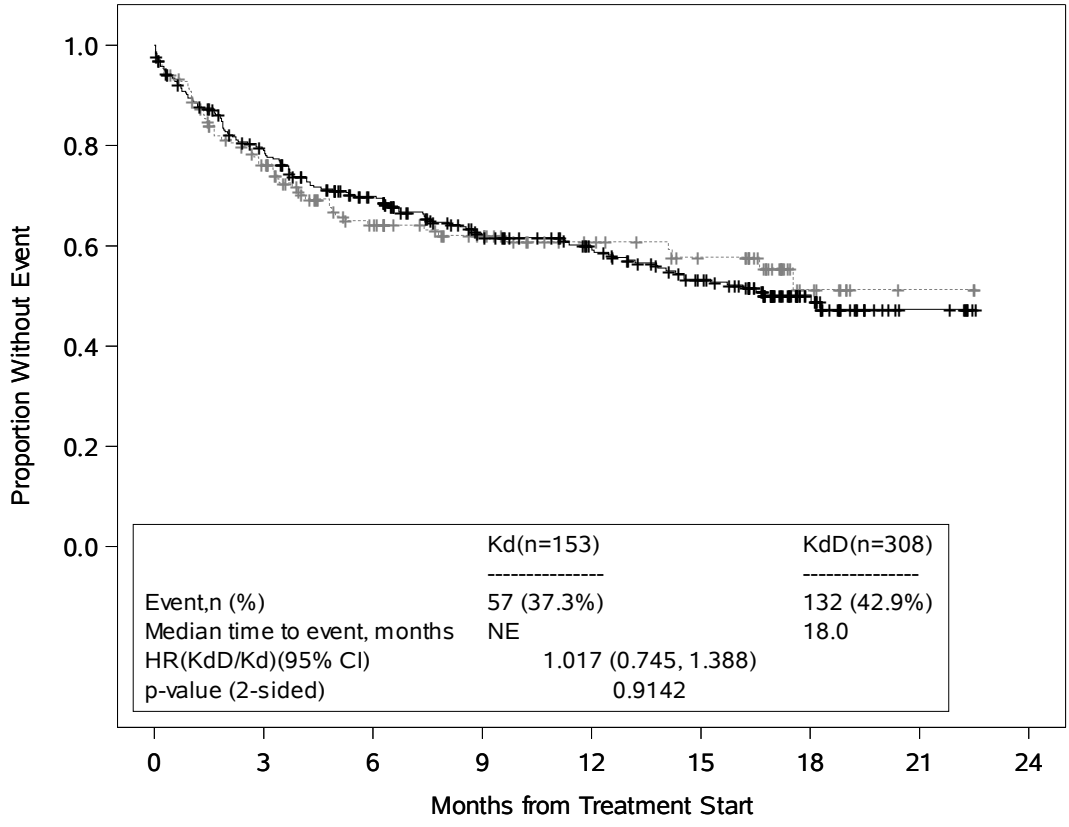


Number of Subjects at Risk:

Kd	153	115	87	67	50	42	14	2	0	
KdD	308	230	189	158	130	114	54	11	1	0

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-ge10.sas.
Output: f14-06-002-584-ae-cox-meta-ge10.rtf (Date Generated: 27MAY20:04:05:15).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.585. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Musculoskeletal and Connective Tissue Disorders) <Safety Population>

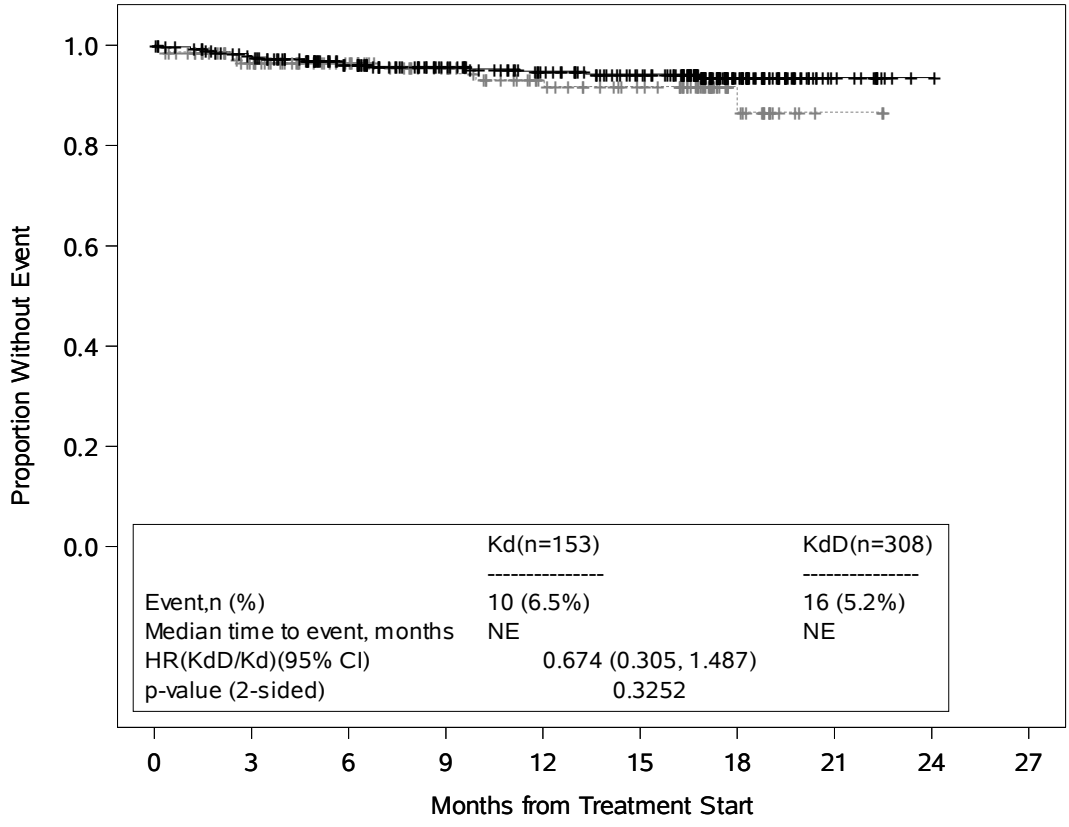


Number of Subjects at Risk:

Kd	153	106	71	55	42	34	10	2	0
KdD	308	230	184	139	119	94	38	8	0

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-ge10.sas.
Output: f14-06-002-585-ae-cox-mus-ge10.rtf (Date Generated: 27MAY20:04:05:16).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.586. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)) <Safety Population>

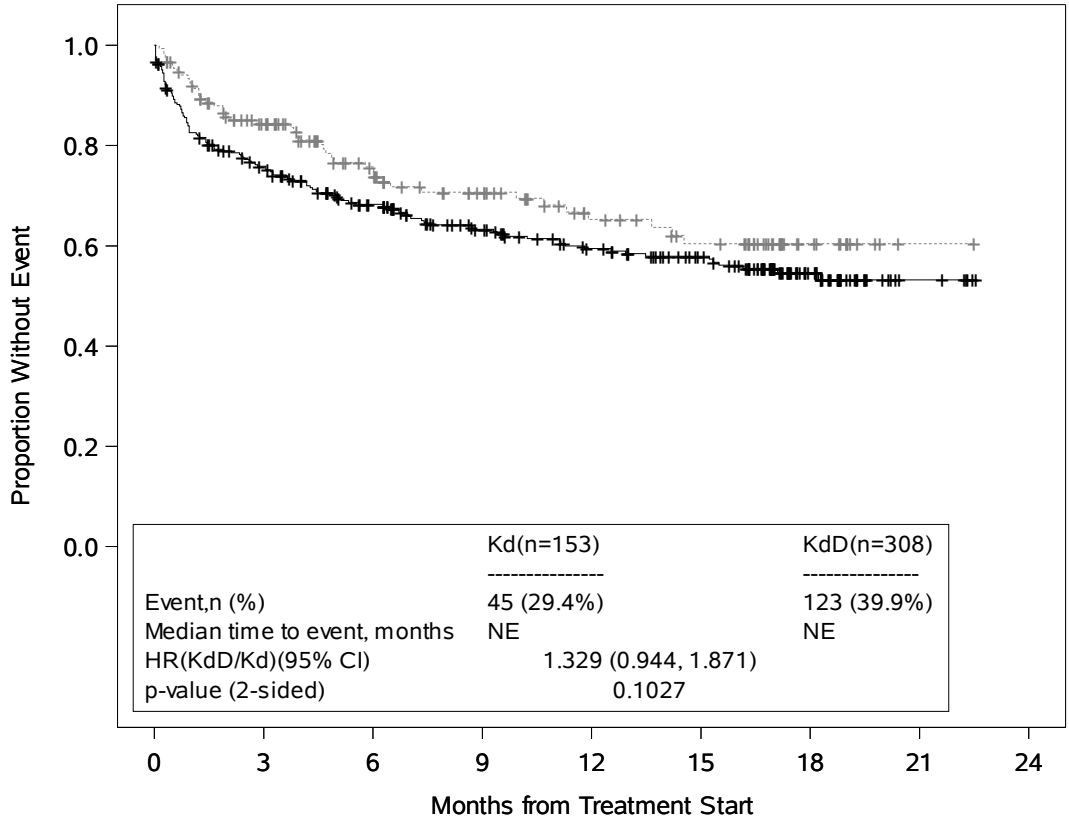


Number of Subjects at Risk:

Kd	153	129	107	87	67	56	17	2	0	
KdD	308	286	249	212	189	167	72	14	1	0

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-ge10.sas.
Output: f14-06-002-586-ae-cox-neo-ge10.rtf (Date Generated: 27MAY20:04:05:18).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.587. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Nervous System Disorders)
<Safety Population>

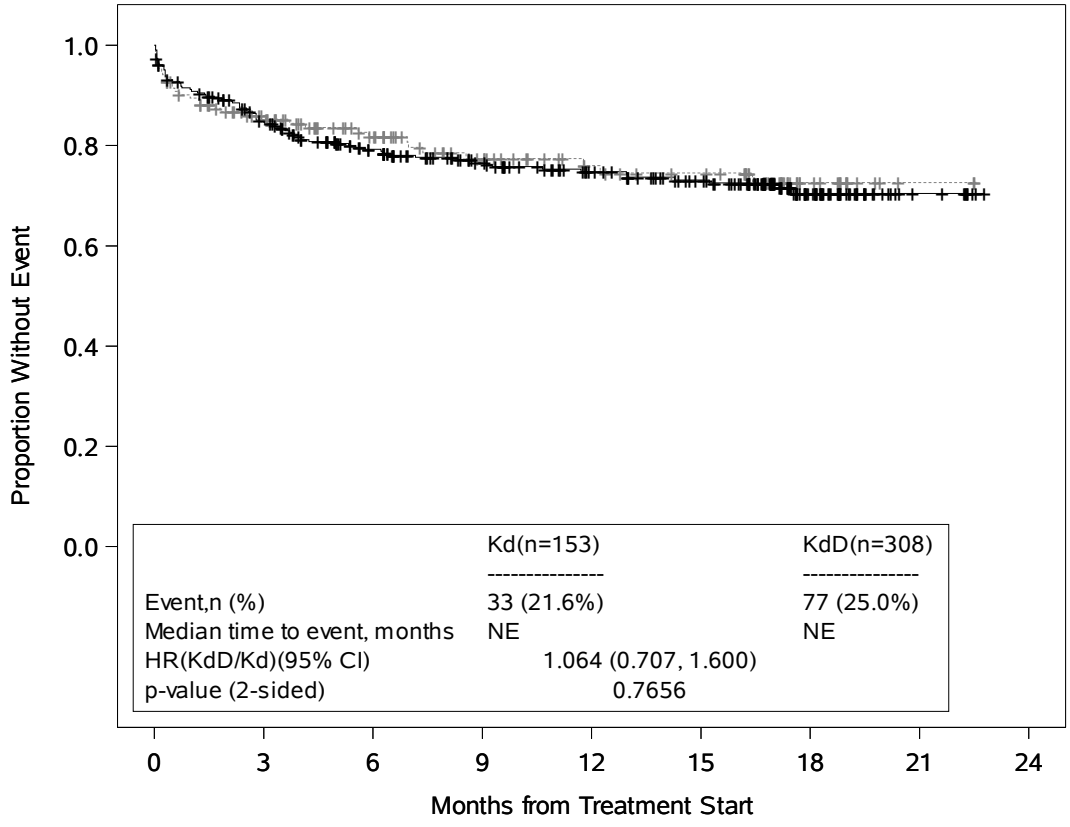


Number of Subjects at Risk:

Kd	153	112	80	61	44	36	13	1	0
KdD	308	220	177	141	119	99	43	6	0

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Harzard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-ge10.sas.
Output: f14-06-002-587-ae-cox-ner-ge10.rtf (Date Generated: 27MAY20:04:05:20).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.588. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Psychiatric Disorders)
<Safety Population>

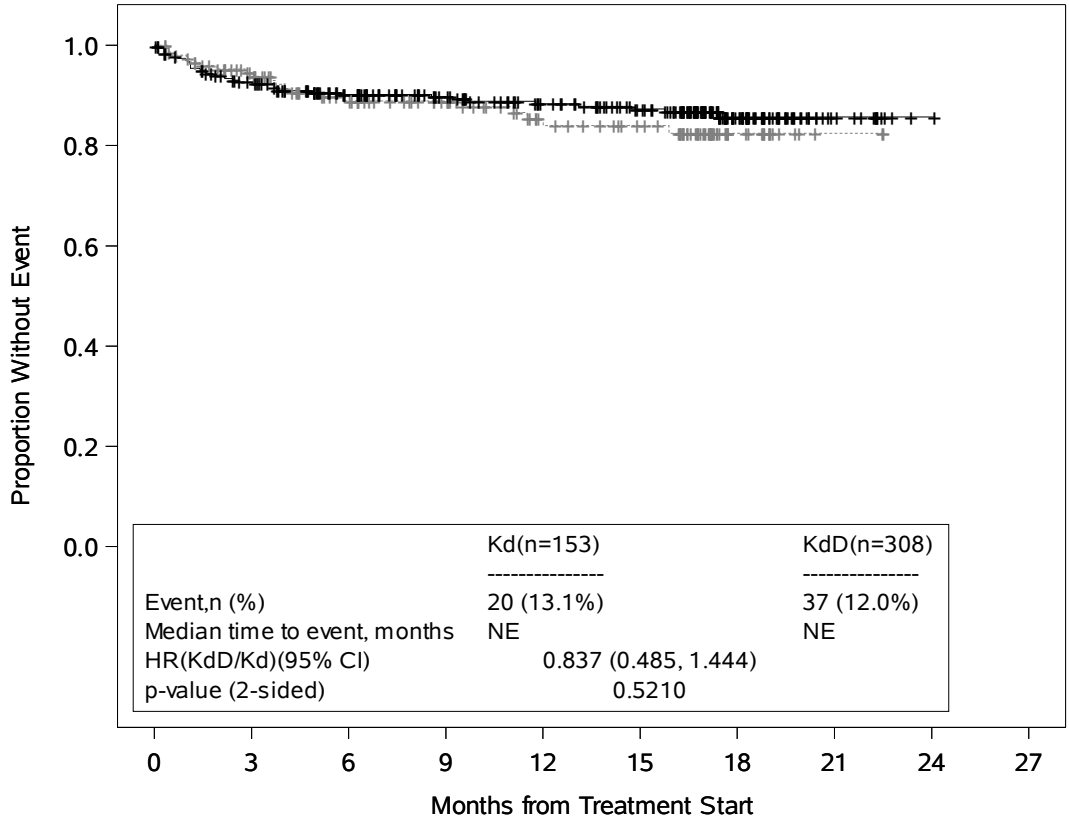


Number of Subjects at Risk:

Kd	153	114	87	66	52	47	15	2	0
KdD	308	245	200	166	142	122	50	9	0

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-ge10.sas.
Output: f14-06-002-588-ae-cox-psy-ge10.rtf (Date Generated: 27MAY20:04:05:22).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.589. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Renal and Urinary Disorders)
<Safety Population>

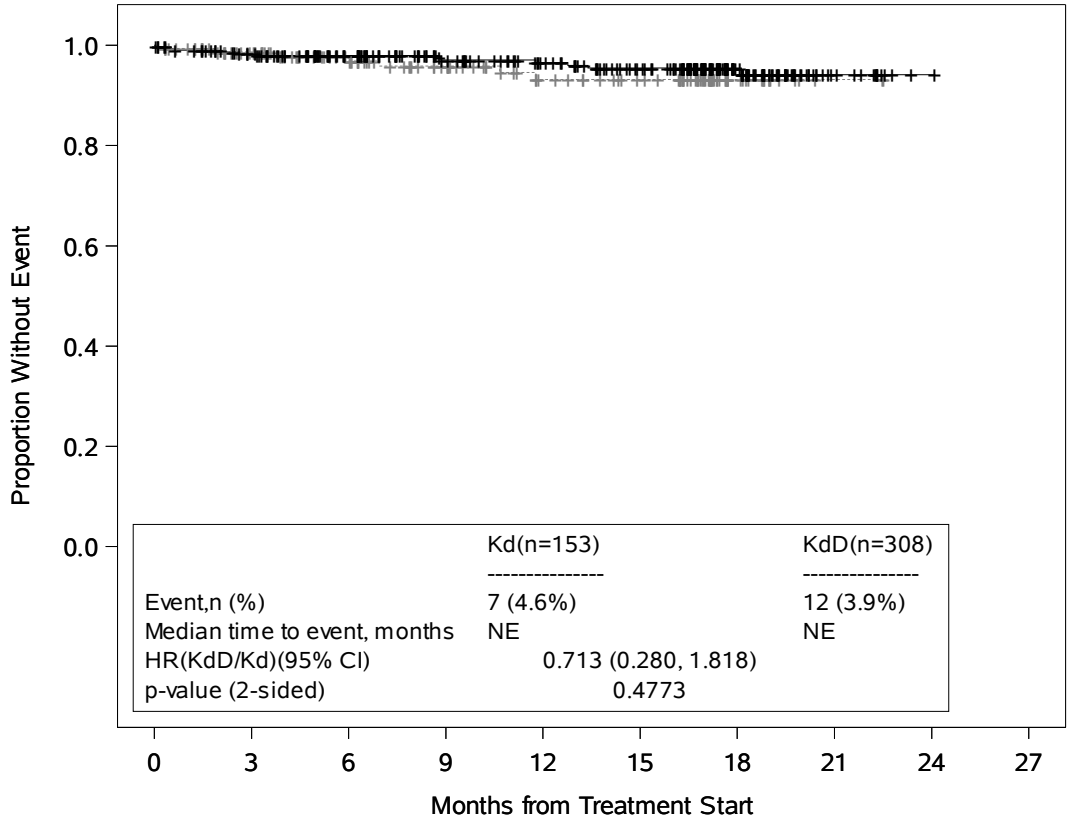


Number of Subjects at Risk:

Kd	153	126	102	85	64	55	16	2	0	
KdD	308	270	234	200	176	155	67	14	1	0

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-ge10.sas.
Output: f14-06-002-589-ae-cox-ren-ge10.rtf (Date Generated: 27MAY20:04:05:23).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.590. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Reproductive System and Breast Disorders)
<Safety Population>

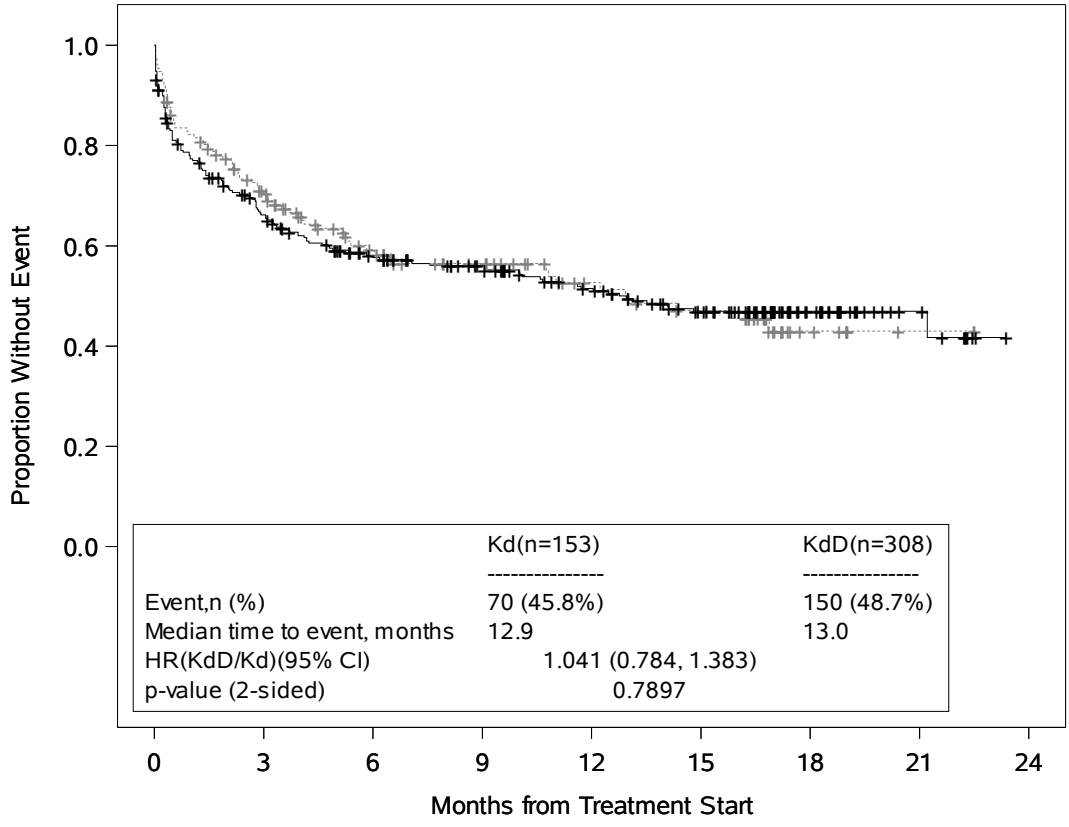


Number of Subjects at Risk:

Kd	153	131	105	84	65	56	17	2	0	
KdD	308	284	247	206	185	161	72	14	1	0

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-ge10.sas.
Output: f14-06-002-590-ae-cox-rep-ge10.rtf (Date Generated: 27MAY20:04:05:25).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.591. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Respiratory, Thoracic and Mediastinal Disorders) <Safety Population>

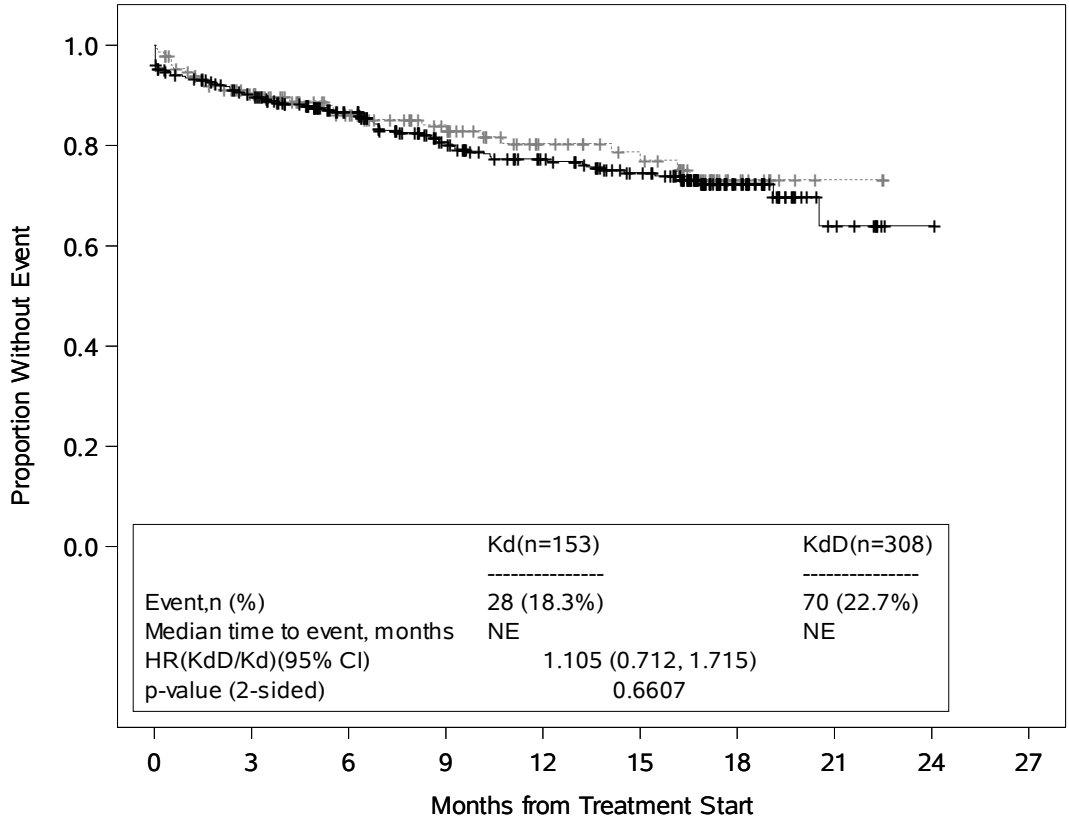


Number of Subjects at Risk:

Kd	153	97	67	53	38	31	8	2	0
KdD	308	192	152	131	108	85	34	10	0

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-ge10.sas.
Output: f14-06-002-591-ae-cox-resp-ge10.rtf (Date Generated: 27MAY20:04:05:27).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.592. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Skin and Subcutaneous Tissue Disorders)
<Safety Population>

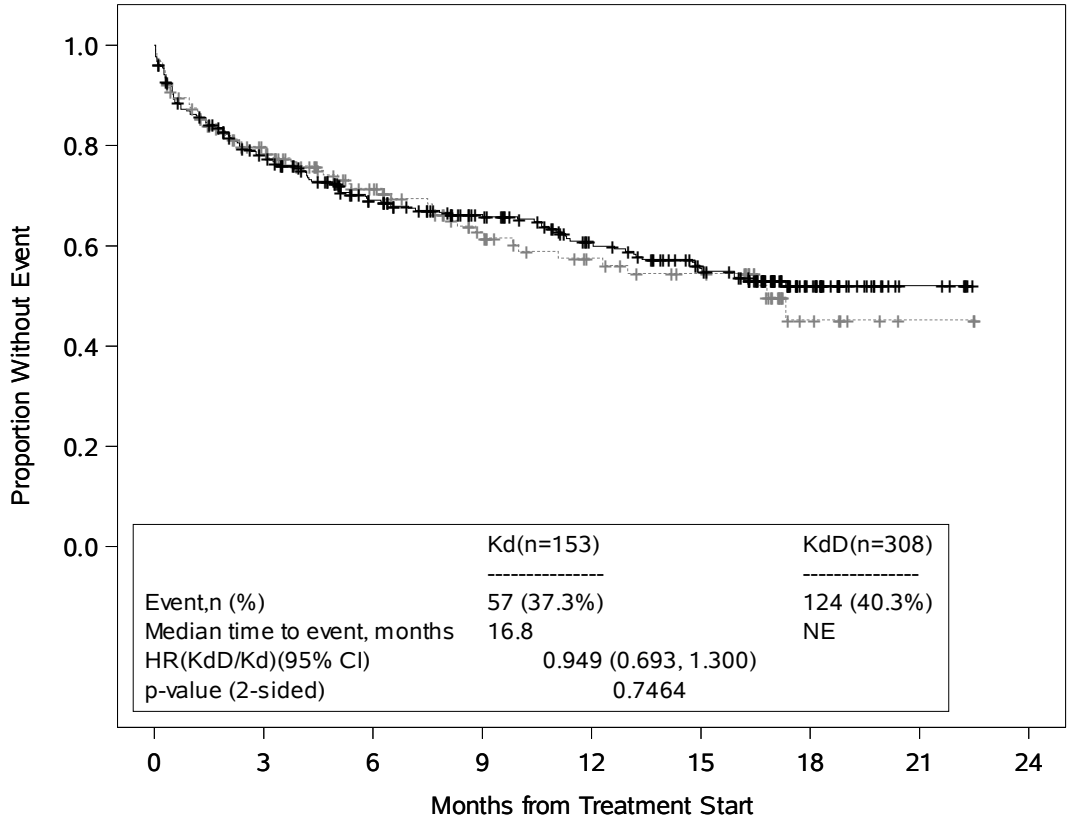


Number of Subjects at Risk:

Kd	153	122	94	74	54	47	12	2	0	
KdD	308	261	218	172	147	126	53	10	1	0

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-ge10.sas.
Output: f14-06-002-592-ae-cox-skin-ge10.rtf (Date Generated: 27MAY20:04:05:29).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.593. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Vascular Disorders)
<Safety Population>

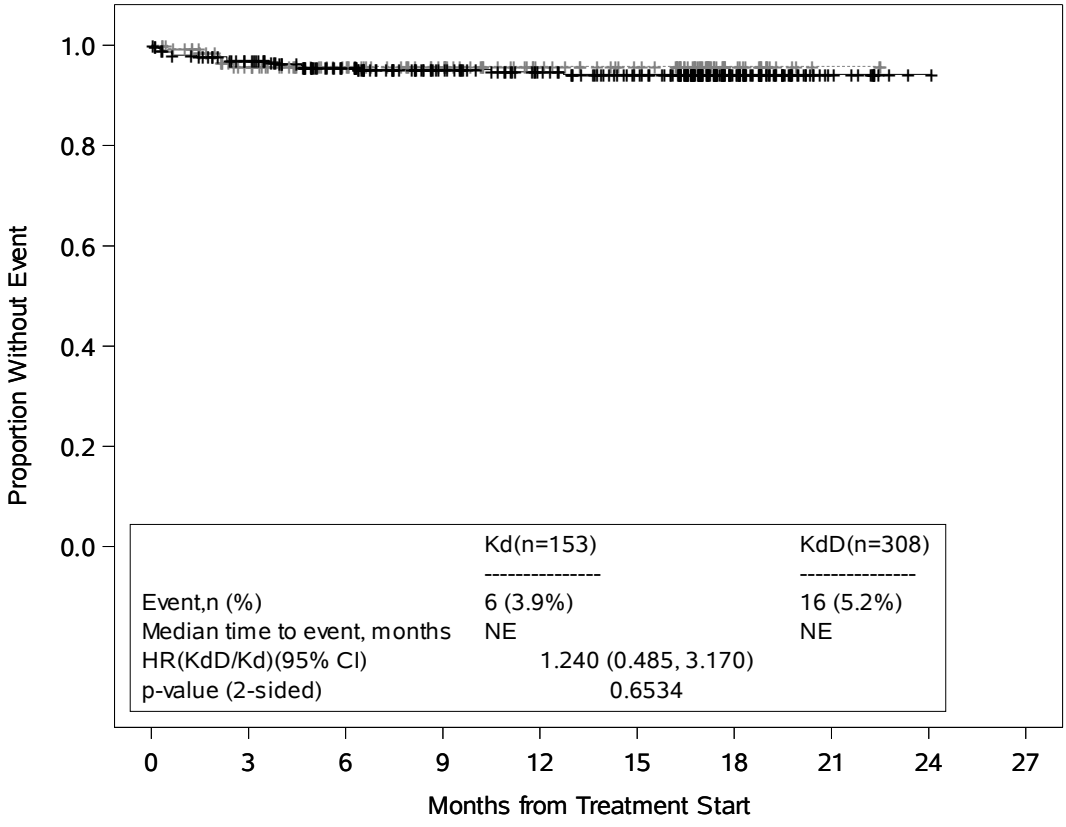


Number of Subjects at Risk:

Kd	153	106	75	52	39	32	8	2	0
KdD	308	227	178	148	118	94	37	7	0

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-ge10.sas.
Output: f14-06-002-593-ae-cox-vas-ge10.rtf (Date Generated: 27MAY20:04:05:30).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.594. KM Curves of Most Frequent Serious Adverse Events by MedDRA SOC (Blood and Lymphatic System Disorders)
<Safety Population>

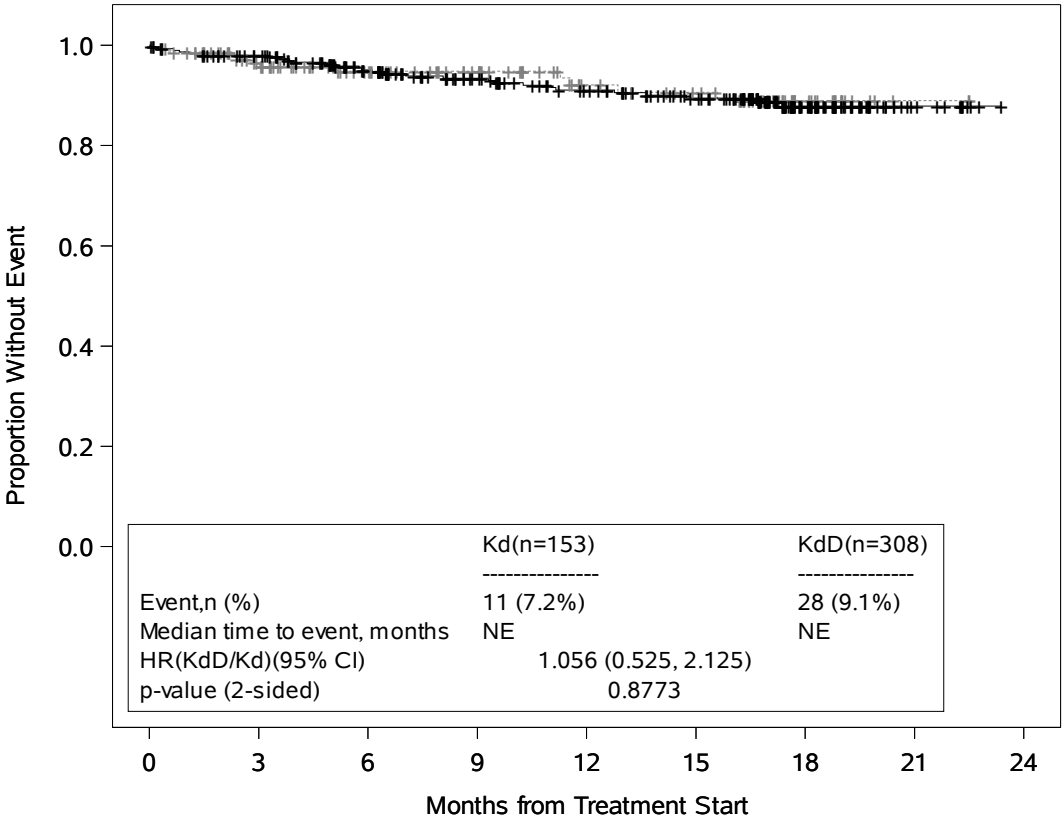


Number of Subjects at Risk:

Kd	153	128	108	88	68	58	18	2	0	
KdD	308	281	244	207	186	165	73	13	1	0

Includes SOC where at least 5% subjects with at least one serious adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-sub.sas.
Output: f14-06-002-594-sae-cox-blolym-ge5pct.rtf (Date Generated: 27MAY20:20:49:40).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.595. KM Curves of Most Frequent Serious Adverse Events by MedDRA SOC (Cardiac Disorders)
<Safety Population>

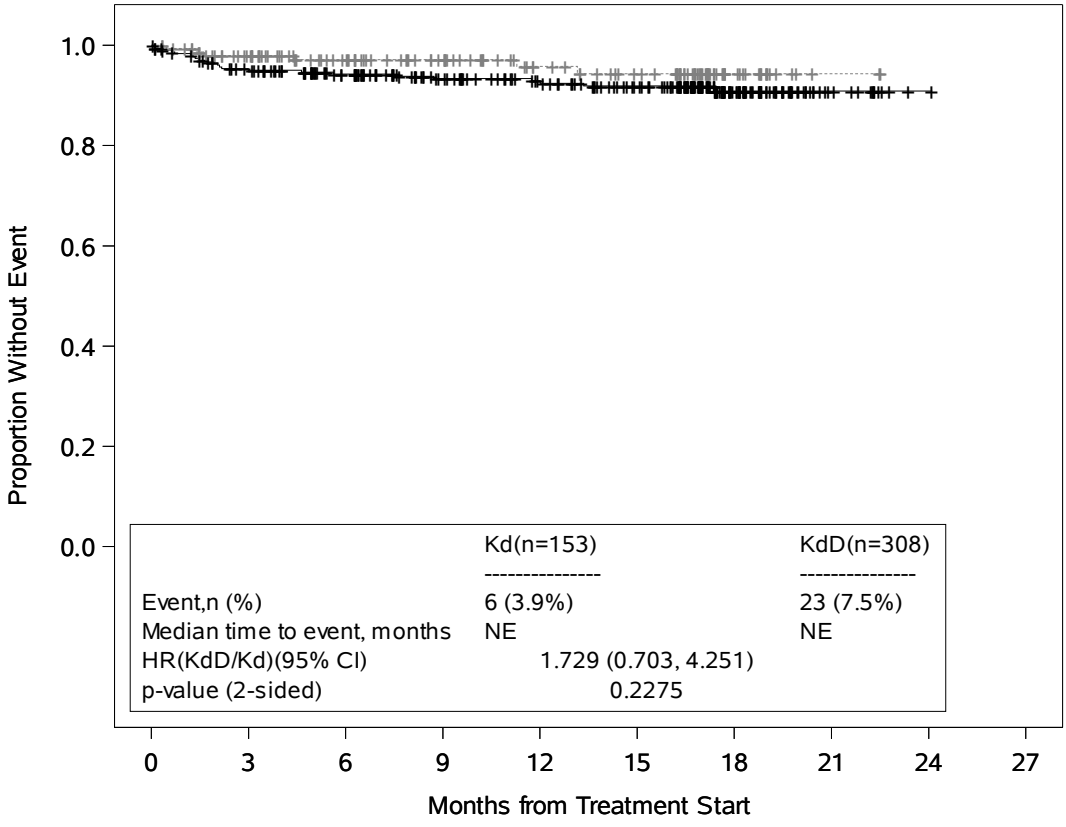


Number of Subjects at Risk:

Kd	153	127	103	84	63	56	18	2	0
KdD	308	285	244	205	183	161	68	12	0

Includes SOC where at least 5% subjects with at least one serious adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-sub.sas.
Output: f14-06-002-595-sae-cox-card-ge5pct.rtf (Date Generated: 27MAY20:20:49:42).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.596. KM Curves of Most Frequent Serious Adverse Events by MedDRA SOC (General Disorders and Administration Site Conditions) <Safety Population>

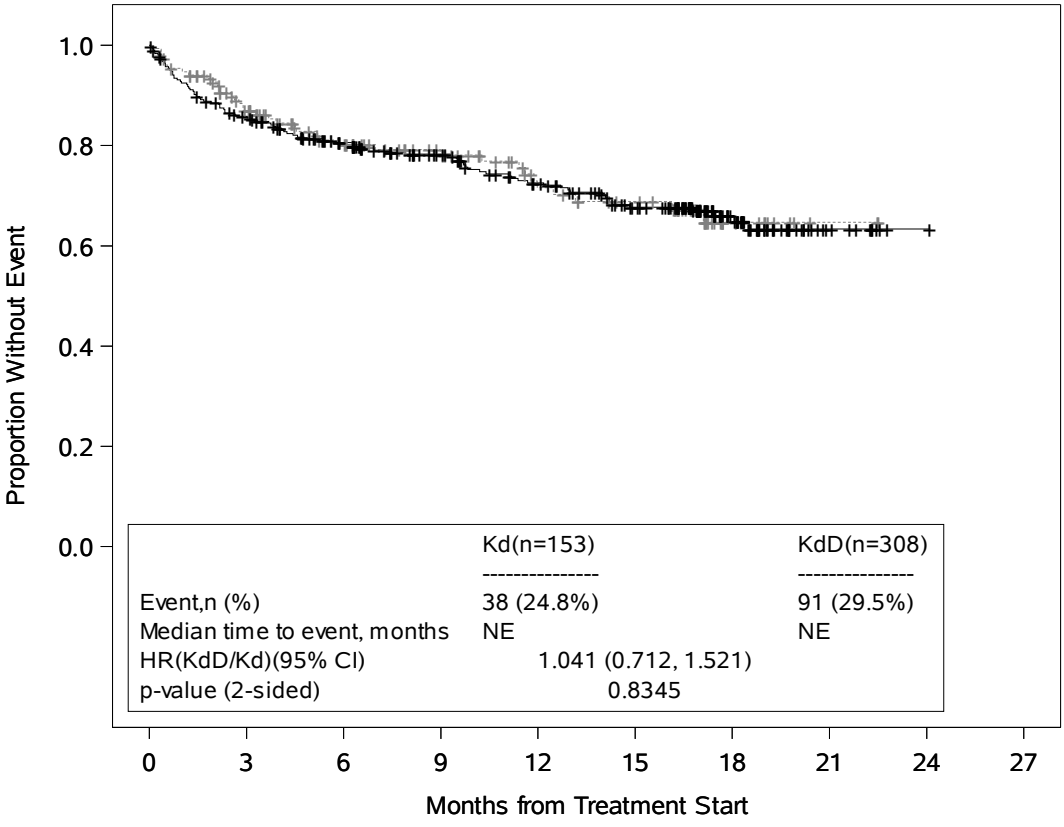


Number of Subjects at Risk:

Kd	153	132	107	87	67	57	18	2	0	
KdD	308	277	245	207	186	164	69	13	1	0

Includes SOC where at least 5% subjects with at least one serious adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-sub.sas.
Output: f14-06-002-596-sae-cox-gen-ge5pct.rtf (Date Generated: 27MAY20:20:49:44).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.597. KM Curves of Most Frequent Serious Adverse Events by MedDRA SOC (Infections and Infestations)
<Safety Population>

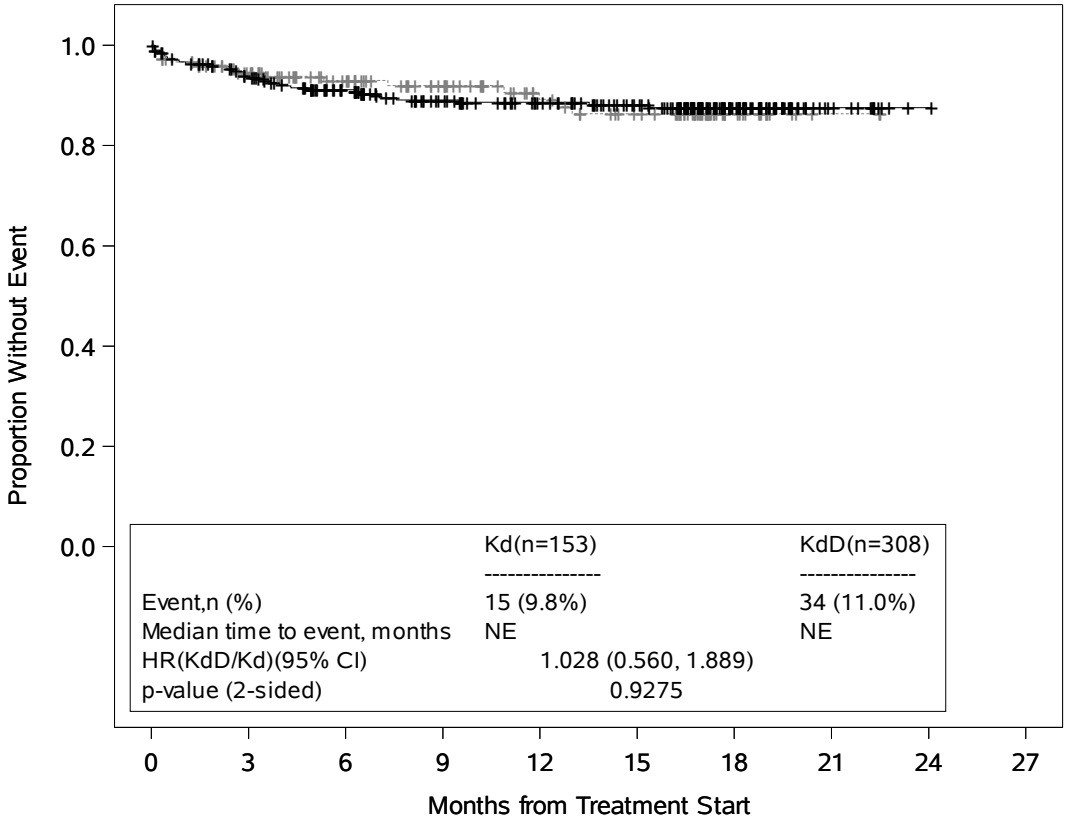


Number of Subjects at Risk:

Kd	153	117	90	71	53	46	13	2	0	
KdD	308	255	217	185	158	130	57	11	1	0

Includes SOC where at least 5% subjects with at least one serious adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-sub.sas.
Output: f14-06-002-597-sae-cox-infe-ge5pct.rtf (Date Generated: 27MAY20:20:49:46).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.599. KM Curves of Most Frequent Serious Adverse Events by MedDRA SOC (Respiratory, Thoracic and Mediastinal Disorders) <Safety Population>

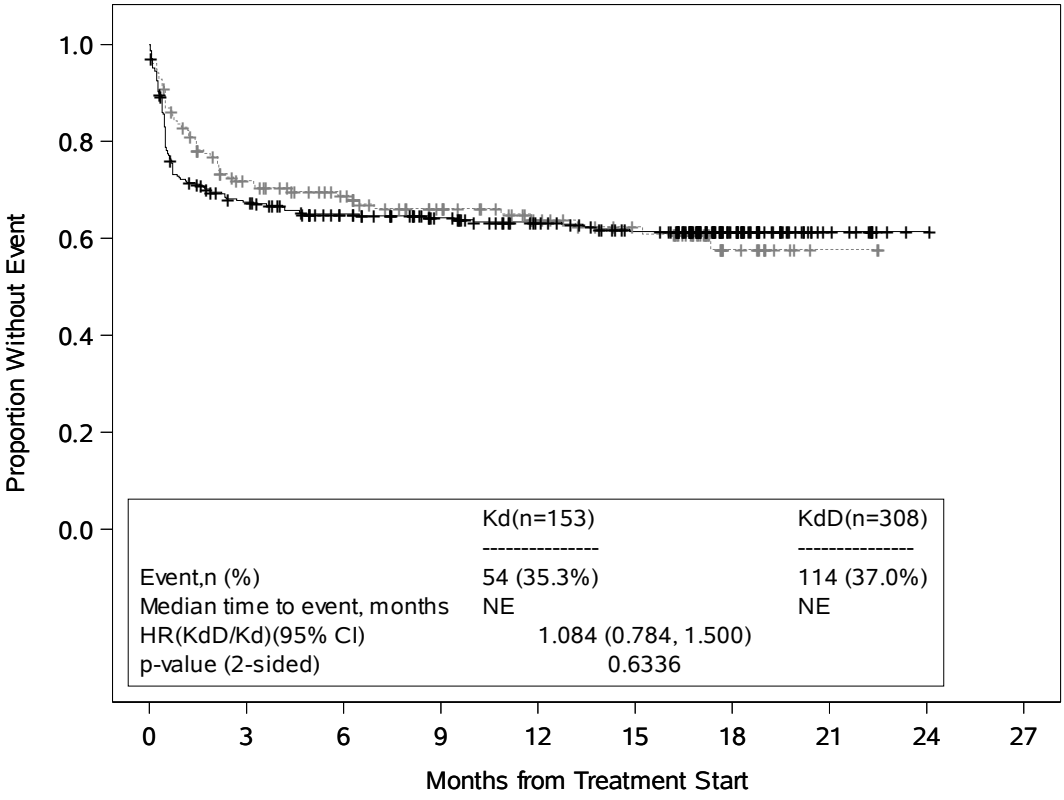


Number of Subjects at Risk:

Kd	153	129	103	83	63	53	16	2	0	
KdD	308	271	236	200	179	156	70	13	1	0

Includes SOC where at least 5% subjects with at least one serious adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-sub.sas.
Output: f14-06-002-599-sae-cox-resp-ge5pct.rtf (Date Generated: 27MAY20:20:49:49).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.600. KM Curves of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC (Blood and Lymphatic System Disorders) <Safety Population>

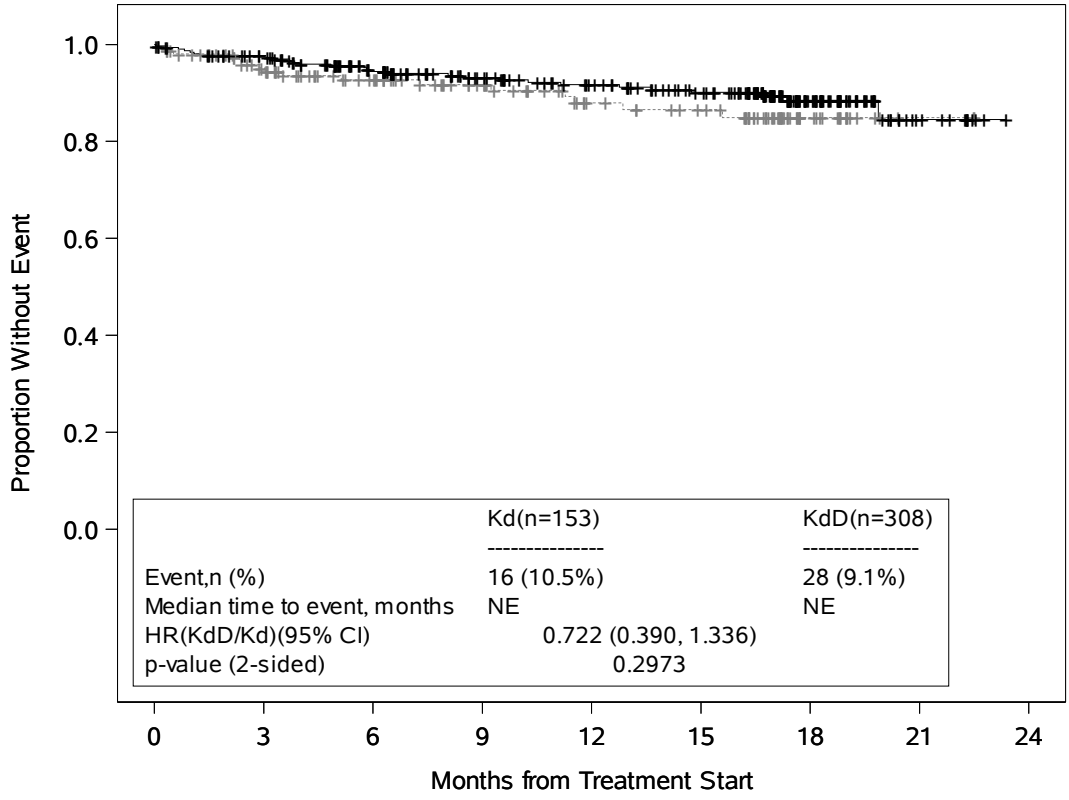


Number of Subjects at Risk:

Kd	153	98	82	65	49	41	13	2	0	
KdD	308	198	174	154	136	120	56	13	1	0

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-sub.sas.
Output: f14-06-002-600-ae-cox-blolym-grd345-ge5pct.rtf (Date Generated: 27MAY20:20:49:52).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.601. KM Curves of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC (Cardiac Disorders)
<Safety Population>

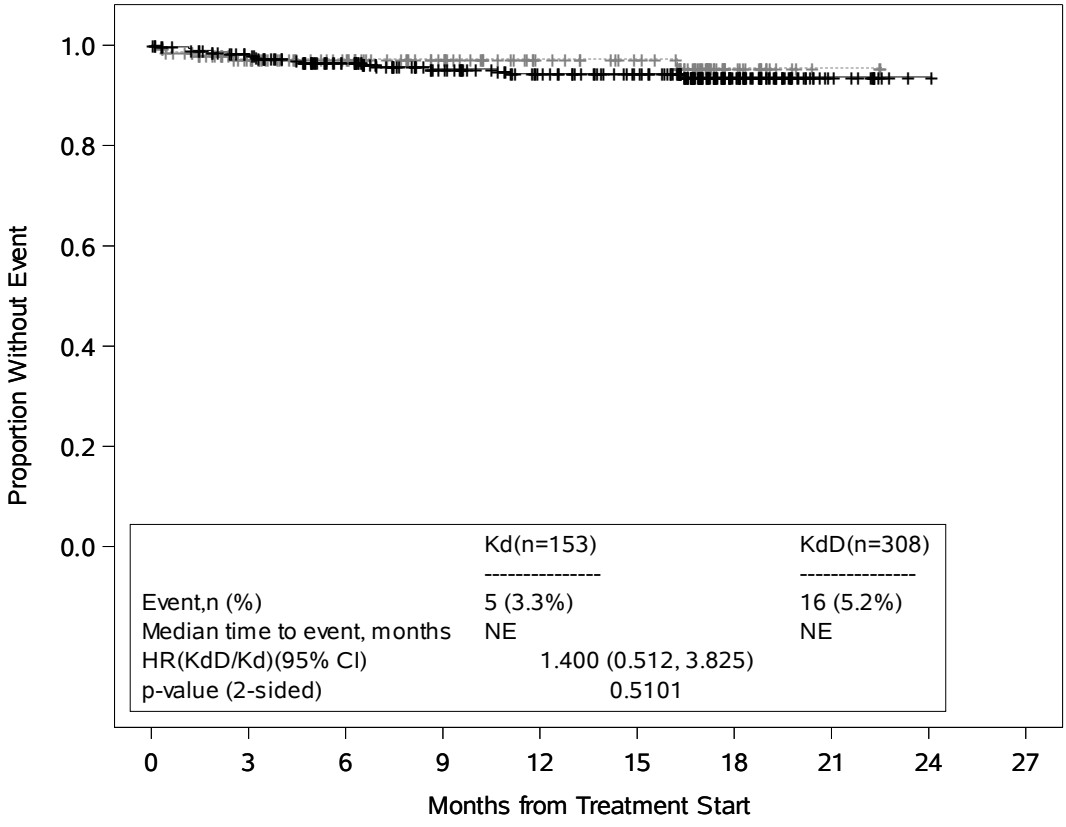


Number of Subjects at Risk:

Kd	153	126	103	83	63	56	18	2	0
KdD	308	284	243	205	184	162	69	12	0

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-sub.sas.
Output: f14-06-002-601-ae-cox-card-grd345-ge5pct.rtf (Date Generated: 27MAY20:20:49:53).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.602. KM Curves of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC (Gastrointestinal Disorders)
<Safety Population>

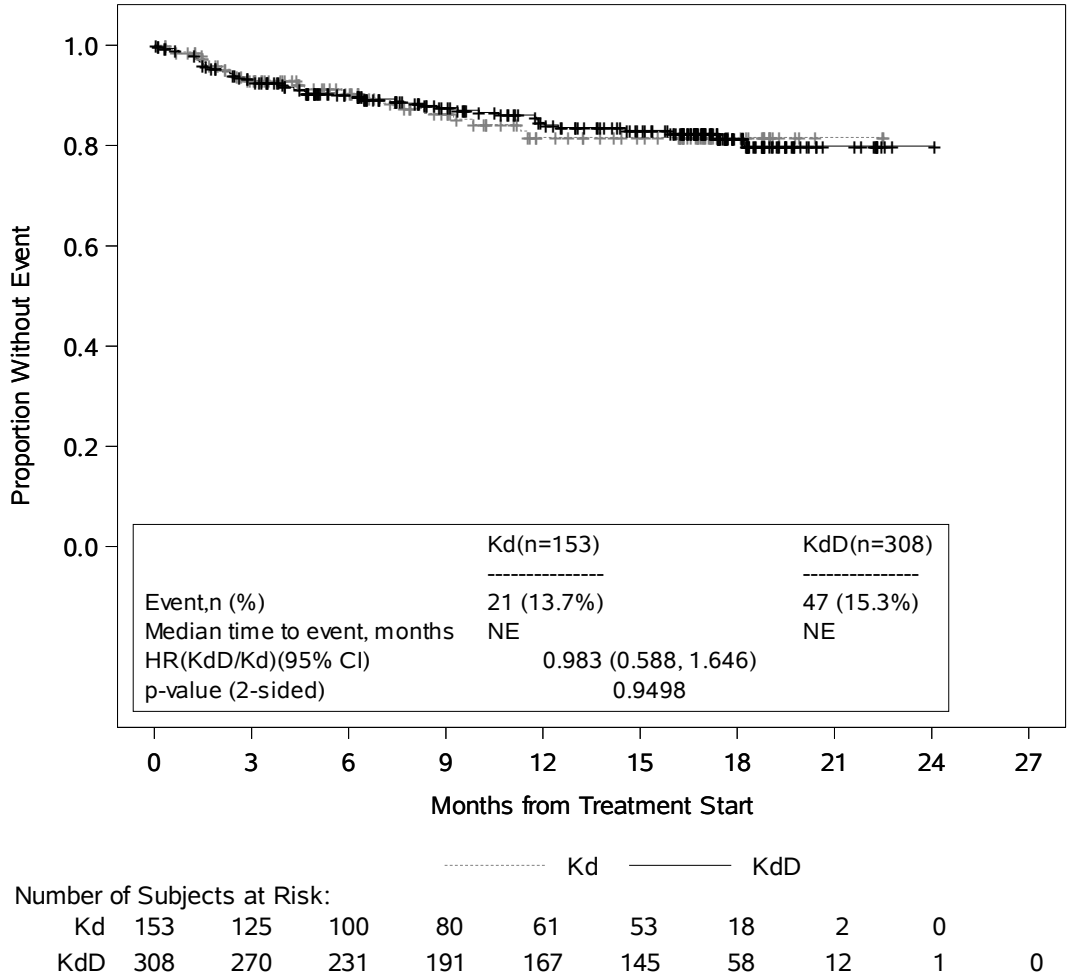


Number of Subjects at Risk:

Kd	153	128	106	86	66	58	17	2	0	
KdD	308	285	246	207	184	166	72	14	1	0

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-sub.sas.
Output: f14-06-002-602-ae-cox-gas-grd345-ge5pct.rtf (Date Generated: 27MAY20:20:49:55).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.603. KM Curves of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC (General Disorders and Administration Site Conditions) <Safety Population>

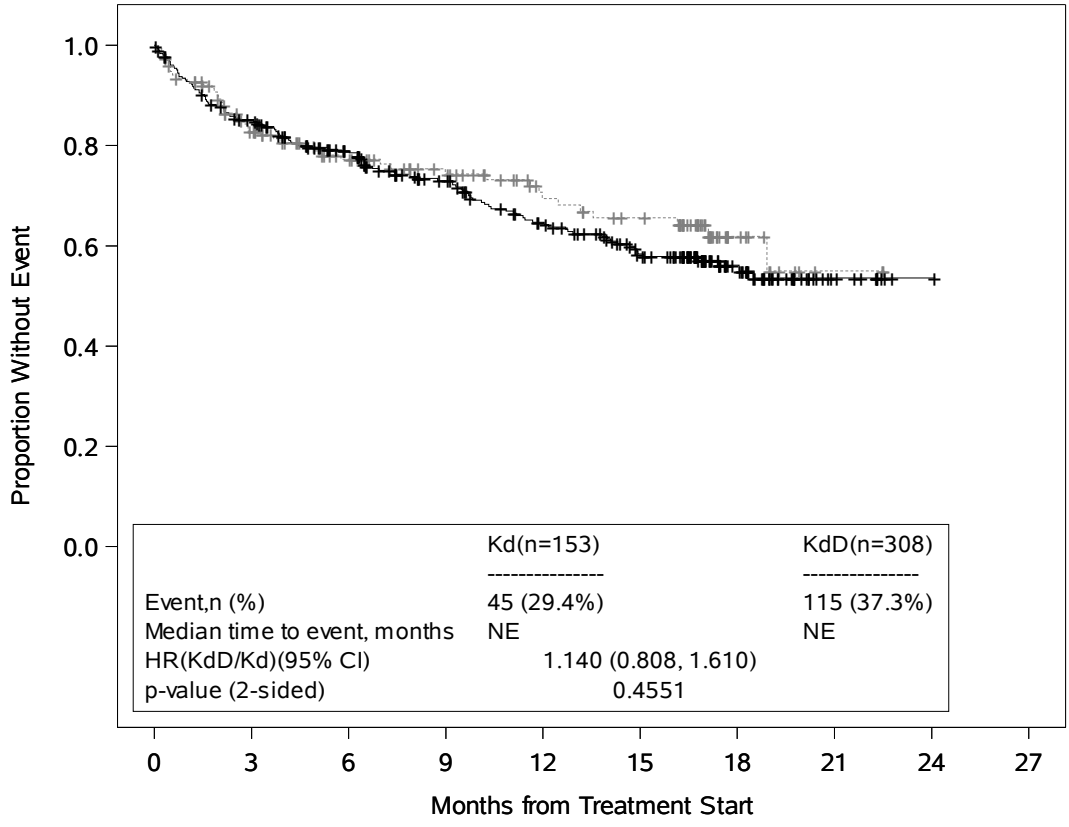


Number of Subjects at Risk:

Kd	153	125	100	80	61	53	18	2	0	
KdD	308	270	231	191	167	145	58	12	1	0

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-sub.sas.
Output: f14-06-002-603-ae-cox-gen-grd345-ge5pct.rtf (Date Generated: 27MAY20:20:49:57).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.604. KM Curves of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC (Infections and Infestations)
<Safety Population>

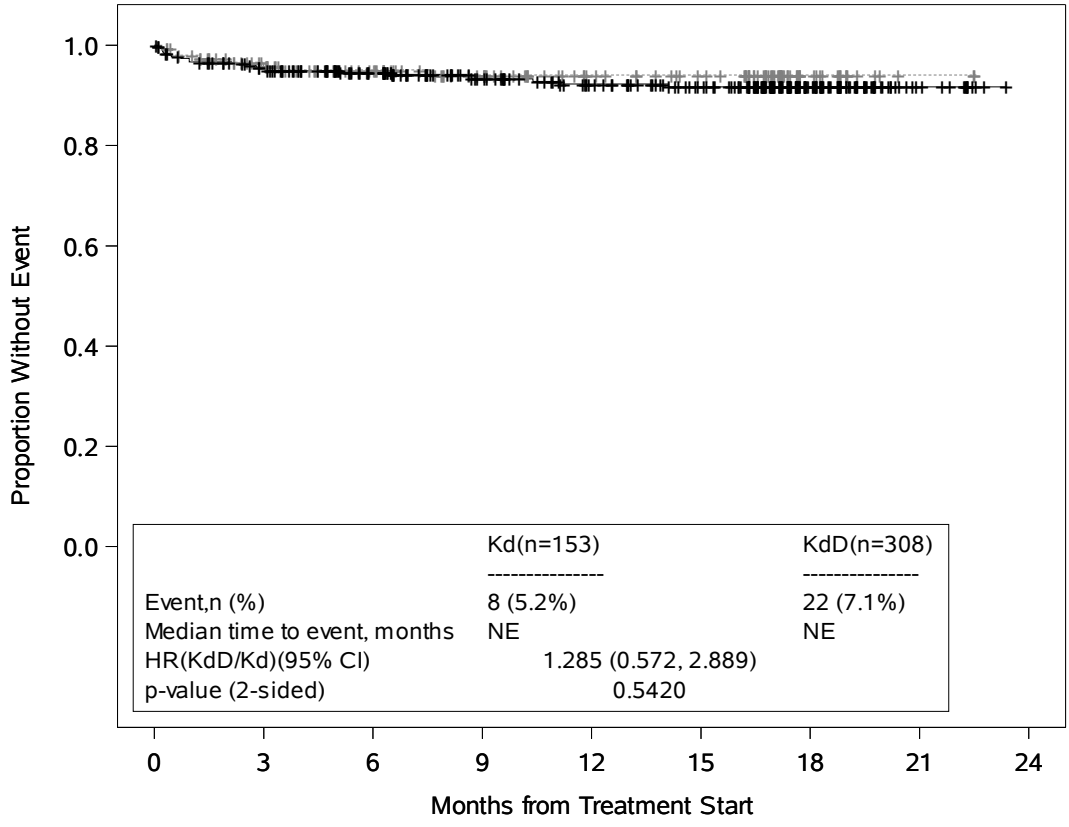


Number of Subjects at Risk:

Kd	153	113	90	72	55	48	13	2	0	
KdD	308	253	211	173	142	112	49	11	1	0

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-sub.sas.
Output: f14-06-002-604-ae-cox-infe-grd345-ge5pct.rtf (Date Generated: 27MAY20:20:49:58).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.605. KM Curves of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC (Investigations)
<Safety Population>

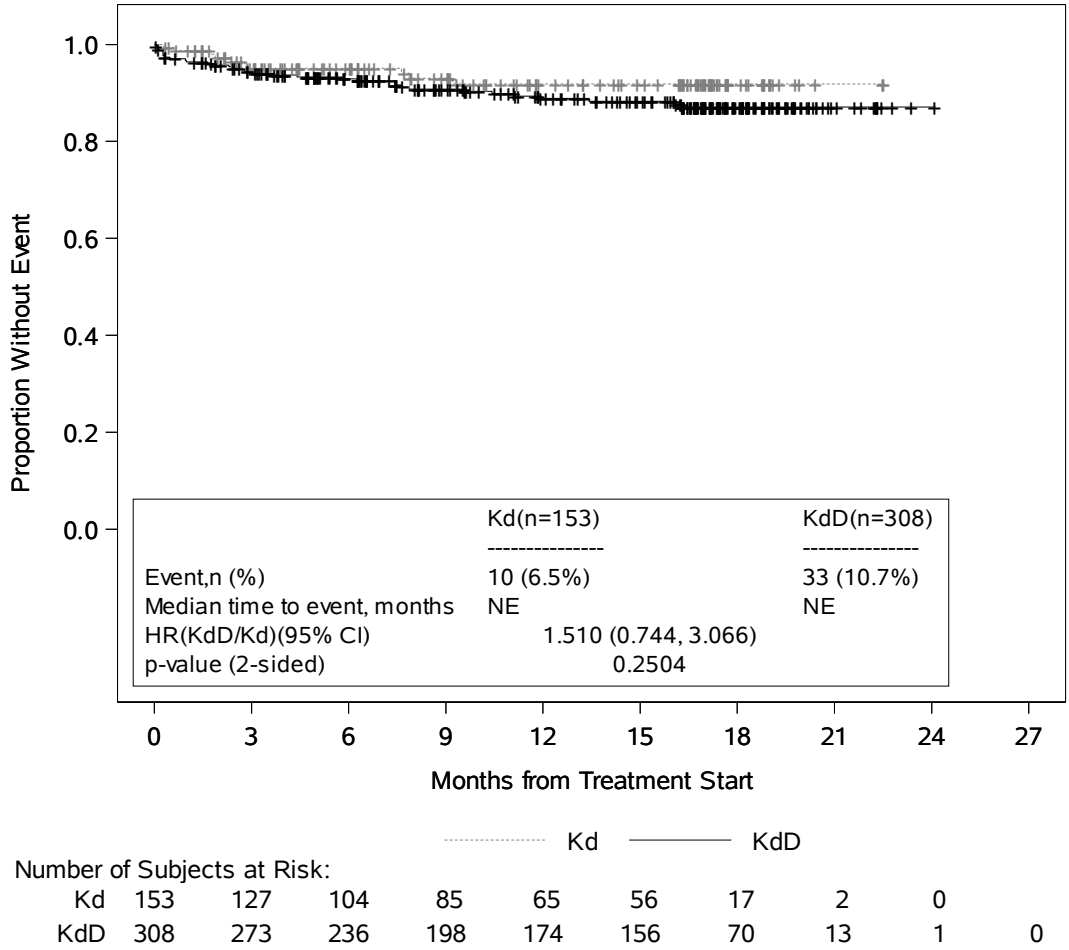


Number of Subjects at Risk:

Kd	153	128	106	85	66	57	17	2	0
KdD	308	277	239	200	177	155	71	13	0

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-sub.sas.
Output: f14-06-002-605-ae-cox-inve-grd345-ge5pct.rtf (Date Generated: 27MAY20:20:50:00).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.606. KM Curves of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC (Metabolism and Nutrition Disorders) <Safety Population>

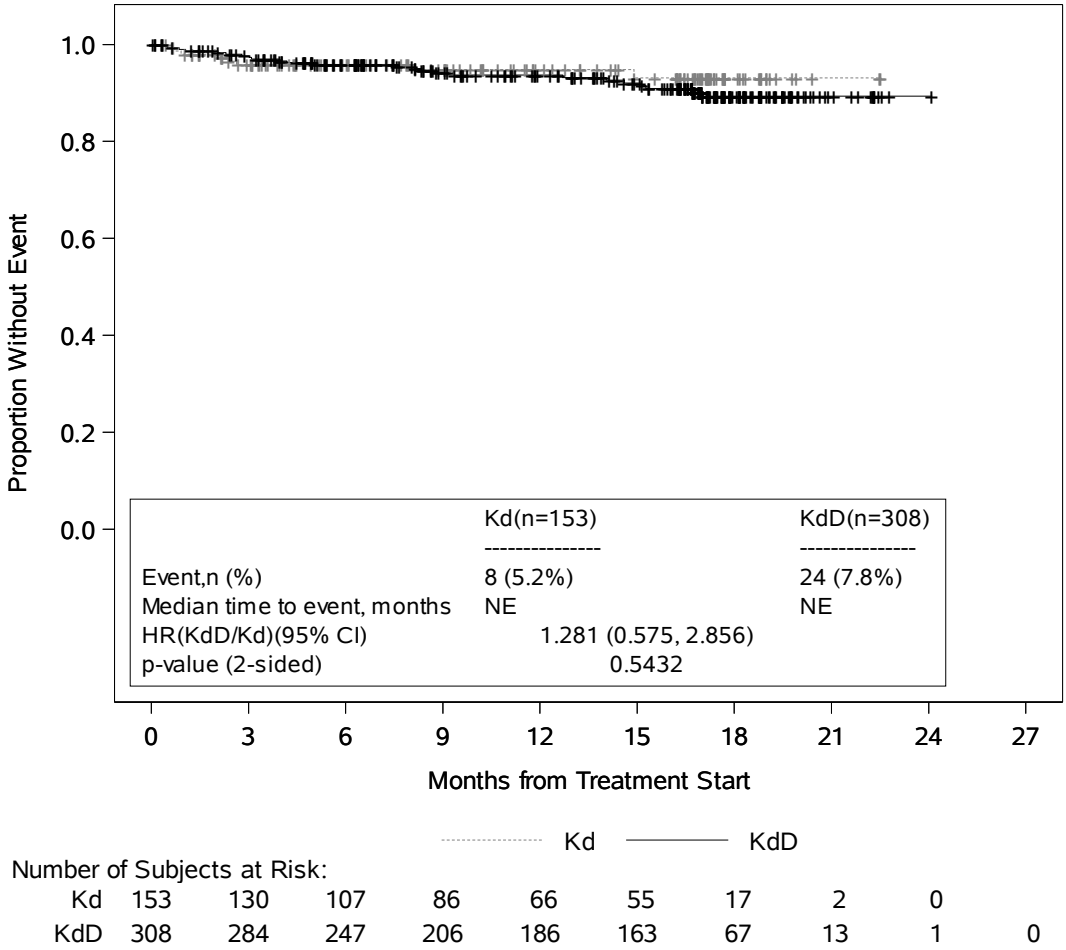


Number of Subjects at Risk:

Kd	153	127	104	85	65	56	17	2	0	
KdD	308	273	236	198	174	156	70	13	1	0

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-sub.sas.
Output: f14-06-002-606-ae-cox-meta-grd345-ge5pct.rtf (Date Generated: 27MAY20:20:50:01).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.607. KM Curves of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC (Musculoskeletal and Connective Tissue Disorders) <Safety Population>

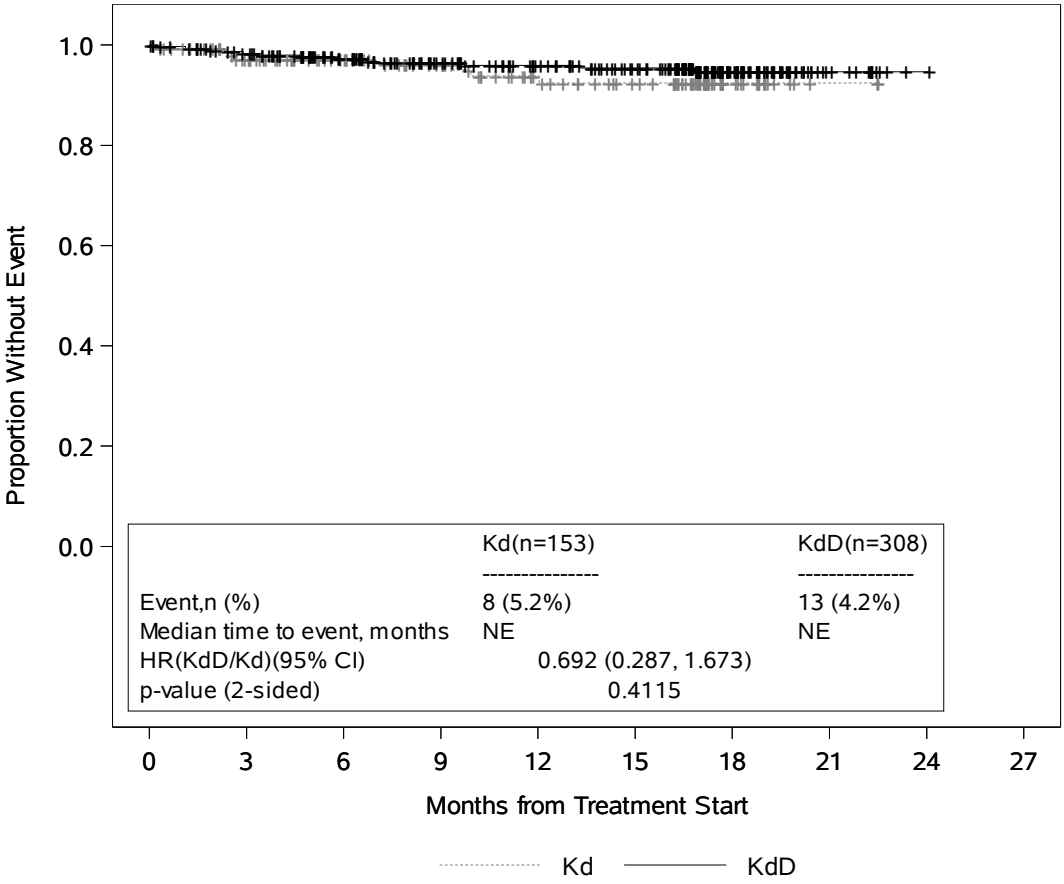


Number of Subjects at Risk:

Kd	153	130	107	86	66	55	17	2	0	
KdD	308	284	247	206	186	163	67	13	1	0

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-sub.sas.
Output: f14-06-002-607-ae-cox-mus-grd345-ge5pct.rtf (Date Generated: 27MAY20:20:50:03).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.608. KM Curves of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC (Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps))
<Safety Population>

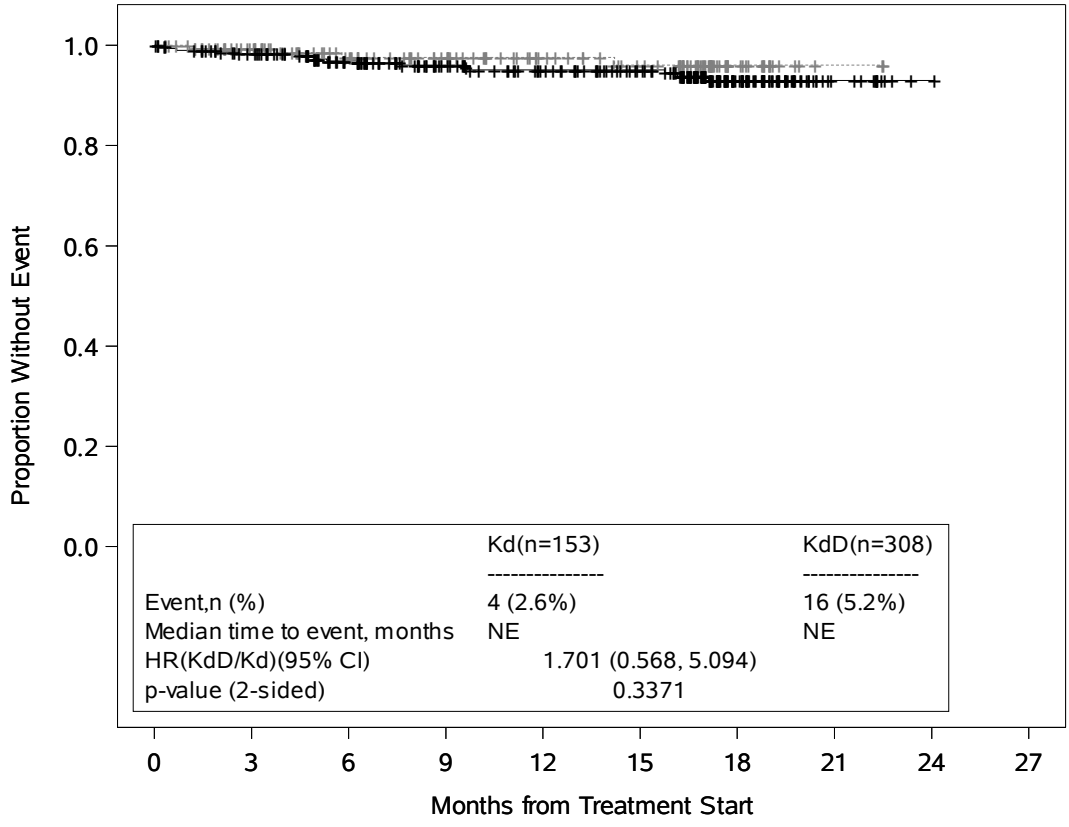


Number of Subjects at Risk:

Kd	153	130	108	88	68	57	18	2	0	
KdD	308	288	252	214	192	170	73	14	1	0

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-sub.sas.
Output: f14-06-002-608-ae-cox-neo-grd345-ge5pct.rtf (Date Generated: 27MAY20:20:50:05).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.609. KM Curves of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC (Nervous System Disorders)
<Safety Population>

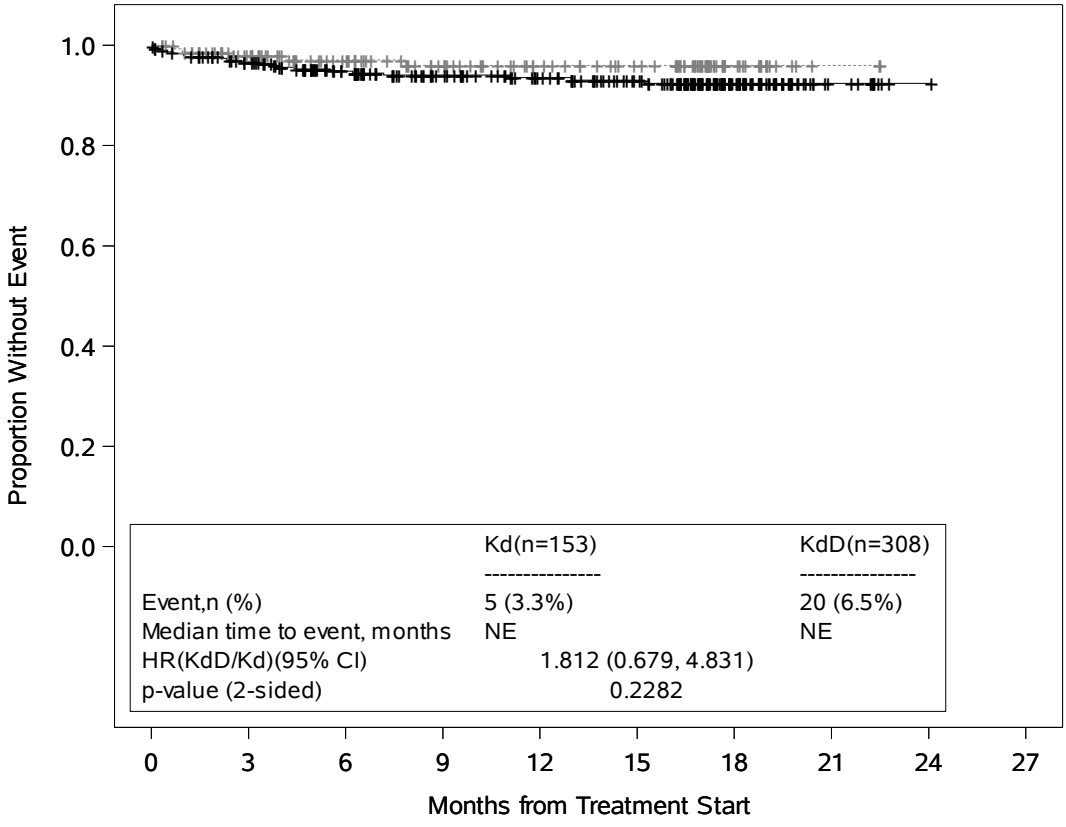


Number of Subjects at Risk:

Kd	153	132	106	88	68	57	18	2	0	
KdD	308	286	250	210	188	166	71	13	1	0

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-sub.sas.
Output: f14-06-002-609-ae-cox-ner-grd345-ge5pct.rtf (Date Generated: 27MAY20:20:50:07).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.610. KM Curves of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC (Psychiatric Disorders)
<Safety Population>

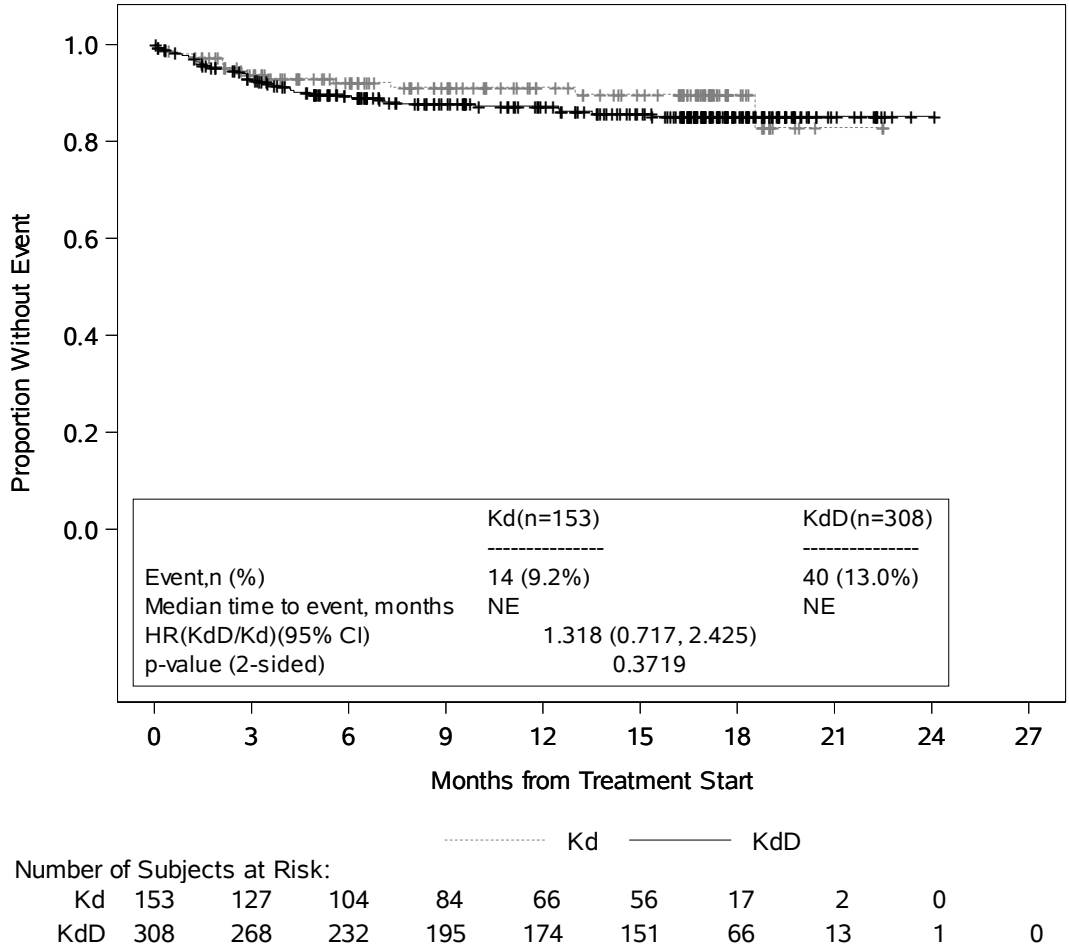


Number of Subjects at Risk:

Kd	153	129	104	83	66	56	18	2	0	
KdD	308	280	241	204	183	160	68	12	1	0

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-sub.sas.
Output: f14-06-002-610-ae-cox-psy-grd345-ge5pct.rtf (Date Generated: 27MAY20:20:50:09).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.612. KM Curves of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC (Respiratory, Thoracic and Mediastinal Disorders) <Safety Population>

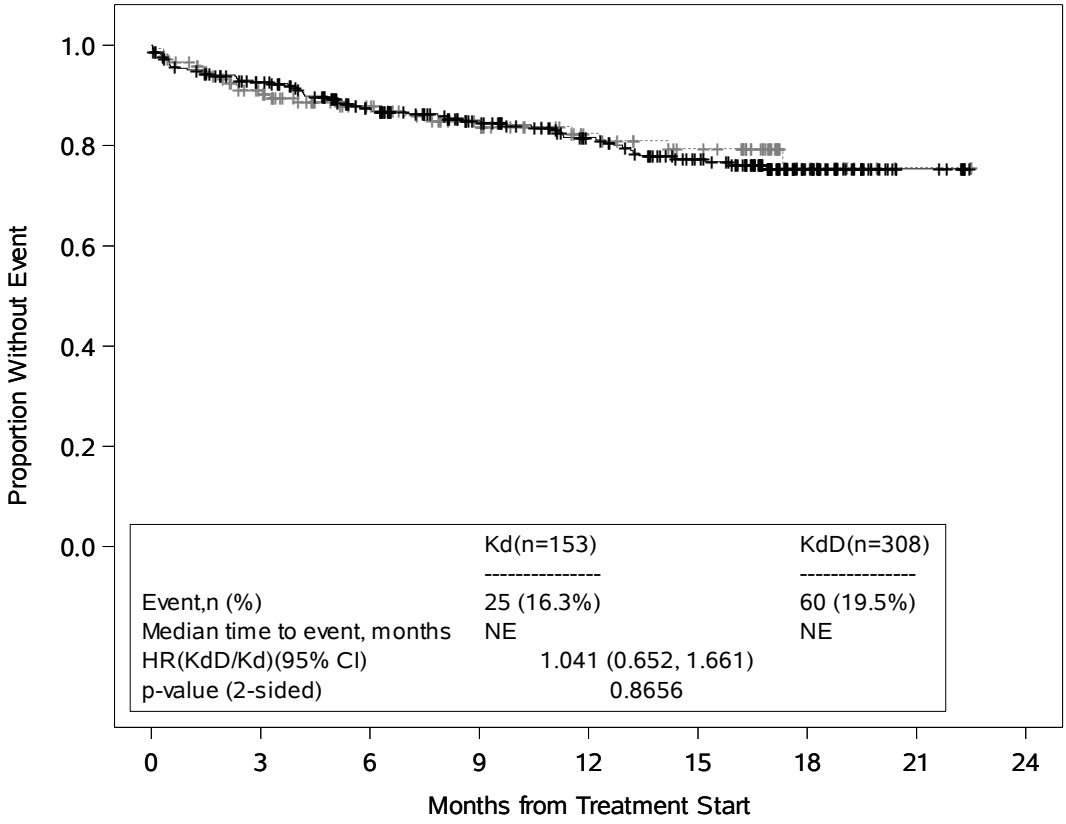


Number of Subjects at Risk:

Kd	153	127	104	84	66	56	17	2	0	
KdD	308	268	232	195	174	151	66	13	1	0

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-sub.sas.
Output: f14-06-002-612-ae-cox-resp-grd345-ge5pct.rtf (Date Generated: 27MAY20:20:50:12).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.613. KM Curves of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC (Vascular Disorders)
<Safety Population>

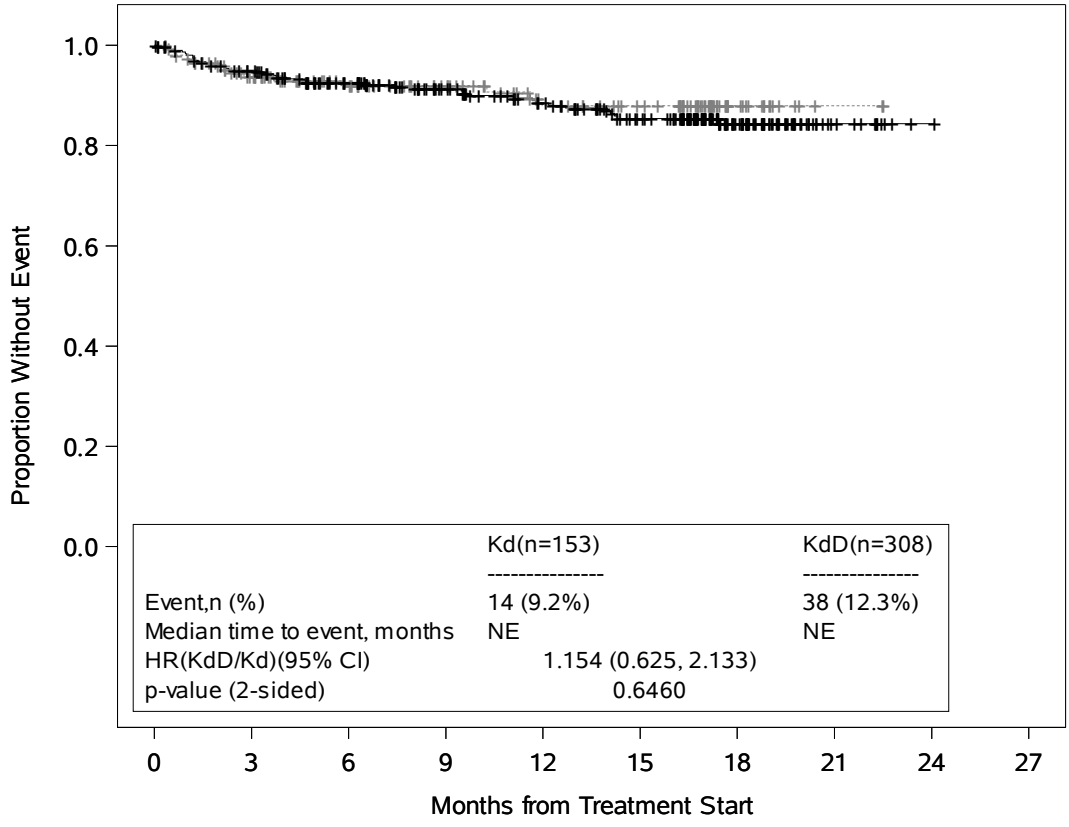


Number of Subjects at Risk:

Kd	153	122	96	75	56	47	13	2	0
KdD	308	267	224	186	158	132	54	9	0

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-sub.sas.
Output: f14-06-002-613-ae-cox-vas-grd345-ge5pct.rtf (Date Generated: 27MAY20:20:50:14).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.614. KM Curves of Most Frequent Serious Adverse Events by MedDRA SOC (Infections and Infestations) and PT (Pneumonia) <Safety Population>

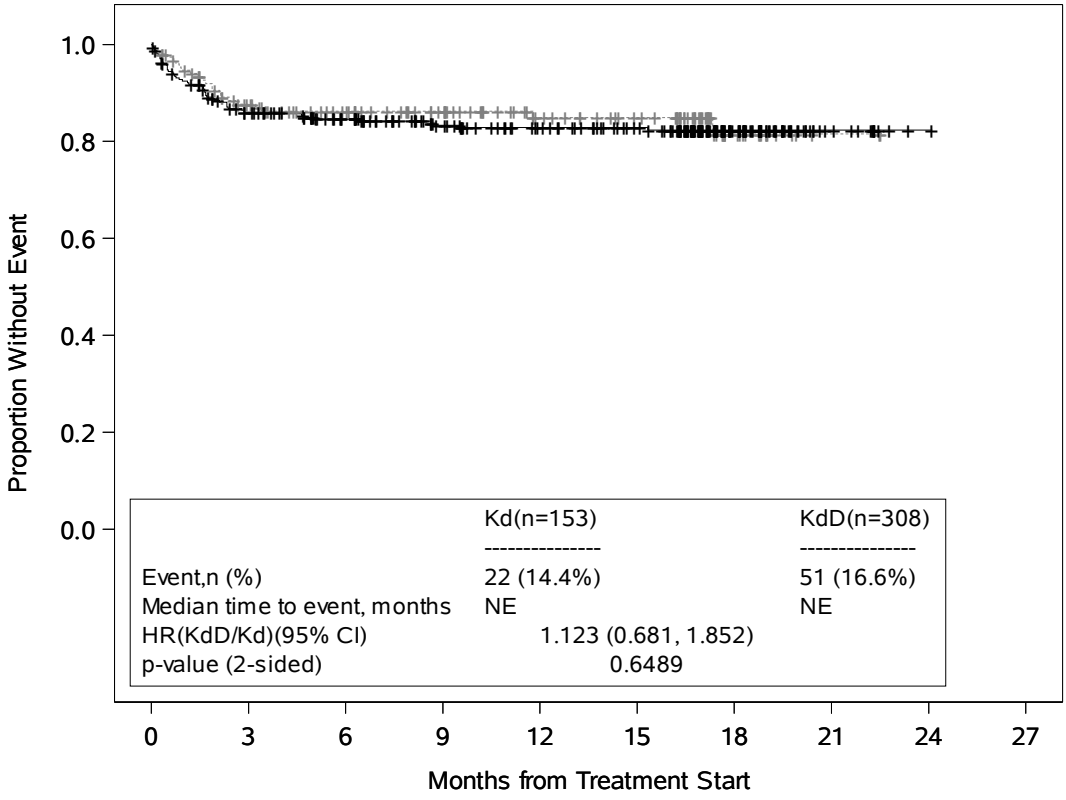


Number of Subjects at Risk:

Kd	153	123	99	80	62	54	16	2	0	
KdD	308	279	243	204	180	152	68	12	1	0

Includes PT where at least 5% subjects with at least one serious adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-sub.sas.
Output: f14-06-002-614-sae-cox-infe-pneu-ge5pct.rtf (Date Generated: 27MAY20:22:57:16).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.615. KM Curves of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC (Blood and Lymphatic System Disorders) and PT (Anaemia) <Safety Population>

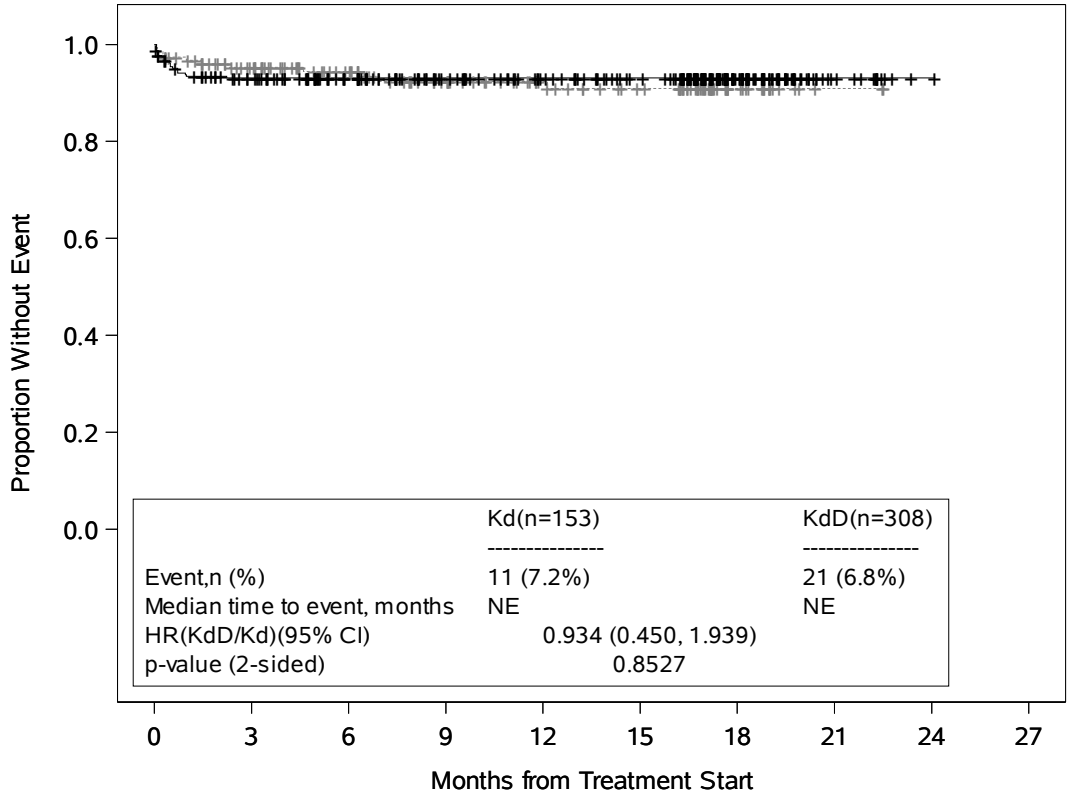


Number of Subjects at Risk:

Kd	153	119	102	85	64	54	16	2	0	
KdD	308	249	220	189	169	152	67	13	1	0

Includes PT where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-sub.sas.
Output: f14-06-002-615-ae-cox-blolym-anaemia-grd345-ge5pct.rtf (Date Generated: 27MAY20:22:57:19).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.616. KM Curves of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC (Blood and Lymphatic System Disorders) and PT (Lymphopenia) <Safety Population>

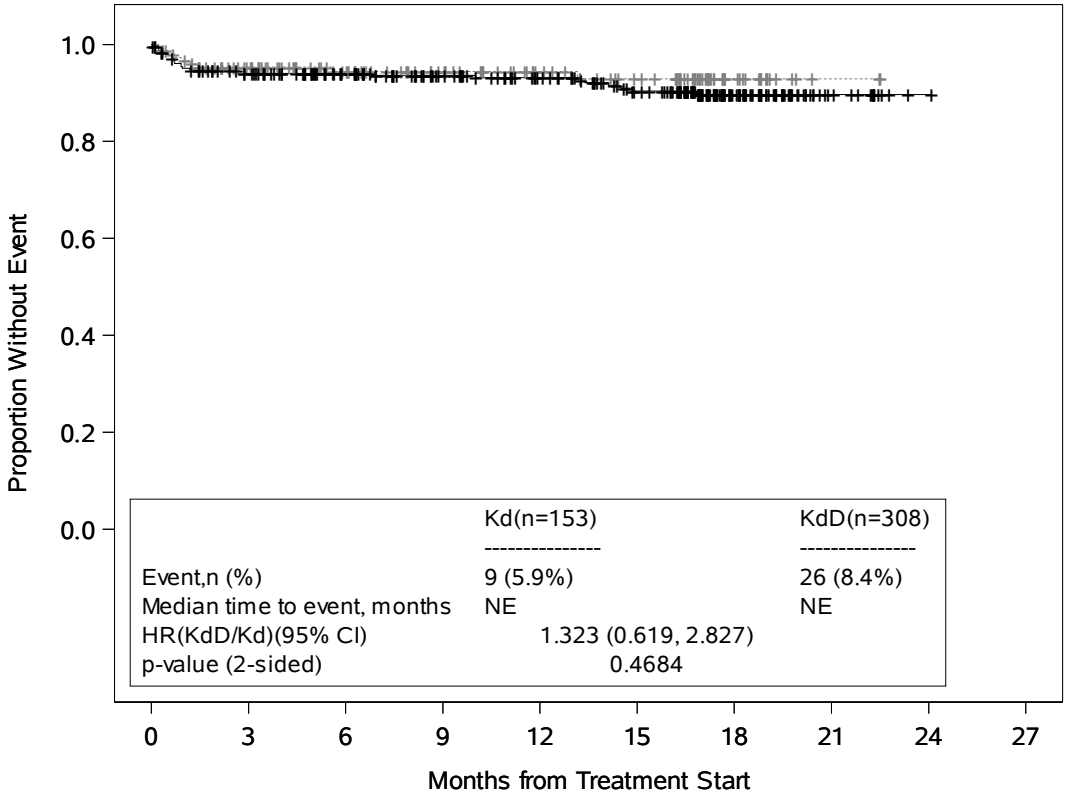


Number of Subjects at Risk:

Kd	153	127	102	80	63	53	18	2	0	
KdD	308	268	235	201	181	163	75	14	1	0

Includes PT where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-sub.sas.
Output: f14-06-002-616-ae-cox-blolym-lym-grd345-ge5pct.rtf (Date Generated: 27MAY20: 22:57:20).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.617. KM Curves of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC (Blood and Lymphatic System Disorders) and PT (Neutropenia) <Safety Population>

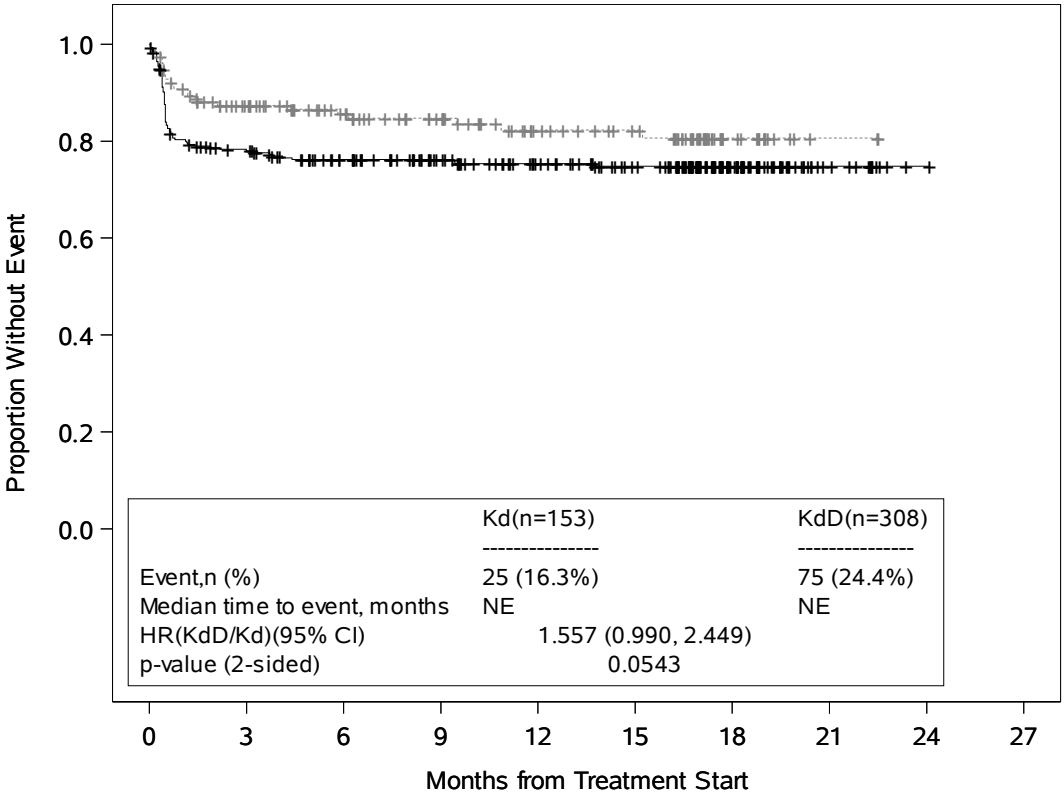


Number of Subjects at Risk:

Kd	153	127	103	83	66	55	18	2	0	
KdD	308	272	239	205	184	158	71	14	1	0

Includes PT where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-sub.sas.
Output: f14-06-002-617-ae-cox-blolym-neu-grd345-ge5pct.rtf (Date Generated: 27MAY20: 22:57:22).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.618. KM Curves of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC (Blood and Lymphatic System Disorders) and PT (Thrombocytopenia)
<Safety Population>

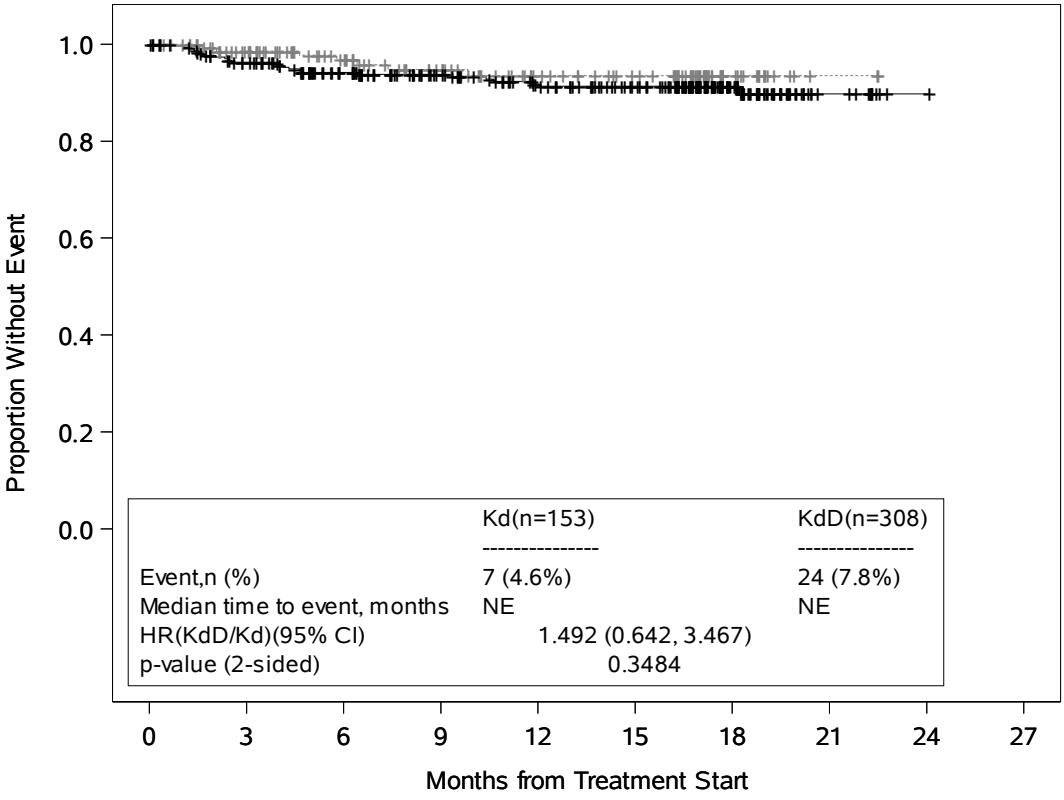


Number of Subjects at Risk:

Kd	153	117	95	78	58	50	16	2	0	
KdD	308	229	204	179	157	138	64	14	1	0

Includes PT where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-sub.sas.
Output: f14-06-002-618-ae-cox-blolym-throm-grd345-ge5pct.rtf (Date Generated: 27MAY20:22:57:24).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.619. KM Curves of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC (General Disorders and Administration Site Conditions) and PT (Fatigue)
<Safety Population>

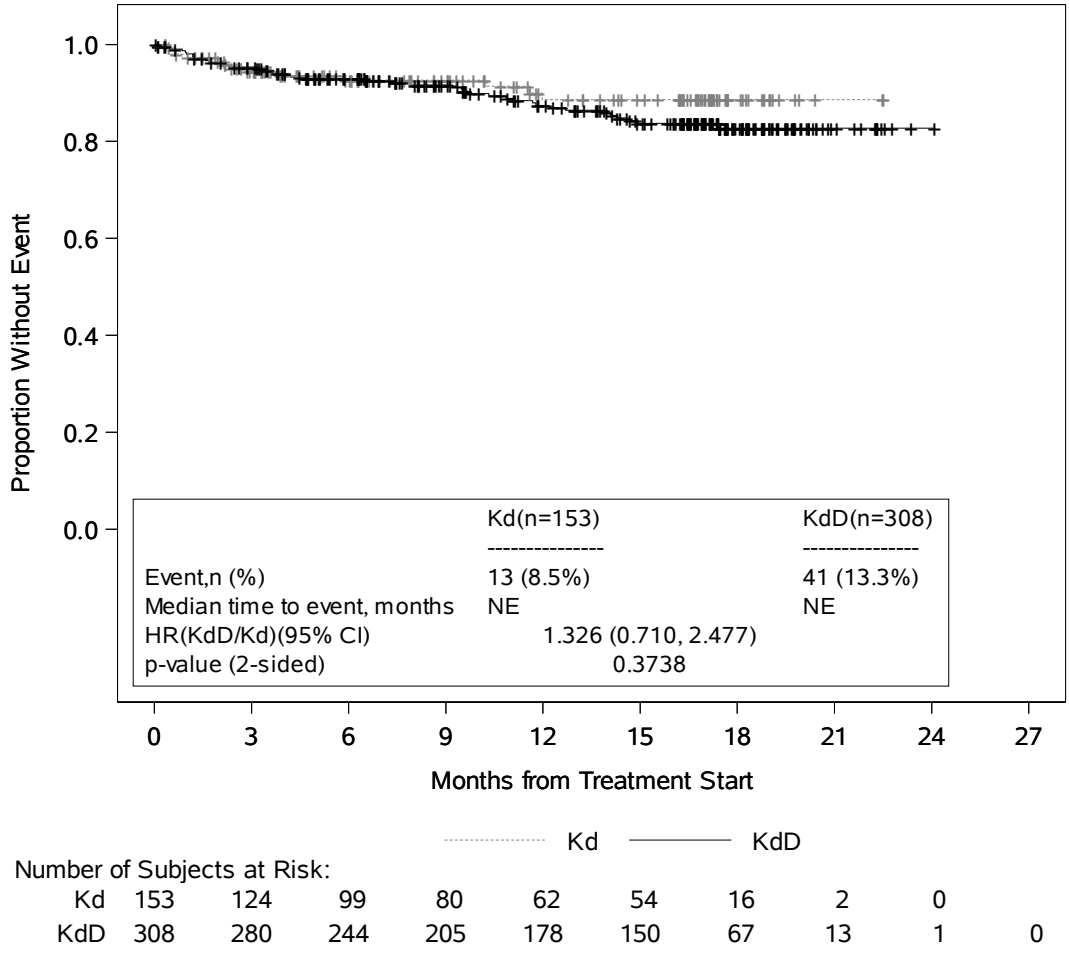


Number of Subjects at Risk:

Kd	153	130	104	84	64	54	18	2	0	
KdD	308	279	240	203	180	158	67	12	1	0

Includes PT where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-sub.sas.
Output: f14-06-002-619-ae-cox-gen-fati-grd345-ge5pct.rtf (Date Generated: 27MAY20:22:57:26).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.620. KM Curves of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC (Infections and Infestations) and PT (Pneumonia) <Safety Population>

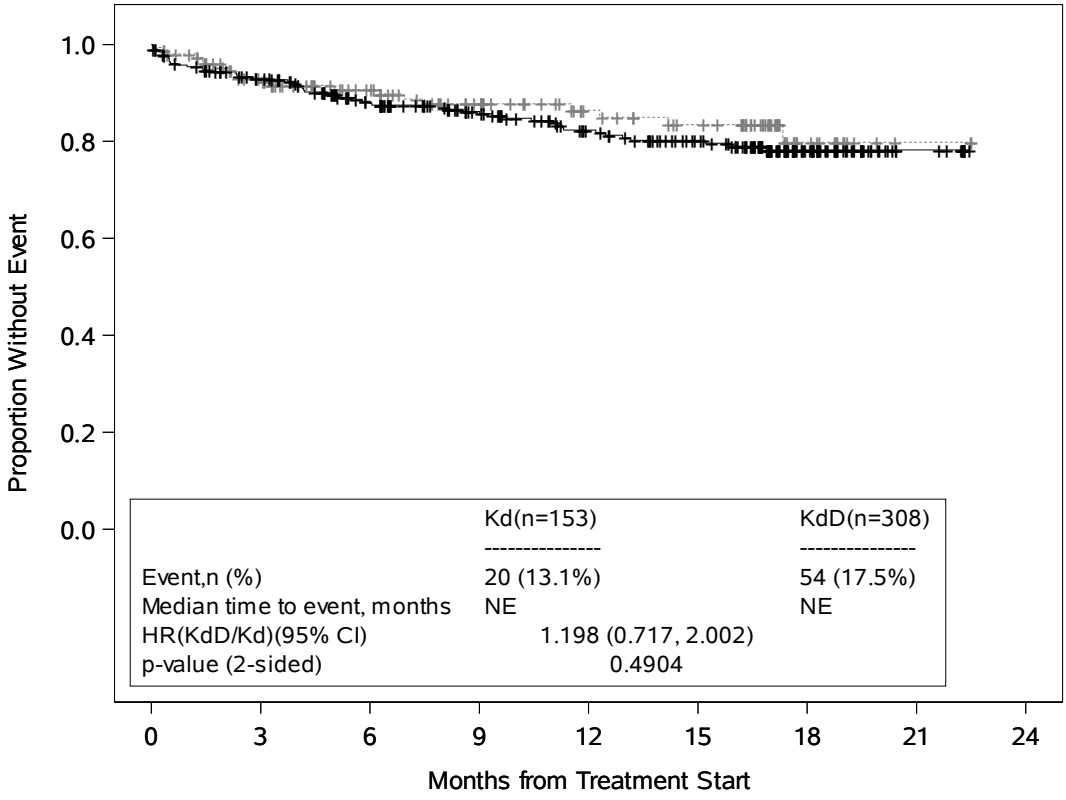


Number of Subjects at Risk:

Kd	153	124	99	80	62	54	16	2	0	
KdD	308	280	244	205	178	150	67	13	1	0

Includes PT where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-sub.sas.
Output: f14-06-002-620-ae-cox-infe-pneu-grd345-ge5pct.rtf (Date Generated: 27MAY20:22:57:27).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.621. KM Curves of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC (Vascular Disorders) and PT (Hypertension) <Safety Population>



Number of Subjects at Risk:

Kd	153	124	99	78	60	51	14	2	0
KdD	308	268	226	189	160	138	57	9	0

Includes PT where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020/figures/f-ae-cox-soc-pt-sub.sas.
Output: f14-06-002-621-ae-cox-vas-hyper-grd345-ge5pct.rtf (Date Generated: 27MAY20:22:57:29).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Table 6.11 EORTC-QLQ C30 Insomnia Symptom: Time to deterioration by at least 10 points by subgroups eCOA-ITT Population

EORTC	KdD (N=281)		Kd (N=128)		Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Age							0.2105
<= 75	154 (59.9%)	4.8 [3.7, 7.5]	66 (58.9%)	3.8 [2.8, 7.5]	0.91 [0.68, 1.21]	0.5041	
> 75	15 (62.5%)	5.6 [2.8, 20.6]	11 (68.8%)	2.0 [1.0, 10.0]	0.49 [0.22, 1.10]	0.0695	
Sex							0.2506
Male	102 (63.4%)	3.8 [2.8, 7.5]	45 (57.7%)	4.7 [2.8, 11.4]	0.97 [0.68, 1.38]	0.8559	
Female	67 (55.8%)	6.6 [3.3, 12.2]	32 (64.0%)	3.8 [1.9, 5.6]	0.71 [0.46, 1.08]	0.0963	
Race							0.5208
White	129 (58.6%)	5.6 [3.7, 9.6]	61 (58.7%)	4.2 [2.8, 8.2]	0.88 [0.65, 1.20]	0.4100	
Non-White	40 (65.6%)	4.0 [2.8, 7.5]	16 (66.7%)	1.9 [1.0, 6.6]	0.71 [0.39, 1.27]	0.2232	
Geographic region							0.7318
Europe	101 (55.5%)	6.6 [3.8, 12.2]	52 (61.9%)	3.8 [2.8, 6.1]	0.71 [0.51, 1.00]	0.0401	
Asia Pacific	54 (66.7%)	3.7 [1.9, 6.5]	19 (55.9%)	3.8 [1.9, NA]	1.12 [0.66, 1.89]	0.6597	
North America	14 (77.8%)	2.4 [1.0, 7.7]	6 (60.0%)	6.8 [1.0, NA]	1.33 [0.51, 3.51]	0.5446	
ECOG performance status							0.6903
0-1	163 (60.8%)	4.7 [3.7, 7.5]	76 (60.8%)	3.8 [2.8, 6.6]	0.88 [0.67, 1.15]	0.3269	
2	5 (41.7%)	7.5 [1.0, NA]	1 (33.3%)	NA [0.9, NA]	0.33 [0.03, 3.77]	0.3487	
Prior bortezomib or ixazomib exposure							0.3975
Yes	155 (59.8%)	5.6 [3.8, 7.7]	69 (61.1%)	3.8 [2.8, 7.5]	0.83 [0.62, 1.10]	0.1708	
No	14 (63.6%)	2.8 [1.0, 7.5]	8 (53.3%)	4.2 [1.0, NA]	1.24 [0.52, 2.97]	0.6058	

Table 6.11 EORTC-QLQ C30 Insomnia Symptom: Time to deterioration by at least 10 points by subgroups eCOA-ITT Population

EORTC	KdD (N=281)		Kd (N=128)		Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Refractory to bortezomib							0.7825
Yes	46 (51.7%)	8.4 [3.8, 20.6]	26 (54.2%)	6.6 [1.9, 12.1]	0.79 [0.48, 1.28]	0.3202	
No	123 (64.1%)	3.8 [2.8, 6.5]	51 (63.8%)	3.8 [2.3, 5.6]	0.87 [0.63, 1.21]	0.4019	
Prior lenalidomide exposure							0.6454
Yes	60 (53.6%)	7.7 [3.7, 21.3]	32 (52.5%)	6.1 [2.8, 18.8]	0.89 [0.58, 1.37]	0.5906	
No	109 (64.5%)	3.8 [2.8, 6.6]	45 (67.2%)	3.1 [1.9, 4.7]	0.78 [0.55, 1.11]	0.1493	
Refractory to lenalidomide							0.7179
Yes	46 (51.7%)	11.9 [4.7, 21.3]	22 (47.8%)	12.1 [2.3, NA]	0.92 [0.55, 1.53]	0.7438	
No	123 (64.1%)	3.8 [2.8, 6.6]	55 (67.1%)	3.8 [1.9, 4.7]	0.81 [0.59, 1.12]	0.1789	
Prior IMiD exposure							0.7167
Yes	109 (58.6%)	4.0 [3.1, 7.5]	55 (61.1%)	3.8 [2.2, 6.1]	0.85 [0.61, 1.17]	0.2940	
No	60 (63.2%)	6.6 [3.7, 10.9]	22 (57.9%)	4.2 [2.0, 15.9]	0.89 [0.54, 1.45]	0.6229	
Refractory to IMiD							0.3149
Yes	66 (56.4%)	4.8 [3.3, 19.6]	27 (50.0%)	6.6 [2.8, NA]	1.04 [0.66, 1.62]	0.8736	
No	103 (62.8%)	4.7 [2.9, 7.5]	50 (67.6%)	3.8 [1.9, 4.7]	0.75 [0.53, 1.05]	0.0831	
International Staging System (ISS)							0.1338
Stage I or II	142 (62.0%)	4.7 [3.7, 7.5]	65 (60.7%)	4.2 [2.8, 8.2]	0.92 [0.69, 1.24]	0.5905	
Stage III	26 (51.0%)	8.4 [3.1, NA]	12 (57.1%)	2.0 [1.9, NA]	0.53 [0.25, 1.10]	0.0706	
Prior proteasome inhibitor exposure							0.6628

Table 6.11 EORTC-QLQ C30 Insomnia Symptom: Time to deterioration by at least 10 points by subgroups eCOA-ITT Population

EORTC	KdD (N=281)		Kd (N=128)		Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Yes	156 (60.0%)	5.6 [3.8, 7.7]	69 (60.5%)	3.8 [2.8, 7.5]	0.84 [0.63, 1.12]	0.2183	
No	13 (61.9%)	2.8 [1.6, NA]	8 (57.1%)	3.8 [1.0, NA]	1.02 [0.42, 2.48]	0.9581	
Number of prior lines of therapy							0.7398
1	85 (65.4%)	3.7 [2.4, 5.9]	39 (68.4%)	3.8 [1.9, 4.7]	0.82 [0.56, 1.20]	0.2810	
>= 2	84 (55.6%)	7.5 [4.7, 11.9]	38 (53.5%)	6.1 [2.8, 15.9]	0.89 [0.61, 1.31]	0.5415	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
NA denotes that the median time (and 95% CI) were not estimable
[a]From Kaplan–Meier estimate
[b]HR: hazard ratio

Table 6.12 EORTC-QLQ C30 Appetite Loss Symptom: Time to deterioration by at least 10 points by subgroups eCOA-ITT Population

EORTC	KdD (N=281)		Kd (N=128)		Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Age							0.9353
<= 75	138 (53.7%)	10.3 [6.6, 13.3]	50 (44.6%)	14.6 [4.7, NA]	1.09 [0.78, 1.50]	0.6140	
> 75	18 (75.0%)	3.8 [1.9, 5.6]	10 (62.5%)	5.2 [1.9, 6.6]	1.09 [0.50, 2.38]	0.8315	
Sex							0.6450
Male	91 (56.5%)	10.3 [6.6, 12.3]	35 (44.9%)	6.6 [4.7, NA]	1.11 [0.75, 1.64]	0.5958	
Female	65 (54.2%)	6.6 [4.7, 16.8]	25 (50.0%)	10.6 [3.1, NA]	0.98 [0.62, 1.55]	0.9201	
Race							0.2364
White	117 (53.2%)	10.9 [7.6, 13.3]	49 (47.1%)	6.6 [4.2, NA]	0.95 [0.68, 1.33]	0.7585	
Non-White	39 (63.9%)	3.8 [1.9, 7.0]	11 (45.8%)	10.6 [3.3, NA]	1.55 [0.79, 3.03]	0.1849	
Geographic region							0.5060
Europe	103 (56.6%)	9.4 [5.6, 12.2]	39 (46.4%)	6.6 [4.0, NA]	1.06 [0.73, 1.53]	0.7575	
Asia Pacific	44 (54.3%)	5.6 [3.8, NA]	17 (50.0%)	13.1 [3.3, NA]	1.03 [0.59, 1.80]	0.9279	
North America	9 (50.0%)	18.7 [4.7, NA]	4 (40.0%)	NA [1.9, NA]	0.92 [0.27, 3.15]	0.8978	
ECOG performance status							0.9751
0-1	150 (56.0%)	9.3 [5.6, 12.2]	60 (48.0%)	6.6 [4.7, 16.8]	1.06 [0.79, 1.43]	0.6959	
2	6 (50.0%)	14.0 [1.9, NA]	0 (0.0%)	NA [NA, NA]	NA [NA, NA]	0.3483	
Prior bortezomib or ixazomib exposure							0.3615
Yes	143 (55.2%)	9.4 [5.9, 12.4]	54 (47.8%)	6.6 [4.0, NA]	1.01 [0.74, 1.38]	0.9513	
No	13 (59.1%)	5.6 [1.0, NA]	6 (40.0%)	15.9 [2.8, NA]	1.60 [0.61, 4.25]	0.3232	

Table 6.12 EORTC-QLQ C30 Appetite Loss Symptom: Time to deterioration by at least 10 points by subgroups eCOA-ITT Population

EORTC	KdD (N=281)		Kd (N=128)		Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Refractory to bortezomib							0.8982
Yes	51 (57.3%)	5.6 [2.8, 12.2]	23 (47.9%)	5.2 [2.0, NA]	1.04 [0.63, 1.71]	0.8713	
No	105 (54.7%)	10.3 [6.6, 14.0]	37 (46.3%)	13.1 [5.6, NA]	1.07 [0.74, 1.56]	0.7017	
Prior lenalidomide exposure							0.1541
Yes	67 (59.8%)	7.0 [3.8, 13.3]	24 (39.3%)	NA [4.0, NA]	1.37 [0.86, 2.18]	0.1820	
No	89 (52.7%)	10.3 [5.6, 13.1]	36 (53.7%)	6.6 [3.8, 16.8]	0.88 [0.60, 1.30]	0.5139	
Refractory to lenalidomide							0.6409
Yes	53 (59.6%)	5.9 [3.8, 15.3]	19 (41.3%)	10.6 [3.3, NA]	1.19 [0.70, 2.02]	0.5088	
No	103 (53.6%)	9.5 [6.6, 12.9]	41 (50.0%)	6.6 [4.7, NA]	1.01 [0.70, 1.45]	0.9488	
Prior IMiD exposure							0.0370
Yes	107 (57.5%)	6.6 [4.2, 11.3]	38 (42.2%)	15.9 [5.6, NA]	1.33 [0.92, 1.92]	0.1242	
No	49 (51.6%)	12.2 [9.3, NA]	22 (57.9%)	5.2 [2.8, 16.8]	0.64 [0.38, 1.06]	0.0750	
Refractory to IMiD							0.4335
Yes	67 (57.3%)	5.9 [4.0, 14.0]	21 (38.9%)	10.6 [3.3, NA]	1.25 [0.76, 2.04]	0.3662	
No	89 (54.3%)	10.3 [6.6, 13.3]	39 (52.7%)	6.6 [4.2, 16.8]	0.96 [0.66, 1.40]	0.8313	
International Staging System (ISS)							0.5770
Stage I or II	127 (55.5%)	9.3 [5.6, 12.2]	51 (47.7%)	10.6 [4.9, NA]	1.10 [0.80, 1.53]	0.5520	
Stage III	28 (54.9%)	12.2 [5.6, 15.3]	9 (42.9%)	3.8 [2.0, NA]	0.86 [0.40, 1.84]	0.6976	
Prior proteasome inhibitor exposure							0.3578

Table 6.12 EORTC-QLQ C30 Appetite Loss Symptom: Time to deterioration by at least 10 points by subgroups eCOA-ITT Population

EORTC	KdD (N=281)		Kd (N=128)		Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Yes	144 (55.4%)	9.4 [5.9, 12.2]	55 (48.2%)	6.6 [4.7, NA]	1.01 [0.74, 1.38]	0.9596	
No	12 (57.1%)	9.4 [1.0, NA]	5 (35.7%)	15.9 [2.8, NA]	1.67 [0.58, 4.77]	0.3211	
Number of prior lines of therapy							0.5138
1	66 (50.8%)	10.4 [6.8, 18.7]	24 (42.1%)	15.9 [4.7, NA]	1.17 [0.73, 1.87]	0.4962	
>= 2	90 (59.6%)	5.9 [4.0, 11.3]	36 (50.7%)	5.6 [3.3, NA]	0.98 [0.66, 1.44]	0.9014	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
NA denotes that the median time (and 95% CI) were not estimable
[a]From Kaplan–Meier estimate
[b]HR: hazard ratio

Table 6.13 EORTC-QLQ C30 Constipation Symptom: Time to deterioration by at least 10 points by subgroups eCOA-ITT Population

EORTC	KdD (N=281)		Kd (N=128)		Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Age							0.1436
<= 75	96 (37.4%)	NA [15.9, NA]	39 (34.8%)	NA [8.5, NA]	0.94 [0.65, 1.36]	0.7359	
> 75	13 (54.2%)	8.4 [2.8, NA]	4 (25.0%)	NA [2.8, NA]	2.20 [0.71, 6.81]	0.1554	
Sex							0.9580
Male	64 (39.8%)	19.2 [12.4, NA]	27 (34.6%)	NA [8.5, NA]	1.01 [0.64, 1.59]	0.9637	
Female	45 (37.5%)	NA [12.9, NA]	16 (32.0%)	NA [5.6, NA]	1.04 [0.59, 1.85]	0.8792	
Race							0.4875
White	79 (35.9%)	NA [17.8, NA]	34 (32.7%)	NA [8.5, NA]	0.95 [0.64, 1.43]	0.8187	
Non-White	30 (49.2%)	12.2 [4.7, NA]	9 (37.5%)	NA [3.3, NA]	1.27 [0.60, 2.68]	0.5247	
Geographic region							0.1083
Europe	61 (33.5%)	19.2 [17.8, NA]	26 (31.0%)	NA [10.0, NA]	0.92 [0.58, 1.47]	0.7364	
Asia Pacific	39 (48.1%)	15.0 [4.7, NA]	11 (32.4%)	NA [3.8, NA]	1.47 [0.75, 2.87]	0.2499	
North America	9 (50.0%)	8.4 [1.9, NA]	6 (60.0%)	5.6 [1.1, NA]	0.74 [0.26, 2.11]	0.5737	
ECOG performance status							0.7086
0-1	103 (38.4%)	NA [15.0, NA]	42 (33.6%)	NA [10.0, NA]	1.03 [0.72, 1.48]	0.8633	
2	5 (41.7%)	18.0 [1.9, NA]	1 (33.3%)	3.8 [, NA]	0.36 [0.03, 4.10]	0.3924	
Prior bortezomib or ixazomib exposure							0.0092
Yes	94 (36.3%)	NA [17.8, NA]	40 (35.4%)	NA [5.6, NA]	0.87 [0.60, 1.26]	0.4644	
No	15 (68.2%)	5.6 [1.6, 11.2]	3 (20.0%)	NA [8.5, NA]	4.99 [1.44, 17.34]	0.0045	

Table 6.13 EORTC-QLQ C30 Constipation Symptom: Time to deterioration by at least 10 points by subgroups eCOA-ITT Population

EORTC	KdD (N=281)		Kd (N=128)		Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Refractory to bortezomib							0.1857
Yes	28 (31.5%)	NA [17.8, NA]	17 (35.4%)	NA [3.8, NA]	0.75 [0.41, 1.37]	0.3418	
No	81 (42.2%)	19.2 [12.4, NA]	26 (32.5%)	NA [8.5, NA]	1.20 [0.77, 1.87]	0.4063	
Prior lenalidomide exposure							0.2113
Yes	43 (38.4%)	19.2 [12.2, NA]	24 (39.3%)	8.5 [3.8, NA]	0.83 [0.50, 1.37]	0.4549	
No	66 (39.1%)	NA [12.9, NA]	19 (28.4%)	NA [NA, NA]	1.30 [0.78, 2.16]	0.3122	
Refractory to lenalidomide							0.6300
Yes	32 (36.0%)	NA [12.2, NA]	15 (32.6%)	NA [3.8, NA]	0.92 [0.50, 1.71]	0.7953	
No	77 (40.1%)	18.0 [12.9, NA]	28 (34.1%)	NA [8.5, NA]	1.09 [0.70, 1.67]	0.7092	
Prior IMiD exposure							0.7343
Yes	73 (39.2%)	19.2 [12.0, NA]	32 (35.6%)	NA [5.6, NA]	1.01 [0.66, 1.53]	0.9732	
No	36 (37.9%)	NA [12.9, NA]	11 (28.9%)	NA [10.0, NA]	1.13 [0.58, 2.23]	0.7133	
Refractory to IMiD							0.3707
Yes	39 (33.3%)	NA [19.2, NA]	17 (31.5%)	NA [3.8, NA]	0.85 [0.48, 1.51]	0.5703	
No	70 (42.7%)	17.8 [12.2, NA]	26 (35.1%)	NA [8.5, NA]	1.17 [0.74, 1.83]	0.4938	
International Staging System (ISS)							0.0751
Stage I or II	95 (41.5%)	19.2 [12.4, NA]	36 (33.6%)	NA [10.0, NA]	1.17 [0.80, 1.71]	0.4239	
Stage III	13 (25.5%)	NA [18.0, NA]	7 (33.3%)	NA [2.8, NA]	0.43 [0.16, 1.11]	0.0712	
Prior proteasome inhibitor exposure							0.0177

Table 6.13 EORTC-QLQ C30 Constipation Symptom: Time to deterioration by at least 10 points by subgroups eCOA-ITT Population

EORTC	KdD (N=281)		Kd (N=128)		Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Yes	95 (36.5%)	NA [17.8, NA]	40 (35.1%)	NA [7.2, NA]	0.89 [0.62, 1.29]	0.5385	
No	14 (66.7%)	5.6 [1.9, 15.9]	3 (21.4%)	NA [3.8, NA]	4.55 [1.30, 15.93]	0.0088	
Number of prior lines of therapy							0.6016
1	55 (42.3%)	NA [11.7, NA]	20 (35.1%)	NA [8.5, NA]	1.13 [0.67, 1.88]	0.6463	
>= 2	54 (35.8%)	19.2 [17.8, NA]	23 (32.4%)	NA [5.6, NA]	0.93 [0.57, 1.53]	0.7798	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
NA denotes that the median time (and 95% CI) were not estimable
[a]From Kaplan–Meier estimate
[b]HR: hazard ratio

Table 6.14 EORTC-QLQ C30 Diarrhea Symptom: Time to deterioration by at least 10 points by subgroups eCOA-ITT Population

EORTC	KdD (N=281)		Kd (N=128)		Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Age							0.3895
<= 75	130 (50.6%)	10.3 [8.4, 12.4]	47 (42.0%)	15.0 [9.4, NA]	1.14 [0.82, 1.59]	0.4350	
> 75	16 (66.7%)	5.7 [1.9, 17.8]	6 (37.5%)	15.2 [4.9, NA]	1.73 [0.68, 4.44]	0.2423	
Sex							0.9469
Male	82 (50.9%)	10.3 [7.5, 14.0]	31 (39.7%)	15.5 [9.4, NA]	1.21 [0.80, 1.82]	0.3687	
Female	64 (53.3%)	9.8 [6.5, 15.9]	22 (44.0%)	15.0 [6.8, NA]	1.18 [0.73, 1.92]	0.4968	
Race							0.9990
White	113 (51.4%)	10.3 [7.0, 12.9]	42 (40.4%)	15.5 [8.2, NA]	1.19 [0.84, 1.70]	0.3200	
Non-White	33 (54.1%)	9.3 [5.9, NA]	11 (45.8%)	15.2 [3.3, NA]	1.18 [0.60, 2.34]	0.6268	
Geographic region							0.1774
Europe	85 (46.7%)	12.2 [9.4, 18.7]	34 (40.5%)	15.5 [8.2, NA]	1.07 [0.72, 1.59]	0.7509	
Asia Pacific	48 (59.3%)	8.4 [4.7, 12.4]	13 (38.2%)	14.0 [7.0, NA]	1.62 [0.87, 2.98]	0.1150	
North America	13 (72.2%)	5.6 [1.9, 10.3]	6 (60.0%)	6.6 [0.9, NA]	1.06 [0.40, 2.81]	0.9066	
ECOG performance status							0.3921
0-1	139 (51.9%)	9.8 [7.5, 12.4]	52 (41.6%)	15.2 [9.4, NA]	1.22 [0.89, 1.67]	0.2186	
2	7 (58.3%)	12.4 [4.2, NA]	1 (33.3%)	NA [0.9, NA]	0.15 [0.01, 2.63]	0.1405	
Prior bortezomib or ixazomib exposure							0.7574
Yes	138 (53.3%)	9.6 [7.0, 12.4]	49 (43.4%)	14.0 [9.4, NA]	1.15 [0.83, 1.59]	0.3932	
No	8 (36.4%)	NA [4.7, NA]	4 (26.7%)	NA [4.9, NA]	1.38 [0.42, 4.58]	0.5946	

Table 6.14 EORTC-QLQ C30 Diarrhea Symptom: Time to deterioration by at least 10 points by subgroups eCOA-ITT Population

EORTC	KdD (N=281)		Kd (N=128)		Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Refractory to bortezomib							0.8764
Yes	47 (52.8%)	10.8 [5.7, 14.0]	19 (39.6%)	NA [5.2, NA]	1.27 [0.74, 2.16]	0.3755	
No	99 (51.6%)	10.3 [7.5, 13.1]	34 (42.5%)	15.2 [9.4, NA]	1.18 [0.80, 1.74]	0.4106	
Prior lenalidomide exposure							0.6730
Yes	63 (56.3%)	7.4 [4.9, 10.5]	25 (41.0%)	15.0 [4.9, NA]	1.32 [0.83, 2.10]	0.2318	
No	83 (49.1%)	11.7 [8.4, 17.8]	28 (41.8%)	15.5 [9.7, NA]	1.15 [0.75, 1.77]	0.5165	
Refractory to lenalidomide							0.2924
Yes	50 (56.2%)	6.6 [3.8, 10.8]	16 (34.8%)	15.2 [4.9, NA]	1.57 [0.89, 2.75]	0.1112	
No	96 (50.0%)	11.3 [8.4, 15.9]	37 (45.1%)	14.0 [7.0, NA]	1.07 [0.73, 1.56]	0.7256	
Prior IMiD exposure							0.3357
Yes	104 (55.9%)	7.4 [5.6, 9.8]	39 (43.3%)	14.0 [9.4, NA]	1.36 [0.94, 1.97]	0.0950	
No	42 (44.2%)	17.8 [11.3, NA]	14 (36.8%)	NA [6.6, NA]	0.96 [0.52, 1.76]	0.8878	
Refractory to IMiD							0.3143
Yes	66 (56.4%)	6.6 [4.7, 10.8]	20 (37.0%)	15.0 [9.4, NA]	1.47 [0.89, 2.42]	0.1253	
No	80 (48.8%)	11.7 [9.4, 17.8]	33 (44.6%)	15.5 [7.0, NA]	1.05 [0.70, 1.57]	0.8255	
International Staging System (ISS)							0.0238
Stage I or II	119 (52.0%)	9.3 [7.4, 12.9]	41 (38.3%)	16.4 [10.3, NA]	1.37 [0.96, 1.96]	0.0737	
Stage III	26 (51.0%)	11.3 [6.5, NA]	12 (57.1%)	6.8 [1.9, 15.5]	0.55 [0.28, 1.11]	0.0865	
Prior proteasome inhibitor exposure							0.6142

Table 6.14 EORTC-QLQ C30 Diarrhea Symptom: Time to deterioration by at least 10 points by subgroups eCOA-ITT Population

EORTC	KdD (N=281)		Kd (N=128)		Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Yes	139 (53.5%)	9.6 [7.0, 12.2]	50 (43.9%)	14.0 [8.2, NA]	1.14 [0.82, 1.57]	0.4209	
No	7 (33.3%)	NA [4.7, NA]	3 (21.4%)	NA [4.7, NA]	1.62 [0.42, 6.25]	0.4770	
Number of prior lines of therapy							0.5413
1	63 (48.5%)	11.7 [8.4, 17.8]	21 (36.8%)	16.4 [10.3, NA]	1.33 [0.81, 2.19]	0.2452	
>= 2	83 (55.0%)	7.5 [5.9, 11.3]	32 (45.1%)	10.6 [4.9, NA]	1.10 [0.73, 1.66]	0.6331	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
NA denotes that the median time (and 95% CI) were not estimable
[a]From Kaplan–Meier estimate
[b]HR: hazard ratio

Table 6.9 EORTC-QLQ C30 Pain Symptom: Time to deterioration by at least 10 points by subgroups eCOA-ITT Population

EORTC	KdD (N=281)		Kd (N=128)		Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Age							0.1053
<= 75	147 (57.2%)	8.4 [4.9, 12.2]	65 (58.0%)	5.8 [4.0, 8.9]	0.87 [0.65, 1.16]	0.3321	
> 75	13 (54.2%)	11.5 [4.7, NA]	11 (68.8%)	2.8 [1.3, 9.3]	0.35 [0.14, 0.87]	0.0161	
Sex							0.7426
Male	96 (59.6%)	7.5 [3.8, 12.2]	46 (59.0%)	4.7 [2.8, 9.3]	0.85 [0.60, 1.21]	0.3537	
Female	64 (53.3%)	11.2 [5.6, 16.3]	30 (60.0%)	5.6 [4.0, 8.4]	0.77 [0.50, 1.19]	0.2302	
Race							0.7236
White	124 (56.4%)	10.3 [5.9, 13.8]	61 (58.7%)	4.7 [3.8, 8.4]	0.78 [0.57, 1.06]	0.1051	
Non-White	36 (59.0%)	5.6 [3.1, NA]	15 (62.5%)	6.5 [2.8, 14.3]	0.94 [0.51, 1.71]	0.8262	
Geographic region							0.3777
Europe	101 (55.5%)	10.5 [5.9, 14.0]	53 (63.1%)	4.0 [3.1, 7.5]	0.69 [0.50, 0.97]	0.0273	
Asia Pacific	49 (60.5%)	5.6 [2.8, 12.2]	18 (52.9%)	5.6 [3.1, NA]	1.06 [0.62, 1.82]	0.8366	
North America	10 (55.6%)	7.2 [1.0, NA]	5 (50.0%)	6.8 [1.0, NA]	0.97 [0.33, 2.87]	0.9574	
ECOG performance status							0.8603
0-1	155 (57.8%)	8.4 [5.6, 11.7]	75 (60.0%)	4.9 [3.8, 8.4]	0.82 [0.62, 1.08]	0.1474	
2	5 (41.7%)	20.6 [1.0, 20.6]	1 (33.3%)	5.6 [, NA]	0.71 [0.08, 6.45]	0.7524	
Prior bortezomib or ixazomib exposure							0.6494
Yes	147 (56.8%)	8.4 [5.2, 12.2]	69 (61.1%)	4.9 [3.8, 7.7]	0.78 [0.59, 1.05]	0.0877	
No	13 (59.1%)	13.8 [2.8, NA]	7 (46.7%)	19.2 [1.3, 19.2]	0.98 [0.39, 2.47]	0.9607	

Table 6.9 EORTC-QLQ C30 Pain Symptom: Time to deterioration by at least 10 points by subgroups eCOA-ITT Population

EORTC	KdD (N=281)		Kd (N=128)		Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Refractory to bortezomib							0.1591
Yes	48 (53.9%)	7.5 [3.8, 15.9]	25 (52.1%)	9.3 [4.0, 14.3]	1.06 [0.65, 1.71]	0.8226	
No	112 (58.3%)	8.5 [5.6, 13.1]	51 (63.8%)	3.8 [2.8, 6.8]	0.69 [0.50, 0.97]	0.0273	
Prior lenalidomide exposure							0.2225
Yes	65 (58.0%)	5.6 [3.8, 12.4]	33 (54.1%)	5.6 [4.0, 19.2]	1.00 [0.66, 1.53]	0.9859	
No	95 (56.2%)	10.5 [5.7, 14.0]	43 (64.2%)	4.1 [3.1, 8.4]	0.69 [0.48, 0.99]	0.0360	
Refractory to lenalidomide							0.0880
Yes	53 (59.6%)	5.9 [3.8, 12.4]	21 (45.7%)	7.5 [4.0, NA]	1.16 [0.69, 1.93]	0.5706	
No	107 (55.7%)	9.6 [5.6, 13.8]	55 (67.1%)	4.1 [2.8, 7.7]	0.68 [0.49, 0.94]	0.0150	
Prior IMiD exposure							0.2076
Yes	106 (57.0%)	5.9 [3.8, 11.3]	52 (57.8%)	6.5 [4.0, 8.9]	0.92 [0.66, 1.29]	0.6236	
No	54 (56.8%)	12.2 [7.1, 15.3]	24 (63.2%)	3.8 [2.8, 9.3]	0.59 [0.36, 0.96]	0.0272	
Refractory to IMiD							0.0906
Yes	69 (59.0%)	5.6 [3.8, 11.5]	26 (48.1%)	7.5 [4.0, NA]	1.11 [0.70, 1.74]	0.6548	
No	91 (55.5%)	10.5 [5.7, 14.2]	50 (67.6%)	4.0 [2.8, 8.4]	0.66 [0.46, 0.93]	0.0141	
International Staging System (ISS)							0.6130
Stage I or II	132 (57.6%)	7.1 [4.9, 12.2]	64 (59.8%)	5.6 [3.8, 8.9]	0.84 [0.62, 1.13]	0.2291	
Stage III	28 (54.9%)	11.2 [4.7, 16.3]	12 (57.1%)	4.9 [1.9, 8.4]	0.64 [0.32, 1.29]	0.1986	
Prior proteasome inhibitor exposure							0.5468

Table 6.9 EORTC-QLQ C30 Pain Symptom: Time to deterioration by at least 10 points by subgroups eCOA-ITT Population

EORTC	KdD (N=281)		Kd (N=128)		Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Yes	148 (56.9%)	8.4 [5.2, 11.7]	70 (61.4%)	4.9 [3.8, 7.7]	0.78 [0.58, 1.04]	0.0771	
No	12 (57.1%)	13.8 [2.8, NA]	6 (42.9%)	19.2 [1.9, 19.2]	1.04 [0.39, 2.79]	0.9399	
Number of prior lines of therapy							0.4301
1	72 (55.4%)	11.7 [5.7, 15.9]	35 (61.4%)	4.9 [2.8, 8.4]	0.73 [0.49, 1.10]	0.1169	
>= 2	88 (58.3%)	6.6 [4.7, 10.3]	41 (57.7%)	5.6 [3.8, 11.3]	0.89 [0.61, 1.30]	0.5421	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
NA denotes that the median time (and 95% CI) were not estimable
[a]From Kaplan–Meier estimate
[b]HR: hazard ratio

Table 6.8 EORTC-QLQ C30 Nausea/Vomiting Symptom: Time to deterioration by at least 10 points by subgroups eCOA-ITT Population

EORTC	KdD (N=281)		Kd (N=128)		Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Age							0.6623
<= 75	130 (50.6%)	12.4 [8.4, 15.9]	40 (35.7%)	17.8 [14.0, NA]	1.43 [1.01, 2.04]	0.0418	
> 75	10 (41.7%)	18.7 [4.7, NA]	5 (31.3%)	NA [6.8, NA]	1.16 [0.40, 3.41]	0.7830	
Sex							0.6234
Male	69 (42.9%)	17.3 [13.1, NA]	21 (26.9%)	NA [16.4, NA]	1.52 [0.93, 2.48]	0.0872	
Female	71 (59.2%)	6.6 [4.7, 10.3]	24 (48.0%)	10.3 [5.6, NA]	1.29 [0.81, 2.05]	0.2653	
Race							0.6627
White	106 (48.2%)	13.2 [8.4, 18.7]	36 (34.6%)	17.8 [14.0, NA]	1.35 [0.92, 1.97]	0.1143	
Non-White	34 (55.7%)	10.3 [5.6, 16.1]	9 (37.5%)	NA [6.6, NA]	1.67 [0.80, 3.48]	0.1630	
Geographic region							0.9527
Europe	84 (46.2%)	14.0 [10.3, NA]	27 (32.1%)	NA [10.3, NA]	1.42 [0.92, 2.19]	0.1061	
Asia Pacific	44 (54.3%)	9.4 [4.7, 16.1]	15 (44.1%)	14.8 [6.6, NA]	1.24 [0.69, 2.23]	0.4641	
North America	12 (66.7%)	6.6 [1.9, NA]	3 (30.0%)	NA [0.9, NA]	2.05 [0.57, 7.34]	0.2550	
ECOG performance status							0.6812
0-1	132 (49.3%)	13.1 [8.4, 17.3]	44 (35.2%)	17.8 [14.0, NA]	1.42 [1.01, 1.99]	0.0416	
2	8 (66.7%)	5.6 [2.8, NA]	1 (33.3%)	NA [2.8, NA]	0.43 [0.04, 4.77]	0.4675	
Prior bortezomib or ixazomib exposure							0.9191
Yes	130 (50.2%)	12.9 [6.8, 16.1]	40 (35.4%)	17.8 [14.0, NA]	1.40 [0.98, 2.00]	0.0559	
No	10 (45.5%)	15.9 [5.6, NA]	5 (33.3%)	14.8 [6.6, NA]	1.20 [0.41, 3.52]	0.7403	

Table 6.8 EORTC-QLQ C30 Nausea/Vomiting Symptom: Time to deterioration by at least 10 points by subgroups eCOA-ITT Population

EORTC	KdD (N=281)		Kd (N=128)		Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Refractory to bortezomib							0.5500
Yes	45 (50.6%)	6.6 [4.7, 18.7]	15 (31.3%)	NA [10.3, NA]	1.61 [0.90, 2.89]	0.1028	
No	95 (49.5%)	14.0 [9.4, 17.8]	30 (37.5%)	17.8 [10.3, NA]	1.31 [0.87, 1.97]	0.1941	
Prior lenalidomide exposure							0.4207
Yes	53 (47.3%)	14.0 [6.6, NA]	22 (36.1%)	14.8 [9.4, NA]	1.20 [0.73, 1.97]	0.4754	
No	87 (51.5%)	12.9 [5.7, 16.1]	23 (34.3%)	NA [16.4, NA]	1.58 [1.00, 2.50]	0.0465	
Refractory to lenalidomide							0.2925
Yes	43 (48.3%)	14.0 [6.6, NA]	17 (37.0%)	14.8 [6.6, NA]	1.09 [0.62, 1.93]	0.7505	
No	97 (50.5%)	12.9 [6.8, 15.9]	28 (34.1%)	NA [14.0, NA]	1.59 [1.04, 2.42]	0.0267	
Prior IMiD exposure							0.4507
Yes	101 (54.3%)	10.3 [5.6, 14.0]	33 (36.7%)	17.0 [10.3, NA]	1.56 [1.05, 2.31]	0.0235	
No	39 (41.1%)	18.7 [12.2, NA]	12 (31.6%)	NA [8.0, NA]	1.16 [0.61, 2.22]	0.6491	
Refractory to IMiD							0.3044
Yes	58 (49.6%)	12.4 [6.6, 17.8]	20 (37.0%)	14.8 [6.6, 17.0]	1.11 [0.67, 1.85]	0.6813	
No	82 (50.0%)	13.1 [6.8, 18.7]	25 (33.8%)	NA [14.0, NA]	1.61 [1.03, 2.52]	0.0335	
International Staging System (ISS)							0.0190
Stage I or II	115 (50.2%)	13.2 [8.0, 17.3]	35 (32.7%)	NA [14.8, NA]	1.62 [1.11, 2.37]	0.0101	
Stage III	24 (47.1%)	12.2 [5.6, NA]	10 (47.6%)	3.8 [1.9, NA]	0.53 [0.25, 1.14]	0.0931	
Prior proteasome inhibitor exposure							0.6575

Table 6.8 EORTC-QLQ C30 Nausea/Vomiting Symptom: Time to deterioration by at least 10 points by subgroups eCOA-ITT Population

EORTC	KdD (N=281)		Kd (N=128)		Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Yes	130 (50.0%)	12.9 [8.0, 16.1]	41 (36.0%)	17.8 [14.0, NA]	1.36 [0.96, 1.93]	0.0804	
No	10 (47.6%)	15.9 [3.8, NA]	4 (28.6%)	NA [6.6, NA]	1.60 [0.50, 5.12]	0.4171	
Number of prior lines of therapy							0.5762
1	60 (46.2%)	15.9 [10.5, NA]	18 (31.6%)	NA [14.0, NA]	1.56 [0.92, 2.64]	0.0914	
>= 2	80 (53.0%)	9.4 [5.6, 15.7]	27 (38.0%)	16.4 [9.4, NA]	1.29 [0.83, 2.00]	0.2461	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
NA denotes that the median time (and 95% CI) were not estimable
[a]From Kaplan–Meier estimate
[b]HR: hazard ratio

Table 6.7 EORTC-QLQ C30 Fatigue Symptom: Time to deterioration by at least 10 points by subgroups eCOA-ITT Population

EORTC	KdD (N=281)		Kd (N=128)		Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Age							0.1671
<= 75	193 (75.1%)	2.8 [1.9, 2.9]	77 (68.8%)	2.8 [1.9, 3.3]	1.05 [0.81, 1.37]	0.6824	
> 75	19 (79.2%)	2.8 [1.0, 3.8]	14 (87.5%)	1.0 [1.0, 2.9]	0.65 [0.32, 1.31]	0.1888	
Sex							0.6638
Male	122 (75.8%)	2.8 [1.9, 2.9]	53 (67.9%)	2.8 [1.9, 3.8]	1.03 [0.75, 1.43]	0.8302	
Female	90 (75.0%)	2.1 [1.3, 3.8]	38 (76.0%)	2.1 [1.9, 2.9]	0.92 [0.63, 1.34]	0.6266	
Race							0.2723
White	163 (74.1%)	2.8 [1.9, 3.7]	73 (70.2%)	2.2 [1.9, 2.9]	0.91 [0.69, 1.20]	0.4747	
Non-White	49 (80.3%)	1.0 [1.0, 1.9]	18 (75.0%)	2.9 [1.0, 4.7]	1.28 [0.75, 2.21]	0.3262	
Geographic region							0.3541
Europe	137 (75.3%)	2.8 [1.9, 3.8]	60 (71.4%)	2.8 [1.9, 3.0]	0.95 [0.70, 1.29]	0.7252	
Asia Pacific	63 (77.8%)	1.4 [1.0, 1.9]	23 (67.6%)	2.8 [1.0, 4.7]	1.16 [0.72, 1.87]	0.5026	
North America	12 (66.7%)	4.3 [1.0, 18.7]	8 (80.0%)	1.5 [0.9, 6.5]	0.53 [0.20, 1.39]	0.1616	
ECOG performance status							0.5594
0-1	201 (75.0%)	2.8 [1.9, 2.8]	90 (72.0%)	2.2 [1.9, 2.9]	0.97 [0.75, 1.24]	0.7911	
2	10 (83.3%)	3.8 [1.0, 11.2]	1 (33.3%)	3.8 [, NA]	1.43 [0.17, 11.68]	0.7025	
Prior bortezomib or ixazomib exposure							0.0976
Yes	194 (74.9%)	2.8 [1.9, 3.1]	83 (73.5%)	2.2 [1.9, 2.9]	0.92 [0.71, 1.19]	0.5107	
No	18 (81.8%)	1.9 [1.0, 2.8]	8 (53.3%)	6.1 [1.0, NA]	1.98 [0.85, 4.64]	0.0775	

Table 6.7 EORTC-QLQ C30 Fatigue Symptom: Time to deterioration by at least 10 points by subgroups eCOA-ITT Population

EORTC	KdD (N=281)		Kd (N=128)		Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Refractory to bortezomib							0.7735
Yes	62 (69.7%)	2.8 [1.9, 4.7]	33 (68.8%)	2.8 [1.9, 4.0]	1.05 [0.68, 1.60]	0.8285	
No	150 (78.1%)	2.4 [1.9, 2.8]	58 (72.5%)	2.3 [1.9, 2.9]	0.95 [0.70, 1.29]	0.7305	
Prior lenalidomide exposure							0.3154
Yes	83 (74.1%)	1.9 [1.2, 3.7]	41 (67.2%)	2.9 [2.1, 3.8]	1.16 [0.79, 1.70]	0.4131	
No	129 (76.3%)	2.8 [1.9, 3.1]	50 (74.6%)	1.9 [1.0, 2.8]	0.86 [0.62, 1.20]	0.3464	
Refractory to lenalidomide							0.2410
Yes	64 (71.9%)	2.8 [1.8, 4.1]	28 (60.9%)	3.3 [2.2, 7.7]	1.26 [0.80, 1.98]	0.2983	
No	148 (77.1%)	2.1 [1.9, 2.8]	63 (76.8%)	1.9 [1.8, 2.8]	0.87 [0.65, 1.17]	0.3257	
Prior IMiD exposure							0.4868
Yes	137 (73.7%)	1.9 [1.8, 2.8]	63 (70.0%)	2.8 [1.9, 3.3]	1.06 [0.78, 1.43]	0.6973	
No	75 (78.9%)	2.8 [1.9, 4.7]	28 (73.7%)	1.9 [1.0, 3.1]	0.84 [0.54, 1.30]	0.4001	
Refractory to IMiD							0.0625
Yes	86 (73.5%)	1.9 [1.2, 3.1]	33 (61.1%)	3.0 [2.3, 7.7]	1.36 [0.91, 2.05]	0.1138	
No	126 (76.8%)	2.8 [1.9, 3.8]	58 (78.4%)	1.9 [1.0, 2.8]	0.80 [0.58, 1.09]	0.1281	
International Staging System (ISS)							0.6655
Stage I or II	176 (76.9%)	2.8 [1.9, 2.8]	79 (73.8%)	2.3 [1.9, 2.9]	0.97 [0.74, 1.26]	0.7937	
Stage III	36 (70.6%)	2.8 [1.2, 10.3]	12 (57.1%)	3.3 [1.9, NA]	1.18 [0.61, 2.29]	0.5955	
Prior proteasome inhibitor exposure							0.0716

Table 6.7 EORTC-QLQ C30 Fatigue Symptom: Time to deterioration by at least 10 points by subgroups eCOA-ITT Population

EORTC	KdD (N=281)		Kd (N=128)		Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Yes	195 (75.0%)	2.8 [1.9, 3.1]	84 (73.7%)	2.2 [1.9, 2.9]	0.92 [0.71, 1.18]	0.4700	
No	17 (81.0%)	1.9 [1.0, 2.8]	7 (50.0%)	6.1 [1.0, NA]	2.23 [0.91, 5.49]	0.0501	
Number of prior lines of therapy							0.3891
1	102 (78.5%)	1.9 [1.2, 2.9]	44 (77.2%)	1.9 [1.0, 2.8]	0.88 [0.61, 1.25]	0.4209	
>= 2	110 (72.8%)	2.8 [1.9, 3.7]	47 (66.2%)	2.8 [1.9, 4.0]	1.10 [0.78, 1.55]	0.5767	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
NA denotes that the median time (and 95% CI) were not estimable
[a]From Kaplan–Meier estimate
[b]HR: hazard ratio

Table 6.10 EORTC-QLQ C30 Dyspnea Symptom: Time to deterioration by at least 10 points by subgroups eCOA-ITT Population

EORTC	KdD (N=281)		Kd (N=128)		Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Age							0.0324
<= 75	166 (64.6%)	3.8 [2.8, 5.6]	69 (61.6%)	3.8 [2.2, 6.6]	0.95 [0.71, 1.25]	0.6846	
> 75	14 (58.3%)	4.7 [1.9, NA]	13 (81.3%)	1.9 [1.0, 3.7]	0.41 [0.19, 0.89]	0.0167	
Sex							0.5465
Male	104 (64.6%)	3.8 [2.8, 5.6]	48 (61.5%)	3.8 [2.8, 5.4]	0.91 [0.65, 1.29]	0.5878	
Female	76 (63.3%)	3.8 [2.8, 6.6]	34 (68.0%)	2.2 [1.9, 5.7]	0.78 [0.52, 1.17]	0.2052	
Race							0.6394
White	138 (62.7%)	4.7 [3.8, 6.6]	65 (62.5%)	3.7 [2.1, 5.2]	0.82 [0.61, 1.10]	0.1636	
Non-White	42 (68.9%)	1.9 [1.8, 3.1]	17 (70.8%)	2.9 [1.0, 7.5]	0.98 [0.56, 1.72]	0.9411	
Geographic region							0.0029
Europe	110 (60.4%)	5.6 [3.8, 9.8]	47 (56.0%)	4.7 [2.8, 7.5]	0.92 [0.65, 1.30]	0.6305	
Asia Pacific	60 (74.1%)	1.9 [1.9, 2.8]	25 (73.5%)	1.9 [1.0, 5.0]	0.94 [0.59, 1.50]	0.7867	
North America	10 (55.6%)	9.4 [1.9, 22.9]	10 (100.0%)	1.5 [0.9, 2.2]	0.25 [0.10, 0.64]	0.0014	
ECOG performance status							0.9691
0-1	173 (64.6%)	3.8 [2.8, 5.6]	82 (65.6%)	3.1 [1.9, 5.0]	0.85 [0.65, 1.11]	0.2087	
2	6 (50.0%)	4.7 [1.9, NA]	0 (0.0%)	NA [NA, NA]	NA [NA, NA]	0.2931	
Prior bortezomib or ixazomib exposure							0.3143
Yes	162 (62.5%)	4.0 [2.9, 5.6]	70 (61.9%)	3.1 [2.1, 5.4]	0.85 [0.64, 1.12]	0.2322	
No	18 (81.8%)	1.9 [1.0, 3.8]	12 (80.0%)	4.7 [1.0, 7.5]	1.31 [0.62, 2.78]	0.4481	

Table 6.10 EORTC-QLQ C30 Dyspnea Symptom: Time to deterioration by at least 10 points by subgroups eCOA-ITT Population

EORTC	KdD (N=281)		Kd (N=128)		Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Refractory to bortezomib							0.9492
Yes	49 (55.1%)	5.6 [2.8, 13.1]	27 (56.3%)	3.8 [1.9, NA]	0.89 [0.55, 1.42]	0.5951	
No	131 (68.2%)	3.1 [2.8, 4.7]	55 (68.8%)	3.1 [2.1, 5.0]	0.84 [0.61, 1.15]	0.2542	
Prior lenalidomide exposure							0.6772
Yes	67 (59.8%)	3.8 [2.8, 11.2]	37 (60.7%)	2.9 [1.9, 6.6]	0.82 [0.54, 1.22]	0.3109	
No	113 (66.9%)	3.8 [2.8, 5.6]	45 (67.2%)	3.7 [1.9, 5.4]	0.89 [0.63, 1.26]	0.4947	
Refractory to lenalidomide							0.6250
Yes	51 (57.3%)	5.6 [2.8, 17.0]	26 (56.5%)	2.9 [1.9, 6.6]	0.81 [0.50, 1.30]	0.3660	
No	129 (67.2%)	3.8 [2.8, 4.7]	56 (68.3%)	3.8 [1.9, 5.2]	0.89 [0.65, 1.22]	0.4558	
Prior IMiD exposure							0.3950
Yes	122 (65.6%)	2.8 [2.0, 4.0]	58 (64.4%)	3.8 [1.9, 5.6]	0.95 [0.69, 1.30]	0.7351	
No	58 (61.1%)	6.6 [3.8, 12.4]	24 (63.2%)	3.1 [1.9, 9.4]	0.72 [0.45, 1.16]	0.1625	
Refractory to IMiD							0.9967
Yes	72 (61.5%)	4.0 [2.8, 10.6]	31 (57.4%)	2.9 [1.9, 6.6]	0.87 [0.57, 1.33]	0.5159	
No	108 (65.9%)	3.8 [2.8, 5.6]	51 (68.9%)	3.8 [1.9, 5.4]	0.86 [0.61, 1.20]	0.3479	
International Staging System (ISS)							0.1627
Stage I or II	152 (66.4%)	3.8 [2.8, 4.7]	76 (71.0%)	2.9 [1.9, 3.8]	0.81 [0.62, 1.07]	0.1214	
Stage III	27 (52.9%)	8.4 [2.9, NA]	6 (28.6%)	NA [1.9, NA]	1.55 [0.64, 3.78]	0.3201	
Prior proteasome inhibitor exposure							0.2687

Table 6.10 EORTC-QLQ C30 Dyspnea Symptom: Time to deterioration by at least 10 points by subgroups eCOA-ITT Population

EORTC	KdD (N=281)		Kd (N=128)		Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Yes	163 (62.7%)	4.0 [2.9, 5.6]	71 (62.3%)	2.9 [1.9, 5.4]	0.84 [0.64, 1.11]	0.2086	
No	17 (81.0%)	1.9 [1.0, 3.8]	11 (78.6%)	4.7 [1.0, 7.5]	1.40 [0.64, 3.05]	0.3651	
Number of prior lines of therapy							0.2609
1	92 (70.8%)	2.9 [2.8, 4.7]	45 (78.9%)	3.1 [1.9, 4.7]	0.71 [0.50, 1.02]	0.0525	
>= 2	88 (58.3%)	4.7 [2.9, 9.4]	37 (52.1%)	3.8 [1.9, NA]	1.01 [0.69, 1.48]	0.9639	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
NA denotes that the median time (and 95% CI) were not estimable
[a]From Kaplan–Meier estimate
[b]HR: hazard ratio

Table 6.15 EORTC-QLQ C30 Financial Difficulties: Time to deterioration by at least 10 points by subgroups eCOA-ITT Population

EORTC	KdD (N=281)		Kd (N=128)		Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Age							0.9777
<= 75	111 (43.2%)	17.8 [11.2, NA]	52 (46.4%)	13.1 [5.6, NA]	0.82 [0.59, 1.14]	0.2327	
> 75	8 (33.3%)	NA [5.7, NA]	5 (31.3%)	NA [2.8, NA]	0.79 [0.25, 2.45]	0.6743	
Sex							0.5708
Male	65 (40.4%)	NA [11.3, NA]	32 (41.0%)	13.2 [5.6, NA]	0.89 [0.58, 1.37]	0.5998	
Female	54 (45.0%)	16.8 [7.5, NA]	25 (50.0%)	7.5 [4.0, NA]	0.74 [0.46, 1.19]	0.2048	
Race							0.9525
White	97 (44.1%)	16.8 [8.8, NA]	48 (46.2%)	10.3 [5.6, NA]	0.83 [0.59, 1.18]	0.2984	
Non-White	22 (36.1%)	NA [11.3, NA]	9 (37.5%)	NA [4.7, NA]	0.83 [0.38, 1.81]	0.6278	
Geographic region							0.1486
Europe	86 (47.3%)	12.2 [8.4, NA]	40 (47.6%)	13.1 [5.4, NA]	0.90 [0.62, 1.31]	0.5695	
Asia Pacific	28 (34.6%)	NA [16.4, NA]	15 (44.1%)	11.2 [3.1, NA]	0.64 [0.34, 1.20]	0.1555	
North America	5 (27.8%)	NA [7.5, NA]	2 (20.0%)	NA [1.0, NA]	1.20 [0.23, 6.23]	0.8270	
ECOG performance status							0.9012
0-1	116 (43.3%)	17.5 [11.2, NA]	56 (44.8%)	13.1 [6.8, NA]	0.86 [0.62, 1.18]	0.3428	
2	3 (25.0%)	NA [4.7, NA]	1 (33.3%)	5.6 [, NA]	0.22 [0.02, 2.45]	0.1762	
Prior bortezomib or ixazomib exposure							0.2212
Yes	111 (42.9%)	17.5 [11.2, NA]	49 (43.4%)	13.2 [7.5, NA]	0.88 [0.63, 1.24]	0.4627	
No	8 (36.4%)	NA [2.8, NA]	8 (53.3%)	3.8 [1.9, NA]	0.58 [0.21, 1.55]	0.2562	

Table 6.15 EORTC-QLQ C30 Financial Difficulties: Time to deterioration by at least 10 points by subgroups eCOA-ITT Population

EORTC	KdD (N=281)		Kd (N=128)		Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Refractory to bortezomib							0.8048
Yes	39 (43.8%)	16.8 [5.7, NA]	22 (45.8%)	11.2 [4.7, NA]	0.90 [0.54, 1.53]	0.6986	
No	80 (41.7%)	NA [11.3, NA]	35 (43.8%)	14.0 [6.8, NA]	0.83 [0.55, 1.23]	0.3391	
Prior lenalidomide exposure							0.8329
Yes	40 (35.7%)	NA [17.5, NA]	24 (39.3%)	13.2 [5.6, NA]	0.81 [0.49, 1.35]	0.4070	
No	79 (46.7%)	16.1 [8.5, NA]	33 (49.3%)	11.2 [4.7, NA]	0.83 [0.56, 1.25]	0.3727	
Refractory to lenalidomide							0.5537
Yes	30 (33.7%)	NA [NA, NA]	18 (39.1%)	13.2 [5.6, NA]	0.76 [0.42, 1.36]	0.3466	
No	89 (46.4%)	12.9 [8.8, NA]	39 (47.6%)	11.2 [5.4, NA]	0.87 [0.59, 1.26]	0.4476	
Prior IMiD exposure							0.9882
Yes	69 (37.1%)	NA [17.5, NA]	37 (41.1%)	13.2 [6.8, NA]	0.84 [0.56, 1.25]	0.3776	
No	50 (52.6%)	11.3 [6.6, 17.8]	20 (52.6%)	7.5 [4.0, NA]	0.80 [0.48, 1.35]	0.3970	
Refractory to IMiD							0.4401
Yes	40 (34.2%)	NA [NA, NA]	21 (38.9%)	13.1 [5.6, NA]	0.75 [0.44, 1.28]	0.2795	
No	79 (48.2%)	11.7 [8.4, NA]	36 (48.6%)	11.2 [4.7, NA]	0.90 [0.61, 1.34]	0.6129	
International Staging System (ISS)							0.5308
Stage I or II	90 (39.3%)	NA [16.4, NA]	47 (43.9%)	13.2 [7.5, NA]	0.78 [0.55, 1.12]	0.1712	
Stage III	29 (56.9%)	6.6 [3.8, 16.1]	10 (47.6%)	5.6 [2.8, NA]	0.98 [0.48, 2.03]	0.9628	
Prior proteasome inhibitor exposure							0.2227

Table 6.15 EORTC-QLQ C30 Financial Difficulties: Time to deterioration by at least 10 points by subgroups eCOA-ITT Population

EORTC	KdD (N=281)		Kd (N=128)		Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Yes	112 (43.1%)	17.5 [11.2, NA]	50 (43.9%)	13.2 [6.8, NA]	0.88 [0.63, 1.23]	0.4363	
No	7 (33.3%)	NA [2.8, NA]	7 (50.0%)	3.8 [1.9, NA]	0.55 [0.19, 1.57]	0.2441	
Number of prior lines of therapy							0.8893
1	62 (47.7%)	16.1 [6.6, NA]	29 (50.9%)	7.5 [4.7, NA]	0.84 [0.54, 1.31]	0.4396	
>= 2	57 (37.7%)	NA [11.7, NA]	28 (39.4%)	13.2 [5.6, NA]	0.83 [0.53, 1.30]	0.4026	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
NA denotes that the median time (and 95% CI) were not estimable
[a]From Kaplan–Meier estimate
[b]HR: hazard ratio

Table 6.1 EORTC-QLQ C30 Global Health status: Time to deterioration by at least 10 points by subgroups eCOA-ITT Population

EORTC	KdD (N=281)		Kd (N=128)		Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Age							0.6917
<= 75	144 (56.0%)	6.6 [4.8, 12.1]	65 (58.0%)	4.7 [3.1, 7.5]	0.82 [0.61, 1.10]	0.1626	
> 75	17 (70.8%)	2.8 [1.9, 10.3]	10 (62.5%)	1.9 [1.0, NA]	0.95 [0.43, 2.09]	0.8825	
Sex							0.8446
Male	92 (57.1%)	7.5 [5.6, 12.4]	45 (57.7%)	4.7 [2.8, 8.1]	0.79 [0.55, 1.13]	0.1810	
Female	69 (57.5%)	4.7 [2.8, 11.7]	30 (60.0%)	3.8 [1.9, 8.4]	0.86 [0.56, 1.32]	0.4629	
Race							0.2393
White	124 (56.4%)	6.5 [4.7, 12.1]	63 (60.6%)	3.8 [2.2, 6.6]	0.76 [0.56, 1.03]	0.0666	
Non-White	37 (60.7%)	6.5 [2.8, 14.2]	12 (50.0%)	7.5 [1.9, NA]	1.15 [0.60, 2.20]	0.6753	
Geographic region							0.8358
Europe	96 (52.7%)	9.6 [5.6, 15.9]	50 (59.5%)	3.8 [2.0, 7.7]	0.69 [0.49, 0.98]	0.0296	
Asia Pacific	54 (66.7%)	3.7 [2.0, 7.5]	19 (55.9%)	6.6 [1.9, NA]	1.17 [0.69, 1.97]	0.5512	
North America	11 (61.1%)	1.9 [1.9, NA]	6 (60.0%)	6.1 [1.0, NA]	1.08 [0.39, 3.00]	0.8718	
ECOG performance status							0.9726
0-1	159 (59.3%)	5.9 [3.8, 9.3]	75 (60.0%)	4.0 [2.3, 7.5]	0.85 [0.64, 1.12]	0.2260	
2	1 (8.3%)	NA [NA, NA]	0 (0.0%)	NA [NA, NA]	NA [NA, NA]	0.7630	
Prior bortezomib or ixazomib exposure							0.9183
Yes	148 (57.1%)	6.6 [4.7, 11.7]	65 (57.5%)	4.7 [3.0, 7.7]	0.83 [0.62, 1.12]	0.2060	
No	13 (59.1%)	1.9 [1.0, NA]	10 (66.7%)	1.9 [1.0, NA]	0.82 [0.36, 1.87]	0.6076	

Table 6.1 EORTC-QLQ C30 Global Health status: Time to deterioration by at least 10 points by subgroups eCOA-ITT Population

EORTC	KdD (N=281)		Kd (N=128)		Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Refractory to bortezomib or ixazomib							0.6638
Yes	47 (52.8%)	7.5 [3.8, 16.8]	27 (56.3%)	4.7 [1.9, 11.3]	0.75 [0.46, 1.21]	0.2177	
No	114 (59.4%)	6.1 [3.7, 10.9]	48 (60.0%)	4.0 [2.2, 8.1]	0.86 [0.61, 1.21]	0.3697	
Prior lenalidomide exposure							0.2381
Yes	59 (52.7%)	6.6 [3.7, NA]	37 (60.7%)	3.7 [1.9, 6.6]	0.70 [0.47, 1.06]	0.0830	
No	102 (60.4%)	6.1 [3.8, 11.2]	38 (56.7%)	6.6 [3.1, 11.3]	0.94 [0.65, 1.37]	0.7568	
Refractory to lenalidomide							0.4573
Yes	47 (52.8%)	6.6 [3.8, NA]	26 (56.5%)	4.0 [1.9, 18.8]	0.72 [0.44, 1.16]	0.1674	
No	114 (59.4%)	6.1 [3.7, 11.2]	49 (59.8%)	4.7 [2.1, 8.1]	0.89 [0.63, 1.24]	0.4612	
Prior IMiD exposure							0.2597
Yes	103 (55.4%)	5.6 [3.1, 9.3]	56 (62.2%)	3.8 [1.9, 6.6]	0.76 [0.55, 1.05]	0.0847	
No	58 (61.1%)	9.6 [4.7, 12.4]	19 (50.0%)	7.7 [3.0, NA]	1.03 [0.61, 1.73]	0.9152	
Refractory to IMiD							0.9465
Yes	66 (56.4%)	5.6 [2.8, 10.3]	30 (55.6%)	4.0 [1.9, 11.3]	0.83 [0.54, 1.27]	0.3731	
No	95 (57.9%)	7.5 [4.7, 12.2]	45 (60.8%)	4.7 [2.1, 8.1]	0.83 [0.58, 1.18]	0.2808	
International Staging System (ISS)							0.5229
Stage I or II	136 (59.4%)	5.9 [3.8, 9.3]	68 (63.6%)	3.8 [2.2, 6.6]	0.81 [0.60, 1.08]	0.1379	
Stage III	25 (49.0%)	12.4 [2.8, NA]	7 (33.3%)	NA [1.9, NA]	1.19 [0.51, 2.78]	0.6704	
Prior proteasome inhibitor exposure							0.9977

Table 6.1 EORTC-QLQ C30 Global Health status: Time to deterioration by at least 10 points by subgroups eCOA-ITT Population

EORTC	KdD (N=281)		Kd (N=128)		Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Yes	149 (57.3%)	6.6 [4.7, 11.2]	66 (57.9%)	4.7 [3.0, 7.7]	0.83 [0.62, 1.11]	0.1840	
No	12 (57.1%)	1.9 [1.6, NA]	9 (64.3%)	1.9 [1.0, NA]	0.85 [0.36, 2.03]	0.7007	
Number of prior lines of therapy							0.9652
1	79 (60.8%)	5.9 [3.7, 11.7]	37 (64.9%)	3.8 [2.1, 7.7]	0.82 [0.55, 1.21]	0.2882	
>= 2	82 (54.3%)	7.5 [3.8, 16.1]	38 (53.5%)	4.7 [1.9, 18.8]	0.84 [0.57, 1.24]	0.3666	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
NA denotes that the median time (and 95% CI) were not estimable
[a]From Kaplan–Meier estimate
[b]HR: hazard ratio

Table 6.2 EORTC-QLQ C30 Physical Functioning: Time to deterioration by at least 10 points by subgroups eCOA-ITT Population

EORTC	KdD (N=281)		Kd (N=128)		Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Age							0.5028
<= 75	156 (60.7%)	6.5 [4.7, 10.6]	69 (61.6%)	4.7 [2.9, 5.8]	0.85 [0.64, 1.13]	0.2422	
> 75	15 (62.5%)	4.7 [1.9, NA]	8 (50.0%)	3.7 [1.9, NA]	1.15 [0.48, 2.74]	0.7414	
Sex							0.9171
Male	94 (58.4%)	6.8 [4.7, 11.7]	45 (57.7%)	4.1 [2.9, 7.7]	0.87 [0.61, 1.24]	0.4255	
Female	77 (64.2%)	5.6 [2.9, 9.8]	32 (64.0%)	4.7 [2.2, 8.9]	0.89 [0.59, 1.35]	0.5843	
Race							0.1729
White	130 (59.1%)	7.9 [4.7, 11.5]	64 (61.5%)	4.7 [2.9, 6.5]	0.79 [0.58, 1.07]	0.1123	
Non-White	41 (67.2%)	4.4 [1.9, 6.5]	13 (54.2%)	4.1 [1.9, NA]	1.29 [0.69, 2.42]	0.4048	
Geographic region							0.3023
Europe	105 (57.7%)	8.4 [4.7, 12.1]	51 (60.7%)	4.7 [2.9, 5.8]	0.83 [0.59, 1.16]	0.2572	
Asia Pacific	57 (70.4%)	4.4 [2.8, 6.2]	18 (52.9%)	4.7 [2.9, NA]	1.23 [0.72, 2.09]	0.4359	
North America	9 (50.0%)	11.7 [1.8, NA]	8 (80.0%)	3.8 [1.0, 9.4]	0.48 [0.18, 1.31]	0.1369	
ECOG performance status							0.9724
0-1	165 (61.6%)	6.2 [4.7, 9.6]	77 (61.6%)	4.2 [2.9, 5.8]	0.88 [0.67, 1.15]	0.3353	
2	5 (41.7%)	NA [1.0, NA]	0 (0.0%)	NA [NA, NA]	NA [NA, NA]	0.3062	
Prior bortezomib or ixazomib exposure							0.7078
Yes	153 (59.1%)	6.5 [4.7, 10.9]	67 (59.3%)	4.7 [3.3, 6.5]	0.88 [0.66, 1.18]	0.3940	
No	18 (81.8%)	3.8 [1.6, 9.6]	10 (66.7%)	2.8 [1.9, 16.4]	0.86 [0.38, 1.95]	0.7144	

Table 6.2 EORTC-QLQ C30 Physical Functioning: Time to deterioration by at least 10 points by subgroups eCOA-ITT Population

EORTC	KdD (N=281)		Kd (N=128)		Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Refractory to bortezomib or ixazomib							0.3813
Yes	48 (53.9%)	5.7 [3.3, 15.9]	29 (60.4%)	3.8 [2.8, 5.6]	0.76 [0.48, 1.21]	0.2406	
No	123 (64.1%)	6.5 [3.8, 9.6]	48 (60.0%)	5.2 [2.9, 8.9]	0.95 [0.68, 1.32]	0.7403	
Prior lenalidomide exposure							0.2170
Yes	62 (55.4%)	7.9 [4.7, 16.6]	36 (59.0%)	3.8 [2.2, 6.5]	0.75 [0.49, 1.14]	0.1612	
No	109 (64.5%)	5.6 [3.8, 9.6]	41 (61.2%)	4.7 [3.7, 8.9]	1.01 [0.71, 1.45]	0.9468	
Refractory to lenalidomide							0.2529
Yes	46 (51.7%)	11.3 [5.6, NA]	25 (54.3%)	3.8 [2.3, 16.1]	0.71 [0.43, 1.17]	0.1660	
No	125 (65.1%)	4.7 [3.7, 8.4]	52 (63.4%)	4.7 [2.9, 5.8]	0.98 [0.71, 1.35]	0.8994	
Prior IMiD exposure							0.4889
Yes	109 (58.6%)	6.2 [4.7, 10.6]	54 (60.0%)	3.8 [2.8, 5.8]	0.83 [0.60, 1.16]	0.2666	
No	62 (65.3%)	6.8 [3.8, 11.7]	23 (60.5%)	5.6 [2.9, 16.1]	1.00 [0.62, 1.61]	0.9942	
Refractory to IMiD							0.3093
Yes	64 (54.7%)	6.6 [4.7, 16.6]	30 (55.6%)	3.8 [2.2, 9.6]	0.75 [0.49, 1.17]	0.1915	
No	107 (65.2%)	4.7 [3.6, 9.6]	47 (63.5%)	4.7 [2.9, 5.8]	0.99 [0.71, 1.40]	0.9754	
International Staging System (ISS)							0.7998
Stage I or II	145 (63.3%)	5.6 [3.8, 8.9]	67 (62.6%)	4.1 [2.9, 5.6]	0.89 [0.67, 1.19]	0.4301	
Stage III	25 (49.0%)	12.2 [4.0, NA]	10 (47.6%)	5.8 [1.9, NA]	0.84 [0.40, 1.76]	0.6409	
Prior proteasome inhibitor exposure							0.7500

Table 6.2 EORTC-QLQ C30 Physical Functioning: Time to deterioration by at least 10 points by subgroups eCOA-ITT Population

EORTC	KdD (N=281)		Kd (N=128)		Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Yes	154 (59.2%)	6.5 [4.7, 10.6]	68 (59.6%)	4.7 [3.3, 6.5]	0.88 [0.66, 1.18]	0.3865	
No	17 (81.0%)	3.8 [1.9, 9.6]	9 (64.3%)	2.8 [1.9, 16.4]	0.86 [0.37, 2.02]	0.7260	
Number of prior lines of therapy							0.8923
1	85 (65.4%)	5.6 [3.8, 9.8]	37 (64.9%)	4.7 [2.8, 5.8]	0.89 [0.60, 1.32]	0.5502	
>= 2	86 (57.0%)	6.6 [4.7, 12.2]	40 (56.3%)	4.1 [2.8, 9.6]	0.87 [0.60, 1.27]	0.4668	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
NA denotes that the median time (and 95% CI) were not estimable
[a]From Kaplan–Meier estimate
[b]HR: hazard ratio

Table 6.3 EORTC-QLQ C30 Role Functioning: Time to deterioration by at least 10 points by subgroups eCOA-ITT Population

EORTC	KdD (N=281)		Kd (N=128)		Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Age							0.7736
<= 75	192 (74.7%)	2.8 [1.9, 3.8]	79 (70.5%)	2.8 [1.9, 4.0]	0.96 [0.74, 1.25]	0.7669	
> 75	18 (75.0%)	2.8 [1.9, 2.9]	12 (75.0%)	2.8 [1.3, 5.2]	0.95 [0.45, 2.00]	0.8940	
Sex							0.6911
Male	120 (74.5%)	2.9 [2.0, 4.7]	52 (66.7%)	2.8 [1.9, 5.2]	0.97 [0.70, 1.35]	0.8494	
Female	90 (75.0%)	1.9 [1.9, 3.1]	39 (78.0%)	2.1 [1.9, 3.8]	0.91 [0.62, 1.32]	0.5792	
Race							0.8623
White	164 (74.5%)	2.8 [1.9, 3.8]	75 (72.1%)	2.8 [1.9, 4.0]	0.93 [0.71, 1.23]	0.6125	
Non-White	46 (75.4%)	3.1 [1.9, 5.0]	16 (66.7%)	2.8 [1.0, 7.5]	1.01 [0.57, 1.79]	0.9724	
Geographic region							0.1372
Europe	135 (74.2%)	2.8 [1.9, 3.8]	61 (72.6%)	2.8 [1.9, 3.8]	0.89 [0.66, 1.21]	0.4399	
Asia Pacific	61 (75.3%)	1.9 [1.9, 3.8]	24 (70.6%)	2.8 [1.4, 4.7]	0.94 [0.59, 1.51]	0.7907	
North America	14 (77.8%)	2.1 [1.9, 17.1]	6 (60.0%)	7.5 [1.0, NA]	1.49 [0.57, 3.94]	0.4048	
ECOG performance status							0.4684
0-1	203 (75.7%)	2.8 [1.9, 3.1]	90 (72.0%)	2.8 [1.9, 3.8]	0.97 [0.75, 1.24]	0.7801	
2	6 (50.0%)	14.0 [2.8, NA]	1 (33.3%)	3.8 [, NA]	0.71 [0.08, 6.43]	0.7493	
Prior bortezomib or ixazomib exposure							0.4193
Yes	191 (73.7%)	2.8 [1.9, 3.8]	82 (72.6%)	2.8 [1.9, 3.8]	0.93 [0.71, 1.20]	0.5436	
No	19 (86.4%)	1.8 [1.0, 2.8]	9 (60.0%)	2.8 [1.0, NA]	1.31 [0.58, 2.97]	0.4855	

Table 6.3 EORTC-QLQ C30 Role Functioning: Time to deterioration by at least 10 points by subgroups eCOA-ITT Population

EORTC	KdD (N=281)		Kd (N=128)		Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Refractory to bortezomib or ixazomib							0.2704
Yes	62 (69.7%)	2.8 [1.9, 4.7]	35 (72.9%)	1.9 [1.9, 3.8]	0.82 [0.54, 1.24]	0.3152	
No	148 (77.1%)	2.8 [1.9, 3.8]	56 (70.0%)	2.9 [2.1, 5.6]	1.03 [0.76, 1.40]	0.8445	
Prior lenalidomide exposure							0.1974
Yes	86 (76.8%)	1.9 [1.9, 3.1]	40 (65.6%)	2.9 [2.0, 5.9]	1.13 [0.77, 1.66]	0.4927	
No	124 (73.4%)	2.8 [1.9, 3.8]	51 (76.1%)	2.1 [1.9, 4.0]	0.82 [0.59, 1.13]	0.1988	
Refractory to lenalidomide							0.1805
Yes	66 (74.2%)	2.8 [1.9, 4.7]	27 (58.7%)	3.8 [1.9, 16.7]	1.19 [0.76, 1.87]	0.4293	
No	144 (75.0%)	2.8 [1.9, 3.8]	64 (78.0%)	2.8 [1.9, 3.1]	0.84 [0.62, 1.13]	0.2126	
Prior IMiD exposure							0.0781
Yes	143 (76.9%)	1.9 [1.9, 2.8]	61 (67.8%)	2.8 [1.9, 4.9]	1.11 [0.82, 1.51]	0.4583	
No	67 (70.5%)	3.8 [2.8, 7.5]	30 (78.9%)	2.8 [1.9, 3.8]	0.65 [0.42, 1.01]	0.0429	
Refractory to IMiD							0.0681
Yes	89 (76.1%)	2.0 [1.9, 3.8]	32 (59.3%)	3.8 [1.9, 8.4]	1.26 [0.84, 1.89]	0.2442	
No	121 (73.8%)	2.8 [1.9, 3.8]	59 (79.7%)	2.8 [1.9, 3.1]	0.78 [0.57, 1.07]	0.0993	
International Staging System (ISS)							0.7776
Stage I or II	176 (76.9%)	2.8 [1.9, 3.3]	79 (73.8%)	2.8 [2.0, 3.8]	0.92 [0.71, 1.21]	0.5328	
Stage III	33 (64.7%)	2.8 [1.2, 13.1]	12 (57.1%)	1.9 [1.9, NA]	1.14 [0.59, 2.22]	0.6783	
Prior proteasome inhibitor exposure							0.3322

Table 6.3 EORTC-QLQ C30 Role Functioning: Time to deterioration by at least 10 points by subgroups eCOA-ITT Population

EORTC	KdD (N=281)		Kd (N=128)		Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Yes	192 (73.8%)	2.8 [1.9, 3.8]	83 (72.8%)	2.8 [1.9, 3.8]	0.92 [0.71, 1.19]	0.5028	
No	18 (85.7%)	1.9 [1.0, 2.8]	8 (57.1%)	2.8 [1.0, NA]	1.42 [0.60, 3.36]	0.3863	
Number of prior lines of therapy							0.3454
1	99 (76.2%)	2.8 [1.9, 4.0]	45 (78.9%)	2.8 [1.9, 3.8]	0.82 [0.58, 1.18]	0.2604	
>= 2	111 (73.5%)	2.8 [1.9, 3.1]	46 (64.8%)	3.8 [1.9, 5.6]	1.08 [0.76, 1.52]	0.6583	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
NA denotes that the median time (and 95% CI) were not estimable
[a]From Kaplan–Meier estimate
[b]HR: hazard ratio

Table 6.4 EORTC-QLQ C30 Emotional Functioning: Time to deterioration by at least 10 points by subgroups eCOA-ITT Population

EORTC	KdD (N=281)		Kd (N=128)		Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Age							0.7211
<= 75	137 (53.3%)	9.3 [6.6, 14.5]	49 (43.8%)	10.8 [6.6, NA]	1.11 [0.80, 1.54]	0.5096	
> 75	13 (54.2%)	7.5 [2.8, NA]	7 (43.8%)	NA [1.0, NA]	1.02 [0.41, 2.56]	0.9635	
Sex							0.3406
Male	88 (54.7%)	8.7 [5.0, 15.2]	32 (41.0%)	11.9 [6.6, NA]	1.23 [0.82, 1.85]	0.3004	
Female	62 (51.7%)	8.4 [5.9, 17.1]	24 (48.0%)	7.5 [4.0, NA]	0.91 [0.57, 1.46]	0.6870	
Race							0.3233
White	121 (55.0%)	8.4 [5.0, 11.3]	44 (42.3%)	10.8 [5.7, NA]	1.19 [0.84, 1.68]	0.3197	
Non-White	29 (47.5%)	15.9 [6.6, NA]	12 (50.0%)	11.3 [4.0, NA]	0.80 [0.40, 1.57]	0.5032	
Geographic region							0.8240
Europe	107 (58.8%)	7.5 [4.7, 8.9]	39 (46.4%)	7.5 [4.2, NA]	1.14 [0.79, 1.65]	0.4723	
Asia Pacific	35 (43.2%)	NA [8.4, NA]	12 (35.3%)	11.3 [7.5, NA]	1.07 [0.56, 2.07]	0.8279	
North America	8 (44.4%)	18.7 [4.9, NA]	5 (50.0%)	10.3 [1.0, NA]	0.55 [0.17, 1.80]	0.3129	
ECOG performance status							0.7187
0-1	144 (53.7%)	8.5 [6.6, 14.2]	55 (44.0%)	10.8 [6.6, NA]	1.11 [0.81, 1.51]	0.5173	
2	6 (50.0%)	9.4 [1.0, NA]	1 (33.3%)	NA [2.8, NA]	0.73 [0.08, 7.01]	0.7793	
Prior bortezomib or ixazomib exposure							0.1285
Yes	140 (54.1%)	8.5 [6.6, 12.7]	48 (42.5%)	11.3 [6.7, NA]	1.18 [0.85, 1.64]	0.3109	
No	10 (45.5%)	15.9 [2.8, NA]	8 (53.3%)	5.7 [1.3, NA]	0.59 [0.22, 1.55]	0.2705	

Table 6.4 EORTC-QLQ C30 Emotional Functioning: Time to deterioration by at least 10 points by subgroups eCOA-ITT Population

EORTC	KdD (N=281)		Kd (N=128)		Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Refractory to bortezomib or ixazomib							0.1412
Yes	46 (51.7%)	8.4 [3.8, 17.8]	17 (35.4%)	NA [7.5, NA]	1.51 [0.87, 2.64]	0.1321	
No	104 (54.2%)	9.5 [6.6, 15.9]	39 (48.8%)	7.5 [4.9, NA]	0.92 [0.64, 1.33]	0.6491	
Prior lenalidomide exposure							0.3908
Yes	59 (52.7%)	8.4 [5.9, 18.7]	28 (45.9%)	7.5 [4.7, NA]	0.94 [0.60, 1.49]	0.8012	
No	91 (53.8%)	8.9 [5.0, 15.2]	28 (41.8%)	11.9 [4.9, NA]	1.23 [0.81, 1.89]	0.3199	
Refractory to lenalidomide							0.3747
Yes	45 (50.6%)	11.3 [6.6, NA]	20 (43.5%)	7.5 [4.7, NA]	0.92 [0.54, 1.56]	0.7468	
No	105 (54.7%)	8.5 [5.0, 14.2]	36 (43.9%)	11.3 [6.6, NA]	1.20 [0.82, 1.76]	0.3308	
Prior IMiD exposure							0.4256
Yes	99 (53.2%)	7.9 [4.9, 15.9]	42 (46.7%)	9.6 [5.2, NA]	1.03 [0.72, 1.47]	0.8828	
No	51 (53.7%)	9.6 [6.6, 17.1]	14 (36.8%)	NA [4.9, NA]	1.32 [0.73, 2.39]	0.3467	
Refractory to IMiD							0.4477
Yes	58 (49.6%)	9.4 [6.6, NA]	23 (42.6%)	9.6 [4.7, NA]	0.95 [0.58, 1.54]	0.8332	
No	92 (56.1%)	8.4 [4.9, 14.5]	33 (44.6%)	11.9 [5.7, NA]	1.20 [0.81, 1.79]	0.3496	
International Staging System (ISS)							0.6066
Stage I or II	123 (53.7%)	8.9 [6.6, 15.0]	47 (43.9%)	11.3 [6.6, NA]	1.12 [0.80, 1.57]	0.4918	
Stage III	26 (51.0%)	8.4 [3.8, NA]	9 (42.9%)	7.5 [1.9, NA]	0.88 [0.41, 1.90]	0.7442	
Prior proteasome inhibitor exposure							0.1778

Table 6.4 EORTC-QLQ C30 Emotional Functioning: Time to deterioration by at least 10 points by subgroups eCOA-ITT Population

EORTC	KdD (N=281)		Kd (N=128)		Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Yes	141 (54.2%)	8.5 [6.6, 12.7]	49 (43.0%)	11.3 [6.6, NA]	1.16 [0.84, 1.61]	0.3482	
No	9 (42.9%)	NA [2.8, NA]	7 (50.0%)	5.7 [1.9, NA]	0.58 [0.21, 1.63]	0.2871	
Number of prior lines of therapy							0.3461
1	66 (50.8%)	12.7 [5.6, 18.7]	28 (49.1%)	7.5 [4.9, NA]	0.93 [0.60, 1.46]	0.7582	
>= 2	84 (55.6%)	8.4 [4.7, 12.2]	28 (39.4%)	NA [5.2, NA]	1.26 [0.82, 1.93]	0.2792	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
NA denotes that the median time (and 95% CI) were not estimable
[a]From Kaplan–Meier estimate
[b]HR: hazard ratio

Table 6.5 EORTC-QLQ C30 Cognitive Functioning: Time to deterioration by at least 10 points by subgroups eCOA-ITT Population

EORTC	KdD (N=281)		Kd (N=128)		Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Age							0.5097
<= 75	170 (66.1%)	5.0 [3.8, 7.5]	66 (58.9%)	5.6 [3.1, 7.5]	0.99 [0.74, 1.31]	0.9199	
> 75	18 (75.0%)	6.5 [2.8, 11.3]	11 (68.8%)	2.8 [1.0, 11.0]	0.79 [0.37, 1.68]	0.5260	
Sex							0.1822
Male	106 (65.8%)	5.8 [3.8, 9.6]	41 (52.6%)	7.5 [3.8, 14.3]	1.10 [0.77, 1.58]	0.5790	
Female	82 (68.3%)	4.7 [3.8, 6.6]	36 (72.0%)	3.1 [1.9, 4.9]	0.76 [0.51, 1.13]	0.1628	
Race							0.9714
White	143 (65.0%)	5.2 [3.8, 7.7]	61 (58.7%)	4.9 [2.8, 7.5]	0.94 [0.70, 1.27]	0.6986	
Non-White	45 (73.8%)	4.7 [2.9, 9.6]	16 (66.7%)	3.8 [1.0, 11.2]	0.91 [0.51, 1.63]	0.7477	
Geographic region							0.1313
Europe	122 (67.0%)	5.0 [3.8, 7.5]	50 (59.5%)	4.7 [2.8, 10.6]	1.03 [0.74, 1.43]	0.8771	
Asia Pacific	52 (64.2%)	5.0 [2.9, 11.3]	19 (55.9%)	6.6 [2.8, 11.2]	1.01 [0.59, 1.71]	0.9795	
North America	14 (77.8%)	8.1 [3.8, 14.0]	8 (80.0%)	2.5 [1.0, 10.3]	0.38 [0.15, 0.97]	0.0349	
ECOG performance status							0.9914
0-1	180 (67.2%)	5.6 [4.7, 7.5]	76 (60.8%)	4.7 [2.9, 7.5]	0.96 [0.74, 1.26]	0.7767	
2	7 (58.3%)	3.8 [1.0, NA]	1 (33.3%)	NA [0.9, NA]	0.45 [0.05, 4.50]	0.4895	
Prior bortezomib or ixazomib exposure							0.6978
Yes	177 (68.3%)	5.0 [3.8, 6.8]	71 (62.8%)	3.8 [2.8, 6.6]	0.92 [0.70, 1.21]	0.5361	
No	11 (50.0%)	6.6 [2.8, NA]	6 (40.0%)	14.3 [1.0, NA]	1.18 [0.43, 3.19]	0.7454	

Table 6.5 EORTC-QLQ C30 Cognitive Functioning: Time to deterioration by at least 10 points by subgroups eCOA-ITT Population

EORTC	KdD (N=281)		Kd (N=128)		Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Refractory to bortezomib							0.8796
Yes	63 (70.8%)	4.7 [2.8, 8.4]	30 (62.5%)	3.8 [1.9, 11.2]	0.99 [0.64, 1.54]	0.9700	
No	125 (65.1%)	5.2 [3.8, 8.4]	47 (58.8%)	5.6 [2.9, 10.3]	0.95 [0.68, 1.33]	0.7633	
Prior lenalidomide exposure							0.8960
Yes	76 (67.9%)	6.8 [3.8, 10.3]	34 (55.7%)	6.6 [2.9, 10.6]	0.94 [0.63, 1.42]	0.7711	
No	112 (66.3%)	4.9 [3.8, 6.6]	43 (64.2%)	3.8 [1.9, 7.5]	0.93 [0.65, 1.32]	0.6794	
Refractory to lenalidomide							0.9506
Yes	59 (66.3%)	7.7 [4.6, 10.8]	23 (50.0%)	7.5 [2.8, 12.1]	0.93 [0.57, 1.52]	0.7715	
No	129 (67.2%)	4.7 [3.8, 5.9]	54 (65.9%)	3.8 [2.0, 6.6]	0.95 [0.69, 1.30]	0.7320	
Prior IMiD exposure							0.9155
Yes	126 (67.7%)	4.9 [3.8, 6.8]	54 (60.0%)	5.6 [2.8, 9.7]	0.96 [0.70, 1.33]	0.8165	
No	62 (65.3%)	5.6 [3.8, 12.2]	23 (60.5%)	4.0 [1.9, NA]	0.94 [0.58, 1.52]	0.8049	
Refractory to IMiD							0.7544
Yes	79 (67.5%)	6.6 [3.8, 9.6]	28 (51.9%)	7.5 [2.8, 12.1]	1.00 [0.65, 1.54]	0.9861	
No	109 (66.5%)	4.9 [3.8, 7.5]	49 (66.2%)	3.8 [2.1, 6.6]	0.92 [0.66, 1.29]	0.6348	
International Staging System (ISS)							0.6841
Stage I or II	154 (67.2%)	5.6 [4.7, 8.4]	65 (60.7%)	5.6 [3.1, 9.7]	0.97 [0.72, 1.29]	0.8115	
Stage III	33 (64.7%)	3.8 [1.9, 10.5]	12 (57.1%)	4.9 [1.0, NA]	0.86 [0.44, 1.68]	0.6562	
Prior proteasome inhibitor exposure							0.5861

Table 6.5 EORTC-QLQ C30 Cognitive Functioning: Time to deterioration by at least 10 points by subgroups eCOA-ITT Population

EORTC	KdD (N=281)		Kd (N=128)		Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Yes	178 (68.5%)	4.9 [3.8, 6.8]	72 (63.2%)	3.8 [2.8, 6.6]	0.91 [0.69, 1.20]	0.4960	
No	10 (47.6%)	9.4 [2.8, NA]	5 (35.7%)	14.3 [4.2, NA]	1.28 [0.44, 3.76]	0.6469	
Number of prior lines of therapy							0.5987
1	87 (66.9%)	4.7 [3.8, 5.9]	35 (61.4%)	4.2 [2.8, 11.0]	1.02 [0.69, 1.51]	0.9161	
>= 2	101 (66.9%)	6.6 [3.8, 9.4]	42 (59.2%)	5.6 [2.2, 10.3]	0.88 [0.61, 1.26]	0.4758	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
NA denotes that the median time (and 95% CI) were not estimable
[a]From Kaplan–Meier estimate
[b]HR: hazard ratio

Table 6.6 EORTC-QLQ C30 Social Functioning: Time to deterioration by at least 10 points by subgroups eCOA-ITT Population

EORTC	KdD (N=281)		Kd (N=128)		Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Age							0.2145
<= 75	166 (64.6%)	3.3 [2.1, 4.7]	80 (71.4%)	2.8 [2.1, 4.7]	0.82 [0.63, 1.07]	0.1204	
> 75	15 (62.5%)	5.6 [1.9, 15.9]	13 (81.3%)	1.9 [1.0, 4.7]	0.37 [0.16, 0.85]	0.0110	
Sex							0.5646
Male	101 (62.7%)	3.3 [1.9, 6.6]	56 (71.8%)	2.8 [1.9, 4.0]	0.73 [0.52, 1.01]	0.0464	
Female	80 (66.7%)	3.8 [2.1, 5.6]	37 (74.0%)	2.1 [1.9, 5.6]	0.84 [0.57, 1.24]	0.3611	
Race							0.6394
White	145 (65.9%)	2.8 [2.0, 4.7]	76 (73.1%)	2.8 [1.9, 4.0]	0.80 [0.61, 1.06]	0.1045	
Non-White	36 (59.0%)	6.5 [3.1, 16.4]	17 (70.8%)	2.8 [1.0, 13.1]	0.67 [0.38, 1.21]	0.1653	
Geographic region							0.2924
Europe	121 (66.5%)	2.9 [2.0, 4.7]	62 (73.8%)	2.8 [1.9, 4.0]	0.76 [0.56, 1.04]	0.0663	
Asia Pacific	51 (63.0%)	3.8 [1.9, 10.3]	25 (73.5%)	3.3 [1.4, 9.4]	0.80 [0.49, 1.28]	0.3273	
North America	9 (50.0%)	11.2 [1.9, NA]	6 (60.0%)	4.3 [1.0, NA]	0.65 [0.23, 1.87]	0.4174	
ECOG performance status							0.9830
0-1	174 (64.9%)	3.8 [2.8, 4.7]	91 (72.8%)	2.8 [1.9, 4.0]	0.78 [0.60, 1.00]	0.0412	
2	7 (58.3%)	4.2 [1.0, NA]	2 (66.7%)	5.6 [1.0, 5.6]	0.89 [0.18, 4.30]	0.8808	
Prior bortezomib or ixazomib exposure							0.2089
Yes	165 (63.7%)	3.8 [2.8, 4.8]	85 (75.2%)	2.8 [1.9, 4.0]	0.73 [0.56, 0.95]	0.0131	
No	16 (72.7%)	2.8 [1.0, 8.9]	8 (53.3%)	3.8 [1.0, NA]	1.30 [0.55, 3.04]	0.5263	

Table 6.6 EORTC-QLQ C30 Social Functioning: Time to deterioration by at least 10 points by subgroups eCOA-ITT Population

EORTC	KdD (N=281)		Kd (N=128)		Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Refractory to bortezomib							0.8782
Yes	53 (59.6%)	4.2 [2.2, 11.3]	32 (66.7%)	3.8 [1.9, 5.6]	0.80 [0.52, 1.25]	0.2991	
No	128 (66.7%)	3.1 [2.0, 4.8]	61 (76.3%)	2.8 [1.9, 4.0]	0.76 [0.56, 1.03]	0.0590	
Prior lenalidomide exposure							0.9075
Yes	69 (61.6%)	3.8 [1.9, 6.6]	42 (68.9%)	3.8 [2.0, 5.6]	0.80 [0.54, 1.17]	0.2307	
No	112 (66.3%)	3.8 [2.0, 5.9]	51 (76.1%)	2.1 [1.9, 4.0]	0.76 [0.54, 1.05]	0.0792	
Refractory to lenalidomide							0.5794
Yes	51 (57.3%)	4.7 [2.8, NA]	30 (65.2%)	3.8 [1.9, 7.5]	0.72 [0.46, 1.14]	0.1425	
No	130 (67.7%)	3.1 [1.9, 4.7]	63 (76.8%)	2.8 [1.9, 4.0]	0.80 [0.59, 1.09]	0.1311	
Prior IMiD exposure							0.1607
Yes	118 (63.4%)	2.8 [1.9, 4.2]	62 (68.9%)	3.8 [2.0, 5.6]	0.88 [0.65, 1.20]	0.3904	
No	63 (66.3%)	4.7 [2.8, 11.3]	31 (81.6%)	1.9 [1.9, 4.0]	0.56 [0.36, 0.86]	0.0052	
Refractory to IMiD							0.8597
Yes	69 (59.0%)	4.2 [2.8, 8.7]	34 (63.0%)	3.8 [2.0, 7.9]	0.82 [0.54, 1.24]	0.3198	
No	112 (68.3%)	2.8 [1.9, 4.7]	59 (79.7%)	2.1 [1.9, 4.0]	0.76 [0.56, 1.05]	0.0734	
International Staging System (ISS)							0.7449
Stage I or II	148 (64.6%)	3.8 [2.8, 5.6]	76 (71.0%)	2.8 [2.0, 4.7]	0.78 [0.59, 1.03]	0.0664	
Stage III	32 (62.7%)	2.8 [1.2, 6.5]	17 (81.0%)	1.9 [1.0, 5.6]	0.71 [0.39, 1.28]	0.2282	
Prior proteasome inhibitor exposure							0.1671

Table 6.6 EORTC-QLQ C30 Social Functioning: Time to deterioration by at least 10 points by subgroups eCOA-ITT Population

EORTC	KdD (N=281)		Kd (N=128)		Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Yes	166 (63.8%)	3.8 [2.8, 4.8]	86 (75.4%)	2.8 [1.9, 4.0]	0.73 [0.56, 0.94]	0.0111	
No	15 (71.4%)	2.8 [1.0, 8.9]	7 (50.0%)	3.8 [1.3, NA]	1.40 [0.57, 3.45]	0.4375	
Number of prior lines of therapy							0.4226
1	85 (65.4%)	3.8 [2.0, 8.4]	46 (80.7%)	2.8 [1.9, 4.0]	0.68 [0.47, 0.97]	0.0250	
>= 2	96 (63.6%)	3.8 [1.9, 4.7]	47 (66.2%)	3.7 [1.9, 5.6]	0.86 [0.61, 1.22]	0.3801	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
NA denotes that the median time (and 95% CI) were not estimable
[a]From Kaplan–Meier estimate
[b]HR: hazard ratio

Table 6a.2 QLQ MY-20 Side-effects: Time to deterioration by at least 10 points by subgroups eCOA-ITT Population

EORTC	KdD (N=278)		Kd (N=133)		Treatment Comparison KdD vs. Kd:		
QLQ MY-20	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Age							0.0882
<= 75	86 (33.9%)	NA [NA, NA]	27 (23.5%)	NA [NA, NA]	1.41 [0.91, 2.17]	0.1162	
> 75	5 (20.8%)	NA [NA, NA]	7 (38.9%)	NA [2.0, NA]	0.49 [0.16, 1.56]	0.2187	
Sex							0.2290
Male	44 (27.5%)	NA [NA, NA]	21 (25.9%)	NA [NA, NA]	0.98 [0.58, 1.65]	0.9480	
Female	47 (39.8%)	NA [8.4, NA]	13 (25.0%)	NA [NA, NA]	1.63 [0.88, 3.00]	0.1122	
Race							0.1331
White	72 (32.9%)	NA [NA, NA]	24 (22.6%)	NA [NA, NA]	1.45 [0.92, 2.31]	0.1067	
Non-White	19 (32.2%)	NA [NA, NA]	10 (37.0%)	NA [5.7, NA]	0.75 [0.35, 1.63]	0.4624	
Geographic region							0.8935
Europe	61 (33.7%)	NA [NA, NA]	17 (19.5%)	NA [NA, NA]	1.75 [1.02, 3.00]	0.0363	
Asia Pacific	26 (32.9%)	NA [NA, NA]	15 (41.7%)	NA [2.8, NA]	0.67 [0.35, 1.26]	0.2030	
North America	4 (22.2%)	NA [8.0, NA]	2 (20.0%)	NA [3.8, NA]	1.06 [0.19, 5.85]	0.9503	
ECOG performance status							0.7011
0-1	87 (32.8%)	NA [NA, NA]	33 (25.6%)	NA [NA, NA]	1.25 [0.83, 1.86]	0.2761	
2	4 (33.3%)	NA [1.0, NA]	1 (25.0%)	NA [1.0, NA]	1.33 [0.15, 11.98]	0.7863	
Prior bortezomib or ixazomib exposure							0.6180
Yes	84 (32.7%)	NA [NA, NA]	29 (24.6%)	NA [NA, NA]	1.29 [0.84, 1.97]	0.2333	
No	7 (33.3%)	NA [2.8, NA]	5 (33.3%)	NA [1.0, NA]	0.95 [0.30, 3.00]	0.9305	

Table 6a.2 QLQ MY-20 Side-effects: Time to deterioration by at least 10 points by subgroups eCOA-ITT Population

EORTC	KdD (N=278)		Kd (N=133)		Treatment Comparison KdD vs. Kd:		
QLQ MY-20	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Refractory to bortezomib or ixazomib							0.9453
Yes	35 (39.3%)	NA [10.3, NA]	15 (30.6%)	NA [10.3, NA]	1.25 [0.68, 2.30]	0.4569	
No	56 (29.6%)	NA [NA, NA]	19 (22.6%)	NA [NA, NA]	1.27 [0.75, 2.13]	0.3678	
Prior lenalidomide exposure							0.7987
Yes	36 (32.4%)	NA [NA, NA]	17 (26.6%)	NA [13.3, NA]	1.18 [0.66, 2.10]	0.5735	
No	55 (32.9%)	NA [NA, NA]	17 (24.6%)	NA [NA, NA]	1.31 [0.76, 2.25]	0.3273	
Refractory to lenalidomide							0.8330
Yes	30 (34.1%)	NA [NA, NA]	12 (25.0%)	NA [10.3, NA]	1.31 [0.67, 2.56]	0.4288	
No	61 (32.1%)	NA [NA, NA]	22 (25.9%)	NA [NA, NA]	1.20 [0.74, 1.96]	0.4466	
Prior IMiD exposure							0.3112
Yes	64 (34.8%)	NA [NA, NA]	23 (24.2%)	NA [NA, NA]	1.43 [0.89, 2.30]	0.1344	
No	27 (28.7%)	NA [NA, NA]	11 (28.9%)	NA [13.6, NA]	0.93 [0.46, 1.87]	0.8295	
Refractory to IMiD							0.8086
Yes	38 (32.8%)	NA [NA, NA]	13 (23.2%)	NA [10.3, NA]	1.28 [0.68, 2.41]	0.4335	
No	53 (32.7%)	NA [NA, NA]	21 (27.3%)	NA [NA, NA]	1.19 [0.72, 1.97]	0.4916	
International Staging System (ISS)							0.7187
Stage I or II	74 (32.7%)	NA [NA, NA]	28 (25.2%)	NA [NA, NA]	1.27 [0.82, 1.97]	0.2700	
Stage III	17 (33.3%)	NA [10.3, NA]	6 (27.3%)	NA [5.6, NA]	1.08 [0.42, 2.75]	0.8709	
Prior proteasome inhibitor exposure							0.5901

Table 6a.2 QLQ MY-20 Side-effects: Time to deterioration by at least 10 points by subgroups eCOA-ITT Population

EORTC	KdD (N=278)		Kd (N=133)		Treatment Comparison KdD vs. Kd:		
QLQ MY-20	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Yes	84 (32.6%)	NA [NA, NA]	29 (24.4%)	NA [NA, NA]	1.29 [0.85, 1.98]	0.2244	
No	7 (35.0%)	NA [2.8, NA]	5 (35.7%)	NA [1.0, NA]	0.92 [0.29, 2.92]	0.8891	
Number of prior lines of therapy							0.9196
1	36 (28.1%)	NA [NA, NA]	13 (22.4%)	NA [NA, NA]	1.22 [0.65, 2.30]	0.5348	
>= 2	55 (36.7%)	NA [NA, NA]	21 (28.0%)	NA [13.6, NA]	1.27 [0.77, 2.10]	0.3444	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
NA denotes that the median time (and 95% CI) were not estimable
[a]From Kaplan–Meier estimate
[b]HR: hazard ratio

Table 6a.3 QLQ MY-20 Body image: Time to deterioration by at least 10 points by subgroups
eCOA-ITT Population

EORTC	KdD (N=278)		Kd (N=133)		Treatment Comparison KdD vs. Kd:		
QLQ MY-20	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Age							0.9834
<= 75	128 (50.4%)	10.3 [7.6, 17.1]	63 (54.8%)	5.6 [3.8, 15.5]	0.82 [0.60, 1.11]	0.1793	
> 75	12 (50.0%)	14.3 [1.9, NA]	10 (55.6%)	7.0 [1.9, NA]	0.86 [0.37, 2.00]	0.7189	
Sex							0.7247
Male	79 (49.4%)	12.9 [7.6, NA]	42 (51.9%)	9.4 [3.8, 16.4]	0.84 [0.58, 1.23]	0.3599	
Female	61 (51.7%)	8.9 [4.7, NA]	31 (59.6%)	4.7 [2.3, 9.4]	0.77 [0.50, 1.19]	0.2305	
Race							0.4476
White	106 (48.4%)	12.4 [8.4, NA]	58 (54.7%)	5.6 [3.8, 15.7]	0.77 [0.56, 1.06]	0.0988	
Non-White	34 (57.6%)	7.5 [2.8, NA]	15 (55.6%)	9.4 [2.7, NA]	1.01 [0.55, 1.85]	0.9816	
Geographic region							0.8069
Europe	88 (48.6%)	10.3 [8.4, NA]	49 (56.3%)	4.7 [3.8, 15.5]	0.75 [0.53, 1.06]	0.0977	
Asia Pacific	40 (50.6%)	7.5 [2.8, NA]	18 (50.0%)	9.4 [2.8, NA]	1.04 [0.60, 1.81]	0.8878	
North America	12 (66.7%)	9.4 [2.8, NA]	6 (60.0%)	4.7 [0.9, NA]	0.78 [0.29, 2.10]	0.6234	
ECOG performance status							0.3043
0-1	134 (50.6%)	10.3 [7.6, 17.1]	70 (54.3%)	5.6 [4.0, 15.5]	0.84 [0.63, 1.12]	0.2210	
2	5 (41.7%)	NA [1.0, NA]	3 (75.0%)	1.8 [0.9, NA]	0.34 [0.08, 1.56]	0.1437	
Prior bortezomib or ixazomib exposure							0.1836
Yes	130 (50.6%)	10.3 [7.6, 17.1]	68 (57.6%)	4.7 [3.8, 9.4]	0.76 [0.56, 1.01]	0.0560	
No	10 (47.6%)	13.3 [1.9, NA]	5 (33.3%)	NA [2.9, NA]	1.62 [0.55, 4.75]	0.3698	

Table 6a.3 QLQ MY-20 Body image: Time to deterioration by at least 10 points by subgroups eCOA-ITT Population

EORTC	KdD (N=278)		Kd (N=133)		Treatment Comparison KdD vs. Kd:		
QLQ MY-20	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Refractory to bortezomib or ixazomib							0.4390
Yes	45 (50.6%)	10.3 [4.8, NA]	29 (59.2%)	3.8 [2.3, 11.5]	0.70 [0.44, 1.12]	0.1199	
No	95 (50.3%)	12.4 [7.5, NA]	44 (52.4%)	9.4 [4.7, 16.4]	0.89 [0.63, 1.28]	0.5342	
Prior lenalidomide exposure							0.3768
Yes	56 (50.5%)	11.5 [4.8, NA]	37 (57.8%)	4.6 [2.8, 13.3]	0.72 [0.47, 1.09]	0.1077	
No	84 (50.3%)	10.3 [6.6, NA]	36 (52.2%)	9.4 [4.0, 16.4]	0.92 [0.62, 1.36]	0.6745	
Refractory to lenalidomide							0.4311
Yes	43 (48.9%)	13.3 [7.5, NA]	26 (54.2%)	3.8 [2.8, NA]	0.69 [0.42, 1.12]	0.1257	
No	97 (51.1%)	9.6 [5.6, NA]	47 (55.3%)	7.0 [4.0, 15.7]	0.89 [0.63, 1.26]	0.4897	
Prior IMiD exposure							0.1739
Yes	90 (48.9%)	9.6 [6.1, NA]	55 (57.9%)	4.7 [2.9, 9.4]	0.73 [0.52, 1.02]	0.0589	
No	50 (53.2%)	10.3 [5.6, NA]	18 (47.4%)	15.5 [4.7, NA]	1.10 [0.64, 1.89]	0.7190	
Refractory to IMiD							0.3028
Yes	57 (49.1%)	12.9 [6.7, NA]	31 (55.4%)	3.8 [2.8, NA]	0.68 [0.44, 1.06]	0.0834	
No	83 (51.2%)	10.3 [5.6, NA]	42 (54.5%)	7.5 [4.7, 16.4]	0.92 [0.64, 1.34]	0.6595	
International Staging System (ISS)							0.9443
Stage I or II	109 (48.2%)	12.9 [7.5, NA]	61 (55.0%)	5.6 [4.6, 15.5]	0.80 [0.58, 1.09]	0.1482	
Stage III	30 (58.8%)	8.4 [2.8, 15.9]	12 (54.5%)	3.8 [1.9, NA]	0.82 [0.42, 1.62]	0.5618	
Prior proteasome inhibitor exposure							0.1619

Table 6a.3 QLQ MY-20 Body image: Time to deterioration by at least 10 points by subgroups eCOA-ITT Population

EORTC	KdD (N=278)		Kd (N=133)		Treatment Comparison KdD vs. Kd:		
QLQ MY-20	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Yes	131 (50.8%)	10.3 [7.6, 17.1]	69 (58.0%)	4.7 [3.8, 9.4]	0.75 [0.56, 1.01]	0.0518	
No	9 (45.0%)	13.3 [2.8, NA]	4 (28.6%)	NA [3.4, NA]	1.82 [0.56, 5.93]	0.3093	
Number of prior lines of therapy							0.3430
1	62 (48.4%)	13.1 [8.5, NA]	28 (48.3%)	15.7 [4.7, NA]	0.95 [0.61, 1.48]	0.8046	
>= 2	78 (52.0%)	8.4 [4.7, NA]	45 (60.0%)	3.8 [2.8, 7.0]	0.73 [0.51, 1.06]	0.0898	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
NA denotes that the median time (and 95% CI) were not estimable
[a]From Kaplan–Meier estimate
[b]HR: hazard ratio

Table 6a.4 QLQ MY-20 Future perspective: Time to deterioration by at least 10 points by subgroups eCOA-ITT Population

EORTC	KdD (N=278)		Kd (N=133)		Treatment Comparison KdD vs. Kd:		
QLQ MY-20	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Age							0.4606
<= 75	142 (55.9%)	7.7 [5.6, 12.2]	63 (54.8%)	7.7 [4.7, 14.5]	0.96 [0.71, 1.29]	0.7763	
> 75	14 (58.3%)	3.7 [1.0, NA]	12 (66.7%)	4.7 [1.3, 8.9]	0.79 [0.36, 1.72]	0.5341	
Sex							0.8244
Male	92 (57.5%)	7.5 [4.7, 14.0]	45 (55.6%)	8.1 [4.7, 15.0]	0.93 [0.65, 1.33]	0.6946	
Female	64 (54.2%)	7.5 [3.8, NA]	30 (57.7%)	7.5 [3.8, 14.5]	0.89 [0.58, 1.38]	0.6003	
Race							0.8579
White	120 (54.8%)	8.9 [4.6, 14.0]	60 (56.6%)	7.5 [4.6, 14.1]	0.91 [0.67, 1.24]	0.5410	
Non-White	36 (61.0%)	7.0 [4.7, 17.5]	15 (55.6%)	8.9 [1.6, NA]	0.98 [0.53, 1.79]	0.9371	
Geographic region							0.0983
Europe	100 (55.2%)	7.7 [4.7, 12.9]	53 (60.9%)	5.6 [3.8, 8.4]	0.81 [0.58, 1.14]	0.2111	
Asia Pacific	48 (60.8%)	5.7 [2.9, 14.0]	19 (52.8%)	8.9 [2.9, NA]	1.12 [0.66, 1.90]	0.6760	
North America	8 (44.4%)	18.7 [2.8, NA]	3 (30.0%)	NA [1.0, NA]	1.18 [0.30, 4.64]	0.8097	
ECOG performance status							0.5403
0-1	148 (55.8%)	7.5 [5.6, 12.2]	74 (57.4%)	7.5 [4.6, 12.2]	0.91 [0.68, 1.20]	0.4739	
2	7 (58.3%)	7.5 [1.0, NA]	1 (25.0%)	5.6 [NA, NA]	1.57 [0.19, 13.23]	0.6698	
Prior bortezomib or ixazomib exposure							0.5531
Yes	144 (56.0%)	7.5 [5.6, 12.2]	68 (57.6%)	7.5 [4.6, 12.2]	0.89 [0.67, 1.19]	0.4291	
No	12 (57.1%)	3.7 [1.0, NA]	7 (46.7%)	NA [1.0, NA]	1.16 [0.45, 2.95]	0.7397	

Table 6a.4 QLQ MY-20 Future perspective: Time to deterioration by at least 10 points by subgroups eCOA-ITT Population

EORTC	KdD (N=278)		Kd (N=133)		Treatment Comparison KdD vs. Kd:		
QLQ MY-20	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Refractory to bortezomib or ixazomib							0.3482
Yes	47 (52.8%)	9.3 [3.8, NA]	30 (61.2%)	4.9 [1.9, 14.1]	0.78 [0.49, 1.24]	0.2691	
No	109 (57.7%)	7.5 [4.8, 12.2]	45 (53.6%)	8.4 [5.0, 15.0]	1.01 [0.71, 1.43]	0.9463	
Prior lenalidomide exposure							0.9859
Yes	59 (53.2%)	7.5 [4.7, 18.7]	33 (51.6%)	8.2 [3.8, NA]	0.91 [0.59, 1.39]	0.6434	
No	97 (58.1%)	7.5 [3.8, 11.3]	42 (60.9%)	7.5 [4.0, 12.2]	0.91 [0.63, 1.31]	0.5967	
Refractory to lenalidomide							0.8743
Yes	47 (53.4%)	7.5 [4.2, NA]	24 (50.0%)	8.2 [3.8, NA]	0.95 [0.58, 1.55]	0.8196	
No	109 (57.4%)	7.5 [4.6, 11.3]	51 (60.0%)	7.5 [3.8, 12.2]	0.90 [0.65, 1.26]	0.5338	
Prior IMiD exposure							0.1446
Yes	102 (55.4%)	7.5 [4.7, 16.6]	47 (49.5%)	8.9 [5.0, NA]	1.06 [0.75, 1.50]	0.7286	
No	54 (57.4%)	7.7 [3.8, 12.9]	28 (73.7%)	4.7 [2.1, 8.1]	0.67 [0.42, 1.06]	0.0737	
Refractory to IMiD							0.6468
Yes	64 (55.2%)	6.6 [3.8, 18.7]	28 (50.0%)	8.2 [3.8, NA]	1.01 [0.64, 1.57]	0.9736	
No	92 (56.8%)	8.9 [4.7, 12.9]	47 (61.0%)	7.5 [2.9, 14.0]	0.87 [0.61, 1.24]	0.4201	
International Staging System (ISS)							0.8666
Stage I or II	127 (56.2%)	7.7 [5.6, 14.0]	63 (56.8%)	8.1 [4.7, 14.1]	0.91 [0.67, 1.23]	0.5060	
Stage III	29 (56.9%)	4.7 [1.9, NA]	12 (54.5%)	3.8 [1.9, NA]	1.00 [0.51, 1.97]	0.9938	
Prior proteasome inhibitor exposure							0.4656

Table 6a.4 QLQ MY-20 Future perspective: Time to deterioration by at least 10 points by subgroups eCOA-ITT Population

EORTC	KdD (N=278)		Kd (N=133)		Treatment Comparison KdD vs. Kd:		
QLQ MY-20	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Yes	145 (56.2%)	7.5 [5.6, 12.1]	69 (58.0%)	7.5 [4.6, 12.2]	0.89 [0.66, 1.18]	0.3950	
No	11 (55.0%)	3.7 [1.0, NA]	6 (42.9%)	NA [1.0, NA]	1.27 [0.47, 3.46]	0.6083	
Number of prior lines of therapy							0.9298
1	75 (58.6%)	7.7 [4.6, 16.1]	34 (58.6%)	5.6 [2.8, 14.1]	0.89 [0.60, 1.34]	0.5769	
>= 2	81 (54.0%)	7.5 [4.2, 17.0]	41 (54.7%)	8.2 [4.6, 14.5]	0.94 [0.64, 1.37]	0.7375	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
NA denotes that the median time (and 95% CI) were not estimable
[a]From Kaplan–Meier estimate
[b]HR: hazard ratio

Table 6a.1 QLQ MY-20 Disease Symptoms: Time to deterioration by at least 10 points by subgroups eCOA-ITT Population

EORTC	KdD (N=278)		Kd (N=133)		Treatment Comparison KdD vs. Kd:		
QLQ MY-20	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Age							0.2822
<= 75	155 (61.0%)	2.9 [2.0, 5.0]	66 (57.4%)	4.7 [2.0, 13.3]	1.04 [0.78, 1.38]	0.8048	
> 75	16 (66.7%)	1.9 [1.0, NA]	8 (44.4%)	14.5 [1.3, NA]	1.69 [0.72, 3.95]	0.2058	
Sex							0.9699
Male	95 (59.4%)	3.4 [2.1, 8.7]	44 (54.3%)	5.7 [2.8, 17.6]	1.09 [0.76, 1.56]	0.6306	
Female	76 (64.4%)	2.2 [1.9, 5.6]	30 (57.7%)	3.0 [1.3, 16.8]	1.08 [0.71, 1.65]	0.6967	
Race							0.4551
White	129 (58.9%)	2.8 [1.9, 7.0]	60 (56.6%)	4.7 [2.6, 14.5]	1.03 [0.76, 1.40]	0.8214	
Non-White	42 (71.2%)	2.9 [1.9, 5.6]	14 (51.9%)	4.7 [1.1, NA]	1.33 [0.72, 2.43]	0.3472	
Geographic region							0.9927
Europe	107 (59.1%)	2.8 [1.9, 5.6]	45 (51.7%)	5.7 [2.8, NA]	1.16 [0.82, 1.64]	0.3742	
Asia Pacific	52 (65.8%)	3.8 [1.9, 10.3]	23 (63.9%)	2.8 [1.2, 17.6]	0.91 [0.56, 1.49]	0.7080	
North America	12 (66.7%)	2.8 [1.9, NA]	6 (60.0%)	9.0 [0.9, NA]	1.39 [0.52, 3.73]	0.5025	
ECOG performance status							0.2909
0-1	159 (60.0%)	3.0 [2.1, 5.6]	71 (55.0%)	5.6 [2.8, 16.8]	1.08 [0.81, 1.43]	0.5862	
2	12 (100.0%)	1.0 [1.0, 2.8]	3 (75.0%)	1.5 [1.0, 1.9]	1.00 [0.26, 3.83]	0.9976	
Prior bortezomib or ixazomib exposure							0.7227
Yes	161 (62.6%)	2.8 [1.9, 4.7]	68 (57.6%)	4.0 [2.0, 9.3]	1.06 [0.80, 1.41]	0.6783	
No	10 (47.6%)	NA [1.0, NA]	6 (40.0%)	17.6 [1.0, NA]	1.27 [0.46, 3.48]	0.6300	

Table 6a.1 QLQ MY-20 Disease Symptoms: Time to deterioration by at least 10 points by subgroups eCOA-ITT Population

EORTC	KdD (N=278)		Kd (N=133)		Treatment Comparison KdD vs. Kd:		
QLQ MY-20	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Refractory to bortezomib or ixazomib							0.3430
Yes	58 (65.2%)	1.9 [1.8, 4.7]	34 (69.4%)	2.8 [1.4, 5.6]	0.95 [0.62, 1.45]	0.7971	
No	113 (59.8%)	3.5 [2.8, 7.5]	40 (47.6%)	16.8 [3.8, NA]	1.25 [0.87, 1.79]	0.2152	
Prior lenalidomide exposure							0.1715
Yes	65 (58.6%)	2.9 [1.9, 9.4]	39 (60.9%)	4.0 [1.4, 13.3]	0.89 [0.60, 1.33]	0.5581	
No	106 (63.5%)	2.8 [1.9, 5.0]	35 (50.7%)	7.5 [2.8, NA]	1.31 [0.90, 1.92]	0.1415	
Refractory to lenalidomide							0.1585
Yes	52 (59.1%)	2.9 [1.9, 13.6]	30 (62.5%)	3.8 [1.4, 9.3]	0.84 [0.54, 1.32]	0.4419	
No	119 (62.6%)	2.8 [1.9, 5.6]	44 (51.8%)	7.5 [2.8, NA]	1.27 [0.90, 1.79]	0.1565	
Prior IMiD exposure							0.9286
Yes	115 (62.5%)	2.9 [2.0, 4.7]	53 (55.8%)	5.6 [1.9, 17.6]	1.09 [0.79, 1.51]	0.5845	
No	56 (59.6%)	2.8 [1.9, 15.4]	21 (55.3%)	3.8 [2.0, NA]	1.14 [0.69, 1.88]	0.5883	
Refractory to IMiD							0.1255
Yes	70 (60.3%)	3.8 [1.9, 13.3]	34 (60.7%)	3.7 [1.9, 9.3]	0.84 [0.56, 1.27]	0.3868	
No	101 (62.3%)	2.8 [1.9, 5.0]	40 (51.9%)	7.5 [2.8, NA]	1.31 [0.91, 1.89]	0.1270	
International Staging System (ISS)							0.7099
Stage I or II	136 (60.2%)	2.9 [2.1, 5.4]	62 (55.9%)	4.7 [2.0, 17.6]	1.06 [0.79, 1.44]	0.6699	
Stage III	34 (66.7%)	2.8 [1.9, 7.5]	12 (54.5%)	5.7 [1.4, 16.8]	1.18 [0.61, 2.28]	0.6092	
Prior proteasome inhibitor exposure							0.7422

Table 6a.1 QLQ MY-20 Disease Symptoms: Time to deterioration by at least 10 points by subgroups eCOA-ITT Population

EORTC	KdD (N=278)		Kd (N=133)		Treatment Comparison KdD vs. Kd:		
QLQ MY-20	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Yes	161 (62.4%)	2.8 [1.9, 4.7]	68 (57.1%)	4.0 [2.6, 9.3]	1.07 [0.80, 1.41]	0.6468	
No	10 (50.0%)	2.9 [1.0, NA]	6 (42.9%)	17.6 [1.0, NA]	1.26 [0.46, 3.47]	0.6339	
Number of prior lines of therapy							0.5095
1	75 (58.6%)	4.6 [2.1, 13.3]	29 (50.0%)	13.3 [2.8, NA]	1.22 [0.80, 1.88]	0.3403	
>= 2	96 (64.0%)	2.2 [1.9, 4.7]	45 (60.0%)	3.8 [1.9, 9.3]	1.01 [0.71, 1.44]	0.9477	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
NA denotes that the median time (and 95% CI) were not estimable
[a]From Kaplan–Meier estimate
[b]HR: hazard ratio

Table 6b.2 EQ5D VAS: Time to deterioration by at least 7 points by subgroups
eCOA-ITT Population

EQ5D	KdD (N=278)		Kd (N=132)		Treatment Comparison KdD vs. Kd:		
VAS	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Age							0.9973
<= 75	171 (67.3%)	4.7 [2.9, 6.8]	81 (70.4%)	3.3 [2.1, 5.6]	0.80 [0.62, 1.05]	0.0896	
> 75	20 (83.3%)	2.8 [1.0, 3.8]	14 (82.4%)	1.9 [1.0, 4.2]	0.84 [0.42, 1.69]	0.6048	
Sex							0.6247
Male	110 (68.8%)	3.8 [2.8, 7.9]	58 (72.5%)	2.8 [1.9, 5.4]	0.76 [0.55, 1.05]	0.0770	
Female	81 (68.6%)	4.6 [2.8, 6.6]	37 (71.2%)	2.8 [1.9, 5.7]	0.85 [0.58, 1.26]	0.3884	
Race							0.5860
White	149 (68.0%)	3.8 [2.8, 6.6]	76 (72.4%)	2.8 [1.9, 4.3]	0.77 [0.59, 1.02]	0.0557	
Non-White	42 (71.2%)	6.5 [1.9, 8.4]	19 (70.4%)	6.1 [1.6, 8.4]	0.94 [0.54, 1.61]	0.8030	
Geographic region							0.5335
Europe	117 (64.6%)	4.7 [2.8, 9.6]	64 (73.6%)	2.8 [1.9, 4.3]	0.67 [0.50, 0.92]	0.0078	
Asia Pacific	61 (77.2%)	2.9 [1.8, 5.6]	24 (68.6%)	4.7 [1.9, 7.5]	1.12 [0.70, 1.80]	0.6263	
North America	13 (72.2%)	4.8 [1.9, 11.2]	7 (70.0%)	5.7 [1.0, 14.5]	0.96 [0.38, 2.43]	0.9353	
ECOG performance status							0.3461
0-1	184 (69.4%)	4.0 [2.8, 6.6]	94 (73.4%)	2.8 [1.9, 4.7]	0.79 [0.62, 1.02]	0.0553	
2	6 (50.0%)	NA [1.0, NA]	1 (25.0%)	5.6 [NA, NA]	1.59 [0.19, 13.26]	0.6599	
Prior bortezomib or ixazomib exposure							0.8871
Yes	176 (68.5%)	4.0 [2.8, 6.6]	83 (70.3%)	2.8 [1.9, 4.7]	0.80 [0.61, 1.04]	0.0744	
No	15 (71.4%)	3.8 [1.0, 15.9]	12 (85.7%)	4.0 [1.0, 7.5]	0.85 [0.39, 1.83]	0.6551	

Table 6b.2 EQ5D VAS: Time to deterioration by at least 7 points by subgroups
eCOA-ITT Population

EQ5D	KdD (N=278)		Kd (N=132)		Treatment Comparison KdD vs. Kd:		
VAS	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Refractory to bortezomib or ixazomib							0.9828
Yes	60 (67.4%)	3.6 [2.8, 6.7]	34 (69.4%)	2.8 [1.3, 5.6]	0.81 [0.53, 1.23]	0.2940	
No	131 (69.3%)	4.7 [2.8, 7.5]	61 (73.5%)	3.3 [1.9, 5.4]	0.79 [0.59, 1.08]	0.1210	
Prior lenalidomide exposure							0.0766
Yes	76 (68.5%)	2.9 [1.9, 6.6]	40 (63.5%)	4.7 [2.7, 7.5]	1.01 [0.69, 1.49]	0.9452	
No	115 (68.9%)	4.1 [2.9, 7.5]	55 (79.7%)	1.9 [1.9, 3.8]	0.64 [0.46, 0.89]	0.0044	
Refractory to lenalidomide							0.1605
Yes	59 (67.0%)	4.7 [2.6, 8.5]	28 (59.6%)	5.6 [2.3, 8.4]	1.01 [0.64, 1.59]	0.9645	
No	132 (69.5%)	3.8 [2.8, 6.6]	67 (78.8%)	2.1 [1.9, 3.8]	0.69 [0.52, 0.94]	0.0107	
Prior IMiD exposure							0.1599
Yes	128 (69.6%)	2.9 [1.9, 4.7]	67 (71.3%)	3.8 [1.9, 5.6]	0.91 [0.67, 1.22]	0.4930	
No	63 (67.0%)	6.6 [3.3, 10.9]	28 (73.7%)	2.0 [1.9, 4.2]	0.57 [0.36, 0.89]	0.0099	
Refractory to IMiD							0.0414
Yes	84 (72.4%)	2.9 [1.9, 4.7]	35 (63.6%)	4.7 [2.3, 7.5]	1.08 [0.73, 1.61]	0.6834	
No	107 (66.0%)	4.9 [2.9, 10.3]	60 (77.9%)	2.1 [1.9, 3.8]	0.63 [0.46, 0.87]	0.0032	
International Staging System (ISS)							0.8100
Stage I or II	159 (70.4%)	3.8 [2.8, 6.5]	81 (73.6%)	3.1 [1.9, 4.7]	0.81 [0.62, 1.06]	0.1018	
Stage III	31 (60.8%)	6.5 [2.6, 13.3]	14 (63.6%)	2.7 [1.3, 17.8]	0.74 [0.39, 1.41]	0.3342	
Prior proteasome inhibitor exposure							0.8237

Table 6b.2 EQ5D VAS: Time to deterioration by at least 7 points by subgroups
eCOA-ITT Population

EQ5D	KdD (N=278)		Kd (N=132)		Treatment Comparison KdD vs. Kd:		
VAS	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Yes	177 (68.6%)	4.1 [2.8, 6.6]	84 (70.6%)	2.8 [1.9, 4.7]	0.79 [0.61, 1.03]	0.0666	
No	14 (70.0%)	2.8 [1.0, 17.1]	11 (84.6%)	4.2 [1.0, 8.0]	0.86 [0.39, 1.91]	0.6932	
Number of prior lines of therapy							0.3603
1	88 (68.8%)	4.7 [2.8, 8.4]	46 (79.3%)	2.8 [1.9, 5.4]	0.68 [0.48, 0.98]	0.0299	
>= 2	103 (68.7%)	3.5 [2.6, 6.6]	49 (66.2%)	2.8 [1.9, 5.6]	0.89 [0.64, 1.26]	0.4977	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
NA denotes that the median time (and 95% CI) were not estimable
[a]From Kaplan–Meier estimate
[b]HR: hazard ratio

Table 6b.1 EQ5D VAS: Time to deterioration by at least 10 points by subgroups
eCOA-ITT Population

EQ5D	KdD (N=278)		Kd (N=132)		Treatment Comparison KdD vs. Kd:		
VAS	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Age							0.6271
<= 75	148 (58.3%)	7.5 [4.7, 11.2]	74 (64.3%)	4.7 [3.1, 7.5]	0.79 [0.60, 1.05]	0.0918	
> 75	20 (83.3%)	2.9 [1.0, 3.8]	13 (76.5%)	2.9 [1.0, 8.0]	0.96 [0.47, 1.95]	0.9071	
Sex							0.9284
Male	97 (60.6%)	7.5 [2.9, 10.9]	52 (65.0%)	4.7 [2.7, 7.5]	0.80 [0.57, 1.12]	0.1808	
Female	71 (60.2%)	5.6 [3.8, 12.2]	35 (67.3%)	4.7 [2.8, 8.4]	0.80 [0.53, 1.20]	0.2671	
Race							0.7680
White	131 (59.8%)	6.5 [3.3, 10.3]	70 (66.7%)	4.7 [2.8, 6.5]	0.78 [0.59, 1.05]	0.0873	
Non-White	37 (62.7%)	7.5 [3.6, 15.9]	17 (63.0%)	7.5 [1.6, 12.4]	0.87 [0.49, 1.55]	0.6347	
Geographic region							0.9237
Europe	103 (56.9%)	8.5 [4.9, 12.2]	59 (67.8%)	4.2 [2.8, 6.5]	0.70 [0.51, 0.97]	0.0247	
Asia Pacific	55 (69.6%)	3.8 [1.9, 7.5]	21 (60.0%)	6.5 [1.9, 8.4]	1.11 [0.67, 1.84]	0.6698	
North America	10 (55.6%)	4.9 [1.9, 22.0]	7 (70.0%)	8.4 [1.0, 14.5]	0.64 [0.23, 1.74]	0.3661	
ECOG performance status							0.4302
0-1	161 (60.8%)	6.6 [4.0, 10.3]	86 (67.2%)	4.7 [2.8, 7.5]	0.79 [0.61, 1.03]	0.0682	
2	6 (50.0%)	NA [1.0, NA]	1 (25.0%)	5.6 [NA, NA]	1.59 [0.19, 13.26]	0.6599	
Prior bortezomib or ixazomib exposure							0.6914
Yes	153 (59.5%)	6.6 [3.8, 10.3]	76 (64.4%)	4.7 [2.8, 7.5]	0.79 [0.60, 1.05]	0.0880	
No	15 (71.4%)	5.6 [1.0, 15.9]	11 (78.6%)	4.0 [2.8, 8.0]	0.92 [0.42, 2.03]	0.8412	

Table 6b.1 EQ5D VAS: Time to deterioration by at least 10 points by subgroups
eCOA-ITT Population

EQ5D	KdD (N=278)		Kd (N=132)		Treatment Comparison KdD vs. Kd:		
VAS	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Refractory to bortezomib or ixazomib							0.9482
Yes	52 (58.4%)	5.3 [2.8, 15.9]	31 (63.3%)	4.7 [1.9, 8.4]	0.80 [0.51, 1.26]	0.3156	
No	116 (61.4%)	7.5 [3.8, 11.2]	56 (67.5%)	4.7 [2.8, 7.5]	0.79 [0.57, 1.09]	0.1362	
Prior lenalidomide exposure							0.1408
Yes	66 (59.5%)	4.9 [2.8, 11.3]	37 (58.7%)	7.5 [4.7, 12.1]	0.99 [0.66, 1.48]	0.9628	
No	102 (61.1%)	7.5 [3.8, 11.2]	50 (72.5%)	3.1 [1.9, 4.7]	0.65 [0.46, 0.92]	0.0108	
Refractory to lenalidomide							0.1833
Yes	50 (56.8%)	6.5 [2.8, 17.1]	25 (53.2%)	8.4 [4.7, 14.9]	1.02 [0.63, 1.66]	0.9177	
No	118 (62.1%)	6.6 [3.6, 10.3]	62 (72.9%)	3.1 [2.1, 5.4]	0.69 [0.51, 0.94]	0.0144	
Prior IMiD exposure							0.1471
Yes	113 (61.4%)	4.9 [2.8, 8.5]	60 (63.8%)	5.6 [2.8, 8.4]	0.91 [0.67, 1.25]	0.5600	
No	55 (58.5%)	9.6 [3.8, 15.9]	27 (71.1%)	3.8 [2.1, 6.5]	0.56 [0.35, 0.90]	0.0125	
Refractory to IMiD							0.0532
Yes	74 (63.8%)	4.7 [1.9, 7.5]	32 (58.2%)	7.5 [3.8, 12.4]	1.09 [0.72, 1.65]	0.6646	
No	94 (58.0%)	9.4 [4.0, 13.1]	55 (71.4%)	3.8 [2.8, 6.5]	0.63 [0.45, 0.89]	0.0055	
International Staging System (ISS)							0.9473
Stage I or II	138 (61.1%)	6.6 [3.8, 10.3]	74 (67.3%)	4.7 [2.9, 7.5]	0.79 [0.60, 1.05]	0.0965	
Stage III	29 (56.9%)	6.5 [2.6, 14.0]	13 (59.1%)	4.7 [1.9, NA]	0.80 [0.41, 1.55]	0.4886	
Prior proteasome inhibitor exposure							0.6278

Table 6b.1 EQ5D VAS: Time to deterioration by at least 10 points by subgroups
eCOA-ITT Population

EQ5D	KdD (N=278)		Kd (N=132)		Treatment Comparison KdD vs. Kd:		
VAS	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Yes	154 (59.7%)	6.7 [4.0, 10.3]	77 (64.7%)	4.7 [2.8, 7.5]	0.79 [0.60, 1.04]	0.0786	
No	14 (70.0%)	3.8 [1.0, 17.1]	10 (76.9%)	4.2 [2.8, 10.1]	0.97 [0.43, 2.22]	0.9504	
Number of prior lines of therapy							0.2906
1	78 (60.9%)	7.9 [4.6, 13.1]	42 (72.4%)	3.8 [2.8, 7.5]	0.66 [0.45, 0.96]	0.0256	
>= 2	90 (60.0%)	4.9 [2.8, 10.3]	45 (60.8%)	5.6 [2.3, 10.1]	0.91 [0.64, 1.30]	0.5925	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
NA denotes that the median time (and 95% CI) were not estimable
[a]From Kaplan–Meier estimate
[b]HR: hazard ratio

Table 7.7 Change from Baseline in EORTC QLQ-C30 - Fatigue Symptom Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
Age									0.7429
<= 75	265	31.9 (19.21)	2.0 (0.86)	119	31.0 (18.80)	0.6 (1.26)	1.4 [-1.52, 4.27]; 0.3507	0.1 [-0.12; 0.32]	
> 75	25	34.1 (16.19)	2.0 (2.31)	16	27.9 (11.37)	-1.7 (2.90)	3.7 [-3.43, 10.92]; 0.2949	0.3 [-0.31; 0.95]	
Sex									0.2395
Male	165	29.3 (18.23)	2.0 (1.05)	81	29.8 (18.54)	1.8 (1.49)	0.3 [-3.15, 3.75]; 0.8647	0.0 [-0.24; 0.29]	
Female	125	35.7 (19.34)	2.1 (1.25)	54	31.8 (17.45)	-1.1 (1.87)	3.2 [-1.09, 7.49]; 0.1425	0.2 [-0.09; 0.55]	
Race									0.6437
White	228	32.3 (19.04)	2.1 (0.91)	109	30.5 (16.73)	0.7 (1.30)	1.4 [-1.60, 4.46]; 0.3530	0.1 [-0.12; 0.33]	
Non-White	62	31.0 (18.78)	1.1 (1.73)	26	31.1 (23.28)	-1.2 (2.64)	2.3 [-3.79, 8.41]; 0.4520	0.2 [-0.29; 0.63]	
Geographic region									0.2984
Europe	189	33.7 (19.64)	3.2 (1.03)	90	29.7 (18.57)	-0.5 (1.46)	3.7 [0.28, 7.05]; 0.0338	0.3 [0.01; 0.51]	
Asia Pacific	83	27.0 (16.89)	-1.1 (1.46)	35	31.2 (17.79)	0.9 (2.23)	-2.0 [-7.08, 3.12]; 0.4423	-0.1 [-0.54; 0.25]	
North America	18	37.4 (16.88)	2.7 (2.90)	10	36.7 (14.45)	5.6 (3.90)	-2.9 [-12.6, 6.82]; 0.5412	-0.2 [-1.01; 0.55]	
ECOG performance status									0.6878
0-1	277	32.1 (18.96)	2.2 (0.83)	132	30.1 (17.88)	0.5 (1.19)	1.8 [-0.98, 4.50]; 0.2062	0.1 [-0.08; 0.34]	
2	12	33.5 (18.72)	-1.7 (3.62)	3	52.2 (15.35)	1.6 (7.82)	-3.3 [-21.5, 14.87]; 0.6995	-0.2 [-1.52; 1.02]	

Table 7.7 Change from Baseline in EORTC QLQ-C30 - Fatigue Symptom Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	N	Baseline Mean (SD)	Change from BL LSMean(SE)	N	Baseline Mean (SD)	Change from BL LSMean(SE)	Difference in LSMean [95%-CI]; p-value	Hedges'g [95%-CI]	
Prior bortezomib or ixazomib exposure									0.0888
Yes	267	32.4 (19.22)	2.1 (0.84)	120	31.9 (18.21)	1.1 (1.23)	1.0 [-1.81, 3.85]; 0.4776	0.1 [-0.14; 0.29]	
No	23	28.0 (15.37)	-0.0 (2.86)	15	20.8 (13.90)	-6.5 (3.58)	6.4 [-2.77, 15.65]; 0.1641	0.5 [-0.20; 1.12]	
Refractory to bortezomib or ixazomib									0.4492
Yes	94	34.1 (17.85)	1.7 (1.26)	49	37.2 (20.91)	2.2 (1.70)	-0.4 [-4.43, 3.53]; 0.8227	-0.0 [-0.38; 0.31]	
No	196	31.0 (19.43)	1.8 (1.04)	86	26.9 (15.13)	-1.4 (1.55)	3.3 [-0.29, 6.81]; 0.0718	0.2 [-0.03; 0.48]	
Prior lenalidomide exposure									0.7997
Yes	115	32.7 (19.92)	2.1 (1.37)	64	31.7 (18.45)	0.1 (1.84)	2.1 [-2.33, 6.50]; 0.3522	0.1 [-0.17; 0.45]	
No	175	31.6 (18.34)	0.1 (0.30)	71	29.6 (17.80)	0.2 (0.44)	-0.1 [-0.95, 0.68]; 0.7483	-0.0 [-0.31; 0.24]	
Refractory to lenalidomide									0.5102
Yes	92	32.4 (20.65)	2.0 (1.45)	48	31.1 (15.66)	-0.1 (2.01)	2.1 [-2.68, 6.86]; 0.3871	0.1 [-0.20; 0.50]	
No	198	31.9 (18.17)	0.4 (0.34)	87	30.4 (19.36)	0.2 (0.45)	0.2 [-0.63, 0.95]; 0.6870	0.0 [-0.22; 0.29]	
Prior IMiD exposure									0.5590
Yes	192	33.4 (19.13)	1.5 (1.05)	94	30.8 (18.18)	-1.0 (1.48)	2.5 [-0.99, 5.90]; 0.1610	0.2 [-0.08; 0.42]	

Table 7.7 Change from Baseline in EORTC QLQ-C30 - Fatigue Symptom Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
No	98	29.3 (18.40)	2.7 (1.26)	41	30.3 (18.05)	2.6 (1.93)	0.1 [-4.25, 4.54]; 0.9478	0.0 [-0.35; 0.38]	
Refractory to IMiD									0.3644
Yes	120	31.9 (19.66)	1.5 (1.28)	56	32.3 (18.53)	0.4 (1.87)	1.1 [-3.23, 5.46]; 0.6116	0.1 [-0.24; 0.40]	
No	170	32.1 (18.50)	0.6 (0.44)	79	29.4 (17.77)	0.4 (0.52)	0.2 [-0.60, 0.99]; 0.6276	0.0 [-0.23; 0.30]	
International Staging System (ISS)									0.3345
Stage I or II	237	32.0 (19.25)	1.9 (0.88)	115	29.0 (16.58)	-0.3 (1.26)	2.2 [-0.74, 5.12]; 0.1429	0.2 [-0.06; 0.38]	
Stage III	52	32.1 (17.94)	2.3 (1.87)	20	40.1 (23.29)	4.2 (3.11)	-1.9 [-9.05, 5.27]; 0.5971	-0.1 [-0.65; 0.38]	
Prior proteasome inhibitor exposure									0.0609
Yes	268	32.4 (19.20)	2.1 (0.84)	121	31.9 (18.13)	1.1 (1.23)	1.0 [-1.84, 3.81]; 0.4918	0.1 [-0.14; 0.29]	
No	22	27.2 (15.23)	0.1 (2.79)	14	19.8 (13.77)	-6.6 (3.54)	6.7 [-2.41, 15.77]; 0.1438	0.5 [-0.18; 1.18]	
Number of prior lines of therapy									0.3981
1	130	30.6 (18.22)	2.1 (1.10)	63	27.5 (17.15)	-0.9 (1.56)	3.0 [-0.63, 6.57]; 0.1054	0.2 [-0.06; 0.54]	
>= 2	160	33.2 (19.52)	1.9 (1.18)	72	33.4 (18.53)	1.5 (1.74)	0.4 [-3.66, 4.37]; 0.8619	0.0 [-0.25; 0.30]	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
Mixed Model Repeated Measurement for change from baseline score, with time and treatment as independent variables, and baseline score included as a covariate

Table 7.8 Change from Baseline in EORTC QLQ-C30 - Nausea/Vomiting Symptom Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
Age									0.5175
<= 75	265	4.0 (6.44)	0.5 (0.35)	119	3.3 (6.41)	0.3 (0.51)	0.2 [-0.89, 1.37]; 0.6771	0.0 [-0.17; 0.26]	
> 75	25	1.5 (3.01)	-0.2 (0.61)	16	1.9 (3.97)	0.2 (0.78)	-0.5 [-2.17, 1.27]; 0.5975	-0.1 [-0.77; 0.48]	
Sex									0.4433
Male	165	2.7 (4.77)	0.3 (0.37)	81	2.6 (5.53)	0.4 (0.51)	-0.1 [-1.18, 1.06]; 0.9157	-0.0 [-0.28; 0.25]	
Female	125	5.3 (7.55)	0.5 (0.58)	54	4.0 (7.01)	-0.0 (0.85)	0.5 [-1.39, 2.36]; 0.6097	0.1 [-0.24; 0.39]	
Race									0.7435
White	228	3.7 (6.24)	0.3 (0.34)	109	3.1 (5.91)	0.1 (0.49)	0.3 [-0.83, 1.33]; 0.6472	0.0 [-0.18; 0.28]	
Non-White	62	4.2 (6.35)	1.1 (0.87)	26	3.6 (7.29)	1.2 (1.31)	-0.1 [-3.14, 2.85]; 0.9236	-0.0 [-0.48; 0.44]	
Geographic region									0.9812
Europe	189	3.4 (6.05)	0.4 (0.39)	90	3.0 (5.89)	0.0 (0.54)	0.4 [-0.82, 1.56]; 0.5378	0.1 [-0.18; 0.32]	
Asia Pacific	83	4.1 (5.77)	0.3 (0.65)	35	3.3 (6.78)	0.6 (0.96)	-0.3 [-2.38, 1.81]; 0.7855	-0.0 [-0.44; 0.35]	
North America	18	7.4 (9.10)	1.5 (1.74)	10	4.0 (6.99)	0.0 (2.34)	1.5 [-4.33, 7.33]; 0.5970	0.2 [-0.58; 0.97]	
ECOG performance status									0.7424
0-1	277	3.8 (6.29)	0.4 (0.34)	132	3.1 (6.15)	0.2 (0.47)	0.2 [-0.82, 1.26]; 0.6741	0.0 [-0.17; 0.25]	
2	12	4.2 (5.65)	0.8 (1.68)	3	4.8 (8.25)	0.8 (3.94)	0.0 [-8.77, 8.80]; 0.9963	0.0 [-1.26; 1.27]	

Table 7.8 Change from Baseline in EORTC QLQ-C30 - Nausea/Vomiting Symptom Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
Prior bortezomib or ixazomib exposure									0.7052
Yes	267	4.0 (6.44)	0.4 (0.35)	120	3.5 (6.42)	0.3 (0.52)	0.1 [-1.03, 1.24]; 0.8568	0.0 [-0.20; 0.23]	
No	23	2.2 (2.99)	0.2 (0.45)	15	0.9 (2.86)	-0.4 (0.58)	0.7 [-0.72, 2.03]; 0.3321	0.3 [-0.36; 0.95]	
Refractory to bortezomib or ixazomib									0.8257
Yes	94	4.1 (6.39)	0.5 (0.65)	49	4.1 (7.14)	0.6 (0.87)	-0.2 [-2.17, 1.85]; 0.8759	-0.0 [-0.37; 0.32]	
No	196	3.7 (6.20)	0.4 (0.39)	86	2.7 (5.53)	-0.0 (0.57)	0.4 [-0.79, 1.68]; 0.4753	0.1 [-0.17; 0.34]	
Prior lenalidomide exposure									0.9776
Yes	115	4.2 (6.96)	0.8 (0.54)	64	3.1 (5.98)	0.1 (0.72)	0.8 [-0.89, 2.41]; 0.3622	0.1 [-0.17; 0.44]	
No	175	3.6 (5.75)	0.2 (0.42)	71	3.2 (6.38)	0.3 (0.62)	-0.1 [-1.45, 1.22]; 0.8696	-0.0 [-0.30; 0.26]	
Refractory to lenalidomide									0.0045
Yes	92	4.4 (7.46)	0.9 (0.63)	48	3.0 (5.35)	0.1 (0.88)	0.7 [-1.31, 2.74]; 0.4861	0.1 [-0.23; 0.47]	
No	198	3.6 (5.61)	0.3 (0.38)	87	3.3 (6.61)	0.2 (0.55)	0.1 [-1.09, 1.28]; 0.8803	0.0 [-0.24; 0.27]	
Prior IMiD exposure									0.9945
Yes	192	4.4 (6.69)	0.6 (0.43)	94	3.6 (6.57)	0.4 (0.59)	0.2 [-1.10, 1.49]; 0.7645	0.0 [-0.21; 0.28]	

Table 7.8 Change from Baseline in EORTC QLQ-C30 - Nausea/Vomiting Symptom Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
No	98	2.6 (5.13)	0.2 (0.48)	41	2.3 (5.11)	-0.3 (0.73)	0.5 [-1.11, 2.12]; 0.5375	0.1 [-0.26; 0.47]	
Refractory to IMiD									0.3246
Yes	120	4.1 (6.83)	0.6 (0.58)	56	3.9 (6.99)	1.0 (0.85)	-0.5 [-2.36, 1.45]; 0.6400	-0.1 [-0.39; 0.25]	
No	170	3.6 (5.83)	0.4 (0.39)	79	2.7 (5.52)	-0.3 (0.55)	0.7 [-0.50, 1.88]; 0.2556	0.1 [-0.13; 0.40]	
International Staging System (ISS)									0.0253
Stage I or II	237	3.7 (5.95)	0.6 (0.34)	115	2.6 (5.30)	-0.2 (0.48)	0.7 [-0.33, 1.80]; 0.1770	0.1 [-0.08; 0.36]	
Stage III	52	4.2 (7.47)	-0.1 (0.89)	20	6.6 (9.26)	2.9 (1.50)	-3.1 [-6.47, 0.34]; 0.0761	-0.5 [-0.99; 0.05]	
Prior proteasome inhibitor exposure									0.3579
Yes	268	4.0 (6.43)	0.4 (0.35)	121	3.5 (6.43)	0.4 (0.51)	0.0 [-1.08, 1.18]; 0.9346	0.0 [-0.21; 0.22]	
No	22	2.2 (3.06)	0.4 (0.42)	14	0.2 (0.51)	-0.7 (0.55)	1.1 [-0.17, 2.44]; 0.0859	0.5 [-0.13; 1.23]	
Number of prior lines of therapy									0.3369
1	130	3.3 (5.83)	0.3 (0.42)	63	2.5 (5.25)	-0.4 (0.59)	0.7 [-0.59, 2.00]; 0.2847	0.1 [-0.15; 0.45]	
>= 2	160	4.3 (6.56)	0.6 (0.50)	72	3.8 (6.86)	0.8 (0.72)	-0.2 [-1.80, 1.37]; 0.7898	-0.0 [-0.31; 0.24]	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
Mixed Model Repeated Measurement for change from baseline score, with time and treatment as independent variables, and baseline score included as a covariate

Table 7.9 Change from Baseline in EORTC QLQ-C30 - Pain Symptom Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
Age									0.5213
<= 75	265	23.4 (19.83)	1.7 (0.95)	119	24.9 (21.24)	2.1 (1.40)	-0.4 [-3.63, 2.79]; 0.7964	-0.0 [-0.24; 0.19]	
> 75	25	16.6 (15.99)	-2.9 (2.84)	16	21.6 (22.12)	2.2 (3.57)	-5.1 [-14.0, 3.78]; 0.2491	-0.4 [-0.99; 0.28]	
Sex									0.8430
Male	165	20.5 (18.79)	1.4 (1.08)	81	23.4 (21.14)	2.6 (1.52)	-1.2 [-4.70, 2.31]; 0.5012	-0.1 [-0.35; 0.18]	
Female	125	25.8 (20.30)	0.8 (1.51)	54	26.2 (21.60)	1.1 (2.27)	-0.3 [-5.55, 4.93]; 0.9077	-0.0 [-0.34; 0.30]	
Race									0.6607
White	228	22.8 (20.23)	1.2 (1.03)	109	24.7 (20.98)	2.5 (1.48)	-1.3 [-4.79, 2.10]; 0.4422	-0.1 [-0.32; 0.14]	
Non-White	62	22.8 (17.23)	1.1 (1.78)	26	23.9 (22.98)	-0.5 (2.72)	1.6 [-4.67, 7.86]; 0.6123	0.1 [-0.35; 0.57]	
Geographic region									0.7518
Europe	189	23.8 (20.23)	1.7 (1.13)	90	23.3 (21.49)	1.2 (1.61)	0.5 [-3.24, 4.22]; 0.7962	0.0 [-0.22; 0.28]	
Asia Pacific	83	18.5 (16.45)	-0.2 (1.59)	35	27.2 (22.00)	4.7 (2.42)	-4.9 [-10.4, 0.69]; 0.0853	-0.3 [-0.73; 0.06]	
North America	18	31.6 (22.70)	3.9 (3.96)	10	26.5 (17.39)	-0.1 (5.33)	4.1 [-9.36, 17.50]; 0.5362	0.2 [-0.54; 1.01]	
ECOG performance status									0.7936
0-1	277	22.8 (19.81)	1.5 (0.92)	132	23.8 (20.89)	1.9 (1.32)	-0.4 [-3.49, 2.60]; 0.7731	-0.0 [-0.24; 0.18]	
2	12	22.9 (14.04)	-1.9 (4.09)	3	55.8 (17.11)	10.8 (8.82)	-12.7 [-33.3, 7.83]; 0.2042	-0.8 [-2.15; 0.48]	

Table 7.9 Change from Baseline in EORTC QLQ-C30 - Pain Symptom Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
Prior bortezomib or ixazomib exposure									0.3045
Yes	267	23.3 (19.95)	1.2 (0.95)	120	26.2 (21.29)	2.6 (1.40)	-1.4 [-4.64, 1.78]; 0.3810	-0.1 [-0.31; 0.12]	
No	23	17.0 (13.91)	1.9 (2.50)	15	11.4 (16.60)	-1.9 (3.12)	3.8 [-4.30, 11.86]; 0.3459	0.3 [-0.35; 0.96]	
Refractory to bortezomib or ixazomib									0.3450
Yes	94	24.9 (18.95)	1.0 (1.58)	49	31.4 (25.11)	3.4 (2.15)	-2.4 [-7.45, 2.68]; 0.3519	-0.2 [-0.50; 0.19]	
No	196	21.8 (19.87)	1.2 (1.09)	86	20.6 (17.77)	0.6 (1.63)	0.6 [-3.12, 4.34]; 0.7468	0.0 [-0.21; 0.29]	
Prior lenalidomide exposure									0.7977
Yes	115	24.2 (20.88)	1.1 (1.55)	64	25.0 (22.09)	0.2 (2.08)	0.8 [-4.14, 5.81]; 0.7399	0.1 [-0.26; 0.36]	
No	175	21.8 (18.71)	1.1 (1.11)	71	24.1 (20.69)	2.9 (1.70)	-1.8 [-5.64, 2.04]; 0.3568	-0.1 [-0.40; 0.15]	
Refractory to lenalidomide									0.1998
Yes	92	24.8 (21.49)	1.3 (1.71)	48	24.9 (20.48)	-0.2 (2.37)	1.5 [-4.11, 7.14]; 0.5944	0.1 [-0.26; 0.44]	
No	198	21.8 (18.64)	1.2 (1.06)	87	24.3 (21.84)	2.9 (1.57)	-1.7 [-5.32, 1.84]; 0.3391	-0.1 [-0.37; 0.14]	
Prior IMiD exposure									0.2840
Yes	192	25.0 (20.23)	1.5 (1.15)	94	24.0 (21.20)	0.4 (1.62)	1.1 [-2.63, 4.90]; 0.5519	0.1 [-0.18; 0.32]	

Table 7.9 Change from Baseline in EORTC QLQ-C30 - Pain Symptom Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
No	98	18.5 (17.62)	0.8 (1.41)	41	25.8 (21.70)	5.0 (2.17)	-4.2 [-9.16, 0.74]; 0.0945	-0.3 [-0.67; 0.07]	
Refractory to IMiD									0.6399
Yes	120	23.8 (20.54)	0.7 (1.47)	56	26.4 (22.54)	1.3 (2.16)	-0.6 [-5.63, 4.40]; 0.8080	-0.0 [-0.36; 0.28]	
No	170	22.0 (18.93)	1.6 (1.14)	79	23.2 (20.40)	2.4 (1.65)	-0.8 [-4.57, 3.01]; 0.6851	-0.1 [-0.32; 0.21]	
International Staging System (ISS)									0.3702
Stage I or II	237	22.2 (19.28)	1.4 (0.97)	115	22.9 (20.40)	1.6 (1.38)	-0.2 [-3.42, 3.00]; 0.8958	-0.0 [-0.24; 0.21]	
Stage III	52	25.7 (21.03)	0.3 (2.26)	20	33.9 (24.31)	4.7 (3.73)	-4.4 [-13.0, 4.20]; 0.3105	-0.3 [-0.78; 0.25]	
Prior proteasome inhibitor exposure									0.1843
Yes	268	23.3 (19.94)	1.2 (0.94)	121	26.2 (21.22)	2.7 (1.39)	-1.5 [-4.71, 1.69]; 0.3535	-0.1 [-0.31; 0.12]	
No	22	15.9 (13.25)	2.3 (2.40)	14	9.7 (15.82)	-2.5 (3.02)	4.7 [-3.08, 12.58]; 0.2238	0.4 [-0.27; 1.09]	
Number of prior lines of therapy									0.5531
1	130	22.4 (19.83)	1.9 (1.30)	63	21.5 (19.77)	1.4 (1.87)	0.5 [-3.84, 4.83]; 0.8221	0.0 [-0.27; 0.33]	
>= 2	160	23.1 (19.47)	0.7 (1.24)	72	27.2 (22.32)	2.7 (1.82)	-1.9 [-6.14, 2.25]; 0.3613	-0.1 [-0.40; 0.15]	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
Mixed Model Repeated Measurement for change from baseline score, with time and treatment as independent variables, and baseline score included as a covariate

Table 7.10 Change from Baseline in EORTC QLQ-C30 - Dyspnoea Symptom Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
Age									0.2615
<= 75	265	18.5 (17.17)	0.9 (0.46)	119	20.0 (16.09)	1.7 (0.62)	-0.8 [-1.96, 0.35]; 0.1716	-0.1 [-0.33; 0.11]	
> 75	25	13.7 (15.95)	-2.6 (3.03)	16	18.0 (16.42)	0.7 (3.82)	-3.4 [-12.7, 6.01]; 0.4698	-0.2 [-0.85; 0.41]	
Sex									0.8179
Male	165	18.1 (16.94)	1.1 (1.19)	81	20.4 (16.07)	2.9 (1.67)	-1.8 [-5.62, 2.03]; 0.3562	-0.1 [-0.38; 0.15]	
Female	125	18.1 (17.37)	-0.1 (1.32)	54	18.9 (16.20)	-0.1 (1.97)	0.0 [-4.47, 4.48]; 0.9996	0.0 [-0.32; 0.32]	
Race									0.0296
White	228	16.6 (16.51)	0.2 (0.98)	109	19.8 (16.55)	2.6 (1.41)	-2.4 [-5.62, 0.85]; 0.1484	-0.2 [-0.39; 0.07]	
Non-White	62	23.5 (18.24)	0.9 (1.85)	26	19.9 (14.25)	-2.4 (2.80)	3.3 [-3.11, 9.64]; 0.3107	0.2 [-0.24; 0.68]	
Geographic region									0.3387
Europe	189	16.3 (17.10)	0.2 (1.11)	90	17.8 (15.56)	1.1 (1.59)	-0.9 [-4.56, 2.70]; 0.6147	-0.1 [-0.31; 0.19]	
Asia Pacific	83	21.1 (17.19)	0.4 (1.64)	35	23.4 (17.36)	1.1 (2.48)	-0.7 [-6.28, 4.84]; 0.7967	-0.0 [-0.44; 0.35]	
North America	18	23.3 (14.18)	1.3 (2.64)	10	24.4 (14.31)	6.0 (3.58)	-4.6 [-13.3, 4.01]; 0.2777	-0.4 [-1.18; 0.38]	
ECOG performance status									0.0811
0-1	277	18.1 (17.00)	0.3 (0.90)	132	19.5 (15.98)	1.5 (1.28)	-1.2 [-4.13, 1.69]; 0.4093	-0.1 [-0.29; 0.13]	
2	12	18.2 (20.68)	3.3 (4.79)	3	31.0 (20.34)	-1.5 (10.40)	4.9 [-19.1, 28.82]; 0.6684	0.3 [-1.00; 1.54]	

Table 7.10 Change from Baseline in EORTC QLQ-C30 - Dyspnoea Symptom Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
Prior bortezomib or ixazomib exposure									0.0614
Yes	267	18.0 (17.28)	0.4 (0.92)	120	20.5 (16.47)	2.0 (1.36)	-1.6 [-4.71, 1.45]; 0.2980	-0.1 [-0.32; 0.11]	
No	23	18.8 (15.08)	1.0 (2.61)	15	14.1 (11.44)	-2.2 (3.30)	3.2 [-5.13, 11.54]; 0.4390	0.2 [-0.40; 0.90]	
Refractory to bortezomib or ixazomib									0.7743
Yes	94	18.9 (17.12)	0.0 (1.71)	49	22.0 (18.15)	1.4 (2.33)	-1.3 [-6.83, 4.17]; 0.6338	-0.1 [-0.43; 0.27]	
No	196	17.7 (17.12)	0.6 (1.02)	86	18.5 (14.74)	1.4 (1.52)	-0.8 [-4.20, 2.59]; 0.6396	-0.1 [-0.31; 0.20]	
Prior lenalidomide exposure									0.5080
Yes	115	20.7 (17.85)	0.3 (1.40)	64	22.0 (16.44)	1.5 (1.88)	-1.2 [-5.66, 3.18]; 0.5805	-0.1 [-0.39; 0.22]	
No	175	16.3 (16.40)	0.7 (1.13)	71	17.8 (15.59)	1.2 (1.71)	-0.5 [-4.30, 3.33]; 0.8023	-0.0 [-0.31; 0.24]	
Refractory to lenalidomide									0.2179
Yes	92	20.1 (18.00)	0.2 (1.54)	48	21.6 (16.62)	1.7 (2.14)	-1.5 [-6.49, 3.53]; 0.5595	-0.1 [-0.45; 0.25]	
No	198	17.2 (16.63)	0.7 (1.08)	87	18.8 (15.79)	1.5 (1.58)	-0.7 [-4.28, 2.82]; 0.6851	-0.0 [-0.30; 0.20]	
Prior IMiD exposure									0.3041
Yes	192	20.9 (17.58)	0.3 (1.08)	94	20.9 (16.22)	0.4 (1.51)	-0.1 [-3.57, 3.31]; 0.9407	-0.0 [-0.26; 0.24]	

Table 7.10 Change from Baseline in EORTC QLQ-C30 - Dyspnoea Symptom Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
No	98	12.6 (14.74)	0.6 (1.47)	41	17.2 (15.64)	3.5 (2.25)	-2.9 [-7.95, 2.25]; 0.2703	-0.2 [-0.56; 0.17]	
Refractory to IMiD									0.7175
Yes	120	20.1 (18.37)	0.5 (1.41)	56	20.5 (15.99)	0.9 (2.06)	-0.4 [-5.08, 4.38]; 0.8835	-0.0 [-0.34; 0.29]	
No	170	16.6 (16.04)	0.6 (1.13)	79	19.3 (16.22)	2.1 (1.61)	-1.5 [-5.13, 2.15]; 0.4217	-0.1 [-0.37; 0.17]	
International Staging System (ISS)									0.2419
Stage I or II	237	18.4 (16.75)	0.2 (0.94)	115	19.8 (16.08)	1.8 (1.34)	-1.5 [-4.61, 1.54]; 0.3271	-0.1 [-0.33; 0.12]	
Stage III	52	16.1 (18.29)	2.2 (2.18)	20	19.9 (16.50)	0.4 (3.63)	1.8 [-6.47, 10.08]; 0.6646	0.1 [-0.40; 0.63]	
Prior proteasome inhibitor exposure									0.0311
Yes	268	18.0 (17.25)	0.4 (0.92)	121	20.6 (16.42)	2.1 (1.36)	-1.7 [-4.82, 1.34]; 0.2670	-0.1 [-0.33; 0.10]	
No	22	19.0 (15.42)	1.2 (2.53)	14	13.0 (11.00)	-3.0 (3.23)	4.2 [-3.94, 12.38]; 0.2985	0.3 [-0.33; 1.02]	
Number of prior lines of therapy									0.5040
1	130	17.8 (15.76)	1.8 (1.16)	63	17.0 (14.93)	1.5 (1.66)	0.3 [-3.41, 4.09]; 0.8567	0.0 [-0.28; 0.33]	
>= 2	160	18.3 (18.15)	-0.7 (1.31)	72	22.2 (16.75)	1.6 (1.92)	-2.3 [-6.71, 2.05]; 0.2954	-0.1 [-0.42; 0.14]	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
Mixed Model Repeated Measurement for change from baseline score, with time and treatment as independent variables, and baseline score included as a covariate

Table 7.11 Change from Baseline in EORTC QLQ-C30 - Dyspnoea Symptom Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
Age									0.7099
<= 75	265	22.9 (20.32)	0.8 (0.49)	119	22.5 (19.70)	0.4 (0.67)	0.4 [-0.88, 1.61]; 0.5615	0.0 [-0.17; 0.26]	
> 75	25	17.5 (16.17)	4.6 (2.70)	16	10.1 (10.96)	0.2 (3.38)	4.4 [-3.73, 12.60]; 0.2765	0.3 [-0.31; 0.95]	
Sex									0.4309
Male	165	20.4 (19.21)	2.6 (1.29)	81	19.4 (19.38)	1.4 (1.82)	1.2 [-2.99, 5.38]; 0.5735	0.1 [-0.19; 0.34]	
Female	125	25.0 (20.86)	-0.0 (1.45)	54	23.7 (19.00)	-0.7 (2.17)	0.7 [-4.24, 5.57]; 0.7888	0.0 [-0.28; 0.36]	
Race									0.8912
White	228	22.3 (19.96)	1.2 (1.07)	109	21.1 (20.12)	0.6 (1.53)	0.6 [-2.94, 4.12]; 0.7417	0.0 [-0.19; 0.26]	
Non-White	62	22.6 (20.46)	1.1 (2.11)	26	21.1 (15.53)	-1.9 (3.20)	3.0 [-4.32, 10.38]; 0.4137	0.2 [-0.28; 0.64]	
Geographic region									0.3477
Europe	189	21.7 (20.49)	1.4 (1.23)	90	21.0 (20.09)	1.1 (1.75)	0.3 [-3.72, 4.31]; 0.8860	0.0 [-0.23; 0.27]	
Asia Pacific	83	20.9 (17.15)	0.6 (1.65)	35	19.4 (16.93)	-1.0 (2.49)	1.6 [-3.95, 7.20]; 0.5649	0.1 [-0.29; 0.50]	
North America	18	36.0 (23.47)	3.9 (3.65)	10	27.8 (19.80)	-3.2 (4.91)	7.0 [-5.24, 19.26]; 0.2456	0.4 [-0.34; 1.22]	
ECOG performance status									0.4416
0-1	277	22.6 (19.98)	1.4 (0.98)	132	20.5 (18.90)	0.0 (1.39)	1.3 [-1.83, 4.51]; 0.4054	0.1 [-0.12; 0.29]	
2	12	17.2 (22.32)	-0.5 (6.41)	3	44.4 (25.46)	8.8 (13.39)	-9.2 [-41.0, 22.48]; 0.5394	-0.4 [-1.66; 0.89]	

Table 7.11 Change from Baseline in EORTC QLQ-C30 - Dyspnoea Symptom Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
Prior bortezomib or ixazomib exposure									0.1598
Yes	267	22.5 (20.39)	1.3 (1.00)	120	22.2 (19.47)	0.9 (1.48)	0.4 [-2.99, 3.73]; 0.8289	0.0 [-0.19; 0.24]	
No	23	21.0 (15.52)	1.8 (3.04)	15	12.4 (15.58)	-4.9 (3.81)	6.7 [-3.04, 16.48]; 0.1700	0.4 [-0.21; 1.11]	
Refractory to bortezomib or ixazomib									0.3256
Yes	94	22.9 (20.99)	1.0 (1.81)	49	25.7 (21.32)	2.3 (2.47)	-1.4 [-7.19, 4.43]; 0.6378	-0.1 [-0.42; 0.27]	
No	196	22.1 (19.61)	1.3 (1.15)	86	18.4 (17.58)	-1.1 (1.71)	2.4 [-1.40, 6.28]; 0.2117	0.2 [-0.10; 0.41]	
Prior lenalidomide exposure									0.7313
Yes	115	21.9 (20.69)	1.4 (1.55)	64	21.3 (20.75)	0.1 (2.08)	1.3 [-3.64, 6.18]; 0.6100	0.1 [-0.23; 0.38]	
No	175	22.7 (19.64)	1.3 (1.24)	71	20.9 (17.99)	0.4 (1.89)	0.9 [-3.28, 5.12]; 0.6660	0.1 [-0.22; 0.33]	
Refractory to lenalidomide									0.6664
Yes	92	22.3 (21.49)	0.9 (1.73)	48	20.5 (20.31)	-1.0 (2.41)	1.9 [-3.81, 7.56]; 0.5151	0.1 [-0.24; 0.46]	
No	198	22.4 (19.37)	1.7 (1.17)	87	21.4 (18.79)	1.1 (1.71)	0.6 [-3.22, 4.48]; 0.7463	0.0 [-0.21; 0.29]	
Prior IMiD exposure									0.7908
Yes	192	25.1 (21.76)	1.6 (1.28)	94	22.2 (19.44)	-0.4 (1.80)	2.0 [-2.14, 6.19]; 0.3395	0.1 [-0.13; 0.36]	

Table 7.11 Change from Baseline in EORTC QLQ-C30 - Dyspnoea Symptom Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
No	98	17.1 (14.87)	0.8 (1.30)	41	18.4 (18.85)	1.1 (1.97)	-0.2 [-4.62, 4.13]; 0.9112	-0.0 [-0.38; 0.35]	
Refractory to IMiD									0.6447
Yes	120	23.2 (20.92)	0.8 (1.49)	56	22.0 (20.25)	-0.1 (2.17)	1.0 [-4.02, 5.95]; 0.7028	0.1 [-0.26; 0.38]	
No	170	21.8 (19.42)	1.9 (1.27)	79	20.4 (18.65)	0.8 (1.82)	1.1 [-3.03, 5.22]; 0.6017	0.1 [-0.20; 0.33]	
International Staging System (ISS)									0.3317
Stage I or II	237	22.9 (20.34)	1.4 (1.06)	115	20.6 (19.53)	-0.2 (1.51)	1.6 [-1.90, 5.04]; 0.3741	0.1 [-0.13; 0.32]	
Stage III	52	20.1 (18.80)	1.2 (2.16)	20	23.6 (17.98)	2.4 (3.59)	-1.2 [-9.41, 6.97]; 0.7663	-0.1 [-0.59; 0.44]	
Prior proteasome inhibitor exposure									0.2842
Yes	268	22.6 (20.42)	1.3 (1.00)	121	22.0 (19.49)	0.7 (1.47)	0.6 [-2.75, 3.93]; 0.7276	0.0 [-0.18; 0.25]	
No	22	19.8 (14.60)	1.7 (3.17)	14	13.2 (15.77)	-3.1 (4.01)	4.7 [-5.51, 15.01]; 0.3524	0.3 [-0.36; 0.99]	
Number of prior lines of therapy									0.2442
1	130	22.8 (21.02)	1.0 (1.42)	63	20.3 (17.67)	-1.1 (2.03)	2.1 [-2.61, 6.74]; 0.3833	0.1 [-0.17; 0.43]	
>= 2	160	22.0 (19.25)	1.7 (1.31)	72	21.7 (20.67)	1.4 (1.92)	0.3 [-4.11, 4.61]; 0.9097	0.0 [-0.26; 0.29]	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
Mixed Model Repeated Measurement for change from baseline score, with time and treatment as independent variables, and baseline score included as a covariate

Table 7.12 Change from Baseline in EORTC QLQ-C30 - Appetite Loss Symptom Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
Age									0.9375
<= 75	265	11.1 (14.50)	-0.0 (0.40)	119	9.7 (14.83)	-0.4 (0.54)	0.4 [-0.60, 1.41]; 0.4342	0.1 [-0.15; 0.28]	
> 75	25	11.3 (13.20)	-0.3 (2.44)	16	9.2 (15.59)	-0.1 (3.07)	-0.3 [-7.66, 7.14]; 0.9431	-0.0 [-0.65; 0.61]	
Sex									0.3945
Male	165	10.6 (15.11)	1.4 (0.99)	81	9.2 (15.21)	0.3 (1.40)	1.1 [-2.12, 4.29]; 0.5040	0.1 [-0.18; 0.35]	
Female	125	11.7 (13.36)	0.4 (1.14)	54	10.4 (14.43)	0.1 (1.70)	0.3 [-3.56, 4.08]; 0.8944	0.0 [-0.30; 0.34]	
Race									0.5184
White	228	10.6 (14.71)	1.2 (0.82)	109	8.6 (13.65)	0.1 (1.17)	1.1 [-1.59, 3.79]; 0.4210	0.1 [-0.14; 0.32]	
Non-White	62	12.9 (12.98)	-0.0 (1.68)	26	13.9 (18.86)	0.7 (2.54)	-0.8 [-6.51, 5.00]; 0.7939	-0.1 [-0.51; 0.40]	
Geographic region									0.9742
Europe	189	10.7 (14.74)	0.9 (0.93)	90	9.4 (15.47)	0.1 (1.33)	0.8 [-2.23, 3.80]; 0.6072	0.1 [-0.19; 0.31]	
Asia Pacific	83	11.2 (13.15)	0.8 (1.38)	35	10.8 (14.31)	1.0 (2.08)	-0.2 [-4.86, 4.46]; 0.9323	-0.0 [-0.41; 0.38]	
North America	18	14.1 (16.14)	1.6 (3.13)	10	8.6 (11.89)	-2.1 (4.22)	3.7 [-6.79, 14.24]; 0.4706	0.3 [-0.51; 1.05]	
ECOG performance status									0.8358
0-1	277	11.1 (14.40)	1.0 (0.77)	132	9.5 (14.85)	0.1 (1.09)	0.9 [-1.59, 3.35]; 0.4842	0.1 [-0.14; 0.28]	
2	12	10.6 (14.50)	-0.4 (2.96)	3	16.7 (16.67)	2.2 (6.82)	-2.6 [-18.5, 13.38]; 0.7230	-0.2 [-1.50; 1.04]	

Table 7.12 Change from Baseline in EORTC QLQ-C30 - Appetite Loss Symptom Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
Prior bortezomib or ixazomib exposure									0.1528
Yes	267	11.2 (14.52)	1.0 (0.78)	120	10.1 (15.40)	0.5 (1.15)	0.5 [-2.11, 3.09]; 0.7112	0.0 [-0.18; 0.25]	
No	23	9.2 (12.54)	0.8 (2.24)	15	6.3 (9.25)	-1.8 (2.82)	2.7 [-4.49, 9.82]; 0.4536	0.2 [-0.41; 0.89]	
Refractory to bortezomib or ixazomib									0.7587
Yes	94	14.0 (16.63)	2.0 (1.47)	49	11.1 (16.32)	-0.3 (1.99)	2.4 [-2.31, 7.04]; 0.3175	0.2 [-0.18; 0.51]	
No	196	9.7 (12.97)	0.5 (0.86)	86	8.8 (14.00)	0.4 (1.28)	0.1 [-2.74, 2.96]; 0.9396	0.0 [-0.24; 0.26]	
Prior lenalidomide exposure									0.3488
Yes	115	12.2 (14.93)	1.2 (1.23)	64	9.4 (15.17)	-1.3 (1.66)	2.5 [-1.36, 6.40]; 0.2017	0.2 [-0.12; 0.50]	
No	175	10.3 (13.98)	0.9 (0.94)	71	9.9 (14.68)	1.5 (1.42)	-0.6 [-3.73, 2.58]; 0.7186	-0.0 [-0.32; 0.23]	
Refractory to lenalidomide									0.5385
Yes	92	13.3 (15.87)	1.1 (1.40)	48	9.3 (12.71)	-1.6 (1.96)	2.7 [-1.87, 7.24]; 0.2445	0.2 [-0.15; 0.55]	
No	198	10.0 (13.53)	0.9 (0.87)	87	9.9 (15.99)	1.1 (1.28)	-0.1 [-2.99, 2.73]; 0.9284	-0.0 [-0.26; 0.24]	
Prior IMiD exposure									0.9610
Yes	192	11.6 (15.21)	0.9 (0.99)	94	10.4 (15.53)	0.2 (1.39)	0.7 [-2.49, 3.87]; 0.6679	0.1 [-0.20; 0.30]	

Table 7.12 Change from Baseline in EORTC QLQ-C30 - Appetite Loss Symptom Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
No	98	10.1 (12.56)	1.2 (1.08)	41	8.0 (13.23)	0.1 (1.64)	1.1 [-2.60, 4.71]; 0.5694	0.1 [-0.27; 0.46]	
Refractory to IMiD									0.8038
Yes	120	12.0 (14.90)	0.7 (1.24)	56	10.6 (15.15)	-0.1 (1.82)	0.8 [-3.34, 4.96]; 0.7015	0.1 [-0.26; 0.38]	
No	170	10.5 (13.99)	1.1 (0.92)	79	9.0 (14.72)	0.4 (1.31)	0.8 [-2.19, 3.73]; 0.6096	0.1 [-0.20; 0.33]	
International Staging System (ISS)									0.1737
Stage I or II	237	10.9 (14.78)	0.9 (0.80)	115	8.3 (12.97)	-0.5 (1.13)	1.4 [-1.17, 4.04]; 0.2790	0.1 [-0.11; 0.34]	
Stage III	52	11.9 (12.56)	1.5 (1.82)	20	17.7 (21.63)	4.6 (3.07)	-3.1 [-10.1, 3.91]; 0.3786	-0.2 [-0.75; 0.29]	
Prior proteasome inhibitor exposure									0.1585
Yes	268	11.3 (14.50)	0.9 (0.78)	121	10.1 (15.33)	0.4 (1.14)	0.5 [-2.09, 3.04]; 0.7153	0.0 [-0.18; 0.25]	
No	22	8.8 (12.70)	1.1 (2.47)	14	6.0 (9.50)	-1.8 (3.13)	2.9 [-5.09, 10.87]; 0.4651	0.2 [-0.43; 0.92]	
Number of prior lines of therapy									0.9095
1	130	9.1 (12.09)	-0.0 (0.92)	63	9.7 (14.15)	0.8 (1.31)	-0.8 [-3.74, 2.15]; 0.5950	-0.1 [-0.38; 0.23]	
>= 2	160	12.7 (15.83)	1.9 (1.16)	72	9.6 (15.55)	-0.4 (1.69)	2.3 [-1.51, 6.19]; 0.2319	0.2 [-0.12; 0.44]	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
Mixed Model Repeated Measurement for change from baseline score, with time and treatment as independent variables, and baseline score included as a covariate

Table 7.13 Change from Baseline in EORTC QLQ-C30 - Constipation Symptom Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
Age									0.0595
<= 75	265	8.0 (14.29)	0.2 (0.35)	119	6.4 (10.59)	0.0 (0.47)	0.1 [-0.73, 1.01]; 0.7477	0.0 [-0.19; 0.24]	
> 75	25	13.4 (19.45)	4.4 (3.05)	16	3.9 (8.00)	-4.1 (3.83)	8.4 [-1.10, 17.99]; 0.0812	0.5 [-0.10; 1.18]	
Sex									0.1970
Male	165	6.5 (11.32)	0.0 (0.82)	81	6.5 (10.93)	0.4 (1.16)	-0.4 [-2.99, 2.28]; 0.7895	-0.0 [-0.30; 0.23]	
Female	125	11.0 (18.23)	1.1 (1.16)	54	5.6 (9.42)	-2.7 (1.74)	3.8 [-0.16, 7.75]; 0.0600	0.3 [-0.03; 0.61]	
Race									0.4614
White	228	7.0 (13.11)	0.7 (0.70)	109	5.7 (10.17)	-0.1 (1.00)	0.8 [-1.52, 3.08]; 0.5055	0.1 [-0.15; 0.30]	
Non-White	62	13.6 (19.21)	0.1 (1.82)	26	8.0 (10.98)	-3.7 (2.78)	3.8 [-2.60, 10.13]; 0.2423	0.3 [-0.20; 0.72]	
Geographic region									0.8868
Europe	189	7.7 (14.64)	0.5 (0.86)	90	5.4 (10.49)	-0.8 (1.23)	1.3 [-1.51, 4.13]; 0.3612	0.1 [-0.14; 0.36]	
Asia Pacific	83	9.5 (15.85)	1.0 (1.36)	35	7.7 (10.93)	-0.2 (2.07)	1.3 [-3.41, 5.93]; 0.5944	0.1 [-0.29; 0.50]	
North America	18	11.1 (11.86)	0.5 (2.19)	10	7.2 (5.84)	-3.5 (2.98)	4.0 [-3.10, 11.12]; 0.2547	0.4 [-0.37; 1.20]	
ECOG performance status									0.7997
0-1	277	8.4 (14.97)	0.7 (0.72)	132	6.2 (10.42)	-0.7 (1.02)	1.4 [-0.92, 3.76]; 0.2329	0.1 [-0.09; 0.33]	
2	12	8.9 (12.10)	-0.4 (2.54)	3	1.6 (2.75)	-4.9 (5.89)	4.5 [-8.43, 17.43]; 0.4734	0.5 [-0.81; 1.75]	

Table 7.13 Change from Baseline in EORTC QLQ-C30 - Constipation Symptom Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
Prior bortezomib or ixazomib exposure									0.0403
Yes	267	8.3 (14.60)	0.6 (0.72)	120	6.4 (10.64)	-0.4 (1.06)	1.0 [-1.42, 3.39]; 0.4191	0.1 [-0.13; 0.30]	
No	23	9.6 (17.68)	1.5 (2.52)	15	3.4 (7.13)	-4.7 (3.15)	6.2 [-1.84, 14.33]; 0.1254	0.5 [-0.16; 1.17]	
Refractory to bortezomib or ixazomib									0.0444
Yes	94	7.2 (11.74)	0.2 (1.11)	49	8.2 (11.67)	2.0 (1.49)	-1.8 [-5.24, 1.71]; 0.3157	-0.2 [-0.51; 0.18]	
No	196	9.0 (16.11)	0.9 (0.88)	86	4.9 (9.34)	-2.3 (1.31)	3.1 [0.17, 6.09]; 0.0383	0.3 [0.00; 0.51]	
Prior lenalidomide exposure									0.7328
Yes	115	8.5 (14.81)	0.2 (1.09)	64	6.2 (9.82)	-1.2 (1.47)	1.3 [-2.13, 4.76]; 0.4510	0.1 [-0.19; 0.42]	
No	175	8.3 (14.90)	1.0 (0.91)	71	6.0 (10.84)	-0.7 (1.39)	1.7 [-1.41, 4.82]; 0.2820	0.1 [-0.13; 0.42]	
Refractory to lenalidomide									0.0852
Yes	92	6.4 (10.11)	-0.4 (0.96)	48	6.8 (10.92)	1.1 (1.34)	-1.5 [-4.58, 1.54]; 0.3276	-0.2 [-0.51; 0.19]	
No	198	9.3 (16.53)	1.2 (0.91)	87	5.8 (10.04)	-1.7 (1.34)	2.9 [-0.16, 5.93]; 0.0636	0.2 [-0.03; 0.48]	
Prior IMiD exposure									0.5374
Yes	192	9.3 (15.76)	0.8 (0.91)	94	6.7 (10.06)	-0.8 (1.27)	1.6 [-1.31, 4.55]; 0.2778	0.1 [-0.12; 0.38]	

Table 7.13 Change from Baseline in EORTC QLQ-C30 - Constipation Symptom Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
No	98	6.8 (12.77)	0.5 (1.04)	41	4.9 (10.95)	-1.1 (1.60)	1.6 [-2.02, 5.21]; 0.3854	0.2 [-0.21; 0.52]	
Refractory to IMiD									0.1031
Yes	120	6.7 (10.86)	0.3 (0.88)	56	6.6 (10.37)	1.3 (1.28)	-1.0 [-3.88, 1.87]; 0.4909	-0.1 [-0.42; 0.21]	
No	170	9.7 (17.02)	0.9 (1.02)	79	5.8 (10.36)	-2.3 (1.46)	3.2 [-0.16, 6.58]; 0.0615	0.2 [-0.02; 0.51]	
International Staging System (ISS)									0.7966
Stage I or II	237	8.4 (14.99)	0.7 (0.77)	115	6.3 (10.70)	-0.6 (1.10)	1.3 [-1.29, 3.79]; 0.3327	0.1 [-0.12; 0.33]	
Stage III	52	7.9 (13.63)	-0.1 (1.41)	20	5.2 (8.02)	-2.5 (2.36)	2.4 [-2.89, 7.76]; 0.3644	0.2 [-0.28; 0.75]	
Prior proteasome inhibitor exposure									0.0974
Yes	268	8.5 (14.74)	0.5 (0.72)	121	6.4 (10.61)	-0.6 (1.05)	1.1 [-1.26, 3.52]; 0.3533	0.1 [-0.12; 0.31]	
No	22	8.1 (16.40)	1.6 (2.72)	14	3.7 (7.33)	-3.7 (3.43)	5.2 [-3.55, 14.05]; 0.2330	0.4 [-0.28; 1.08]	
Number of prior lines of therapy									0.4936
1	130	9.0 (16.85)	1.0 (1.09)	63	6.2 (10.21)	-1.2 (1.56)	2.1 [-1.48, 5.77]; 0.2446	0.2 [-0.13; 0.47]	
>= 2	160	7.9 (13.01)	0.5 (0.88)	72	6.0 (10.51)	-0.4 (1.28)	0.9 [-1.99, 3.79]; 0.5390	0.1 [-0.20; 0.36]	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
Mixed Model Repeated Measurement for change from baseline score, with time and treatment as independent variables, and baseline score included as a covariate

Table 7.14 Change from Baseline in EORTC QLQ-C30 - Diarrhoea Symptom Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
Age									0.3468
<= 75	265	8.5 (13.26)	1.1 (0.39)	119	7.9 (11.61)	0.9 (0.53)	0.2 [-0.77, 1.21]; 0.6628	0.0 [-0.18; 0.25]	
> 75	25	7.6 (11.46)	1.9 (1.75)	16	2.9 (4.52)	-1.5 (2.21)	3.4 [-1.76, 8.47]; 0.1911	0.4 [-0.26; 1.01]	
Sex									0.5505
Male	165	7.6 (11.60)	1.1 (0.80)	81	7.6 (11.96)	0.7 (1.11)	0.3 [-2.12, 2.82]; 0.7814	0.0 [-0.23; 0.30]	
Female	125	9.5 (14.83)	1.5 (1.07)	54	6.8 (9.80)	-0.2 (1.60)	1.8 [-1.81, 5.35]; 0.3305	0.1 [-0.17; 0.47]	
Race									0.4684
White	228	8.0 (13.53)	1.4 (0.72)	109	6.3 (10.15)	0.1 (1.03)	1.3 [-1.04, 3.63]; 0.2746	0.1 [-0.11; 0.35]	
Non-White	62	9.8 (11.37)	1.2 (1.37)	26	11.3 (14.01)	1.6 (2.03)	-0.4 [-4.81, 4.10]; 0.8744	-0.0 [-0.49; 0.42]	
Geographic region									0.1419
Europe	189	6.9 (11.59)	1.8 (0.76)	90	6.0 (10.31)	1.0 (1.08)	0.8 [-1.65, 3.16]; 0.5359	0.1 [-0.18; 0.32]	
Asia Pacific	83	9.7 (12.15)	0.3 (1.14)	35	10.3 (13.39)	0.1 (1.68)	0.2 [-3.46, 3.77]; 0.9322	0.0 [-0.38; 0.41]	
North America	18	17.8 (24.36)	1.7 (3.76)	10	8.5 (7.59)	-4.8 (5.09)	6.5 [-6.15, 19.12]; 0.2986	0.4 [-0.39; 1.17]	
ECOG performance status									0.0844
0-1	277	8.6 (13.33)	1.5 (0.66)	132	7.2 (10.97)	0.3 (0.94)	1.2 [-0.89, 3.29]; 0.2587	0.1 [-0.10; 0.32]	
2	12	4.7 (5.33)	-0.6 (2.58)	3	11.1 (19.25)	11.1 (6.20)	-11.7 [-25.1, 1.75]; 0.0843	-1.2 [-2.55; 0.17]	

Table 7.14 Change from Baseline in EORTC QLQ-C30 - Diarrhoea Symptom Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
Prior bortezomib or ixazomib exposure									0.9601
Yes	267	8.6 (13.44)	1.5 (0.68)	120	7.6 (11.24)	0.4 (1.00)	1.1 [-1.16, 3.28]; 0.3488	0.1 [-0.12; 0.31]	
No	23	5.6 (7.89)	-0.4 (1.61)	15	5.1 (10.17)	-0.3 (2.05)	-0.1 [-5.23, 4.96]; 0.9578	-0.0 [-0.67; 0.63]	
Refractory to bortezomib or ixazomib									0.9599
Yes	94	10.2 (15.05)	2.8 (1.37)	49	9.0 (13.31)	1.3 (1.86)	1.4 [-2.90, 5.77]; 0.5133	0.1 [-0.24; 0.45]	
No	196	7.5 (12.00)	0.7 (0.72)	86	6.3 (9.60)	-0.4 (1.06)	1.0 [-1.27, 3.34]; 0.3763	0.1 [-0.15; 0.36]	
Prior lenalidomide exposure									0.6297
Yes	115	12.3 (16.85)	2.5 (1.29)	64	9.3 (13.55)	-0.2 (1.73)	2.7 [-1.34, 6.78]; 0.1869	0.2 [-0.11; 0.50]	
No	175	5.9 (9.08)	0.3 (0.63)	71	5.4 (7.99)	0.2 (0.92)	0.1 [-1.79, 2.08]; 0.8830	0.0 [-0.26; 0.29]	
Refractory to lenalidomide									0.6115
Yes	92	11.7 (17.03)	1.9 (1.31)	48	9.8 (13.46)	-0.2 (1.83)	2.1 [-2.18, 6.31]; 0.3366	0.2 [-0.19; 0.51]	
No	198	6.8 (10.49)	1.0 (0.70)	87	5.9 (9.38)	0.4 (1.01)	0.6 [-1.61, 2.77]; 0.6027	0.1 [-0.19; 0.31]	
Prior IMiD exposure									0.6143
Yes	192	10.5 (14.66)	1.6 (0.88)	94	9.0 (12.50)	0.1 (1.23)	1.5 [-1.24, 4.28]; 0.2777	0.1 [-0.12; 0.37]	

Table 7.14 Change from Baseline in EORTC QLQ-C30 - Diarrhoea Symptom Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
No	98	4.3 (7.91)	0.6 (0.67)	41	3.2 (5.15)	0.3 (1.01)	0.2 [-1.94, 2.39]; 0.8363	0.0 [-0.33; 0.40]	
Refractory to IMiD									0.5999
Yes	120	11.1 (16.41)	1.5 (1.15)	56	9.6 (13.07)	-0.3 (1.68)	1.8 [-1.99, 5.59]; 0.3494	0.1 [-0.17; 0.46]	
No	170	6.5 (9.76)	1.0 (0.72)	79	5.6 (9.23)	0.7 (1.00)	0.3 [-1.84, 2.51]; 0.7636	0.0 [-0.23; 0.30]	
International Staging System (ISS)									0.2200
Stage I or II	237	8.6 (13.39)	1.3 (0.69)	115	7.0 (10.82)	0.0 (0.97)	1.2 [-0.96, 3.44]; 0.2674	0.1 [-0.11; 0.34]	
Stage III	52	7.2 (11.87)	1.1 (1.64)	20	9.0 (12.85)	2.4 (2.75)	-1.3 [-7.52, 4.90]; 0.6751	-0.1 [-0.62; 0.41]	
Prior proteasome inhibitor exposure									0.8341
Yes	268	8.7 (13.42)	1.5 (0.68)	121	7.6 (11.19)	0.4 (0.99)	1.0 [-1.17, 3.25]; 0.3569	0.1 [-0.12; 0.31]	
No	22	5.3 (7.85)	-0.6 (1.65)	14	4.9 (10.54)	-0.4 (2.12)	-0.2 [-5.46, 5.13]; 0.9492	-0.0 [-0.69; 0.65]	
Number of prior lines of therapy									0.9395
1	130	7.0 (11.90)	0.1 (0.85)	63	6.1 (9.61)	-0.7 (1.20)	0.9 [-1.82, 3.53]; 0.5296	0.1 [-0.21; 0.39]	
>= 2	160	9.5 (13.93)	2.5 (0.97)	72	8.3 (12.26)	1.5 (1.40)	1.0 [-2.10, 4.15]; 0.5171	0.1 [-0.19; 0.36]	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
Mixed Model Repeated Measurement for change from baseline score, with time and treatment as independent variables, and baseline score included as a covariate

Table 7.15 Change from Baseline in EORTC QLQ-C30 - Financial Difficulities Symptom Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
Age									0.3159
<= 75	265	18.1 (20.11)	0.4 (0.40)	119	17.7 (22.74)	-0.1 (0.54)	0.5 [-0.47, 1.52]; 0.3026	0.1 [-0.13; 0.30]	
> 75	25	11.1 (16.28)	0.4 (1.79)	16	8.7 (13.52)	0.5 (2.25)	-0.1 [-5.72, 5.44]; 0.9590	-0.0 [-0.64; 0.61]	
Sex									0.9232
Male	165	17.0 (20.41)	1.7 (1.20)	81	19.0 (22.62)	2.5 (1.69)	-0.7 [-4.67, 3.20]; 0.7126	-0.0 [-0.31; 0.22]	
Female	125	18.2 (19.23)	1.5 (1.30)	54	13.2 (20.77)	-1.7 (1.96)	3.2 [-1.35, 7.66]; 0.1678	0.2 [-0.10; 0.54]	
Race									0.9443
White	228	17.6 (19.33)	1.7 (0.99)	109	17.7 (22.75)	1.5 (1.42)	0.2 [-3.10, 3.51]; 0.9024	0.0 [-0.21; 0.24]	
Non-White	62	17.2 (21.99)	0.1 (1.86)	26	12.2 (18.27)	-3.5 (2.85)	3.6 [-3.02, 10.20]; 0.2815	0.2 [-0.22; 0.70]	
Geographic region									0.2529
Europe	189	18.3 (19.64)	2.1 (1.03)	90	15.1 (20.57)	-0.4 (1.48)	2.5 [-0.92, 5.89]; 0.1510	0.2 [-0.08; 0.43]	
Asia Pacific	83	15.0 (19.60)	-0.2 (1.86)	35	21.0 (25.29)	3.8 (2.84)	-4.0 [-10.6, 2.57]; 0.2289	-0.2 [-0.63; 0.16]	
North America	18	20.4 (23.55)	4.1 (3.99)	10	15.9 (22.60)	2.5 (5.34)	1.6 [-12.0, 15.22]; 0.8086	0.1 [-0.68; 0.87]	
ECOG performance status									0.6984
0-1	277	17.4 (19.59)	1.6 (0.89)	132	16.6 (21.91)	0.7 (1.27)	0.9 [-2.02, 3.85]; 0.5393	0.1 [-0.15; 0.27]	
2	12	20.2 (26.89)	1.6 (0.89)	3	21.8 (30.87)	0.7 (1.27)	0.9 [-2.02, 3.85]; 0.5393	0.3 [-0.98; 1.56]	

Table 7.15 Change from Baseline in EORTC QLQ-C30 - Financial Difficulities Symptom Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
Prior bortezomib or ixazomib exposure									0.7366
Yes	267	18.2 (20.14)	1.6 (0.93)	120	17.6 (22.85)	0.9 (1.38)	0.6 [-2.53, 3.82]; 0.6880	0.0 [-0.17; 0.26]	
No	23	9.1 (14.52)	-0.2 (2.13)	15	9.3 (11.37)	-1.0 (2.68)	0.7 [-6.08, 7.56]; 0.8257	0.1 [-0.58; 0.72]	
Refractory to bortezomib or ixazomib									0.1795
Yes	94	20.4 (18.49)	1.0 (1.42)	49	23.1 (25.04)	2.5 (1.92)	-1.6 [-6.08, 2.92]; 0.4878	-0.1 [-0.46; 0.23]	
No	196	16.1 (20.43)	1.5 (1.10)	86	13.0 (19.28)	-1.1 (1.65)	2.6 [-1.16, 6.44]; 0.1720	0.2 [-0.08; 0.42]	
Prior lenalidomide exposure									0.8774
Yes	115	16.4 (19.15)	1.1 (1.43)	64	14.6 (19.92)	-0.4 (1.92)	1.5 [-3.12, 6.09]; 0.5254	0.1 [-0.21; 0.40]	
No	175	18.3 (20.38)	1.8 (1.13)	71	18.5 (23.72)	1.5 (1.73)	0.2 [-3.68, 4.15]; 0.9042	0.0 [-0.26; 0.29]	
Refractory to lenalidomide									0.7703
Yes	92	17.3 (19.62)	1.7 (1.75)	48	15.0 (19.87)	-0.1 (2.42)	1.8 [-4.01, 7.56]; 0.5450	0.1 [-0.24; 0.45]	
No	198	17.6 (20.06)	1.6 (1.02)	87	17.6 (23.16)	1.0 (1.50)	0.5 [-2.88, 3.96]; 0.7554	0.0 [-0.21; 0.29]	
Prior IMiD exposure									0.8050
Yes	192	15.9 (19.05)	0.4 (1.12)	94	15.4 (20.77)	-0.3 (1.58)	0.7 [-3.02, 4.37]; 0.7199	0.0 [-0.20; 0.29]	

Table 7.15 Change from Baseline in EORTC QLQ-C30 - Financial Difficulities Symptom Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-Cl]; p-value**	**Hedges'g [95%-Cl]**	
No	98	20.6 (21.18)	3.1 (1.45)	41	19.6 (24.63)	2.1 (2.22)	1.0 [-4.07, 6.09]; 0.6937	0.1 [-0.29; 0.43]	
Refractory to IMiD									0.5463
Yes	120	15.7 (18.51)	1.2 (1.49)	56	14.9 (19.68)	0.6 (2.18)	0.6 [-4.50, 5.70]; 0.8162	0.0 [-0.28; 0.35]	
No	170	18.8 (20.76)	1.8 (1.09)	79	18.0 (23.55)	0.7 (1.56)	1.2 [-2.43, 4.75]; 0.5250	0.1 [-0.19; 0.35]	
International Staging System (ISS)									0.6334
Stage I or II	237	16.9 (20.22)	1.1 (0.96)	115	17.1 (22.54)	0.9 (1.38)	0.3 [-2.95, 3.47]; 0.8734	0.0 [-0.21; 0.24]	
Stage III	52	20.4 (18.27)	2.7 (2.02)	20	14.1 (18.95)	-1.2 (3.35)	3.9 [-3.76, 11.60]; 0.3108	0.3 [-0.25; 0.78]	
Prior proteasome inhibitor exposure									0.6887
Yes	268	18.3 (20.13)	1.6 (0.93)	121	17.6 (22.76)	0.9 (1.38)	0.7 [-2.49, 3.86]; 0.6720	0.0 [-0.17; 0.26]	
No	22	7.8 (13.52)	-0.2 (1.98)	14	8.9 (11.70)	-0.5 (2.52)	0.3 [-6.09, 6.69]; 0.9233	0.0 [-0.64; 0.70]	
Number of prior lines of therapy									0.3038
1	130	17.2 (20.54)	1.7 (1.14)	63	16.5 (20.92)	0.6 (1.62)	1.1 [-2.61, 4.84]; 0.5552	0.1 [-0.22; 0.39]	
>= 2	160	17.7 (19.40)	1.2 (1.37)	72	16.8 (23.05)	0.4 (2.02)	0.8 [-3.87, 5.52]; 0.7292	0.0 [-0.23; 0.33]	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
Mixed Model Repeated Measurement for change from baseline score, with time and treatment as independent variables, and baseline score included as a covariate

Table 7.1 Change from Baseline in EORTC QLQ-C30 - Global Health Status Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
Age									0.4170
<= 75	265	64.0 (14.42)	-0.9 (0.71)	119	64.9 (13.72)	-0.0 (1.05)	-0.9 [-3.31, 1.49]; 0.4557	-0.1 [-0.29; 0.14]	
> 75	25	61.9 (14.80)	-1.9 (2.35)	16	67.4 (8.41)	1.7 (2.94)	-3.6 [-10.9, 3.65]; 0.3190	-0.3 [-0.93; 0.33]	
Sex									0.0470
Male	165	66.2 (14.86)	-0.8 (0.91)	81	65.7 (14.07)	-0.9 (1.29)	0.1 [-2.91, 3.02]; 0.9712	0.0 [-0.26; 0.27]	
Female	125	60.7 (13.30)	-1.3 (1.00)	54	64.4 (11.86)	1.5 (1.49)	-2.8 [-6.18, 0.62]; 0.1080	-0.2 [-0.57; 0.07]	
Race									0.5714
White	228	63.6 (14.33)	-1.0 (0.76)	109	65.0 (12.16)	-0.2 (1.10)	-0.9 [-3.38, 1.68]; 0.5089	-0.1 [-0.30; 0.15]	
Non-White	62	64.7 (14.92)	-1.3 (1.44)	26	66.3 (17.13)	1.2 (2.19)	-2.5 [-7.51, 2.57]; 0.3310	-0.2 [-0.68; 0.24]	
Geographic region									0.8718
Europe	189	62.4 (13.37)	-1.7 (0.82)	90	65.0 (13.07)	0.5 (1.17)	-2.2 [-4.85, 0.50]; 0.1106	-0.2 [-0.45; 0.06]	
Asia Pacific	83	67.7 (15.48)	0.7 (1.32)	35	65.3 (14.39)	-0.5 (2.01)	1.2 [-3.30, 5.77]; 0.5893	0.1 [-0.29; 0.50]	
North America	18	61.4 (17.59)	-1.8 (3.24)	10	66.6 (10.99)	1.2 (4.35)	-2.9 [-13.9, 8.06]; 0.5858	-0.2 [-0.98; 0.57]	
ECOG performance status									0.8929
0-1	277	63.9 (14.56)	-1.1 (0.70)	132	65.6 (13.06)	0.2 (1.00)	-1.3 [-3.60, 0.99]; 0.2629	-0.1 [-0.32; 0.10]	
2	12	59.9 (9.77)	2.0 (3.07)	3	49.6 (11.49)	-4.5 (6.45)	6.5 [-8.54, 21.60]; 0.3676	0.6 [-0.71; 1.86]	

Table 7.1 Change from Baseline in EORTC QLQ-C30 - Global Health Status Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
Prior bortezomib or ixazomib exposure									0.5927
Yes	267	63.1 (14.40)	-1.2 (0.71)	120	64.5 (13.32)	0.2 (1.04)	-1.4 [-3.75, 1.01]; 0.2579	-0.1 [-0.33; 0.10]	
No	23	71.7 (12.75)	1.4 (2.16)	15	70.6 (11.19)	-1.0 (2.70)	2.4 [-4.50, 9.38]; 0.4781	0.2 [-0.42; 0.88]	
Refractory to bortezomib or ixazomib									0.7552
Yes	94	62.6 (13.49)	0.1 (0.43)	49	63.3 (14.75)	0.5 (0.55)	-0.4 [-1.47, 0.69]; 0.4805	-0.1 [-0.44; 0.25]	
No	196	64.4 (14.87)	0.3 (0.30)	86	66.3 (12.19)	0.2 (0.40)	0.1 [-0.60, 0.81]; 0.7669	0.0 [-0.23; 0.28]	
Prior lenalidomide exposure									0.6667
Yes	115	62.3 (15.96)	-1.3 (1.16)	64	64.7 (14.23)	0.8 (1.56)	-2.2 [-5.85, 1.55]; 0.2519	-0.2 [-0.48; 0.13]	
No	175	64.8 (13.30)	-0.9 (0.85)	71	65.7 (12.28)	-0.3 (1.29)	-0.6 [-3.47, 2.31]; 0.6917	-0.1 [-0.33; 0.22]	
Refractory to lenalidomide									0.5113
Yes	92	62.7 (16.69)	-1.5 (1.33)	48	64.9 (13.79)	0.5 (1.85)	-2.0 [-6.40, 2.35]; 0.3610	-0.2 [-0.51; 0.19]	
No	198	64.3 (13.28)	-0.8 (0.80)	87	65.4 (12.94)	-0.0 (1.17)	-0.8 [-3.40, 1.90]; 0.5775	-0.1 [-0.32; 0.18]	
Prior IMiD exposure									0.2149
Yes	192	62.5 (15.08)	-0.9 (0.88)	94	65.9 (13.79)	1.7 (1.24)	-2.7 [-5.53, 0.19]; 0.0669	-0.2 [-0.47; 0.03]	

Table 7.1 Change from Baseline in EORTC QLQ-C30 - Global Health Status Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
No	98	66.4 (12.78)	-1.1 (1.08)	41	63.6 (11.72)	-2.8 (1.66)	1.7 [-2.03, 5.45]; 0.3678	0.2 [-0.21; 0.52]	
Refractory to IMiD									0.1323
Yes	120	62.9 (15.87)	-1.1 (1.13)	56	65.1 (15.05)	1.5 (1.66)	-2.6 [-6.42, 1.22]; 0.1809	-0.2 [-0.53; 0.11]	
No	170	64.5 (13.35)	-0.9 (0.86)	79	65.3 (11.82)	-0.7 (1.24)	-0.2 [-3.04, 2.61]; 0.8806	-0.0 [-0.29; 0.25]	
International Staging System (ISS)									0.9278
Stage I or II	237	64.1 (14.40)	-0.9 (0.74)	115	66.4 (12.44)	0.3 (1.06)	-1.1 [-3.56, 1.33]; 0.3686	-0.1 [-0.32; 0.12]	
Stage III	52	62.8 (14.79)	-1.9 (1.65)	20	58.4 (15.61)	-0.8 (2.74)	-1.1 [-7.34, 5.24]; 0.7387	-0.1 [-0.60; 0.43]	
Prior proteasome inhibitor exposure									0.1867
Yes	268	63.1 (14.38)	-1.1 (0.71)	121	64.6 (13.26)	0.2 (1.04)	-1.4 [-3.74, 0.99]; 0.2551	-0.1 [-0.33; 0.10]	
No	22	72.4 (12.49)	1.5 (2.22)	14	70.9 (11.56)	-1.4 (2.80)	2.9 [-4.35, 10.05]; 0.4237	0.3 [-0.41; 0.94]	
Number of prior lines of therapy									0.4702
1	130	65.5 (13.86)	-0.7 (0.96)	63	66.5 (11.69)	-0.3 (1.37)	-0.3 [-3.48, 2.83]; 0.8383	-0.0 [-0.33; 0.27]	
>= 2	160	62.5 (14.80)	-1.3 (0.97)	72	64.1 (14.39)	0.6 (1.42)	-1.9 [-5.17, 1.36]; 0.2515	-0.2 [-0.43; 0.12]	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
Mixed Model Repeated Measurement for change from baseline score, with time and treatment as independent variables, and baseline score included as a covariate

Table 7.2 Change from Baseline in EORTC QLQ-C30 - Physical Functioning Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
Age									0.2089
<= 75	265	77.2 (17.87)	-2.7 (0.78)	119	79.8 (17.29)	-0.7 (1.15)	-2.0 [-4.65, 0.71]; 0.1499	-0.2 [-0.37; 0.06]	
> 75	25	72.6 (20.19)	-3.3 (2.14)	16	83.8 (12.44)	3.5 (2.67)	-6.8 [-13.6, 0.04]; 0.0511	-0.6 [-1.27; 0.02]	
Sex									0.5768
Male	165	79.6 (17.68)	-2.8 (0.91)	81	81.3 (16.99)	-1.5 (1.28)	-1.3 [-4.28, 1.73]; 0.4034	-0.1 [-0.38; 0.16]	
Female	125	73.1 (18.01)	-2.6 (1.20)	54	78.8 (16.56)	1.5 (1.81)	-4.1 [-8.29, 0.14]; 0.0578	-0.3 [-0.62; 0.02]	
Race									0.5541
White	228	75.6 (19.27)	-3.0 (0.84)	109	80.1 (15.98)	0.0 (1.20)	-3.0 [-5.83, -0.17]; 0.0379	-0.2 [-0.47; -0.01]	
Non-White	62	81.1 (12.02)	-1.6 (1.41)	26	81.1 (20.23)	-0.9 (2.16)	-0.7 [-5.70, 4.38]; 0.7937	-0.1 [-0.52; 0.40]	
Geographic region									0.3431
Europe	189	74.2 (19.61)	-3.8 (0.98)	90	80.2 (17.82)	0.8 (1.41)	-4.6 [-7.91, -1.29]; 0.0067	-0.3 [-0.59; -0.09]	
Asia Pacific	83	82.6 (13.05)	-0.4 (1.09)	35	80.5 (14.94)	-1.9 (1.66)	1.5 [-2.29, 5.34]; 0.4283	0.2 [-0.24; 0.55]	
North America	18	77.0 (15.80)	-2.4 (2.78)	10	80.1 (14.77)	-2.0 (3.73)	-0.4 [-9.87, 9.13]; 0.9360	-0.0 [-0.80; 0.74]	
ECOG performance status									0.5793
0-1	277	77.0 (18.03)	-2.8 (0.75)	132	80.8 (16.44)	-0.3 (1.07)	-2.5 [-5.03, -0.00]; 0.0496	-0.2 [-0.41; 0.01]	
2	12	69.4 (18.20)	-1.1 (3.72)	3	57.9 (21.01)	-3.4 (7.80)	2.3 [-16.2, 20.78]; 0.7940	0.2 [-1.10; 1.43]	

Table 7.2 Change from Baseline in EORTC QLQ-C30 - Physical Functioning Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-Cl]; p-value**	**Hedges'g [95%-Cl]**	
Prior bortezomib or ixazomib exposure									0.2091
Yes	267	76.4 (18.29)	-2.8 (0.78)	120	79.4 (17.03)	-0.5 (1.16)	-2.3 [-4.96, 0.43]; 0.0996	-0.2 [-0.39; 0.04]	
No	23	81.8 (14.95)	-1.1 (1.77)	15	87.3 (13.27)	1.3 (2.21)	-2.4 [-8.18, 3.31]; 0.3901	-0.3 [-0.93; 0.37]	
Refractory to bortezomib or ixazomib									0.0983
Yes	94	74.2 (18.55)	-2.8 (1.31)	49	73.8 (20.77)	-2.1 (1.79)	-0.7 [-5.01, 3.56]; 0.7372	-0.1 [-0.40; 0.29]	
No	196	78.0 (17.78)	-0.2 (0.23)	86	84.0 (12.77)	0.2 (0.31)	-0.3 [-0.85, 0.24]; 0.2712	-0.1 [-0.35; 0.16]	
Prior lenalidomide exposure									0.7871
Yes	115	76.5 (19.47)	-3.2 (1.42)	64	79.7 (18.18)	-0.0 (1.91)	-3.1 [-7.77, 1.49]; 0.1825	-0.2 [-0.51; 0.10]	
No	175	77.0 (17.17)	-2.4 (0.83)	71	80.8 (15.57)	-0.1 (1.27)	-2.2 [-5.13, 0.64]; 0.1268	-0.2 [-0.48; 0.07]	
Refractory to lenalidomide									0.7392
Yes	92	77.0 (19.91)	-2.9 (1.52)	48	80.4 (16.22)	0.3 (2.11)	-3.2 [-8.32, 1.84]; 0.2088	-0.2 [-0.57; 0.13]	
No	198	76.7 (17.23)	-2.7 (0.83)	87	80.2 (17.21)	-0.4 (1.23)	-2.2 [-5.06, 0.62]; 0.1249	-0.2 [-0.44; 0.06]	
Prior IMiD exposure									0.8469
Yes	192	76.7 (17.95)	-2.5 (0.97)	94	80.9 (16.69)	0.5 (1.37)	-2.9 [-6.18, 0.29]; 0.0738	-0.2 [-0.47; 0.03]	

Table 7.2 Change from Baseline in EORTC QLQ-C30 - Physical Functioning Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
No	98	77.0 (18.45)	-3.0 (1.12)	41	78.8 (17.17)	-1.2 (1.71)	-1.8 [-5.77, 2.12]; 0.3599	-0.2 [-0.53; 0.20]	
Refractory to IMiD									0.9025
Yes	120	77.5 (19.31)	-2.3 (1.30)	56	79.2 (18.62)	-0.5 (1.89)	-1.8 [-6.30, 2.64]; 0.4189	-0.1 [-0.45; 0.19]	
No	170	76.3 (17.21)	-3.1 (0.88)	79	81.0 (15.46)	-0.1 (1.27)	-3.0 [-5.98, -0.05]; 0.0465	-0.3 [-0.53; 0.01]	
International Staging System (ISS)									0.0656
Stage I or II	237	77.2 (18.19)	-2.8 (0.78)	115	82.2 (14.40)	0.3 (1.12)	-3.1 [-5.76, -0.50]; 0.0199	-0.3 [-0.48; -0.04]	
Stage III	52	75.2 (17.89)	-1.4 (1.96)	20	69.4 (24.50)	-3.0 (3.22)	1.6 [-5.87, 9.09]; 0.6673	0.1 [-0.40; 0.63]	
Prior proteasome inhibitor exposure									0.2757
Yes	268	76.3 (18.27)	-2.8 (0.78)	121	79.5 (17.01)	-0.5 (1.15)	-2.3 [-5.02, 0.34]; 0.0867	-0.2 [-0.40; 0.03]	
No	22	82.4 (14.99)	-1.0 (1.80)	14	86.9 (13.69)	0.8 (2.27)	-1.8 [-7.73, 4.06]; 0.5260	-0.2 [-0.88; 0.46]	
Number of prior lines of therapy									0.7382
1	130	78.8 (16.45)	-2.2 (0.86)	63	82.9 (14.07)	0.0 (1.23)	-2.3 [-5.15, 0.60]; 0.1195	-0.2 [-0.53; 0.07]	
>= 2	160	75.2 (19.21)	-3.0 (1.17)	72	78.0 (18.67)	-0.4 (1.73)	-2.6 [-6.68, 1.42]; 0.2023	-0.2 [-0.46; 0.10]	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
Mixed Model Repeated Measurement for change from baseline score, with time and treatment as independent variables, and baseline score included as a covariate

Table 7.3 Change from Baseline in EORTC QLQ-C30 - Role Functioning Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
Age									0.8624
<= 75	265	73.2 (21.94)	-2.4 (0.97)	119	73.6 (22.65)	-1.8 (1.44)	-0.6 [-3.92, 2.65]; 0.7035	-0.0 [-0.26; 0.18]	
> 75	25	76.3 (20.29)	-3.0 (3.39)	16	76.9 (19.36)	-1.9 (4.25)	-1.1 [-11.8, 9.55]; 0.8279	-0.1 [-0.69; 0.56]	
Sex									0.6298
Male	165	76.7 (20.97)	-2.4 (1.28)	81	74.4 (22.27)	-3.4 (1.81)	1.0 [-3.16, 5.25]; 0.6240	0.1 [-0.20; 0.33]	
Female	125	69.2 (22.21)	-2.8 (1.37)	54	73.4 (22.41)	-0.0 (2.06)	-2.8 [-7.49, 1.90]; 0.2411	-0.2 [-0.50; 0.14]	
Race									0.5105
White	228	72.7 (22.72)	-2.5 (1.04)	109	73.4 (22.35)	-1.7 (1.50)	-0.8 [-4.24, 2.69]; 0.6594	-0.0 [-0.28; 0.18]	
Non-White	62	76.4 (17.80)	-2.2 (2.08)	26	76.3 (22.11)	-1.4 (3.19)	-0.8 [-8.17, 6.61]; 0.8340	-0.0 [-0.51; 0.41]	
Geographic region									0.7895
Europe	189	71.4 (23.38)	-3.5 (1.19)	90	75.1 (22.80)	-0.4 (1.70)	-3.1 [-7.04, 0.81]; 0.1195	-0.2 [-0.44; 0.06]	
Asia Pacific	83	79.1 (17.45)	0.3 (1.68)	35	71.8 (21.52)	-4.3 (2.55)	4.6 [-1.25, 10.37]; 0.1221	0.3 [-0.10; 0.69]	
North America	18	69.4 (18.37)	-2.7 (3.42)	10	70.9 (20.84)	-4.1 (4.60)	1.5 [-10.1, 13.05]; 0.7922	0.1 [-0.67; 0.87]	
ECOG performance status									0.4171
0-1	277	73.3 (21.95)	-2.7 (0.97)	132	74.3 (22.26)	-1.9 (1.38)	-0.8 [-4.00, 2.37]; 0.6137	-0.1 [-0.26; 0.16]	
2	12	74.7 (17.94)	0.3 (4.17)	3	57.9 (17.27)	1.5 (9.14)	-1.2 [-22.2, 19.73]; 0.9008	-0.1 [-1.34; 1.19]	

Table 7.3 Change from Baseline in EORTC QLQ-C30 - Role Functioning Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
Prior bortezomib or ixazomib exposure									0.5312
Yes	267	72.5 (22.01)	-2.7 (0.99)	120	72.9 (22.75)	-2.0 (1.46)	-0.7 [-4.07, 2.62]; 0.6683	-0.0 [-0.26; 0.17]	
No	23	85.2 (14.91)	1.0 (2.63)	15	82.6 (15.75)	-0.2 (3.29)	1.2 [-7.20, 9.69]; 0.7651	0.1 [-0.55; 0.75]	
Refractory to bortezomib or ixazomib									0.0367
Yes	94	70.4 (21.01)	-2.9 (1.68)	49	67.5 (25.58)	-4.0 (2.29)	1.1 [-4.28, 6.54]; 0.6795	0.1 [-0.28; 0.41]	
No	196	75.0 (22.05)	-2.0 (1.12)	86	77.6 (19.32)	0.2 (1.68)	-2.2 [-6.05, 1.60]; 0.2521	-0.1 [-0.40; 0.11]	
Prior lenalidomide exposure									0.6610
Yes	115	71.6 (23.05)	-2.7 (1.50)	64	73.8 (21.89)	-0.8 (2.01)	-1.9 [-6.72, 2.87]; 0.4278	-0.1 [-0.43; 0.19]	
No	175	74.7 (20.89)	-2.5 (1.22)	71	74.2 (22.72)	-2.4 (1.87)	-0.0 [-4.24, 4.20]; 0.9935	-0.0 [-0.28; 0.27]	
Refractory to lenalidomide									0.8087
Yes	92	72.0 (23.99)	-2.6 (1.65)	48	74.1 (20.30)	-1.0 (2.29)	-1.7 [-7.09, 3.78]; 0.5472	-0.1 [-0.45; 0.25]	
No	198	74.2 (20.72)	-2.6 (1.15)	87	73.9 (23.37)	-2.3 (1.70)	-0.3 [-4.19, 3.58]; 0.8764	-0.0 [-0.27; 0.23]	
Prior IMiD exposure									0.7907
Yes	192	72.7 (22.22)	-2.0 (1.15)	94	75.2 (20.85)	-0.3 (1.62)	-1.7 [-5.44, 2.09]; 0.3811	-0.1 [-0.35; 0.14]	

Table 7.3 Change from Baseline in EORTC QLQ-C30 - Role Functioning Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-Cl]; p-value**	**Hedges'g [95%-Cl]**	
No	98	75.1 (20.95)	-3.5 (1.65)	41	71.1 (25.20)	-4.7 (2.53)	1.1 [-4.64, 6.94]; 0.6954	0.1 [-0.29; 0.43]	
Refractory to IMiD									0.9366
Yes	120	73.4 (23.36)	-1.8 (1.48)	56	73.7 (22.46)	-1.4 (2.16)	-0.4 [-5.46, 4.57]; 0.8610	-0.0 [-0.34; 0.29]	
No	170	73.5 (20.68)	-3.3 (1.23)	79	74.2 (22.24)	-2.2 (1.77)	-1.0 [-5.09, 3.04]; 0.6185	-0.1 [-0.33; 0.20]	
International Staging System (ISS)									0.4680
Stage I or II	237	74.2 (21.71)	-2.6 (1.02)	115	76.0 (20.97)	-1.5 (1.46)	-1.2 [-4.55, 2.25]; 0.5052	-0.1 [-0.30; 0.15]	
Stage III	52	69.9 (22.18)	-0.8 (2.25)	20	62.1 (26.07)	-2.2 (3.73)	1.4 [-7.14, 9.99]; 0.7397	0.1 [-0.43; 0.60]	
Prior proteasome inhibitor exposure									0.7106
Yes	268	72.4 (22.00)	-2.7 (0.99)	121	73.0 (22.68)	-1.9 (1.46)	-0.8 [-4.17, 2.52]; 0.6272	-0.1 [-0.27; 0.16]	
No	22	86.6 (13.72)	1.1 (2.45)	14	82.4 (16.33)	-1.1 (3.11)	2.1 [-5.84, 10.10]; 0.5874	0.2 [-0.49; 0.85]	
Number of prior lines of therapy									0.7625
1	130	76.3 (19.38)	-1.8 (1.24)	63	75.9 (20.51)	-1.4 (1.77)	-0.4 [-4.46, 3.67]; 0.8489	-0.0 [-0.33; 0.27]	
>= 2	160	71.2 (23.37)	-3.1 (1.40)	72	72.3 (23.68)	-1.9 (2.05)	-1.2 [-5.93, 3.57]; 0.6244	-0.1 [-0.35; 0.21]	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
Mixed Model Repeated Measurement for change from baseline score, with time and treatment as independent variables, and baseline score included as a covariate

Table 7.4 Change from Baseline in EORTC QLQ-C30 - Emotional Functioning Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	N	Baseline Mean (SD)	Change from BL LSMean(SE)	N	Baseline Mean (SD)	Change from BL LSMean(SE)	Difference in LSMean [95%-CI]; p-value	Hedges'g [95%-CI]	
Age									0.6161
<= 75	265	82.7 (14.95)	-1.1 (0.69)	119	81.9 (14.58)	-1.5 (1.02)	0.4 [-1.92, 2.76]; 0.7228	0.0 [-0.18; 0.25]	
> 75	25	82.3 (15.44)	0.5 (2.99)	16	81.1 (14.86)	-1.4 (3.74)	1.9 [-7.53, 11.36]; 0.6836	0.1 [-0.50; 0.75]	
Sex									0.8169
Male	165	85.6 (13.59)	-0.8 (0.88)	81	82.6 (15.00)	-2.5 (1.24)	1.7 [-1.20, 4.59]; 0.2496	0.1 [-0.12; 0.42]	
Female	125	78.7 (15.83)	-1.0 (1.06)	54	80.8 (13.93)	-0.3 (1.58)	-0.7 [-4.36, 2.90]; 0.6910	-0.1 [-0.38; 0.26]	
Race									0.4329
White	228	83.0 (14.76)	-0.9 (0.75)	109	82.0 (14.33)	-1.7 (1.09)	0.8 [-1.74, 3.31]; 0.5409	0.1 [-0.16; 0.30]	
Non-White	62	81.3 (15.74)	-0.7 (1.55)	26	81.3 (15.75)	-0.5 (2.37)	-0.2 [-5.64, 5.29]; 0.9491	-0.0 [-0.47; 0.44]	
Geographic region									0.8912
Europe	189	82.0 (14.85)	-1.7 (0.84)	90	83.0 (14.28)	-0.9 (1.20)	-0.8 [-3.57, 1.99]; 0.5774	-0.1 [-0.32; 0.18]	
Asia Pacific	83	85.1 (14.50)	1.4 (1.27)	35	80.9 (14.23)	-1.2 (1.94)	2.6 [-1.84, 7.04]; 0.2474	0.2 [-0.17; 0.62]	
North America	18	78.5 (17.31)	-1.9 (3.02)	10	74.6 (17.21)	-5.8 (4.07)	3.9 [-6.45, 14.19]; 0.4430	0.3 [-0.48; 1.07]	
ECOG performance status									0.4381
0-1	277	82.3 (14.89)	-1.1 (0.70)	132	81.9 (14.63)	-1.3 (1.00)	0.2 [-2.05, 2.54]; 0.8325	0.0 [-0.19; 0.23]	
2	12	88.9 (15.82)	-0.6 (4.19)	3	80.2 (13.38)	-12.0 (8.70)	11.3 [-9.34, 32.02]; 0.2563	0.7 [-0.57; 2.03]	

Table 7.4 Change from Baseline in EORTC QLQ-C30 - Emotional Functioning Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
Prior bortezomib or ixazomib exposure									0.3235
Yes	267	82.2 (15.21)	-1.2 (0.71)	120	81.5 (14.39)	-1.6 (1.05)	0.4 [-2.00, 2.82]; 0.7372	0.0 [-0.18; 0.25]	
No	23	87.9 (10.72)	2.1 (2.39)	15	84.6 (16.05)	-0.7 (2.97)	2.8 [-4.88, 10.48]; 0.4617	0.2 [-0.41; 0.89]	
Refractory to bortezomib or ixazomib									0.5985
Yes	94	80.9 (15.64)	-2.0 (1.17)	49	79.3 (15.45)	-1.9 (1.60)	-0.1 [-3.88, 3.71]; 0.9650	-0.0 [-0.35; 0.34]	
No	196	83.5 (14.60)	-0.3 (0.84)	86	83.3 (13.91)	-1.0 (1.26)	0.7 [-2.16, 3.59]; 0.6266	0.1 [-0.19; 0.31]	
Prior lenalidomide exposure									0.8044
Yes	115	81.7 (16.59)	-1.3 (1.21)	64	81.0 (15.87)	-1.8 (1.62)	0.5 [-3.38, 4.43]; 0.7904	0.0 [-0.27; 0.35]	
No	175	83.3 (13.81)	-0.6 (0.82)	71	82.6 (13.33)	-1.1 (1.26)	0.5 [-2.37, 3.29]; 0.7485	0.0 [-0.23; 0.32]	
Refractory to lenalidomide									0.7805
Yes	92	81.8 (17.37)	-1.3 (1.38)	48	81.2 (15.49)	-2.0 (1.92)	0.6 [-3.95, 5.22]; 0.7829	0.0 [-0.30; 0.40]	
No	198	83.0 (13.74)	-0.7 (0.78)	87	82.2 (14.09)	-1.1 (1.15)	0.4 [-2.21, 3.03]; 0.7569	0.0 [-0.21; 0.29]	
Prior IMiD exposure									0.5534
Yes	192	82.0 (15.55)	-0.9 (0.88)	94	81.5 (14.88)	-1.2 (1.25)	0.3 [-2.65, 3.18]; 0.8573	0.0 [-0.22; 0.27]	

Table 7.4 Change from Baseline in EORTC QLQ-C30 - Emotional Functioning Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
No	98	83.8 (13.76)	-1.1 (1.06)	41	82.6 (13.92)	-2.0 (1.63)	0.9 [-2.83, 4.57]; 0.6410	0.1 [-0.28; 0.45]	
Refractory to IMiD									0.7496
Yes	120	82.7 (16.37)	-0.8 (1.12)	56	80.7 (15.95)	-1.8 (1.63)	1.1 [-2.76, 4.86]; 0.5850	0.1 [-0.23; 0.40]	
No	170	82.6 (13.94)	0.1 (0.25)	79	82.7 (13.52)	0.1 (0.34)	-0.0 [-0.71, 0.62]; 0.8995	-0.0 [-0.28; 0.25]	
International Staging System (ISS)									0.4716
Stage I or II	237	82.4 (15.42)	-1.1 (0.76)	115	82.8 (14.08)	-0.9 (1.09)	-0.2 [-2.69, 2.37]; 0.9017	-0.0 [-0.24; 0.21]	
Stage III	52	84.0 (12.92)	-0.0 (1.38)	20	76.5 (16.40)	-4.8 (2.31)	4.8 [-0.46, 10.05]; 0.0728	0.5 [-0.05; 0.99]	
Prior proteasome inhibitor exposure									0.6340
Yes	268	82.2 (15.18)	-1.1 (0.71)	121	81.4 (14.41)	-1.7 (1.05)	0.6 [-1.83, 2.98]; 0.6375	0.0 [-0.17; 0.26]	
No	22	88.1 (10.94)	1.7 (2.35)	14	86.0 (15.67)	0.3 (2.96)	1.4 [-6.20, 9.09]; 0.7012	0.1 [-0.54; 0.80]	
Number of prior lines of therapy									0.7594
1	130	83.4 (14.33)	-0.9 (0.89)	63	83.8 (13.05)	-0.9 (1.28)	-0.1 [-3.02, 2.86]; 0.9571	-0.0 [-0.31; 0.29]	
>= 2	160	82.0 (15.48)	-0.9 (1.03)	72	80.2 (15.65)	-2.2 (1.53)	1.2 [-2.29, 4.78]; 0.4884	0.1 [-0.18; 0.37]	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
Mixed Model Repeated Measurement for change from baseline score, with time and treatment as independent variables, and baseline score included as a covariate

Table 7.5 Change from Baseline in EORTC QLQ-C30 - Cognitive Functioning Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	N	Baseline Mean (SD)	Change from BL LSMean(SE)	N	Baseline Mean (SD)	Change from BL LSMean(SE)	Difference in LSMean [95%-CI]; p-value	Hedges'g [95%-CI]	
Age									<.0001
<= 75	265	82.7 (14.95)	-1.1 (0.69)	119	81.9 (14.58)	-1.5 (1.02)	0.4 [-1.92, 2.76]; 0.7228	0.0 [-0.18; 0.25]	
> 75	25	82.3 (15.44)	0.5 (2.99)	16	81.1 (14.86)	-1.4 (3.74)	1.9 [-7.53, 11.36]; 0.6836	0.1 [-0.50; 0.75]	
Sex									0.2205
Male	165	85.6 (13.59)	-0.8 (0.88)	81	82.6 (15.00)	-2.5 (1.24)	1.7 [-1.20, 4.59]; 0.2496	0.1 [-0.12; 0.42]	
Female	125	78.7 (15.83)	-1.0 (1.06)	54	80.8 (13.93)	-0.3 (1.58)	-0.7 [-4.36, 2.90]; 0.6910	-0.1 [-0.38; 0.26]	
Race									0.2671
White	228	83.0 (14.76)	-0.9 (0.75)	109	82.0 (14.33)	-1.7 (1.09)	0.8 [-1.74, 3.31]; 0.5409	0.1 [-0.16; 0.30]	
Non-White	62	81.3 (15.74)	-0.7 (1.55)	26	81.3 (15.75)	-0.5 (2.37)	-0.2 [-5.64, 5.29]; 0.9491	-0.0 [-0.47; 0.44]	
Geographic region									0.5481
Europe	189	82.0 (14.85)	-1.7 (0.84)	90	83.0 (14.28)	-0.9 (1.20)	-0.8 [-3.57, 1.99]; 0.5774	-0.1 [-0.32; 0.18]	
Asia Pacific	83	85.1 (14.50)	1.4 (1.27)	35	80.9 (14.23)	-1.2 (1.94)	2.6 [-1.84, 7.04]; 0.2474	0.2 [-0.17; 0.62]	
North America	18	78.5 (17.31)	-1.9 (3.02)	10	74.6 (17.21)	-5.8 (4.07)	3.9 [-6.45, 14.19]; 0.4430	0.3 [-0.48; 1.07]	
ECOG performance status									0.7295
0-1	277	82.3 (14.89)	-1.1 (0.70)	132	81.9 (14.63)	-1.3 (1.00)	0.2 [-2.05, 2.54]; 0.8325	0.0 [-0.19; 0.23]	
2	12	88.9 (15.82)	-0.6 (4.19)	3	80.2 (13.38)	-12.0 (8.70)	11.3 [-9.34, 32.02]; 0.2563	0.7 [-0.57; 2.03]	

Table 7.5 Change from Baseline in EORTC QLQ-C30 - Cognitive Functioning Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
Prior bortezomib or ixazomib exposure									0.8880
Yes	267	82.2 (15.21)	-1.2 (0.71)	120	81.5 (14.39)	-1.6 (1.05)	0.4 [-2.00, 2.82]; 0.7372	0.0 [-0.18; 0.25]	
No	23	87.9 (10.72)	2.1 (2.39)	15	84.6 (16.05)	-0.7 (2.97)	2.8 [-4.88, 10.48]; 0.4617	0.2 [-0.41; 0.89]	
Refractory to bortezomib or ixazomib									0.4712
Yes	94	80.9 (15.64)	-2.0 (1.17)	49	79.3 (15.45)	-1.9 (1.60)	-0.1 [-3.88, 3.71]; 0.9650	-0.0 [-0.35; 0.34]	
No	196	83.5 (14.60)	-0.3 (0.84)	86	83.3 (13.91)	-1.0 (1.26)	0.7 [-2.16, 3.59]; 0.6266	0.1 [-0.19; 0.31]	
Prior lenalidomide exposure									0.4545
Yes	115	81.7 (16.59)	-1.3 (1.21)	64	81.0 (15.87)	-1.8 (1.62)	0.5 [-3.38, 4.43]; 0.7904	0.0 [-0.27; 0.35]	
No	175	83.3 (13.81)	-0.6 (0.82)	71	82.6 (13.33)	-1.1 (1.26)	0.5 [-2.37, 3.29]; 0.7485	0.0 [-0.23; 0.32]	
Refractory to lenalidomide									0.8618
Yes	92	81.8 (17.37)	-1.3 (1.38)	48	81.2 (15.49)	-2.0 (1.92)	0.6 [-3.95, 5.22]; 0.7829	0.0 [-0.30; 0.40]	
No	198	83.0 (13.74)	-0.7 (0.78)	87	82.2 (14.09)	-1.1 (1.15)	0.4 [-2.21, 3.03]; 0.7569	0.0 [-0.21; 0.29]	
Prior IMiD exposure									0.8900
Yes	192	82.0 (15.55)	-0.9 (0.88)	94	81.5 (14.88)	-1.2 (1.25)	0.3 [-2.65, 3.18]; 0.8573	0.0 [-0.22; 0.27]	

Table 7.5 Change from Baseline in EORTC QLQ-C30 - Cognitive Functioning Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
No	98	83.8 (13.76)	-1.1 (1.06)	41	82.6 (13.92)	-2.0 (1.63)	0.9 [-2.83, 4.57]; 0.6410	0.1 [-0.28; 0.45]	
Refractory to IMiD									0.9316
Yes	120	82.7 (16.37)	-0.8 (1.12)	56	80.7 (15.95)	-1.8 (1.63)	1.1 [-2.76, 4.86]; 0.5850	0.1 [-0.23; 0.40]	
No	170	82.6 (13.94)	0.1 (0.25)	79	82.7 (13.52)	0.1 (0.34)	-0.0 [-0.71, 0.62]; 0.8995	-0.0 [-0.28; 0.25]	
International Staging System (ISS)									0.4917
Stage I or II	237	82.4 (15.42)	-1.1 (0.76)	115	82.8 (14.08)	-0.9 (1.09)	-0.2 [-2.69, 2.37]; 0.9017	-0.0 [-0.24; 0.21]	
Stage III	52	84.0 (12.92)	-0.0 (1.38)	20	76.5 (16.40)	-4.8 (2.31)	4.8 [-0.46, 10.05]; 0.0728	0.5 [-0.05; 0.99]	
Prior proteasome inhibitor exposure									0.4597
Yes	268	82.2 (15.18)	-1.1 (0.71)	121	81.4 (14.41)	-1.7 (1.05)	0.6 [-1.83, 2.98]; 0.6375	0.0 [-0.17; 0.26]	
No	22	88.1 (10.94)	1.7 (2.35)	14	86.0 (15.67)	0.3 (2.96)	1.4 [-6.20, 9.09]; 0.7012	0.1 [-0.54; 0.80]	
Number of prior lines of therapy									0.0002
1	130	83.4 (14.33)	-0.9 (0.89)	63	83.8 (13.05)	-0.9 (1.28)	-0.1 [-3.02, 2.86]; 0.9571	-0.0 [-0.31; 0.29]	
>= 2	160	82.0 (15.48)	-0.9 (1.03)	72	80.2 (15.65)	-2.2 (1.53)	1.2 [-2.29, 4.78]; 0.4884	0.1 [-0.18; 0.37]	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
Mixed Model Repeated Measurement for change from baseline score, with time and treatment as independent variables, and baseline score included as a covariate

Table 7.6 Change from Baseline in EORTC QLQ-C30 - Social Functioning Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
Age									0.0242
<= 75	265	75.8 (20.68)	-2.1 (0.92)	119	78.9 (19.64)	-0.2 (1.35)	-1.9 [-4.98, 1.20]; 0.2297	-0.1 [-0.34; 0.09]	
> 75	25	82.1 (17.66)	2.4 (3.04)	16	77.3 (21.30)	-4.1 (3.82)	6.5 [-3.14, 16.10]; 0.1790	0.4 [-0.22; 1.05]	
Sex									0.6171
Male	165	79.7 (19.01)	-1.4 (1.13)	81	78.2 (19.77)	-2.4 (1.60)	1.0 [-2.67, 4.69]; 0.5892	0.1 [-0.20; 0.34]	
Female	125	71.8 (21.57)	-2.4 (1.39)	54	79.4 (19.93)	1.8 (2.08)	-4.2 [-8.95, 0.58]; 0.0847	-0.3 [-0.59; 0.05]	
Race									0.6610
White	228	76.5 (20.03)	-1.7 (0.97)	109	78.3 (19.28)	-1.0 (1.40)	-0.7 [-3.96, 2.52]; 0.6605	-0.0 [-0.28; 0.18]	
Non-White	62	75.6 (22.27)	-2.3 (1.96)	26	80.5 (22.02)	0.8 (3.00)	-3.2 [-10.1, 3.78]; 0.3646	-0.2 [-0.66; 0.25]	
Geographic region									0.2928
Europe	189	75.7 (20.58)	-2.7 (1.09)	90	80.5 (19.70)	0.6 (1.56)	-3.3 [-6.91, 0.25]; 0.0685	-0.2 [-0.47; 0.03]	
Asia Pacific	83	79.6 (20.03)	1.1 (1.61)	35	76.3 (19.40)	-1.7 (2.46)	2.8 [-2.82, 8.39]; 0.3259	0.2 [-0.21; 0.58]	
North America	18	67.4 (19.46)	-3.5 (3.91)	10	71.2 (21.07)	-3.7 (5.25)	0.2 [-13.1, 13.40]; 0.9804	0.0 [-0.76; 0.78]	
ECOG performance status									0.9592
0-1	277	76.1 (20.64)	-1.9 (0.90)	132	78.9 (19.74)	-0.4 (1.28)	-1.5 [-4.49, 1.40]; 0.3036	-0.1 [-0.31; 0.10]	
2	12	78.5 (16.93)	0.3 (5.30)	3	70.6 (23.52)	-8.9 (11.34)	9.2 [-17.1, 35.51]; 0.4642	0.5 [-0.81; 1.75]	

Table 7.6 Change from Baseline in EORTC QLQ-C30 - Social Functioning Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-Cl]; p-value**	**Hedges'g [95%-Cl]**	
Prior bortezomib or ixazomib exposure									0.8437
Yes	267	75.4 (20.82)	-2.1 (0.93)	120	77.9 (20.19)	-0.8 (1.37)	-1.3 [-4.40, 1.88]; 0.4287	-0.1 [-0.30; 0.13]	
No	23	86.2 (12.79)	1.1 (2.38)	15	84.7 (15.20)	0.2 (2.99)	0.9 [-6.78, 8.56]; 0.8135	0.1 [-0.57; 0.73]	
Refractory to bortezomib or ixazomib									0.9215
Yes	94	74.3 (18.85)	-3.1 (1.50)	49	73.9 (23.65)	-2.8 (2.02)	-0.3 [-5.08, 4.43]; 0.8926	-0.0 [-0.37; 0.32]	
No	196	77.3 (21.21)	-0.9 (1.10)	86	81.4 (16.73)	1.2 (1.64)	-2.1 [-5.80, 1.68]; 0.2783	-0.1 [-0.39; 0.12]	
Prior lenalidomide exposure									0.7020
Yes	115	74.5 (21.50)	-2.6 (1.37)	64	78.1 (20.61)	-0.3 (1.83)	-2.3 [-6.67, 2.05]; 0.2965	-0.2 [-0.46; 0.15]	
No	175	77.5 (19.78)	0.5 (0.44)	71	79.2 (19.11)	0.3 (0.56)	0.1 [-0.75, 1.02]; 0.7689	0.0 [-0.25; 0.30]	
Refractory to lenalidomide									0.9562
Yes	92	74.3 (22.73)	-2.5 (1.57)	48	78.8 (18.88)	0.1 (2.18)	-2.6 [-7.76, 2.53]; 0.3162	-0.2 [-0.52; 0.18]	
No	198	77.2 (19.36)	-1.5 (1.07)	87	78.6 (20.35)	-0.9 (1.58)	-0.6 [-4.24, 2.95]; 0.7227	-0.0 [-0.30; 0.21]	
Prior IMiD exposure									0.5408
Yes	192	75.4 (21.17)	-1.6 (1.08)	94	79.2 (19.22)	0.5 (1.52)	-2.2 [-5.70, 1.35]; 0.2247	-0.1 [-0.39; 0.10]	

Table 7.6 Change from Baseline in EORTC QLQ-C30 - Social Functioning Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-Cl]; p-value**	**Hedges'g [95%-Cl]**	
No	98	78.1 (19.08)	-2.2 (1.53)	41	77.6 (21.17)	-3.0 (2.35)	0.7 [-4.64, 6.07]; 0.7913	0.0 [-0.32; 0.41]	
Refractory to IMiD									0.7739
Yes	120	76.0 (21.78)	-1.7 (1.35)	56	78.6 (21.18)	-0.2 (1.97)	-1.6 [-6.10, 2.99]; 0.4986	-0.1 [-0.42; 0.21]	
No	170	76.5 (19.59)	-0.1 (0.41)	79	78.8 (18.85)	0.1 (0.51)	-0.2 [-1.04, 0.64]; 0.6350	-0.0 [-0.31; 0.23]	
International Staging System (ISS)									0.1507
Stage I or II	237	76.1 (20.84)	-1.9 (0.96)	115	80.1 (18.63)	0.2 (1.37)	-2.1 [-5.25, 1.13]; 0.2045	-0.1 [-0.36; 0.08]	
Stage III	52	77.5 (19.18)	-1.8 (2.13)	20	70.8 (24.44)	-5.6 (3.53)	3.7 [-4.41, 11.83]; 0.3636	0.2 [-0.28; 0.75]	
Prior proteasome inhibitor exposure									0.7403
Yes	268	75.4 (20.81)	-2.0 (0.93)	121	77.8 (20.16)	-0.8 (1.37)	-1.2 [-4.31, 1.96]; 0.4610	-0.1 [-0.29; 0.14]	
No	22	87.5 (11.58)	0.9 (2.06)	14	86.3 (14.48)	0.4 (2.62)	0.4 [-6.27, 7.13]; 0.8958	0.0 [-0.63; 0.71]	
Number of prior lines of therapy									0.7401
1	130	77.9 (19.46)	-1.1 (1.20)	63	80.1 (16.18)	0.1 (1.72)	-1.2 [-5.17, 2.74]; 0.5451	-0.1 [-0.39; 0.21]	
>= 2	160	75.0 (21.26)	-2.5 (1.30)	72	77.5 (22.49)	-1.2 (1.91)	-1.4 [-5.75, 3.05]; 0.5445	-0.1 [-0.36; 0.20]	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
Mixed Model Repeated Measurement for change from baseline score, with time and treatment as independent variables, and baseline score included as a covariate

Table 7a.3 Change from Baseline in EORTC MY20 - Body Image Score over time by Sub-groups
eCOA-ITT Population

	KdD (N=278)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
Age									0.7598
<= 75	268	81.0 (21.05)	-1.6 (1.11)	122	82.1 (19.10)	-1.3 (1.57)	-0.3 [-3.87, 3.19]; 0.8498	-0.0 [-0.23; 0.20]	
> 75	25	84.5 (15.42)	4.2 (3.11)	16	86.3 (18.42)	4.4 (3.91)	-0.2 [-9.82, 9.42]; 0.9661	-0.0 [-0.64; 0.61]	
Sex									0.2466
Male	166	85.1 (17.49)	-0.8 (1.28)	83	83.5 (18.00)	-2.5 (1.77)	1.7 [-2.39, 5.75]; 0.4171	0.1 [-0.16; 0.37]	
Female	127	76.4 (23.30)	-1.6 (1.76)	55	81.2 (20.51)	0.7 (2.52)	-2.3 [-7.71, 3.15]; 0.4072	-0.1 [-0.43; 0.20]	
Race									0.0762
White	231	83.0 (18.85)	-0.9 (1.11)	112	81.6 (19.10)	-2.7 (1.53)	1.8 [-1.70, 5.24]; 0.3162	0.1 [-0.12; 0.33]	
Non-White	62	75.1 (25.46)	-0.0 (2.48)	26	86.6 (18.38)	8.1 (3.74)	-8.1 [-16.6, 0.52]; 0.0650	-0.4 [-0.87; 0.05]	
Geographic region									0.8674
Europe	191	81.7 (20.85)	-1.1 (1.22)	92	83.5 (19.54)	-0.3 (1.74)	-0.7 [-4.79, 3.29]; 0.7160	-0.0 [-0.29; 0.20]	
Asia Pacific	84	81.5 (20.08)	-0.0 (1.87)	36	81.3 (18.32)	-0.7 (2.83)	0.7 [-5.82, 7.21]; 0.8324	0.0 [-0.35; 0.43]	
North America	18	77.1 (21.46)	-2.5 (4.12)	10	78.8 (17.32)	-1.3 (5.53)	-1.2 [-15.0, 12.65]; 0.8606	-0.1 [-0.84; 0.71]	
ECOG performance status									0.5610
0-1	279	81.4 (20.61)	-0.6 (1.09)	135	82.6 (19.11)	-0.2 (1.50)	-0.4 [-3.75, 3.05]; 0.8386	-0.0 [-0.23; 0.19]	
2	13	77.8 (21.85)	2.4 (3.78)	3	83.3 (16.67)	3.9 (8.62)	-1.5 [-21.1, 18.16]; 0.8725	-0.1 [-1.36; 1.15]	

Table 7a.3 Change from Baseline in EORTC MY20 - Body Image Score over time by Sub-groups eCOA-ITT Population

	KdD (N=278)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
Prior bortezomib or ixazomib exposure									0.5124
Yes	270	81.4 (20.91)	-0.7 (1.12)	123	81.9 (19.11)	-0.8 (1.58)	0.1 [-3.39, 3.67]; 0.9388	0.0 [-0.21; 0.22]	
No	23	80.8 (17.41)	-0.7 (3.00)	15	88.5 (17.58)	2.7 (3.75)	-3.4 [-12.9, 6.17]; 0.4783	-0.2 [-0.88; 0.43]	
Refractory to bortezomib or ixazomib									0.4164
Yes	94	79.1 (20.49)	1.8 (1.88)	51	76.9 (21.53)	-0.2 (2.47)	2.1 [-3.56, 7.72]; 0.4660	0.1 [-0.23; 0.46]	
No	199	82.4 (20.67)	-1.8 (1.23)	87	85.9 (16.59)	0.3 (1.79)	-2.1 [-6.10, 1.99]; 0.3186	-0.1 [-0.37; 0.13]	
Prior lenalidomide exposure									0.6420
Yes	116	80.0 (21.86)	-0.1 (1.68)	65	81.3 (18.21)	0.6 (2.19)	-0.7 [-5.74, 4.32]; 0.7799	-0.0 [-0.34; 0.26]	
No	177	82.2 (19.80)	-0.9 (1.33)	73	83.7 (19.74)	-0.5 (1.98)	-0.4 [-4.84, 4.02]; 0.8544	-0.0 [-0.30; 0.25]	
Refractory to lenalidomide									0.7249
Yes	93	78.7 (22.72)	-0.2 (1.89)	49	79.3 (18.19)	0.0 (2.56)	-0.3 [-6.18, 5.63]; 0.9261	-0.0 [-0.36; 0.33]	
No	200	82.6 (19.52)	-1.0 (1.24)	89	84.4 (19.29)	-0.4 (1.77)	-0.6 [-4.60, 3.38]; 0.7639	-0.0 [-0.28; 0.21]	
Prior IMiD exposure									0.5870
Yes	195	80.4 (22.02)	-0.5 (1.28)	96	81.9 (18.10)	-0.4 (1.78)	-0.1 [-4.22, 4.02]; 0.9606	-0.0 [-0.25; 0.24]	

Table 7a.3 Change from Baseline in EORTC MY20 - Body Image Score over time by Sub-groups eCOA-ITT Population

	KdD (N=278)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
No	98	83.2 (17.49)	-1.3 (1.60)	42	84.1 (21.07)	-0.3 (2.44)	-1.1 [-6.66, 4.51]; 0.7038	-0.1 [-0.43; 0.29]	
Refractory to IMiD									0.6997
Yes	122	80.4 (21.77)	-0.6 (1.62)	58	81.3 (18.05)	-0.5 (2.32)	-0.1 [-5.41, 5.14]; 0.9589	-0.0 [-0.32; 0.30]	
No	171	82.0 (19.81)	-0.9 (1.37)	80	83.5 (19.72)	-0.4 (1.89)	-0.5 [-4.79, 3.79]; 0.8181	-0.0 [-0.29; 0.24]	
International Staging System (ISS)									0.7030
Stage I or II	239	81.3 (20.70)	-0.5 (1.13)	117	82.5 (19.19)	-0.3 (1.57)	-0.2 [-3.79, 3.43]; 0.9227	-0.0 [-0.23; 0.21]	
Stage III	53	81.6 (20.68)	-2.0 (2.24)	21	82.8 (18.38)	-0.9 (3.65)	-1.1 [-9.51, 7.29]; 0.7919	-0.1 [-0.57; 0.44]	
Prior proteasome inhibitor exposure									0.4443
Yes	271	81.3 (20.89)	-0.6 (1.12)	124	81.8 (19.06)	-0.9 (1.57)	0.2 [-3.30, 3.75]; 0.9003	0.0 [-0.20; 0.22]	
No	22	81.4 (17.60)	-0.7 (2.87)	14	89.8 (17.48)	3.1 (3.62)	-3.8 [-13.0, 5.46]; 0.4099	-0.3 [-0.95; 0.40]	
Number of prior lines of therapy									0.2247
1	131	83.8 (18.87)	-1.3 (1.43)	63	86.8 (18.18)	0.8 (1.99)	-2.1 [-6.70, 2.43]; 0.3568	-0.1 [-0.43; 0.17]	
>= 2	162	79.4 (21.81)	-0.1 (1.47)	75	79.0 (19.08)	-1.3 (2.10)	1.2 [-3.49, 5.94]; 0.6084	0.1 [-0.21; 0.34]	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
Mixed Model Repeated Measurement for change from baseline score, with time and treatment as independent variables, and baseline score included as a covariate

Table 7a.4 Change from Baseline in EORTC MY20 - Futrue Perspective Score over time by Sub-groups eCOA-ITT Population

	KdD (N=278)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-Cl]; p-value**	**Hedges'g [95%-Cl]**	
Age									0.5519
<= 75	268	72.2 (19.53)	-0.8 (0.94)	122	71.7 (20.18)	-0.7 (1.33)	-0.1 [-3.03, 2.92]; 0.9710	-0.0 [-0.22; 0.21]	
> 75	25	75.1 (17.01)	4.6 (3.25)	16	70.4 (19.39)	1.8 (4.07)	2.8 [-7.34, 12.94]; 0.5780	0.2 [-0.46; 0.80]	
Sex									0.3388
Male	166	75.2 (18.11)	-0.2 (1.20)	83	71.7 (20.28)	-2.1 (1.66)	1.9 [-1.92, 5.74]; 0.3258	0.1 [-0.14; 0.39]	
Female	127	68.9 (20.32)	-0.0 (1.41)	55	71.4 (19.83)	1.7 (2.02)	-1.7 [-6.07, 2.60]; 0.4302	-0.1 [-0.43; 0.21]	
Race									0.9336
White	231	72.3 (19.12)	-0.6 (1.00)	112	71.2 (20.25)	-0.9 (1.39)	0.4 [-2.80, 3.51]; 0.8235	0.0 [-0.20; 0.25]	
Non-White	62	73.0 (20.20)	1.1 (1.98)	26	73.0 (19.37)	1.8 (2.97)	-0.7 [-7.50, 6.01]; 0.8267	-0.0 [-0.51; 0.41]	
Geographic region									0.5313
Europe	191	70.4 (18.60)	-0.7 (1.02)	92	72.8 (18.75)	1.3 (1.45)	-1.9 [-5.28, 1.41]; 0.2564	-0.1 [-0.39; 0.11]	
Asia Pacific	84	78.1 (18.85)	1.5 (1.64)	36	72.3 (22.85)	-0.8 (2.48)	2.3 [-3.45, 8.03]; 0.4301	0.2 [-0.24; 0.54]	
North America	18	68.2 (24.13)	-0.9 (3.80)	10	57.2 (16.52)	-10.1 (5.14)	9.2 [-3.76, 22.21]; 0.1541	0.6 [-0.23; 1.34]	
ECOG performance status									0.7039
0-1	279	72.4 (19.20)	-0.2 (0.94)	135	72.1 (19.89)	-0.1 (1.29)	-0.0 [-2.95, 2.86]; 0.9752	-0.0 [-0.21; 0.20]	
2	13	72.4 (22.21)	1.8 (3.47)	3	47.0 (7.21)	-5.4 (7.72)	7.2 [-11.0, 25.37]; 0.4044	0.5 [-0.74; 1.81]	

Table 7a.4 Change from Baseline in EORTC MY20 - Futrue Perspective Score over time by Sub-groups eCOA-ITT Population

	KdD (N=278)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
Prior bortezomib or ixazomib exposure									0.8966
Yes	270	72.0 (19.61)	-0.3 (0.96)	123	70.8 (20.36)	-0.8 (1.36)	0.5 [-2.55, 3.56]; 0.7437	0.0 [-0.18; 0.25]	
No	23	77.5 (14.86)	1.2 (2.52)	15	77.5 (16.48)	2.7 (3.15)	-1.6 [-9.55, 6.42]; 0.6914	-0.1 [-0.78; 0.52]	
Refractory to bortezomib or ixazomib									0.3035
Yes	94	68.3 (20.05)	-0.4 (1.55)	51	68.8 (18.44)	0.6 (2.03)	-1.0 [-5.63, 3.59]; 0.6623	-0.1 [-0.41; 0.27]	
No	199	74.4 (18.69)	0.1 (1.10)	87	73.2 (20.83)	-0.4 (1.60)	0.5 [-3.11, 4.09]; 0.7885	0.0 [-0.22; 0.28]	
Prior lenalidomide exposure									0.4134
Yes	116	72.2 (20.35)	0.8 (1.52)	65	69.2 (19.27)	-1.4 (1.99)	2.1 [-2.45, 6.75]; 0.3575	0.1 [-0.17; 0.44]	
No	177	72.6 (18.67)	-0.5 (1.11)	73	73.7 (20.58)	1.1 (1.64)	-1.6 [-5.25, 2.07]; 0.3922	-0.1 [-0.38; 0.16]	
Refractory to lenalidomide									0.3686
Yes	93	73.1 (20.95)	0.9 (1.73)	49	67.8 (19.72)	-2.8 (2.35)	3.7 [-1.77, 9.18]; 0.1822	0.2 [-0.12; 0.57]	
No	200	72.2 (18.55)	-0.5 (1.05)	89	73.6 (20.01)	1.1 (1.49)	-1.6 [-4.99, 1.69]; 0.3312	-0.1 [-0.36; 0.14]	
Prior IMiD exposure									0.7300
Yes	195	73.1 (19.11)	0.2 (1.09)	96	70.7 (19.68)	-1.0 (1.52)	1.3 [-2.25, 4.75]; 0.4826	0.1 [-0.16; 0.33]	

Table 7a.4 Change from Baseline in EORTC MY20 - Futrue Perspective Score over time by Sub-groups eCOA-ITT Population

	KdD (N=278)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
No	98	71.2 (19.76)	-0.7 (1.43)	42	73.7 (20.89)	1.5 (2.18)	-2.2 [-7.16, 2.83]; 0.3922	-0.2 [-0.51; 0.21]	
Refractory to IMiD									0.4042
Yes	122	74.5 (20.32)	1.0 (1.48)	58	69.7 (18.99)	-2.7 (2.14)	3.7 [-1.23, 8.58]; 0.1406	0.2 [-0.09; 0.54]	
No	171	71.0 (18.48)	-1.1 (1.14)	80	72.9 (20.76)	1.1 (1.55)	-2.2 [-5.70, 1.28]; 0.2134	-0.2 [-0.42; 0.11]	
International Staging System (ISS)									0.8631
Stage I or II	239	72.8 (19.77)	-0.1 (0.97)	117	71.9 (20.29)	-0.4 (1.35)	0.2 [-2.85, 3.34]; 0.8775	0.0 [-0.20; 0.24]	
Stage III	53	71.2 (17.20)	0.1 (1.99)	21	69.9 (18.88)	0.1 (3.22)	0.0 [-7.42, 7.42]; 1.0000	0.0 [-0.51; 0.51]	
Prior proteasome inhibitor exposure									0.4967
Yes	271	72.1 (19.58)	-0.3 (0.96)	124	70.7 (20.32)	-1.0 (1.36)	0.7 [-2.35, 3.74]; 0.6551	0.0 [-0.17; 0.26]	
No	22	77.3 (15.20)	0.8 (2.46)	14	79.1 (15.90)	4.0 (3.12)	-3.2 [-11.1, 4.67]; 0.4099	-0.3 [-0.94; 0.40]	
Number of prior lines of therapy									0.1133
1	131	72.6 (18.79)	-1.3 (1.19)	63	74.9 (18.86)	1.3 (1.63)	-2.6 [-6.33, 1.04]; 0.1584	-0.2 [-0.50; 0.10]	
>= 2	162	72.4 (19.79)	1.1 (1.33)	75	68.8 (20.68)	-1.6 (1.91)	2.7 [-1.66, 6.98]; 0.2262	0.2 [-0.12; 0.43]	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
Mixed Model Repeated Measurement for change from baseline score, with time and treatment as independent variables, and baseline score included as a covariate

Table 7a.1 Change from Baseline in EORTC MY20 - Disease Symptoms Score over time by Sub-groups eCOA-ITT Population

	KdD (N=278)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
Age									0.2616
<= 75	268	82.4 (14.01)	-0.9 (0.65)	122	81.8 (14.87)	-1.1 (0.91)	0.2 [-1.81, 2.27]; 0.8242	0.0 [-0.19; 0.24]	
> 75	25	88.3 (11.52)	1.4 (2.15)	16	85.1 (16.26)	-1.9 (2.70)	3.3 [-3.52, 10.02]; 0.3347	0.3 [-0.34; 0.93]	
Sex									0.9041
Male	166	84.5 (14.03)	-0.4 (0.81)	83	82.8 (14.88)	-1.3 (1.11)	0.9 [-1.71, 3.42]; 0.5110	0.1 [-0.18; 0.35]	
Female	127	80.8 (13.49)	-0.6 (0.98)	55	81.2 (15.30)	-0.7 (1.40)	0.1 [-2.90, 3.07]; 0.9568	0.0 [-0.31; 0.32]	
Race									0.1733
White	231	83.1 (14.34)	-0.6 (0.71)	112	81.6 (15.89)	-1.7 (0.99)	1.1 [-1.19, 3.31]; 0.3538	0.1 [-0.13; 0.32]	
Non-White	62	82.1 (12.19)	-0.2 (1.15)	26	84.6 (10.35)	1.9 (1.69)	-2.1 [-5.85, 1.68]; 0.2727	-0.2 [-0.69; 0.23]	
Geographic region									0.9195
Europe	191	82.7 (14.03)	-0.3 (0.73)	92	83.2 (14.89)	-0.1 (1.04)	-0.2 [-2.63, 2.18]; 0.8527	-0.0 [-0.27; 0.23]	
Asia Pacific	84	85.0 (12.20)	0.6 (0.99)	36	80.3 (15.73)	-1.9 (1.49)	2.5 [-0.90, 5.88]; 0.1474	0.3 [-0.12; 0.67]	
North America	18	74.8 (17.32)	-3.6 (2.94)	10	79.4 (13.99)	-0.6 (3.94)	-3.0 [-13.0, 7.03]; 0.5397	-0.2 [-1.01; 0.54]	
ECOG performance status									0.1791
0-1	279	83.0 (13.91)	-0.4 (0.64)	135	82.5 (14.88)	-0.7 (0.87)	0.3 [-1.71, 2.23]; 0.7968	0.0 [-0.18; 0.23]	
2	13	80.0 (13.40)	1.8 (2.34)	3	66.7 (15.59)	-8.0 (5.39)	9.8 [-2.31, 21.89]; 0.1051	1.1 [-0.25; 2.41]	

Table 7a.1 Change from Baseline in EORTC MY20 - Disease Symptoms Score over time by Sub-groups eCOA-ITT Population

	KdD (N=278)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
Prior bortezomib or ixazomib exposure									0.4335
Yes	270	82.5 (14.13)	-0.1 (0.66)	123	81.1 (15.13)	-0.9 (0.93)	0.8 [-1.26, 2.91]; 0.4369	0.1 [-0.14; 0.29]	
No	23	87.3 (9.96)	-1.9 (1.55)	15	90.5 (11.33)	-0.2 (1.93)	-1.6 [-6.61, 3.33]; 0.5034	-0.2 [-0.87; 0.44]	
Refractory to bortezomib or ixazomib									0.1713
Yes	94	81.6 (13.37)	0.5 (1.03)	51	77.8 (17.25)	-1.3 (1.34)	1.8 [-1.16, 4.76]; 0.2312	0.2 [-0.16; 0.52]	
No	199	83.5 (14.13)	-0.7 (0.77)	87	84.7 (12.97)	0.1 (1.12)	-0.8 [-3.38, 1.72]; 0.5206	-0.1 [-0.33; 0.17]	
Prior lenalidomide exposure									0.7211
Yes	116	82.2 (14.68)	0.6 (1.13)	65	82.3 (14.90)	0.9 (1.48)	-0.3 [-3.75, 3.18]; 0.8713	-0.0 [-0.33; 0.28]	
No	177	83.4 (13.38)	-0.7 (0.71)	73	82.0 (15.22)	-1.4 (1.05)	0.7 [-1.64, 3.02]; 0.5572	0.1 [-0.20; 0.35]	
Refractory to lenalidomide									0.6418
Yes	93	81.6 (15.41)	0.1 (1.27)	49	81.9 (15.51)	0.5 (1.73)	-0.4 [-4.43, 3.66]; 0.8510	-0.0 [-0.38; 0.31]	
No	200	83.5 (13.13)	-0.6 (0.68)	89	82.3 (14.82)	-1.2 (0.97)	0.6 [-1.55, 2.79]; 0.5764	0.1 [-0.19; 0.31]	
Prior IMiD exposure									0.5578
Yes	195	81.3 (14.35)	-0.4 (0.80)	96	82.6 (14.62)	0.1 (1.11)	-0.5 [-3.01, 2.10]; 0.7264	-0.0 [-0.29; 0.20]	

Table 7a.1 Change from Baseline in EORTC MY20 - Disease Symptoms Score over time by Sub-groups eCOA-ITT Population

	KdD (N=278)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
No	98	86.1 (12.40)	-0.0 (0.84)	42	81.0 (16.01)	-1.6 (1.28)	1.6 [-1.27, 4.53]; 0.2681	0.2 [-0.17; 0.56]	
Refractory to IMiD									0.8002
Yes	122	82.2 (14.69)	0.0 (1.02)	58	82.1 (14.85)	-0.4 (1.46)	0.4 [-2.91, 3.78]; 0.7988	0.0 [-0.27; 0.35]	
No	171	83.4 (13.32)	-0.8 (0.78)	80	82.2 (15.23)	-1.1 (1.06)	0.2 [-2.16, 2.62]; 0.8495	0.0 [-0.24; 0.29]	
International Staging System (ISS)									0.4707
Stage I or II	239	83.4 (13.90)	-0.5 (0.67)	117	82.7 (15.19)	-0.9 (0.94)	0.4 [-1.75, 2.56]; 0.7121	0.0 [-0.18; 0.26]	
Stage III	53	80.7 (13.90)	0.5 (1.30)	21	79.2 (13.99)	-0.2 (2.13)	0.8 [-4.11, 5.62]; 0.7571	0.1 [-0.43; 0.58]	
Prior proteasome inhibitor exposure									0.1759
Yes	271	82.5 (14.11)	-0.1 (0.66)	124	81.0 (15.14)	-1.0 (0.93)	1.0 [-1.11, 3.04]; 0.3617	0.1 [-0.12; 0.30]	
No	22	87.6 (10.04)	-2.1 (1.37)	14	92.3 (9.16)	0.9 (1.74)	-3.0 [-7.43, 1.47]; 0.1803	-0.5 [-1.13; 0.23]	
Number of prior lines of therapy									0.4572
1	131	83.4 (14.03)	-1.1 (0.81)	63	83.9 (14.87)	-0.7 (1.12)	-0.5 [-3.02, 2.10]; 0.7219	-0.1 [-0.35; 0.25]	
>= 2	162	82.5 (13.81)	0.3 (0.89)	75	80.7 (15.08)	-0.9 (1.28)	1.2 [-1.66, 4.08]; 0.4056	0.1 [-0.17; 0.38]	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
Mixed Model Repeated Measurement for change from baseline score, with time and treatment as independent variables, and baseline score included as a covariate

Table 7a.2 Change from Baseline in EORTC MY20 - Side Effects Score over time by Sub-groups
eCOA-ITT Population

	KdD (N=278)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
Age									0.8733
<= 75	268	84.5 (11.41)	-1.3 (0.56)	122	86.0 (10.19)	-0.2 (0.80)	-1.1 [-2.92, 0.73]; 0.2378	-0.1 [-0.33; 0.09]	
> 75	25	84.8 (10.36)	-1.2 (1.55)	16	88.4 (8.69)	1.3 (1.94)	-2.5 [-7.36, 2.29]; 0.2921	-0.3 [-0.95; 0.31]	
Sex									0.7202
Male	166	87.1 (9.38)	-1.0 (0.61)	83	87.6 (9.40)	-0.4 (0.83)	-0.7 [-2.59, 1.27]; 0.5004	-0.1 [-0.35; 0.18]	
Female	127	81.2 (12.71)	-1.4 (0.94)	55	84.2 (10.67)	0.5 (1.36)	-1.9 [-4.86, 1.11]; 0.2165	-0.2 [-0.50; 0.14]	
Race									0.1584
White	231	84.7 (11.22)	-1.3 (0.58)	112	86.2 (10.46)	-0.4 (0.81)	-0.9 [-2.76, 0.95]; 0.3388	-0.1 [-0.33; 0.12]	
Non-White	62	83.9 (11.72)	-1.0 (1.22)	26	86.7 (8.07)	2.0 (1.85)	-2.9 [-7.22, 1.33]; 0.1732	-0.3 [-0.77; 0.15]	
Geographic region									0.4924
Europe	191	84.3 (12.16)	-1.6 (0.64)	92	87.0 (10.38)	0.2 (0.91)	-1.8 [-3.93, 0.34]; 0.0994	-0.2 [-0.45; 0.05]	
Asia Pacific	84	86.1 (9.15)	0.1 (0.89)	36	85.8 (8.32)	0.4 (1.34)	-0.3 [-3.41, 2.78]; 0.8415	-0.0 [-0.43; 0.35]	
North America	18	80.1 (10.06)	-1.4 (2.04)	10	81.5 (11.83)	-1.0 (2.73)	-0.3 [-7.23, 6.61]; 0.9266	-0.0 [-0.81; 0.74]	
ECOG performance status									0.3393
0-1	279	84.5 (11.33)	-1.2 (0.54)	135	86.3 (10.03)	0.2 (0.75)	-1.4 [-3.08, 0.36]; 0.1200	-0.2 [-0.36; 0.05]	
2	13	85.3 (11.14)	-0.7 (2.87)	3	83.4 (11.89)	-0.1 (6.12)	-0.6 [-15.1, 13.89]; 0.9290	-0.1 [-1.31; 1.20]	

Table 7a.2 Change from Baseline in EORTC MY20 - Side Effects Score over time by Sub-groups
eCOA-ITT Population

	KdD (N=278)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
Prior bortezomib or ixazomib exposure									0.0756
Yes	270	84.5 (11.47)	-1.1 (0.56)	123	85.6 (10.14)	-0.4 (0.80)	-0.8 [-2.59, 1.03]; 0.3976	-0.1 [-0.30; 0.13]	
No	23	84.9 (9.41)	-1.8 (1.51)	15	91.3 (7.58)	3.6 (1.89)	-5.3 [-10.2, -0.50]; 0.0317	-0.7 [-1.39; -0.05]	
Refractory to bortezomib or ixazomib									0.9058
Yes	94	84.0 (11.52)	-1.2 (0.88)	51	84.7 (11.34)	-0.3 (1.16)	-1.0 [-3.65, 1.72]; 0.4780	-0.1 [-0.46; 0.23]	
No	199	84.8 (11.23)	-1.1 (0.66)	87	87.2 (9.12)	0.6 (0.97)	-1.6 [-3.85, 0.58]; 0.1478	-0.2 [-0.43; 0.08]	
Prior lenalidomide exposure									0.6526
Yes	116	83.9 (12.12)	-1.0 (0.88)	65	86.4 (10.15)	0.9 (1.16)	-1.9 [-4.65, 0.83]; 0.1707	-0.2 [-0.51; 0.10]	
No	177	85.0 (10.76)	-1.2 (0.65)	73	86.1 (9.99)	-0.3 (0.97)	-0.9 [-3.12, 1.23]; 0.3927	-0.1 [-0.38; 0.16]	
Refractory to lenalidomide									0.5923
Yes	93	84.1 (12.56)	-1.0 (1.00)	49	87.1 (10.17)	1.2 (1.36)	-2.1 [-5.34, 1.11]; 0.1967	-0.2 [-0.57; 0.13]	
No	200	84.8 (10.71)	-1.3 (0.62)	89	85.8 (9.98)	-0.4 (0.89)	-0.9 [-2.93, 1.08]; 0.3631	-0.1 [-0.36; 0.14]	
Prior IMiD exposure									0.9503
Yes	195	83.1 (11.70)	-1.3 (0.67)	96	86.0 (10.11)	0.8 (0.94)	-2.1 [-4.34, 0.05]; 0.0557	-0.2 [-0.47; 0.02]	

Table 7a.2 Change from Baseline in EORTC MY20 - Side Effects Score over time by Sub-groups eCOA-ITT Population

	KdD (N=278)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
No	98	87.5 (9.89)	-0.8 (0.74)	42	86.8 (9.94)	-0.8 (1.13)	0.0 [-2.57, 2.60]; 0.9895	0.0 [-0.36; 0.36]	
Refractory to IMiD									0.9743
Yes	122	83.9 (11.97)	-0.9 (0.86)	58	86.5 (10.42)	1.0 (1.24)	-1.9 [-4.81, 0.95]; 0.1872	-0.2 [-0.52; 0.11]	
No	171	85.0 (10.83)	-1.4 (0.67)	80	86.1 (9.80)	-0.4 (0.93)	-1.0 [-3.10, 1.13]; 0.3591	-0.1 [-0.38; 0.15]	
International Staging System (ISS)									0.5027
Stage I or II	239	84.6 (11.37)	-1.2 (0.59)	117	86.3 (9.94)	-0.1 (0.83)	-1.1 [-3.06, 0.79]; 0.2472	-0.1 [-0.35; 0.10]	
Stage III	53	84.6 (11.23)	-1.0 (0.98)	21	86.1 (10.76)	1.2 (1.60)	-2.1 [-5.83, 1.55]; 0.2504	-0.3 [-0.80; 0.21]	
Prior proteasome inhibitor exposure									0.0374
Yes	271	84.5 (11.46)	-1.1 (0.56)	124	85.6 (10.14)	-0.4 (0.80)	-0.7 [-2.51, 1.10]; 0.4430	-0.1 [-0.29; 0.14]	
No	22	85.3 (9.43)	-2.0 (1.42)	14	92.4 (6.50)	4.0 (1.79)	-6.1 [-10.7, -1.46]; 0.0116	-0.9 [-1.59; -0.18]	
Number of prior lines of therapy									0.7033
1	131	85.7 (10.81)	-1.0 (0.72)	63	87.1 (9.78)	0.2 (0.99)	-1.2 [-3.46, 1.13]; 0.3160	-0.1 [-0.44; 0.16]	
>= 2	162	83.6 (11.66)	-1.3 (0.76)	75	85.5 (10.24)	0.2 (1.09)	-1.5 [-3.97, 1.02]; 0.2445	-0.2 [-0.43; 0.12]	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
Mixed Model Repeated Measurement for change from baseline score, with time and treatment as independent variables, and baseline score included as a covariate

Table 7b Change from Baseline in EQ-5D - VAS Score over time by Sub-groups
eCOA-ITT Population

	KdD (N=278)			Kd (N=127)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-Cl]; p-value**	**Hedges'g [95%-Cl]**	
Age									0.8196
<= 75	278	67.3 (18.88)	0.7 (0.76)	127	72.9 (16.64)	0.1 (1.07)	0.6 [-1.80, 3.01]; 0.6224	0.0 [-0.16; 0.26]	
> 75	278	67.3 (18.88)	0.7 (0.76)	127	72.9 (16.64)	0.1 (1.07)	0.6 [-1.80, 3.01]; 0.6224	0.0 [-0.16; 0.26]	
Sex									0.2487
Male	278	67.3 (18.88)	0.7 (0.76)	127	72.9 (16.64)	0.1 (1.07)	0.6 [-1.80, 3.01]; 0.6224	0.0 [-0.16; 0.26]	
Female	278	67.3 (18.88)	0.7 (0.76)	127	72.9 (16.64)	0.1 (1.07)	0.6 [-1.80, 3.01]; 0.6224	0.0 [-0.16; 0.26]	
Race									0.6536
White	278	67.3 (18.88)	0.7 (0.76)	127	72.9 (16.64)	0.1 (1.07)	0.6 [-1.80, 3.01]; 0.6224	0.0 [-0.16; 0.26]	
Non-White	278	67.3 (18.88)	0.7 (0.76)	127	72.9 (16.64)	0.1 (1.07)	0.6 [-1.80, 3.01]; 0.6224	0.0 [-0.16; 0.26]	
Geographic region									0.6658
Europe	278	67.3 (18.88)	0.7 (0.76)	127	72.9 (16.64)	0.1 (1.07)	0.6 [-1.80, 3.01]; 0.6224	0.0 [-0.16; 0.26]	
Asia Pacific	278	67.3 (18.88)	0.7 (0.76)	127	72.9 (16.64)	0.1 (1.07)	0.6 [-1.80, 3.01]; 0.6224	0.0 [-0.16; 0.26]	
North America	278	67.3 (18.88)	0.7 (0.76)	127	72.9 (16.64)	0.1 (1.07)	0.6 [-1.80, 3.01]; 0.6224	0.0 [-0.16; 0.26]	
ECOG performance status									0.6257
0-1	278	67.3 (18.88)	0.7 (0.76)	127	72.9 (16.64)	0.1 (1.07)	0.6 [-1.80, 3.01]; 0.6224	0.0 [-0.16; 0.26]	
2	278	67.3 (18.88)	0.7 (0.76)	127	72.9 (16.64)	0.1 (1.07)	0.6 [-1.80, 3.01]; 0.6224	0.0 [-0.16; 0.26]	

Table 7b Change from Baseline in EQ-5D - VAS Score over time by Sub-groups
eCOA-ITT Population

	KdD (N=278)			Kd (N=127)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
Prior bortezomib or ixazomib exposure									0.9076
Yes	278	67.3 (18.88)	0.7 (0.76)	127	72.9 (16.64)	0.1 (1.07)	0.6 [-1.80, 3.01]; 0.6224	0.0 [-0.16; 0.26]	
No	278	67.3 (18.88)	0.7 (0.76)	127	72.9 (16.64)	0.1 (1.07)	0.6 [-1.80, 3.01]; 0.6224	0.0 [-0.16; 0.26]	
Refractory to bortezomib or ixazomib									0.4915
Yes	278	67.3 (18.88)	0.7 (0.76)	127	72.9 (16.64)	0.1 (1.07)	0.6 [-1.80, 3.01]; 0.6224	0.0 [-0.16; 0.26]	
No	278	67.3 (18.88)	0.7 (0.76)	127	72.9 (16.64)	0.1 (1.07)	0.6 [-1.80, 3.01]; 0.6224	0.0 [-0.16; 0.26]	
Prior lenalidomide exposure									0.6633
Yes	278	67.3 (18.88)	0.7 (0.76)	127	72.9 (16.64)	0.1 (1.07)	0.6 [-1.80, 3.01]; 0.6224	0.0 [-0.16; 0.26]	
No	278	67.3 (18.88)	0.7 (0.76)	127	72.9 (16.64)	0.1 (1.07)	0.6 [-1.80, 3.01]; 0.6224	0.0 [-0.16; 0.26]	
Refractory to lenalidomide									0.9378
Yes	278	67.3 (18.88)	0.7 (0.76)	127	72.9 (16.64)	0.1 (1.07)	0.6 [-1.80, 3.01]; 0.6224	0.0 [-0.16; 0.26]	
No	278	67.3 (18.88)	0.7 (0.76)	127	72.9 (16.64)	0.1 (1.07)	0.6 [-1.80, 3.01]; 0.6224	0.0 [-0.16; 0.26]	
Prior IMiD exposure									0.4049
Yes	278	67.3 (18.88)	0.7 (0.76)	127	72.9 (16.64)	0.1 (1.07)	0.6 [-1.80, 3.01]; 0.6224	0.0 [-0.16; 0.26]	

Table 7b Change from Baseline in EQ-5D - VAS Score over time by Sub-groups
eCOA-ITT Population

	KdD (N=278)			Kd (N=127)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
No	278	67.3 (18.88)	0.7 (0.76)	127	72.9 (16.64)	0.1 (1.07)	0.6 [-1.80, 3.01]; 0.6224	0.0 [-0.16; 0.26]	
Refractory to IMiD									0.4446
Yes	278	67.3 (18.88)	0.7 (0.76)	127	72.9 (16.64)	0.1 (1.07)	0.6 [-1.80, 3.01]; 0.6224	0.0 [-0.16; 0.26]	
No	278	67.3 (18.88)	0.7 (0.76)	127	72.9 (16.64)	0.1 (1.07)	0.6 [-1.80, 3.01]; 0.6224	0.0 [-0.16; 0.26]	
International Staging System (ISS)									0.8792
Stage I or II	278	67.3 (18.88)	0.7 (0.76)	127	72.9 (16.64)	0.1 (1.07)	0.6 [-1.80, 3.01]; 0.6224	0.0 [-0.16; 0.26]	
Stage III	278	67.3 (18.88)	0.7 (0.76)	127	72.9 (16.64)	0.1 (1.07)	0.6 [-1.80, 3.01]; 0.6224	0.0 [-0.16; 0.26]	
Prior proteasome inhibitor exposure									0.9928
Yes	278	67.3 (18.88)	0.7 (0.76)	127	72.9 (16.64)	0.1 (1.07)	0.6 [-1.80, 3.01]; 0.6224	0.0 [-0.16; 0.26]	
No	278	67.3 (18.88)	0.7 (0.76)	127	72.9 (16.64)	0.1 (1.07)	0.6 [-1.80, 3.01]; 0.6224	0.0 [-0.16; 0.26]	
Number of prior lines of therapy									0.3474
1	278	67.3 (18.88)	0.7 (0.76)	127	72.9 (16.64)	0.1 (1.07)	0.6 [-1.80, 3.01]; 0.6224	0.0 [-0.16; 0.26]	
>= 2	278	67.3 (18.88)	0.7 (0.76)	127	72.9 (16.64)	0.1 (1.07)	0.6 [-1.80, 3.01]; 0.6224	0.0 [-0.16; 0.26]	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
Mixed Model Repeated Measurement for change from baseline score, with time and treatment as independent variables, and baseline score included as a covariate

Post-hoc Analysen zum zweiten Datenschnitt vom 15.06.2020 für den Anhang 4-G

Table 14-4.1.501. Cox Regression of Overall Survival
<Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
All randomized subjects		154	51 (33.1)	33.2 [33.2, NE)	312	89 (28.5)	NE [NE, NE)		0.758 (0.536, 1.073)	0.1180
Age - at baseline (years)	<= 75	136	47 (34.6)	33.2 [33.2, NE)	287	82 (28.6)	NE [NE, NE)	0.4033	0.775 (0.541, 1.109)	0.1619
	> 75	18	4 (22.2)	NE [NE, NE)	25	7 (28.0)	NE [18.8, NE)		1.356 (0.397, 4.632)	0.6262

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified or unstratified log-rank test as specified.

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Output: t14-04-001-501-eff-cox-os.rtf (Date Generated: 27AUG2020:00:30) Source Data: adam.adsl, adam.adbase, adam.adttepfs

Table 14-4.1.501. Cox Regression of Overall Survival
<Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Sex	Male	91	27 (29.7)	33.2 [33.2, NE)	177	49 (27.7)	NE [NE, NE)	0.4669	0.921 (0.575, 1.473)	0.7304
	Female	63	24 (38.1)	NE [26.1, NE)	135	40 (29.6)	NE [NE, NE)		0.710 (0.428, 1.178)	0.1825
Race	White	123	43 (35.0)	33.2 [33.2, NE)	243	77 (31.7)	NE [NE, NE)	0.4098	0.892 (0.614, 1.295)	0.5476
	Asian	20	5 (25.0)	NE [17.1, NE)	46	10 (21.7)	NE [NE, NE)		0.764 (0.261, 2.236)	0.6220
	Other or Unknown	11	3 (27.3)	NE [6.6, NE)	23	2 (8.7)	NE [NE, NE)		0.282 (0.047, 1.695)	0.1400

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-4.1.501. Cox Regression of Overall Survival
<Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Region	North America	12	2 (16.7)	NE [18.6, NE)	21	1 (4.8)	NE [NE, NE)	0.6638	0.313 (0.028, 3.459)	0.3168
	Europe	103	39 (37.9)	33.2 [28.7, NE)	207	70 (33.8)	NE [NE, NE)		0.859 (0.580, 1.271)	0.4453
	Asia Pacific	39	10 (25.6)	NE [NE, NE)	84	18 (21.4)	NE [NE, NE)		0.764 (0.352, 1.655)	0.4931
Baseline ECOG PS	0-1	147	46 (31.3)	33.2 [33.2, NE)	295	85 (28.8)	NE [NE, NE)	0.0382	0.886 (0.619, 1.269)	0.5091
	2	7	5 (71.4)	8.5 [0.5, NE)	15	4 (26.7)	NE [1.3, NE)		0.304 (0.081, 1.148)	0.0634

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified or unstratified log-rank test as specified.

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Table 14-4.1.501. Cox Regression of Overall Survival
<Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	137	49 (35.8)	33.2 [28.7, NE)	289	87 (30.1)	NE [NE, NE)	0.9323	0.791 (0.557, 1.123)	0.1891
	No	17	2 (11.8)	NE [27.0, NE)	23	2 (8.7)	NE [NE, NE)		0.673 (0.094, 4.804)	0.6910
Refractory to Bortezomib or Ixazomib	Yes	55	26 (47.3)	28.7 [17.8, NE)	100	38 (38.0)	NE [25.9, NE)	0.5888	0.761 (0.462, 1.253)	0.2813
	No	99	25 (25.3)	NE [NE, NE)	212	51 (24.1)	NE [NE, NE)		0.920 (0.570, 1.485)	0.7322

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-4.1.501. Cox Regression of Overall Survival
<Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	27 (36.5)	33.2 [28.7, NE)	123	37 (30.1)	NE [NE, NE)	0.9035	0.813 (0.495, 1.336)	0.4143
	No	80	24 (30.0)	NE [NE, NE)	189	52 (27.5)	NE [NE, NE)		0.852 (0.525, 1.382)	0.5171
Refractory to Lenalidomide	Yes	55	20 (36.4)	NE [25.1, NE)	99	28 (28.3)	NE [NE, NE)	0.6480	0.753 (0.424, 1.338)	0.3333
	No	99	31 (31.3)	33.2 [33.2, NE)	213	61 (28.6)	NE [NE, NE)		0.870 (0.565, 1.341)	0.5277

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-4.1.501. Cox Regression of Overall Survival
<Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	37 (33.6)	33.2 [33.2, NE)	206	62 (30.1)	NE [NE, NE)	0.7543	0.852 (0.567, 1.281)	0.4425
	No	44	14 (31.8)	NE [28.7, NE)	106	27 (25.5)	NE [NE, NE)		0.762 (0.400, 1.454)	0.4088
Refractory to IMiD	Yes	65	27 (41.5)	NE [21.7, NE)	130	39 (30.0)	NE [NE, NE)	0.2774	0.685 (0.419, 1.120)	0.1300
	No	89	24 (27.0)	33.2 [33.2, NE)	182	50 (27.5)	NE [NE, NE)		0.982 (0.603, 1.597)	0.9406

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-4.1.501. Cox Regression of Overall Survival
<Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	127	32 (25.2)	33.2 [33.2, NE)	252	60 (23.8)	NE [NE, NE)	0.0661	0.931 (0.606, 1.430)	0.7444
	3	27	19 (70.4)	11.3 [4.9, 17.8)	60	29 (48.3)	26.3 [21.4, NE)		0.477 (0.266, 0.856)	0.0114
Prior proteasome inhibitor exposure per IXRS	Yes	139	49 (35.3)	33.2 [33.2, NE)	279	84 (30.1)	NE [NE, NE)	0.6261	0.802 (0.564, 1.141)	0.2188
	No	15	2 (13.3)	NE [27.0, NE)	33	5 (15.2)	NE [NE, NE)		1.142 (0.221, 5.896)	0.8736

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified or unstratified log-rank test as specified.

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Table 14-4.1.501. Cox Regression of Overall Survival
<Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	67	18 (26.9)	NE [NE, NE)	133	27 (20.3)	NE [NE, NE)	0.4851	0.700 (0.385, 1.271)	0.2390
	>= 2	87	33 (37.9)	33.2 [28.7, NE)	179	62 (34.6)	NE [NE, NE)		0.893 (0.586, 1.363)	0.6020

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified or unstratified log-rank test as specified.

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Table 14-4.1.502. Cox Regression of Progression-free Survival as Determined by Independent Review Committee <Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
All randomized subjects		154	69 (44.8)	15.8 [12.1, 33.2)	312	111 (35.6)	NE [NE, NE)		0.629 (0.465, 0.852)	0.0025
Age - at baseline (years)	<= 75	136	64 (47.1)	15.3 [11.1, 33.2)	287	100 (34.8)	NE [NE, NE)	0.1068	0.600 (0.438, 0.822)	0.0013
	> 75	18	5 (27.8)	NE [7.4, NE)	25	11 (44.0)	NE [7.4, NE)		1.531 (0.532, 4.411)	0.4245

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified or unstratified log-rank test as specified.

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Table 14-4.1.502. Cox Regression of Progression-free Survival as Determined by Independent Review Committee <Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Sex	Male	91	40 (44.0)	17.6 [12.5, 33.2)	177	58 (32.8)	NE [NE, NE)	0.8130	0.633 (0.422, 0.947)	0.0250
	Female	63	29 (46.0)	14.6 [9.3, NE)	135	53 (39.3)	NE [18.5, NE)		0.686 (0.436, 1.080)	0.1024
Race	White	123	59 (48.0)	15.2 [11.1, 33.2)	243	95 (39.1)	NE [NE, NE)	0.8526	0.680 (0.491, 0.941)	0.0195
	Asian	20	6 (30.0)	NE [8.4, NE)	46	11 (23.9)	NE [NE, NE)		0.683 (0.252, 1.850)	0.4436
	Other or Unknown	11	4 (36.4)	NE [1.0, NE)	23	5 (21.7)	NE [16.0, NE)		0.454 (0.121, 1.701)	0.2296

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-4.1.502. Cox Regression of Progression-free Survival as Determined by Independent Review Committee <Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Region	North America	12	8 (66.7)	12.1 [3.3, 15.7)	21	1 (4.8)	NE [NE, NE)	0.0107	0.041 (0.005, 0.339)	<.0001
	Europe	103	45 (43.7)	15.8 [11.1, 33.2)	207	89 (43.0)	NE [15.5, NE)		0.849 (0.593, 1.215)	0.3716
	Asia Pacific	39	16 (41.0)	NE [10.8, NE)	84	21 (25.0)	NE [NE, NE)		0.494 (0.258, 0.949)	0.0301
Baseline ECOG PS	0-1	147	65 (44.2)	16.6 [12.5, 33.2)	295	106 (35.9)	NE [NE, NE)	0.0281	0.684 (0.502, 0.932)	0.0155
	2	7	4 (57.1)	3.3 [0.5, 9.3)	15	5 (33.3)	NE [1.2, NE)		0.311 (0.081, 1.190)	0.0725

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-4.1.502. Cox Regression of Progression-free Survival as Determined by Independent Review Committee <Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	137	64 (46.7)	15.3 [11.1, 33.2)	289	106 (36.7)	NE [NE, NE)	0.9667	0.641 (0.470, 0.875)	0.0048
	No	17	5 (29.4)	NE [11.1, NE)	23	5 (21.7)	NE [NE, NE)		0.616 (0.178, 2.134)	0.4401
Refractory to Bortezomib or Ixazomib	Yes	55	27 (49.1)	15.7 [6.5, 33.2)	100	48 (48.0)	14.2 [9.2, NE)	0.2417	0.839 (0.523, 1.345)	0.4677
	No	99	42 (42.4)	17.5 [12.3, NE)	212	63 (29.7)	NE [NE, NE)		0.572 (0.386, 0.845)	0.0046

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-4.1.502. Cox Regression of Progression-free Survival as Determined by Independent Review Committee <Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	41 (55.4)	12.1 [8.4, 15.3)	123	44 (35.8)	NE [NE, NE)	0.0764	0.511 (0.333, 0.784)	0.0018
	No	80	28 (35.0)	NE [15.8, NE)	189	67 (35.4)	NE [NE, NE)		0.886 (0.570, 1.377)	0.5930
Refractory to Lenalidomide	Yes	55	32 (58.2)	11.1 [7.4, 14.9)	99	34 (34.3)	NE [NE, NE)	0.0413	0.457 (0.281, 0.743)	0.0012
	No	99	37 (37.4)	33.2 [15.7, 33.2)	213	77 (36.2)	NE [NE, NE)		0.837 (0.565, 1.239)	0.3739

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified or unstratified log-rank test as specified.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-eff-cox-itt.sas
Output: t14-04-001-502-eff-cox-pfs-irc.rtf (Date Generated: 27AUG2020:00:30) Source Data: adam.adsl, adam.adbase, adam.adttepfs

Table 14-4.1.502. Cox Regression of Progression-free Survival as Determined by Independent Review Committee <Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	55 (50.0)	14.9 [10.8, 33.2)	206	76 (36.9)	NE [NE, NE)	0.3304	0.613 (0.433, 0.868)	0.0054
	No	44	14 (31.8)	NE [14.6, NE)	106	35 (33.0)	NE [NE, NE)		0.874 (0.470, 1.625)	0.6702
Refractory to IMiD	Yes	65	38 (58.5)	11.1 [7.4, 14.9)	130	44 (33.8)	NE [NE, NE)	0.0140	0.452 (0.292, 0.699)	0.0003
	No	89	31 (34.8)	33.2 [16.6, 33.2)	182	67 (36.8)	NE [NE, NE)		0.919 (0.600, 1.407)	0.7000

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified or unstratified log-rank test as specified.

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Output: t14-04-001-502-eff-cox-pfs-irc.rtf (Date Generated: 27AUG2020:00:30) Source Data: adam.adsl, adam.adbase, adam.adttepfs

Table 14-4.1.502. Cox Regression of Progression-free Survival as Determined by Independent Review Committee <Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	127	56 (44.1)	17.6 [13.2, 33.2)	252	79 (31.3)	NE [NE, NE)	0.7449	0.606 (0.430, 0.854)	0.0038
	3	27	13 (48.1)	7.6 [3.3, NE)	60	32 (53.3)	13.1 [8.8, NE)		0.714 (0.373, 1.365)	0.3086
Prior proteasome inhibitor exposure per IXRS	Yes	139	65 (46.8)	15.3 [11.1, 33.2)	279	102 (36.6)	NE [NE, NE)	0.5735	0.642 (0.470, 0.876)	0.0050
	No	15	4 (26.7)	NE [8.4, NE)	33	9 (27.3)	NE [NE, NE)		0.911 (0.280, 2.959)	0.8762

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified or unstratified log-rank test as specified.

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Output: t14-04-001-502-eff-cox-pfs-irc.rtf (Date Generated: 27AUG2020:00:30) Source Data: adam.adsl, adam.adbase, adam.adttepfs

Table 14-4.1.502. Cox Regression of Progression-free Survival as Determined by Independent Review Committee <Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	67	23 (34.3)	NE [11.1, NE)	133	39 (29.3)	NE [NE, NE)	0.7453	0.700 (0.418, 1.173)	0.1754
	>= 2	87	46 (52.9)	14.9 [9.3, 17.6)	179	72 (40.2)	NE [18.5, NE)		0.633 (0.437, 0.917)	0.0149

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified or unstratified log-rank test as specified.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-eff-cox-itt.sas
Output: t14-04-001-502-eff-cox-pfs-irc.rtf (Date Generated: 27AUG2020:00:30) Source Data: adam.adsl, adam.adbase, adam.adttepfs

Table 14-4.1.503. Cox Regression of Time to Next Treatment
<Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
All randomized subjects		154	84 (54.5)	18.1 [13.6, 25.0)	312	107 (34.3)	NE [30.1, NE)		0.473 (0.354, 0.633)	<.0001
Age - at baseline (years)	<= 75	136	76 (55.9)	17.1 [12.2, 20.0)	287	99 (34.5)	NE [28.8, NE)	0.4374	0.475 (0.352, 0.642)	<.0001
	> 75	18	8 (44.4)	26.7 [11.1, NE)	25	8 (32.0)	NE [17.6, NE)		0.711 (0.266, 1.903)	0.4954

Time to next treatment is defined as the time (in months) from randomization to the initiation of subsequent non-protocol anti-cancer treatment for multiple myeloma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified or unstratified log-rank test as specified.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-eff-cox-itt.sas
Output: t14-04-001-503-eff-cox-tnt.rtf (Date Generated: 27AUG2020:00:30) Source Data: adam.adsl, adam.adbase, adam.adtteef

Table 14-4.1.503. Cox Regression of Time to Next Treatment
<Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Sex	Male	91	48 (52.7)	20.0 [12.2, 28.4)	177	60 (33.9)	NE [28.7, NE)	0.6661	0.523 (0.358, 0.766)	0.0007
	Female	63	36 (57.1)	14.9 [11.5, 20.0)	135	47 (34.8)	NE [27.6, NE)		0.469 (0.303, 0.725)	0.0005
Race	White	123	67 (54.5)	17.8 [12.2, 25.0)	243	83 (34.2)	NE [28.7, NE)	0.9979	0.499 (0.361, 0.689)	<.0001
	Asian	20	11 (55.0)	18.3 [8.1, NE)	46	16 (34.8)	NE [22.2, NE)		0.514 (0.238, 1.109)	0.0840
	Other or Unknown	11	6 (54.5)	22.0 [1.7, NE)	23	8 (34.8)	NE [17.9, NE)		0.487 (0.169, 1.405)	0.1739

Time to next treatment is defined as the time (in months) from randomization to the initiation of subsequent non-protocol anti-cancer treatment for multiple myeloma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified or unstratified log-rank test as specified.

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Output: t14-04-001-503-eff-cox-tnt.rtf (Date Generated: 27AUG2020:00:30) Source Data: adam.adsl, adam.adbase, adam.adtteef

Table 14-4.1.503. Cox Regression of Time to Next Treatment
<Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Region	North America	12	10 (83.3)	11.5 [4.5, 17.3)	21	4 (19.0)	NE [28.2, NE)	0.0207	0.084 (0.025, 0.288)	<.0001
	Europe	103	51 (49.5)	19.0 [13.4, NE)	207	75 (36.2)	NE [26.3, NE)		0.613 (0.429, 0.876)	0.0066
	Asia Pacific	39	23 (59.0)	18.3 [10.1, NE)	84	28 (33.3)	NE [30.1, NE)		0.453 (0.260, 0.790)	0.0042
Baseline ECOG PS	0-1	147	82 (55.8)	17.8 [13.5, 24.1)	295	104 (35.3)	NE [28.8, NE)	0.7586	0.504 (0.377, 0.674)	<.0001
	2	7	2 (28.6)	NE [1.4, NE)	15	3 (20.0)	NE [10.0, NE)		0.456 (0.075, 2.767)	0.3813

Time to next treatment is defined as the time (in months) from randomization to the initiation of subsequent non-protocol anti-cancer treatment for multiple myeloma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified or unstratified log-rank test as specified.

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Output: t14-04-001-503-eff-cox-tnt.rtf (Date Generated: 27AUG2020:00:30) Source Data: adam.adsl, adam.adbase, adam.adtteef

Table 14-4.1.503. Cox Regression of Time to Next Treatment
<Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	137	78 (56.9)	17.3 [12.1, 20.0)	289	99 (34.3)	NE [28.8, NE)	0.3057	0.468 (0.347, 0.630)	<.0001
	No	17	6 (35.3)	NE [10.1, NE)	23	8 (34.8)	NE [22.2, NE)		0.835 (0.289, 2.413)	0.7392
Refractory to Bortezomib or Ixazomib	Yes	55	34 (61.8)	13.5 [9.3, 19.0)	100	39 (39.0)	28.6 [15.1, NE)	0.9896	0.523 (0.329, 0.830)	0.0051
	No	99	50 (50.5)	20.0 [14.9, NE)	212	68 (32.1)	NE [30.1, NE)		0.501 (0.347, 0.722)	0.0002

Time to next treatment is defined as the time (in months) from randomization to the initiation of subsequent non-protocol anti-cancer treatment for multiple myeloma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified or unstratified log-rank test as specified.

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Output: t14-04-001-503-eff-cox-tnt.rtf (Date Generated: 27AUG2020:00:30) Source Data: adam.adsl, adam.adbase, adam.adtteef

Table 14-4.1.503. Cox Regression of Time to Next Treatment
<Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	47 (63.5)	15.2 [10.1, 19.0)	123	45 (36.6)	30.1 [27.3, NE)	0.2537	0.420 (0.278, 0.635)	<.0001
	No	80	37 (46.3)	25.6 [13.4, NE)	189	62 (32.8)	NE [NE, NE)		0.600 (0.399, 0.902)	0.0131
Refractory to Lenalidomide	Yes	55	35 (63.6)	14.1 [9.2, 20.0)	99	36 (36.4)	28.8 [27.3, NE)	0.2514	0.379 (0.236, 0.608)	<.0001
	No	99	49 (49.5)	19.0 [14.9, NE)	213	71 (33.3)	NE [NE, NE)		0.572 (0.397, 0.824)	0.0023

Time to next treatment is defined as the time (in months) from randomization to the initiation of subsequent non-protocol anti-cancer treatment for multiple myeloma.
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Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified or unstratified log-rank test as specified.

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Output: t14-04-001-503-eff-cox-tnt.rtf (Date Generated: 27AUG2020:00:30) Source Data: adam.adsl, adam.adbase, adam.adtteef

Table 14-4.1.503. Cox Regression of Time to Next Treatment
<Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	63 (57.3)	17.1 [12.1, 20.0)	206	84 (40.8)	28.8 [26.3, NE)	0.1969	0.563 (0.406, 0.782)	0.0005
	No	44	21 (47.7)	25.6 [11.1, NE)	106	23 (21.7)	NE [NE, NE)		0.364 (0.202, 0.659)	0.0005
Refractory to IMiD	Yes	65	43 (66.2)	12.1 [9.3, 17.8)	130	53 (40.8)	28.6 [25.5, NE)	0.3996	0.415 (0.276, 0.625)	<.0001
	No	89	41 (46.1)	25.6 [17.1, NE)	182	54 (29.7)	NE [NE, NE)		0.556 (0.370, 0.834)	0.0040

Time to next treatment is defined as the time (in months) from randomization to the initiation of subsequent non-protocol anti-cancer treatment for multiple myeloma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified or unstratified log-rank test as specified.

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Output: t14-04-001-503-eff-cox-tnt.rtf (Date Generated: 27AUG2020:00:30) Source Data: adam.adsl, adam.adbase, adam.adtteef

Table 14-4.1.503. Cox Regression of Time to Next Treatment
<Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	127	70 (55.1)	19.0 [14.1, 26.7)	252	81 (32.1)	NE [NE, NE)	0.9156	0.476 (0.346, 0.657)	<.0001
	3	27	14 (51.9)	9.6 [3.5, 20.1)	60	26 (43.3)	21.7 [14.0, NE)		0.486 (0.252, 0.936)	0.0276
Prior proteasome inhibitor exposure per IXRS	Yes	139	77 (55.4)	17.8 [13.5, 20.0)	279	96 (34.4)	NE [28.8, NE)	0.6166	0.485 (0.359, 0.656)	<.0001
	No	15	7 (46.7)	NE [3.8, NE)	33	11 (33.3)	NE [26.1, NE)		0.627 (0.243, 1.619)	0.3303

Time to next treatment is defined as the time (in months) from randomization to the initiation of subsequent non-protocol anti-cancer treatment for multiple myeloma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified or unstratified log-rank test as specified.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-eff-cox-itt.sas
Output: t14-04-001-503-eff-cox-tnt.rtf (Date Generated: 27AUG2020:00:30) Source Data: adam.adsl, adam.adbase, adam.adtteef

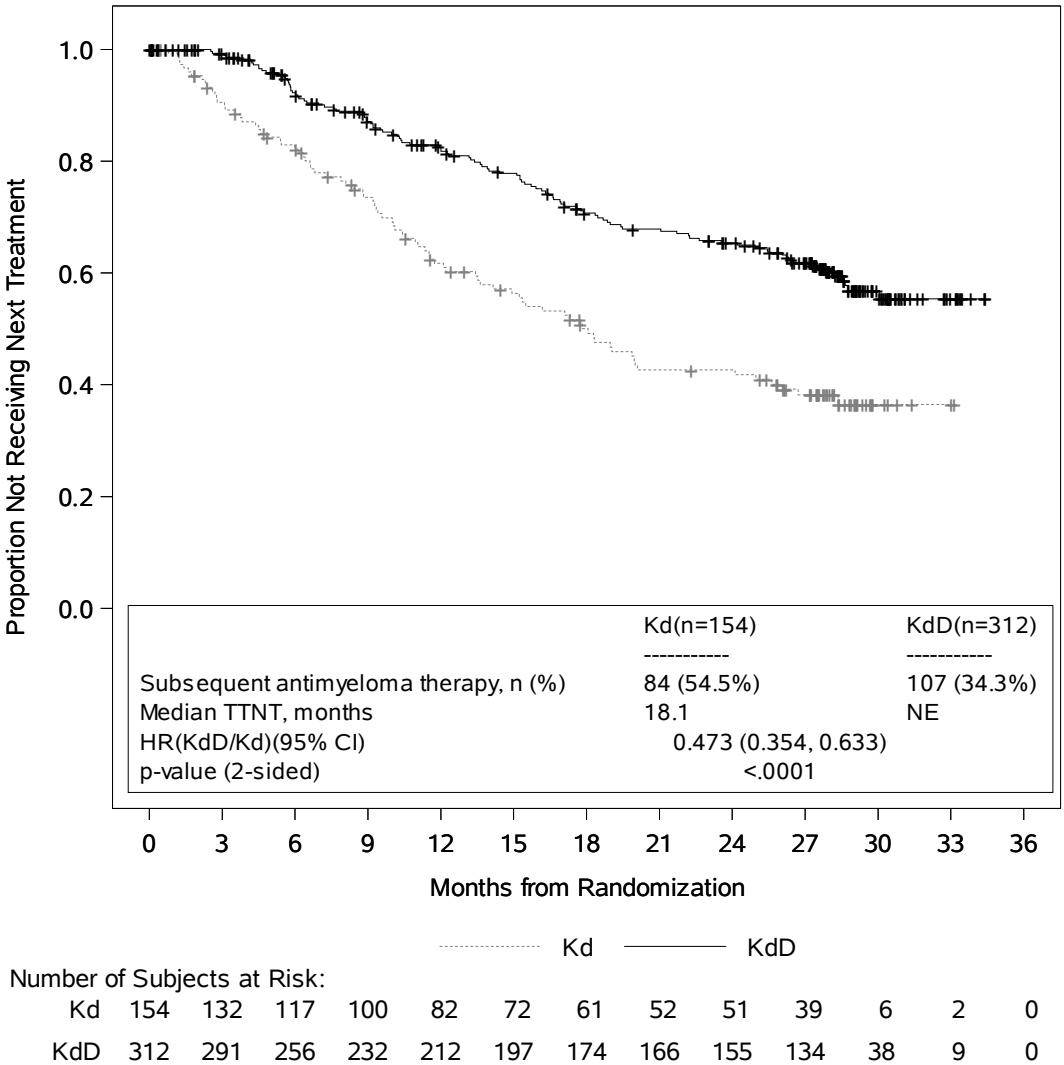
Table 14-4.1.503. Cox Regression of Time to Next Treatment
<Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	67	31 (46.3)	25.6 [13.4, NE)	133	45 (33.8)	NE [28.7, NE)	0.3725	0.588 (0.372, 0.929)	0.0214
	>= 2	87	53 (60.9)	16.2 [10.4, 20.0)	179	62 (34.6)	NE [28.2, NE)		0.440 (0.304, 0.636)	<.0001

Time to next treatment is defined as the time (in months) from randomization to the initiation of subsequent non-protocol anti-cancer treatment for multiple myeloma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified or unstratified log-rank test as specified.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-eff-cox-itt.sas
Output: t14-04-001-503-eff-cox-tnt.rtf (Date Generated: 27AUG2020:00:30) Source Data: adam.adsl, adam.adbase, adam.adtteef

Figure 14-4.3.501. Time to Next Treatment KM Curves
<Intent-to-Treat Population>



Number of Subjects at Risk:

Kd	154	132	117	100	82	72	61	52	51	39	6	2	0
KdD	312	291	256	232	212	197	174	166	155	134	38	9	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to next treatment in this plot were derived by stratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from stratified Cox proportional hazards model, and 2-sided p-value was from stratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-eff-km.sas.
Output: f14-04-003-501-eff-km-tnt.rtf (Date Generated: 16SEP20:00:48:57).
Source Data:adam.adsl, adam.adtteef.

Table 14-4.2.501. Logistic Regression of Overall Response Rate as Determined by Independent Review Committee <Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
All randomized subjects		154	115 (74.7)	(67.0, 81.3)	312	263 (84.3)	(79.8, 88.1)		0.096 (0.017, 0.176)	1.925 (1.184, 3.129)	1.135 (1.025, 1.257)	0.0080
Age - at baseline (years)	<= 75	136	101 (74.3)	(66.1, 81.4)	287	242 (84.3)	(79.6, 88.3)	0.7930	0.101 (0.016, 0.185)	1.864 (1.131, 3.070)	1.135 (1.016, 1.268)	0.0167
	> 75	18	14 (77.8)	(52.4, 93.6)	25	21 (84.0)	(63.9, 95.5)		0.062 (-0.178, 0.302)	1.500 (0.321, 7.012)	1.080 (0.800, 1.458)	0.7010

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'All randomized subjects', and the Fisher's exact test for subgroups.

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Table 14-4.2.501. Logistic Regression of Overall Response Rate as Determined by Independent Review Committee <Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Sex	Male	91	70 (76.9)	(66.9, 85.1)	177	151 (85.3)	(79.2, 90.2)	0.8189	0.084 (-0.017, 0.185)	1.742 (0.918, 3.308)	1.109 (0.976, 1.261)	0.0927
	Female	63	45 (71.4)	(58.7, 82.1)	135	112 (83.0)	(75.5, 88.9)		0.115 (-0.013, 0.244)	1.948 (0.960, 3.951)	1.161 (0.976, 1.382)	0.0890

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'All randomized subjects', and the Fisher's exact test for subgroups.

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Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Race	White	123	92 (74.8)	(66.2, 82.2)	243	198 (81.5)	(76.0, 86.2)	0.1651	0.067 (-0.024, 0.158)	1.483 (0.881, 2.494)	1.089 (0.967, 1.227)	0.1721
	Asian	20	15 (75.0)	(50.9, 91.3)	46	43 (93.5)	(82.1, 98.6)		0.185 (-0.018, 0.388)	4.778 (1.017, 22.450)	1.246 (0.957, 1.623)	0.0486
	Other or Unknown	11	8 (72.7)	(39.0, 94.0)	23	22 (95.7)	(78.1, 99.9)		0.229 (-0.047, 0.505)	8.250 (0.746, 91.259)	1.315 (0.906, 1.908)	0.0889

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Region	North America	12	7 (58.3)	(27.7, 84.8)	21	19 (90.5)	(69.6, 98.8)	0.2020	0.321 (0.016, 0.627)	6.786 (1.062, 43.360)	1.551 (0.943, 2.552)	0.0709
	Europe	103	79 (76.7)	(67.3, 84.5)	207	170 (82.1)	(76.2, 87.1)		0.054 (-0.043, 0.151)	1.396 (0.782, 2.490)	1.071 (0.946, 1.212)	0.2891
	Asia Pacific	39	29 (74.4)	(57.9, 87.0)	84	74 (88.1)	(79.2, 94.1)		0.137 (-0.016, 0.291)	2.552 (0.961, 6.772)	1.185 (0.970, 1.448)	0.0681

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'All randomized subjects', and the Fisher's exact test for subgroups.

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		Kd (N = 154)			KdD (N = 312)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Baseline ECOG PS	0-1	147	114 (77.6)	(69.9, 84.0)	295	255 (86.4)	(82.0, 90.1)	0.3937	0.089 (0.011, 0.167)	1.845 (1.107, 3.076)	1.115 (1.011, 1.229)	0.0209
	2	7	1 (14.3)	(0.4, 57.9)	15	7 (46.7)	(21.3, 73.4)		0.324 (-0.038, 0.686)	5.250 (0.502, 54.911)	3.267 (0.492, 21.699)	0.1932

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	137	101 (73.7)	(65.5, 80.9)	289	241 (83.4)	(78.6, 87.5)	0.4310	0.097 (0.011, 0.182)	1.790 (1.096, 2.923)	1.131 (1.011, 1.266)	0.0262
	No	17	14 (82.4)	(56.6, 96.2)	23	22 (95.7)	(78.1, 99.9)		0.133 (-0.066, 0.332)	4.714 (0.445, 49.943)	1.161 (0.917, 1.472)	0.2941

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Refractory to Bortezomib or Ixazomib	Yes	55	38 (69.1)	(55.2, 80.9)	100	79 (79.0)	(69.7, 86.5)	0.8251	0.099 (-0.047, 0.245)	1.683 (0.797, 3.554)	1.143 (0.933, 1.402)	0.1781
	No	99	77 (77.8)	(68.3, 85.5)	212	184 (86.8)	(81.5, 91.0)		0.090 (-0.004, 0.184)	1.878 (1.012, 3.485)	1.116 (0.992, 1.255)	0.0482

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'All randomized subjects', and the Fisher's exact test for subgroups.

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Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	55 (74.3)	(62.8, 83.8)	123	97 (78.9)	(70.6, 85.7)	0.1986	0.045 (-0.078, 0.168)	1.289 (0.654, 2.538)	1.061 (0.902, 1.248)	0.4868
	No	80	60 (75.0)	(64.1, 84.0)	189	166 (87.8)	(82.3, 92.1)		0.128 (0.023, 0.234)	2.406 (1.233, 4.692)	1.171 (1.021, 1.343)	0.0111

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'All randomized subjects', and the Fisher's exact test for subgroups.

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Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Refractory to Lenalidomide	Yes	55	40 (72.7)	(59.0, 83.9)	99	79 (79.8)	(70.5, 87.2)	0.5277	0.071 (-0.071, 0.213)	1.481 (0.686, 3.199)	1.097 (0.908, 1.327)	0.3233
	No	99	75 (75.8)	(66.1, 83.8)	213	184 (86.4)	(81.0, 90.7)		0.106 (0.010, 0.202)	2.030 (1.110, 3.714)	1.140 (1.008, 1.290)	0.0237

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	81 (73.6)	(64.4, 81.6)	206	173 (84.0)	(78.2, 88.7)	0.8134	0.103 (0.007, 0.200)	1.877 (1.067, 3.300)	1.140 (1.005, 1.295)	0.0368
	No	44	34 (77.3)	(62.2, 88.5)	106	90 (84.9)	(76.6, 91.1)		0.076 (-0.065, 0.218)	1.654 (0.684, 4.001)	1.099 (0.918, 1.314)	0.3429

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Refractory to IMiD	Yes	65	47 (72.3)	(59.8, 82.7)	130	106 (81.5)	(73.8, 87.8)	0.7786	0.092 (-0.035, 0.220)	1.691 (0.839, 3.410)	1.128 (0.950, 1.338)	0.1445
	No	89	68 (76.4)	(66.2, 84.8)	182	157 (86.3)	(80.4, 90.9)		0.099 (-0.003, 0.200)	1.939 (1.016, 3.701)	1.129 (0.992, 1.285)	0.0572

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	127	101 (79.5)	(71.5, 86.2)	252	219 (86.9)	(82.1, 90.8)	0.4751	0.074 (-0.008, 0.155)	1.708 (0.971, 3.007)	1.093 (0.988, 1.208)	0.0718
	3	27	14 (51.9)	(31.9, 71.3)	60	44 (73.3)	(60.3, 83.9)		0.215 (-0.004, 0.434)	2.554 (0.990, 6.585)	1.414 (0.954, 2.098)	0.0839

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Prior proteasome inhibitor exposure per IXRS	Yes	139	102 (73.4)	(65.2, 80.5)	279	233 (83.5)	(78.6, 87.7)	0.8594	0.101 (0.016, 0.187)	1.837 (1.124, 3.003)	1.138 (1.017, 1.274)	0.0188
	No	15	13 (86.7)	(59.5, 98.3)	33	30 (90.9)	(75.7, 98.1)		0.042 (-0.156, 0.240)	1.538 (0.229, 10.326)	1.049 (0.837, 1.315)	0.6415

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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[b] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'All randomized subjects', and the Fisher's exact test for subgroups.

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Output: t14-04-002-501-eff-logr-orr-irc.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adef, adam.adbase

Table 14-4.2.501. Logistic Regression of Overall Response Rate as Determined by Independent Review Committee <Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	67	51 (76.1)	(64.1, 85.7)	133	120 (90.2)	(83.9, 94.7)	0.1664	0.141 (0.027, 0.255)	2.896 (1.299, 6.457)	1.185 (1.025, 1.371)	0.0104
	>= 2	87	64 (73.6)	(63.0, 82.4)	179	143 (79.9)	(73.3, 85.5)		0.063 (-0.046, 0.173)	1.428 (0.783, 2.602)	1.086 (0.939, 1.256)	0.2720

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'All randomized subjects', and the Fisher's exact test for subgroups.

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Output: t14-04-002-501-eff-logr-orr-irc.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adef, adam.adbase

Table 14-4.2.502. Logistic Regression of Minimal Residual Disease Negative Complete Response as Determined by Independent Review Committee
<Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
All randomized subjects		154	2 (1.3)	(0.2, 4.6)	312	39 (12.5)	(9.0, 16.7)		0.112 (0.071, 0.153)	11.329 (2.703, 47.476)	9.816 (2.402, 40.110)	<.0001
Age - at baseline (years)	<= 75	136	1 (0.7)	(0.0, 4.0)	287	37 (12.9)	(9.2, 17.3)	0.1962	0.122 (0.080, 0.163)	19.980 (2.711, 147.231)	17.533 (2.431, 126.451)	<.0001
	> 75	18	1 (5.6)	(0.1, 27.3)	25	2 (8.0)	(1.0, 26.0)		0.024 (-0.126, 0.174)	1.478 (0.124, 17.669)	1.440 (0.141, 14.693)	1.0000

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from an exact logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'All randomized subjects', and the Fisher's exact test for subgroups.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-eff-logr-irc.sas
Output: t14-04-002-502-eff-logr-mrd-irc.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adpf, adam.adbase

Table 14-4.2.502. Logistic Regression of Minimal Residual Disease Negative Complete Response as Determined by Independent Review Committee
<Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Sex	Male	91	2 (2.2)	(0.3, 7.7)	177	24 (13.6)	(8.9, 19.5)	0.5392	0.114 (0.055, 0.172)	6.980 (1.611, 30.237)	6.169 (1.491, 25.528)	0.0020
	Female	63	0 (0.0)	(0.0, 5.7)	135	15 (11.1)	(6.4, 17.7)		0.111 (0.058, 0.164)	NE (NE, NE)	NE (NE, NE)	0.0032

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from an exact logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'All randomized subjects', and the Fisher's exact test for subgroups.

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Table 14-4.2.502. Logistic Regression of Minimal Residual Disease Negative Complete Response as Determined by Independent Review Committee
<Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Race	White	123	1 (0.8)	(0.0, 4.4)	243	28 (11.5)	(7.8, 16.2)	0.4860	0.107 (0.064, 0.150)	15.888 (2.135, 118.224)	14.173 (1.951, 102.941)	0.0001
	Asian	20	1 (5.0)	(0.1, 24.9)	46	9 (19.6)	(9.4, 33.9)		0.146 (-0.004, 0.295)	4.622 (0.544, 39.232)	3.913 (0.531, 28.861)	0.2607
	Other or Unknown	11	0 (0.0)	(0.0, 28.5)	23	2 (8.7)	(1.1, 28.0)		0.087 (-0.028, 0.202)	NE (NE, NE)	NE (NE, NE)	1.0000

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from an exact logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'All randomized subjects', and the Fisher's exact test for subgroups.

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Table 14-4.2.502. Logistic Regression of Minimal Residual Disease Negative Complete Response as Determined by Independent Review Committee
<Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Region	North America	12	0 (0.0)	(0.0, 26.5)	21	2 (9.5)	(1.2, 30.4)	1.0000	0.095 (-0.030, 0.221)	NE (NE, NE)	NE (NE, NE)	0.5227
	Europe	103	1 (1.0)	(0.0, 5.3)	207	24 (11.6)	(7.6, 16.8)		0.106 (0.059, 0.154)	13.377 (1.783, 100.336)	11.942 (1.638, 87.046)	0.0006
	Asia Pacific	39	1 (2.6)	(0.1, 13.5)	84	13 (15.5)	(8.5, 25.0)		0.129 (0.037, 0.221)	6.958 (0.876, 55.236)	6.036 (0.818, 44.517)	0.0368

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from an exact logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'All randomized subjects', and the Fisher's exact test for subgroups.

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Table 14-4.2.502. Logistic Regression of Minimal Residual Disease Negative Complete Response as Determined by Independent Review Committee
<Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Baseline ECOG PS	0-1	147	2 (1.4)	(0.2, 4.8)	295	39 (13.2)	(9.6, 17.6)	1.0000	0.119 (0.076, 0.162)	11.045 (2.629, 46.409)	9.717 (2.379, 39.687)	<.0001
	2	7	0 (0.0)	(0.0, 41.0)	15	0 (0.0)	(0.0, 21.8)		NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from an exact logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'All randomized subjects', and the Fisher's exact test for subgroups.

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Table 14-4.2.502. Logistic Regression of Minimal Residual Disease Negative Complete Response as Determined by Independent Review Committee
<Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	137	2 (1.5)	(0.2, 5.2)	289	34 (11.8)	(8.3, 16.1)	1.0000	0.103 (0.061, 0.145)	9.000 (2.130, 38.034)	8.059 (1.965, 33.059)	0.0001
	No	17	0 (0.0)	(0.0, 19.5)	23	5 (21.7)	(7.5, 43.7)		0.217 (0.049, 0.386)	NE (NE, NE)	NE (NE, NE)	0.0605

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from an exact logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'All randomized subjects', and the Fisher's exact test for subgroups.

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Table 14-4.2.502. Logistic Regression of Minimal Residual Disease Negative Complete Response as Determined by Independent Review Committee
<Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Refractory to Bortezomib or Ixazomib	Yes	55	1 (1.8)	(0.0, 9.7)	100	7 (7.0)	(2.9, 13.9)	0.3776	0.052 (-0.009, 0.113)	4.065 (0.487, 33.928)	3.850 (0.486, 30.489)	0.2609
	No	99	1 (1.0)	(0.0, 5.5)	212	32 (15.1)	(10.6, 20.6)		0.141 (0.089, 0.193)	17.422 (2.345, 129.444)	14.943 (2.071, 107.799)	<.0001

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from an exact logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'All randomized subjects', and the Fisher's exact test for subgroups.

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Table 14-4.2.502. Logistic Regression of Minimal Residual Disease Negative Complete Response as Determined by Independent Review Committee
<Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	(0.0, 4.9)	123	14 (11.4)	(6.4, 18.4)	0.4969	0.114 (0.058, 0.170)	NE (NE, NE)	NE (NE, NE)	0.0012
	No	80	2 (2.5)	(0.3, 8.7)	189	25 (13.2)	(8.7, 18.9)		0.107 (0.048, 0.166)	5.945 (1.373, 25.735)	5.291 (1.284, 21.810)	0.0067

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from an exact logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'All randomized subjects', and the Fisher's exact test for subgroups.

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Table 14-4.2.502. Logistic Regression of Minimal Residual Disease Negative Complete Response as Determined by Independent Review Committee
<Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Refractory to Lenalidomide	Yes	55	0 (0.0)	(0.0, 6.5)	99	13 (13.1)	(7.2, 21.4)	0.5256	0.131 (0.065, 0.198)	NE (NE, NE)	NE (NE, NE)	0.0044
	No	99	2 (2.0)	(0.2, 7.1)	213	26 (12.2)	(8.1, 17.4)		0.102 (0.050, 0.154)	6.743 (1.568, 29.007)	6.042 (1.463, 24.956)	0.0024

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from an exact logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'All randomized subjects', and the Fisher's exact test for subgroups.

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Table 14-4.2.502. Logistic Regression of Minimal Residual Disease Negative Complete Response as Determined by Independent Review Committee
<Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	0 (0.0)	(0.0, 3.3)	206	24 (11.7)	(7.6, 16.8)	0.1259	0.117 (0.073, 0.160)	NE (NE, NE)	NE (NE, NE)	<.0001
	No	44	2 (4.5)	(0.6, 15.5)	106	15 (14.2)	(8.1, 22.3)		0.096 (0.006, 0.187)	3.462 (0.757, 15.827)	3.113 (0.743, 13.047)	0.1543

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from an exact logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'All randomized subjects', and the Fisher's exact test for subgroups.

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Table 14-4.2.502. Logistic Regression of Minimal Residual Disease Negative Complete Response as Determined by Independent Review Committee
<Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Refractory to IMiD	Yes	65	0 (0.0)	(0.0, 5.5)	130	16 (12.3)	(7.2, 19.2)	0.5070	0.123 (0.067, 0.180)	NE (NE, NE)	NE (NE, NE)	0.0016
	No	89	2 (2.2)	(0.3, 7.9)	182	23 (12.6)	(8.2, 18.4)		0.104 (0.047, 0.161)	6.292 (1.449, 27.322)	5.624 (1.356, 23.324)	0.0061

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from an exact logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'All randomized subjects', and the Fisher's exact test for subgroups.

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Table 14-4.2.502. Logistic Regression of Minimal Residual Disease Negative Complete Response as Determined by Independent Review Committee
<Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	127	2 (1.6)	(0.2, 5.6)	252	38 (15.1)	(10.9, 20.1)	1.0000	0.135 (0.086, 0.184)	11.098 (2.632, 46.791)	9.575 (2.348, 39.057)	<.0001
	3	27	0 (0.0)	(0.0, 12.8)	60	1 (1.7)	(0.0, 8.9)		0.017 (-0.016, 0.049)	NE (NE, NE)	NE (NE, NE)	1.0000

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from an exact logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'All randomized subjects', and the Fisher's exact test for subgroups.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-eff-logr-irc.sas
Output: t14-04-002-502-eff-logr-mrd-irc.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adpf, adam.adbase

Table 14-4.2.502. Logistic Regression of Minimal Residual Disease Negative Complete Response as Determined by Independent Review Committee
<Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Prior proteasome inhibitor exposure per IXRS	Yes	139	2 (1.4)	(0.2, 5.1)	279	32 (11.5)	(8.0, 15.8)	1.0000	0.100 (0.058, 0.143)	8.874 (2.095, 37.597)	7.971 (1.938, 32.781)	0.0002
	No	15	0 (0.0)	(0.0, 21.8)	33	7 (21.2)	(9.0, 38.9)		0.212 (0.073, 0.352)	NE (NE, NE)	NE (NE, NE)	0.0819

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from an exact logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'All randomized subjects', and the Fisher's exact test for subgroups.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-eff-logr-irc.sas
Output: t14-04-002-502-eff-logr-mrd-irc.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adpf, adam.adbase

Table 14-4.2.502. Logistic Regression of Minimal Residual Disease Negative Complete Response as Determined by Independent Review Committee
<Intent-to-Treat Population>

		Kd (N = 154)			KdD (N = 312)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	67	1 (1.5)	(0.0, 8.0)	133	22 (16.5)	(10.7, 24.0)	1.0000	0.150 (0.081, 0.220)	13.081 (1.723, 99.306)	11.083 (1.527, 80.461)	0.0008
	>= 2	87	1 (1.1)	(0.0, 6.2)	179	17 (9.5)	(5.6, 14.8)		0.083 (0.035, 0.132)	9.025 (1.181, 68.967)	8.263 (1.118, 61.080)	0.0087

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratified analysis was conducted for all randomized subjects, and unstratified analysis was conducted for subgroups.
[a] The p-value (2-sided) for interaction was from an exact logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the stratified Cochran-Mantel-Haenszel test for 'All randomized subjects', and the Fisher's exact test for subgroups.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-eff-logr-irc.sas
Output: t14-04-002-502-eff-logr-mrd-irc.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adpf, adam.adbase

Table 14-4.3.501. Analysis of Best Overall Response and Duration of Response as Assessed by the Independent Review Committee <Intent to Treat Population>

	Kd (N=154)	KdD (N=312)	Treatment Difference
Best overall response[a] - n(%)			
Complete response (CR)[b]	16 (10.4)	89 (28.5)	
MRD[-]CR[c]	6 (3.9)	49 (15.7)	
Very good partial response (VGPR)	59 (38.3)	127 (40.7)	
Partial response (PR)	40 (26.0)	47 (15.1)	
Stable disease (SD)	18 (11.7)	19 (6.1)	
Progressive disease (PD)	4 (2.6)	4 (1.3)	
Not evaluable (NE)	17 (11.0)	26 (8.3)	

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratification factors (as assessed at randomization): International Staging System (ISS) stage (Stage 1 or 2 vs Stage 3) at screening; prior proteasome inhibitor exposure (yes vs no); number of prior lines of therapy (1 vs ≥ 2).
[a] Overall response rate is defined as the proportion of subjects in each treatment group who achieve sCR, CR, VGPR, or PR per the International Myeloma Working Group Uniform Response Criteria (IMWG-URC) as their best response. Complete response rate is defined as the proportion of subjects in each treatment group who achieve sCR or CR per IMWG-URC as their best response.
[b] sCR and CR cannot be differentiated due to lack of kappa/lambda ratio by IHC.
[c] MRD[-]CR is defined as achievement of CR (includes sCR) per IMWG-URC by IRC and MRD[-] status as assessed by NGS at any time during the study.
[d] 95% CIs for proportions were estimated using the Clopper-Pearson method.
[e] Odds ratios and corresponding 95% CIs were estimated by a stratified analysis by stratification factors using the Mantel-Haenszel method.
[f] P-values were calculated using the stratified by stratification factors Cochran-Mantel-Haenszel Chi-Square test.
[g] Durations were calculated for responders. Medians and percentiles were estimated using the Kaplan-Meier method. 95% CIs for medians and percentiles were estimated using the method by Klein and Moeschberger (1997) with log-log transformation.
[h] Time to overall response is defined as the time from randomization to the earliest of sCR, CR, VGPR, or PR per IMWG-URC. Time to complete response is defined as the time from randomization to the earliest of sCR, CR per IMWG-URC.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-eff-bor.sas
Output: t14-04-003-501-eff-bor-irc.rtf (Date Generated: 27AUG2020:20:00) Source Data: adam.adsl, adam.adef, adam.adtteef, adam.adpf

Table 14-4.3.501. Analysis of Best Overall Response and Duration of Response as Assessed by the Independent Review Committee <Intent to Treat Population>

	Kd (N=154)	KdD (N=312)	Treatment Difference
Overall response rate[a] (ORR)			
Number of subjects who achieved overall response	115	263	
ORR (95% CI)[d]	74.7 (67.0, 81.3)	84.3 (79.8, 88.1)	
Odds ratio (KdD/Kd) (95% CI)[e]			1.925 (1.184, 3.129)
1-sided p-value[f]			0.0040
Complete response rate[a] [b] (CRR)			
Number of subjects who achieved sCR or CR	16	89	
CRR (95% CI)[d]	10.4 (6.1, 16.3)	28.5 (23.6, 33.9)	
Odds ratio (KdD/Kd) (95% CI)[e]			3.507 (1.971, 6.238)
1-sided p-value[f]			<.0001

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratification factors (as assessed at randomization): International Staging System (ISS) stage (Stage 1 or 2 vs Stage 3) at screening; prior proteasome inhibitor exposure (yes vs no); number of prior lines of therapy (1 vs ≥ 2).
[a] Overall response rate is defined as the proportion of subjects in each treatment group who achieve sCR, CR, VGPR, or PR per the International Myeloma Working Group Uniform Response Criteria (IMWG-URC) as their best response. Complete response rate is defined as the proportion of subjects in each treatment group who achieve sCR or CR per IMWG-URC as their best response.
[b] sCR and CR cannot be differentiated due to lack of kappa/lambda ratio by IHC.
[c] MRD[-]CR is defined as achievement of CR (includes sCR) per IMWG-URC by IRC and MRD[-] status as assessed by NGS at any time during the study.
[d] 95% CIs for proportions were estimated using the Clopper-Pearson method.
[e] Odds ratios and corresponding 95% CIs were estimated by a stratified analysis by stratification factors using the Mantel-Haenszel method.
[f] P-values were calculated using the stratified by stratification factors Cochran-Mantel-Haenszel Chi-Square test.
[g] Durations were calculated for responders. Medians and percentiles were estimated using the Kaplan-Meier method. 95% CIs for medians and percentiles were estimated using the method by Klein and Moeschberger (1997) with log-log transformation.
[h] Time to overall response is defined as the time from randomization to the earliest of sCR, CR, VGPR, or PR per IMWG-URC. Time to complete response is defined as the time from randomization to the earliest of sCR, CR per IMWG-URC.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-eff-bor.sas
Output: t14-04-003-501-eff-bor-irc.rtf (Date Generated: 27AUG2020:20:00) Source Data: adam.adsl, adam.adef, adam.adtteef, adam.adpf

Table 14-4.3.501. Analysis of Best Overall Response and Duration of Response as Assessed by the Independent Review Committee <Intent to Treat Population>

	Kd (N=154)	KdD (N=312)	Treatment Difference
Duration of overall response (months)[g]			
Number of subjects with overall response	115 (74.7)	263 (84.3)	
Subject status - n(%)			
Events	47 (30.5)	74 (23.7)	
Progressive disease	44 (28.6)	58 (18.6)	
Death	3 (1.9)	16 (5.1)	
Censored	68 (44.2)	189 (60.6)	
25th percentile (95% CI)	8.3 [6.7, 10.3)	12.3 [9.5, NE)	
Median (95% CI)	30.4 [13.9, NE)	NE [NE, NE)	
75th percentile (95% CI)	NE [30.4, NE)	NE [NE, NE)	
Min, Max (+ for censored)	1+, 30+	1, 33+	

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratification factors (as assessed at randomization): International Staging System (ISS) stage (Stage 1 or 2 vs Stage 3) at screening; prior proteasome inhibitor exposure (yes vs no); number of prior lines of therapy (1 vs ≥ 2).
[a] Overall response rate is defined as the proportion of subjects in each treatment group who achieve sCR, CR, VGPR, or PR per the International Myeloma Working Group Uniform Response Criteria (IMWG-URC) as their best response. Complete response rate is defined as the proportion of subjects in each treatment group who achieve sCR or CR per IMWG-URC as their best response.
[b] sCR and CR cannot be differentiated due to lack of kappa/lambda ratio by IHC.
[c] MRD[-]CR is defined as achievement of CR (includes sCR) per IMWG-URC by IRC and MRD[-] status as assessed by NGS at any time during the study.
[d] 95% CIs for proportions were estimated using the Clopper-Pearson method.
[e] Odds ratios and corresponding 95% CIs were estimated by a stratified analysis by stratification factors using the Mantel-Haenszel method.
[f] P-values were calculated using the stratified by stratification factors Cochran-Mantel-Haenszel Chi-Square test.
[g] Durations were calculated for responders. Medians and percentiles were estimated using the Kaplan-Meier method. 95% CIs for medians and percentiles were estimated using the method by Klein and Moeschberger (1997) with log-log transformation.
[h] Time to overall response is defined as the time from randomization to the earliest of sCR, CR, VGPR, or PR per IMWG-URC. Time to complete response is defined as the time from randomization to the earliest of sCR, CR per IMWG-URC.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-eff-bor.sas
Output: t14-04-003-501-eff-bor-irc.rtf (Date Generated: 27AUG2020:20:00) Source Data: adam.adsl, adam.adef, adam.adtteef, adam.adpf

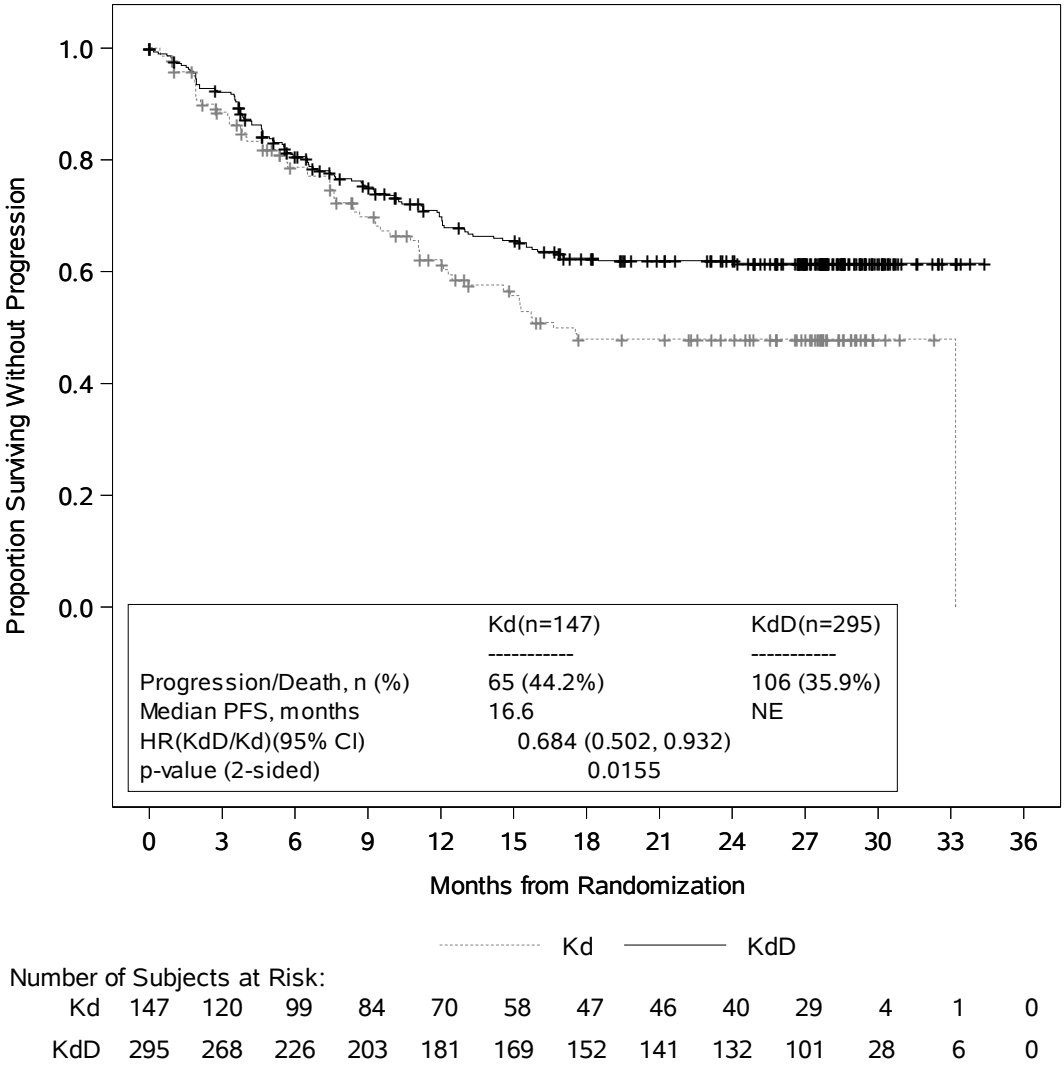
Table 14-4.3.501. Analysis of Best Overall Response and Duration of Response as Assessed by the Independent Review Committee <Intent to Treat Population>

	Kd (N=154)	KdD (N=312)	Treatment Difference
Time to overall response (months)[h]			
n	115	263	
Mean (SD)	1.5 (1.1)	1.4 (1.4)	
Median	1.0	1.0	
Min, Max	1, 10	1, 14	
Time to complete response (months)[h]			
n	16	89	
Mean (SD)	7.5 (3.4)	8.7 (3.1)	
Median	7.0	8.4	
Min, Max	3, 14	2, 16	

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Stratification factors (as assessed at randomization): International Staging System (ISS) stage (Stage 1 or 2 vs Stage 3) at screening; prior proteasome inhibitor exposure (yes vs no); number of prior lines of therapy (1 vs ≥ 2).
[a] Overall response rate is defined as the proportion of subjects in each treatment group who achieve sCR, CR, VGPR, or PR per the International Myeloma Working Group Uniform Response Criteria (IMWG-URC) as their best response. Complete response rate is defined as the proportion of subjects in each treatment group who achieve sCR or CR per IMWG-URC as their best response.
[b] sCR and CR cannot be differentiated due to lack of kappa/lambda ratio by IHC.
[c] MRD[-]CR is defined as achievement of CR (includes sCR) per IMWG-URC by IRC and MRD[-] status as assessed by NGS at any time during the study.
[d] 95% CIs for proportions were estimated using the Clopper-Pearson method.
[e] Odds ratios and corresponding 95% CIs were estimated by a stratified analysis by stratification factors using the Mantel-Haenszel method.
[f] P-values were calculated using the stratified by stratification factors Cochran-Mantel-Haenszel Chi-Square test.
[g] Durations were calculated for responders. Medians and percentiles were estimated using the Kaplan-Meier method. 95% CIs for medians and percentiles were estimated using the method by Klein and Moeschberger (1997) with log-log transformation.
[h] Time to overall response is defined as the time from randomization to the earliest of sCR, CR, VGPR, or PR per IMWG-URC. Time to complete response is defined as the time from randomization to the earliest of sCR, CR per IMWG-URC.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-eff-bor.sas
Output: t14-04-003-501-eff-bor-irc.rtf (Date Generated: 27AUG2020:20:00) Source Data: adam.adsl, adam.adef, adam.adtteef, adam.adpf

Figure 14-4.2.604. Progression-free Survival KM Curves as Assessed by the Independent Review Committee
<Intent-to-Treat Population: Subjects With Baseline ECOG PS = 0-1>

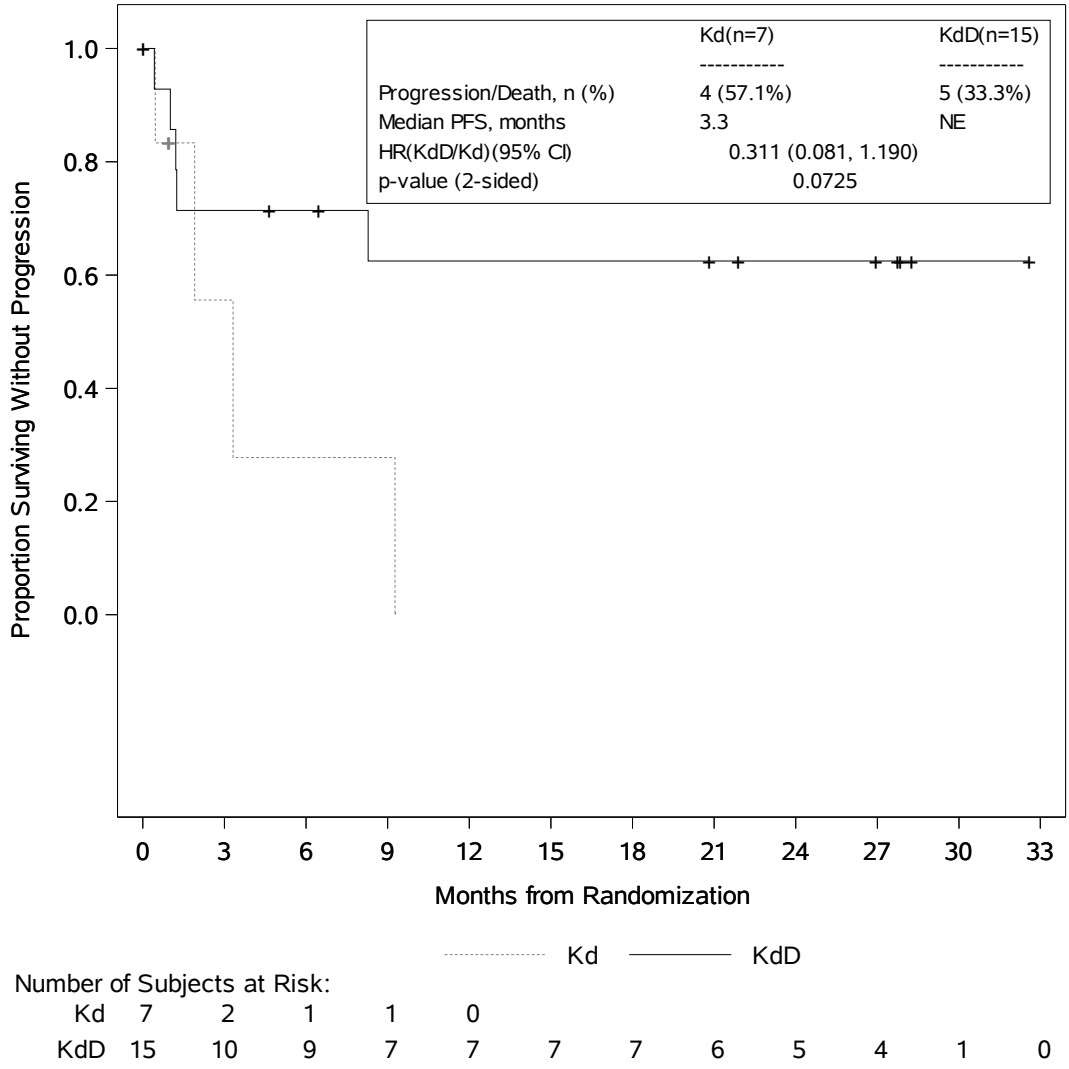


Number of Subjects at Risk:

Kd	147	120	99	84	70	58	47	46	40	29	4	1	0
KdD	295	268	226	203	181	169	152	141	132	101	28	6	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median PFS in this plot were derived by unstratified Kaplan-Meier method. Harzard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-eff-km-sub.sas.
Output: f14-04-002-604-eff-km-pfs-irc-sub-ecog01.rtf (Date Generated: 16SEP20:01:05:28).
Source Data:adam.adsl, adam.adttepfs, adam.adbase.

Figure 14-4.2.605. Progression-free Survival KM Curves as Assessed by the Independent Review Committee
<Intent-to-Treat Population: Subjects With Baseline ECOG PS = 2>



Number of Subjects at Risk:

Kd	7	2	1	1	0							
KdD	15	10	9	7	7	7	7	6	5	4	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median PFS in this plot were derived by unstratified Kaplan-Meier method. Harzard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
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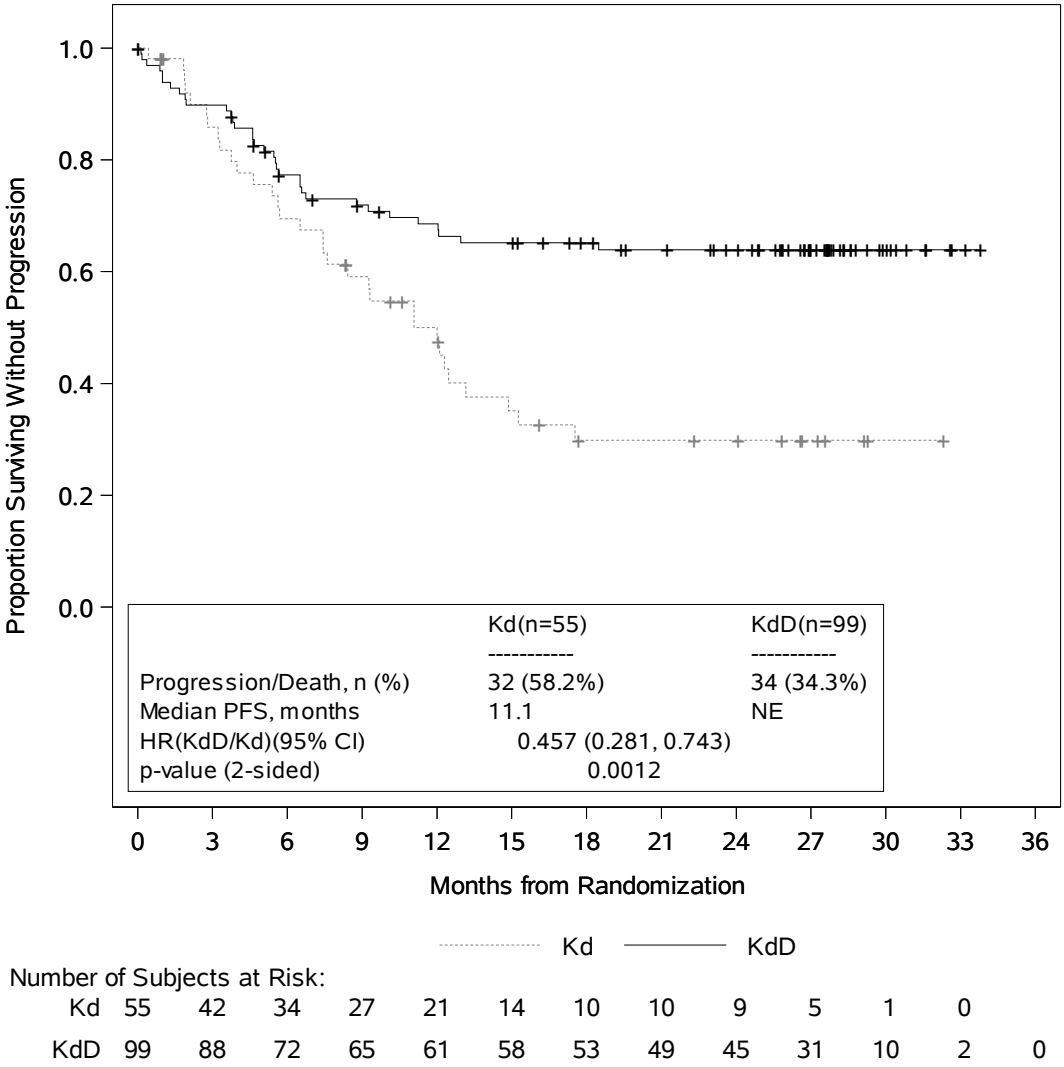
Output: f14-04-002-605-eff-km-pfs-irc-sub-ecog2.rtf (Date Generated: 16SEP20:01:04:47).
Source Data:adam.adsl, adam.adttepfs, adam.adbase.

Figure 14-4.2.606. Progression-free Survival KM Curves as Assessed by the Independent Review Committee
<Intent-to-Treat Population: Subjects Refractory to Lenalidomide>

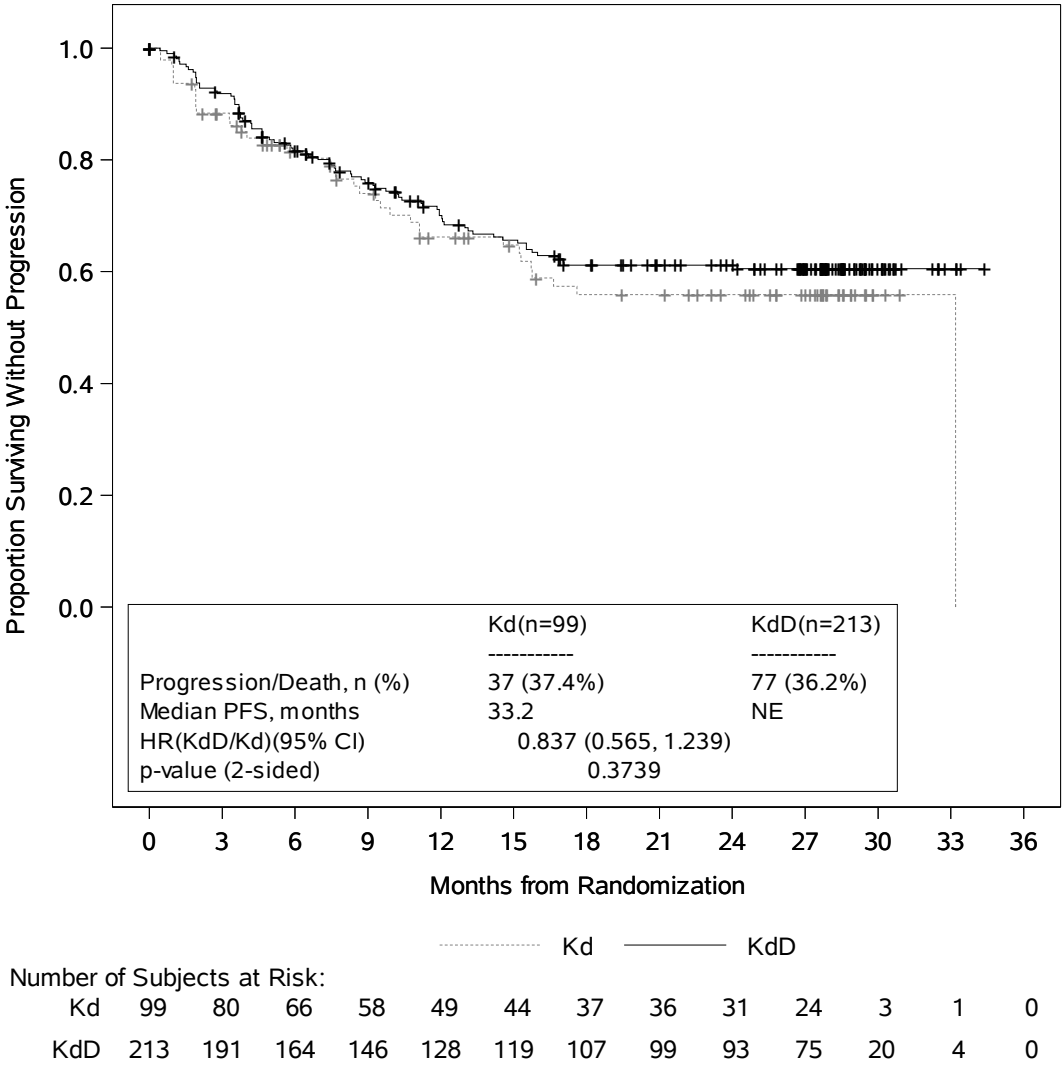


Number of Subjects at Risk:

Kd	55	42	34	27	21	14	10	10	9	5	1	0	
KdD	99	88	72	65	61	58	53	49	45	31	10	2	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median PFS in this plot were derived by unstratified Kaplan-Meier method. Harzard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-eff-km-sub.sas.
Output: f14-04-002-606-eff-km-pfs-irc-sub-reflen.rtf (Date Generated: 16SEP20:01:05:29).
Source Data:adam.adsl, adam.adttepfs, adam.adbase.

Figure 14-4.2.607. Progression-free Survival KM Curves as Assessed by the Independent Review Committee
<Intent-to-Treat Population: Subjects Non-refractory to Lenalidomide>

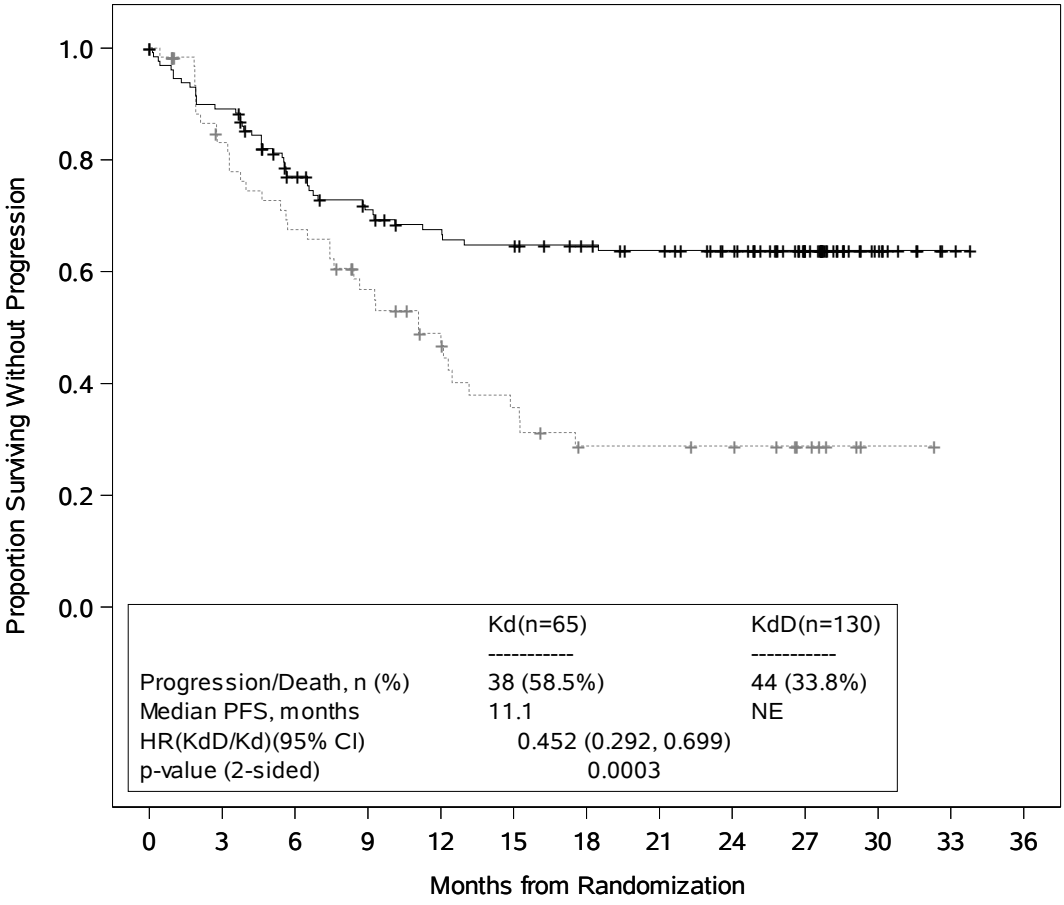


Number of Subjects at Risk:

Kd	99	80	66	58	49	44	37	36	31	24	3	1	0
KdD	213	191	164	146	128	119	107	99	93	75	20	4	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median PFS in this plot were derived by unstratified Kaplan-Meier method. Harzard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-eff-km-sub.sas.
Output: f14-04-002-607-eff-km-pfs-irc-sub-noreflen.rtf (Date Generated: 16SEP20:01:05:31).
Source Data:adam.adsl, adam.adttepfs, adam.adbase.

Figure 14-4.2.608. Progression-free Survival KM Curves as Assessed by the Independent Review Committee
<Intent-to-Treat Population: Subjects Refractory to IMiD>



Number of Subjects at Risk:

Kd	65	48	39	30	23	16	11	11	10	6	1	0	
KdD	130	115	92	81	74	71	66	62	55	38	11	2	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median PFS in this plot were derived by unstratified Kaplan-Meier method. Harzard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
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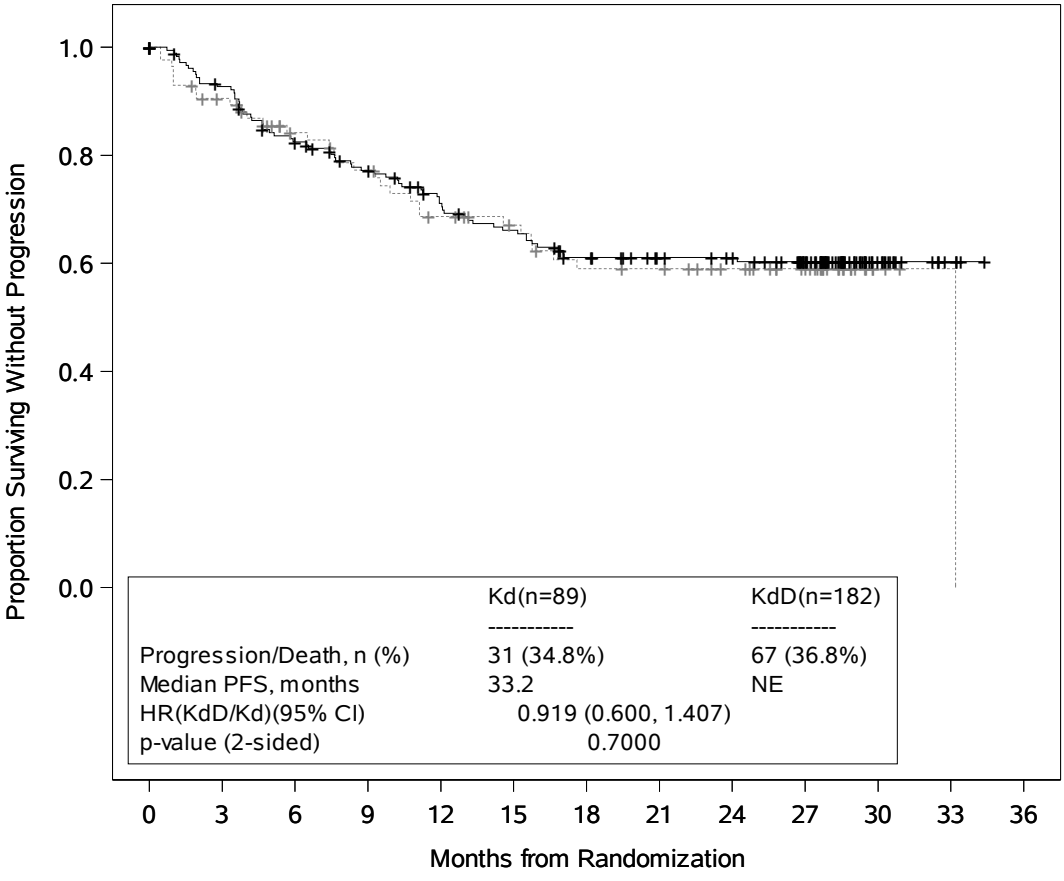
Output: f14-04-002-608-eff-km-pfs-irc-sub-refimid.rtf (Date Generated: 16SEP20:01:05:33).
Source Data:adam.adsl, adam.adttepfs, adam.adbase.

Figure 14-4.2.609. Progression-free Survival KM Curves as Assessed by the Independent Review Committee
<Intent-to-Treat Population: Subjects Non-refractory to IMiD>

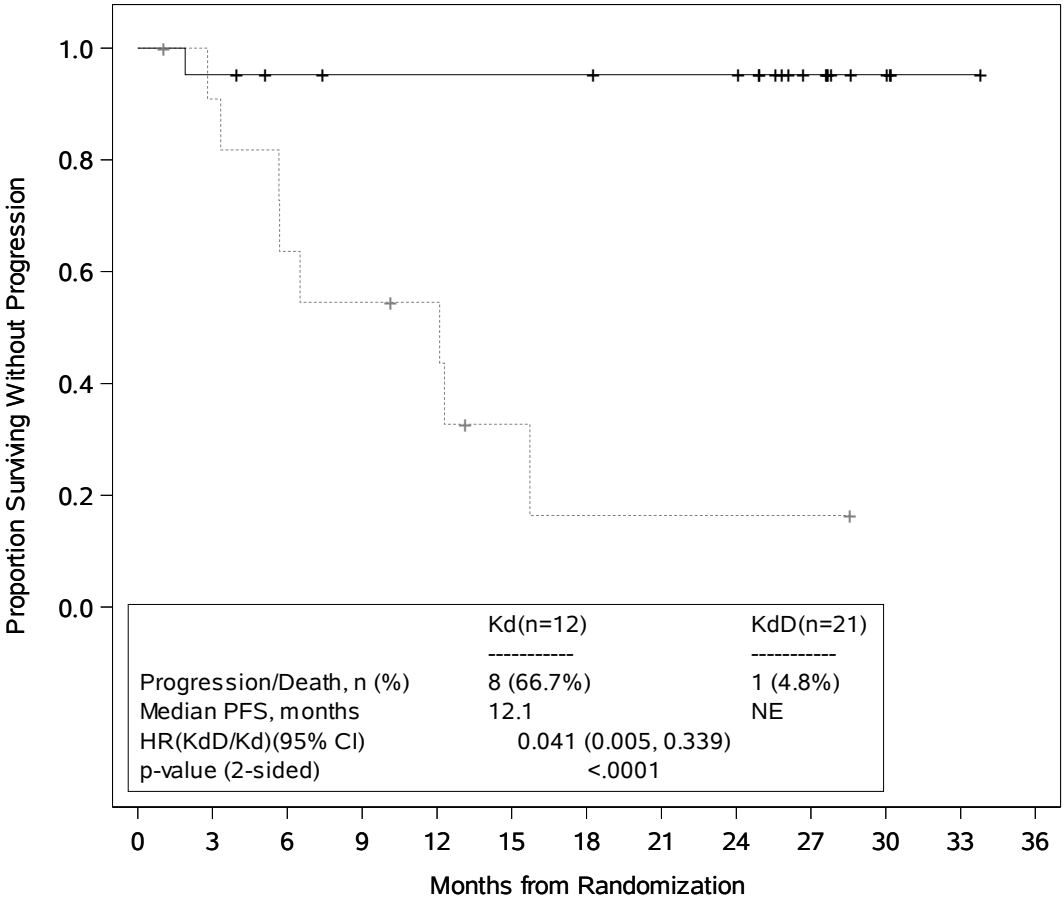


Number of Subjects at Risk:

Kd	89	74	61	55	47	42	36	35	30	23	3	1	0
KdD	182	164	144	130	115	106	94	86	83	68	19	4	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median PFS in this plot were derived by unstratified Kaplan-Meier method. Harzard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-eff-km-sub.sas.
Output: f14-04-002-609-eff-km-pfs-irc-sub-norefimid.rtf (Date Generated: 16SEP20:01:05:34).
Source Data:adam.adsl, adam.adttepfs, adam.adbase.

Figure 14-4.2.601. Progression-free Survival KM Curves as Assessed by the Independent Review Committee
<Intent-to-Treat Population: Region - North America>



Number of Subjects at Risk:

Kd	12	10	7	6	5	2	1	1	1	1	0	
KdD	21	20	18	17	17	17	17	16	16	9	4	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median PFS in this plot were derived by unstratified Kaplan-Meier method. Harzard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-eff-km-sub.sas.
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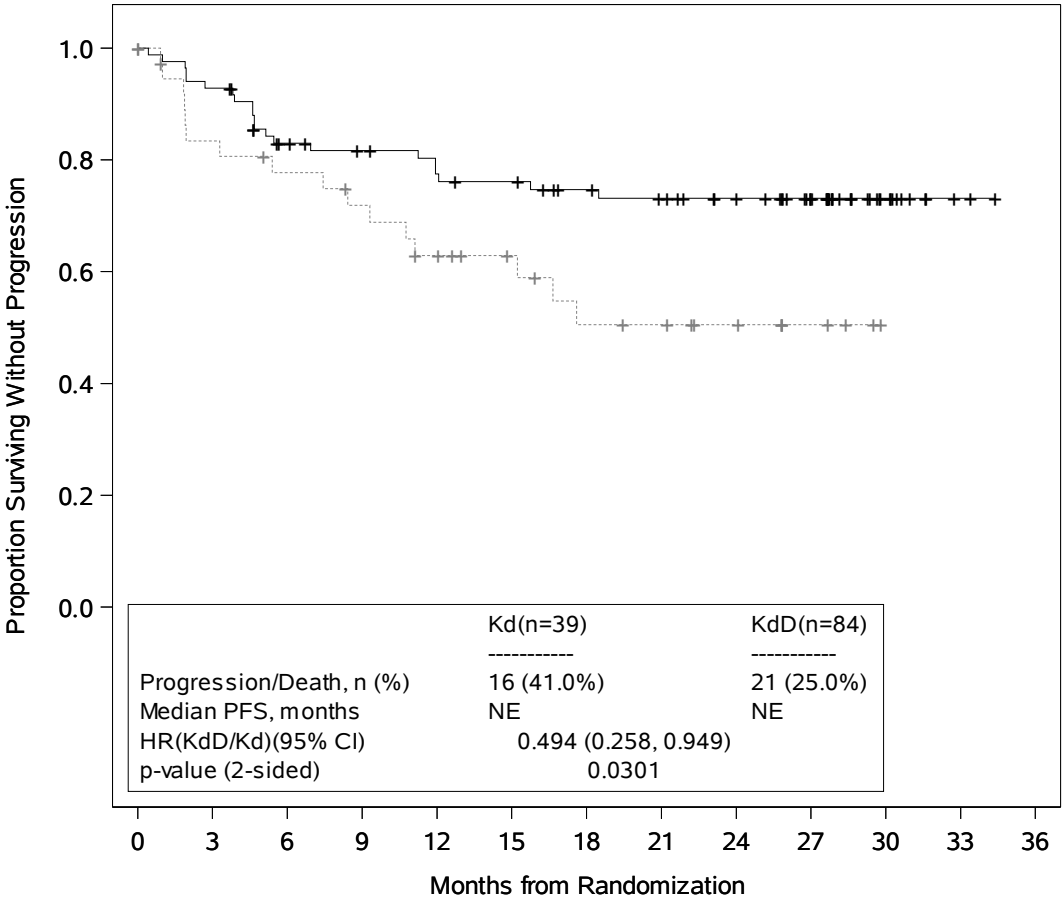
Source Data:adam.adsl, adam.adttepfs, adam.adbase.

Figure 14-4.2.602. Progression-free Survival KM Curves as Assessed by the Independent Review Committee
<Intent-to-Treat Population: Region - Asia Pacific>

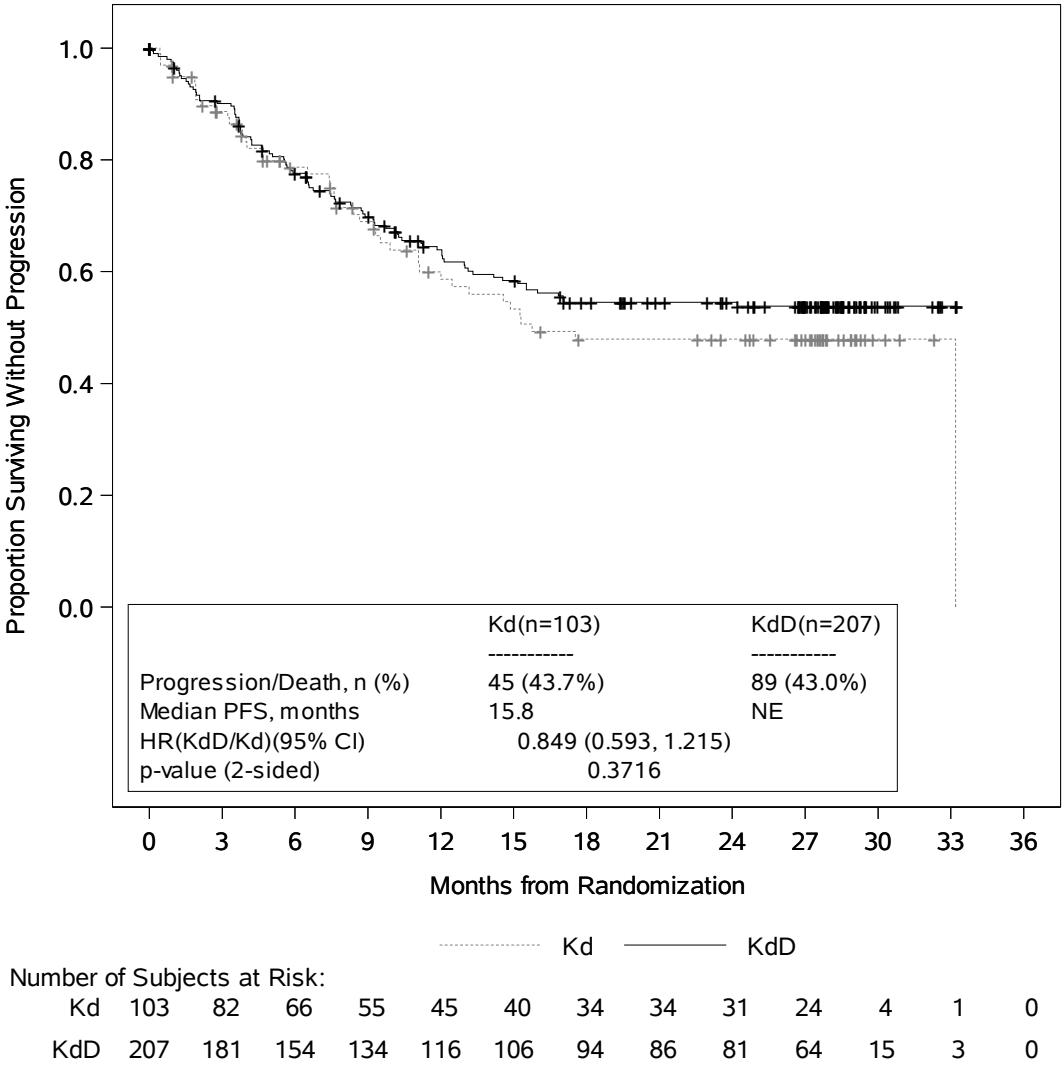


Number of Subjects at Risk:

Kd	39	30	27	24	20	16	12	11	8	4	0		
KdD	84	78	64	60	56	54	49	46	41	33	11	2	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median PFS in this plot were derived by unstratified Kaplan-Meier method. Harzard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-eff-km-sub.sas.
Output: f14-04-002-602-eff-km-pfs-irc-sub-asia.rtf (Date Generated: 16SEP20:01:05:24).
Source Data:adam.adsl, adam.adttepfs, adam.adbase.

Figure 14-4.2.603. Progression-free Survival KM Curves as Assessed by the Independent Review Committee
<Intent-to-Treat Population: Region - Europe>



Number of Subjects at Risk:

Kd	103	82	66	55	45	40	34	34	31	24	4	1	0
KdD	207	181	154	134	116	106	94	86	81	64	15	3	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median PFS in this plot were derived by unstratified Kaplan-Meier method. Harzard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-eff-km-sub.sas.
Output: f14-04-002-603-eff-km-pfs-irc-sub-europe.rtf (Date Generated: 16SEP20:01:05:26).
Source Data:adam.adsl, adam.adttepfs, adam.adbase.

Table 8.1 Return rates for EORTC QLQ-C30 Questionnaire: eCOA-ITT Population

	KdD		Kd	
Timepoint	**Patients under treatment (n)[a] at time of assessment**	**Number of patients assessed at the respective time point**	**Patients under treatment (n)[a] at time of assessment**	**Number of patients assessed at the respective time point**
Baseline	312	290 (92.9%)	154	139 (90.3%)
Baseline + at least one post-baseline value	302	280 (92.7%)	145	126 (86.9%)
Cycle 2	302	280 (92.7%)	145	126 (86.9%)
Cycle 3	295	262 (88.8%)	136	124 (91.2%)
Cycle 4	286	258 (90.2%)	128	112 (87.5%)
Cycle 5	274	252 (92.0%)	115	105 (91.3%)
Cycle 6	264	244 (92.4%)	109	96 (88.1%)
Cycle 7	245	223 (91.0%)	102	94 (92.2%)
Cycle 8	234	206 (88.0%)	97	87 (89.7%)
Cycle 9	225	203 (90.2%)	91	79 (86.8%)
Cycle 10	214	198 (92.5%)	83	73 (88.0%)
Cycle 11	206	190 (92.2%)	78	66 (84.6%)
Cycle 12	200	188 (94.0%)	73	65 (89.0%)
Cycle 13	194	175 (90.2%)	68	61 (89.7%)
Cycle 14	189	169 (89.4%)	65	59 (90.8%)
Cycle 15	183	167 (91.3%)	62	53 (85.5%)
Cycle 16	179	165 (92.2%)	60	54 (90.0%)
Cycle 17	176	159 (90.3%)	59	54 (91.5%)

Table 8.1 Return rates for EORTC QLQ-C30 Questionnaire: eCOA-ITT Population

	KdD		Kd	
Timepoint	**Patients under treatment (n)[a] at time of assessment**	**Number of patients assessed at the respective time point**	**Patients under treatment (n)[a] at time of assessment**	**Number of patients assessed at the respective time point**
Cycle 18	169	155 (91.7%)	55	52 (94.5%)
Cycle 19	162	150 (92.6%)	49	47 (95.9%)
Cycle 20	158	141 (89.2%)	43	40 (93.0%)
Cycle 21	152	143 (94.1%)	42	39 (92.9%)
Cycle 22	149	139 (93.3%)	39	36 (92.3%)
Cycle 23	141	131 (92.9%)	39	35 (89.7%)
Cycle 24	137	125 (91.2%)	38	35 (92.1%)
Cycle 25	136	127 (93.4%)	37	33 (89.2%)
Cycle 26	132	120 (90.9%)	35	32 (91.4%)
Cycle 27	122	109 (89.3%)	32	28 (87.5%)
Cycle 28	116	102 (87.9%)	30	27 (90.0%)
Cycle 29	110	96 (87.3%)	26	22 (84.6%)
Cycle 30	96	83 (86.5%)	20	16 (80.0%)
Cycle 31	66	59 (89.4%)	13	11 (84.6%)
Cycle 32	41	37 (90.2%)	9	7 (77.8%)
Cycle 33	30	28 (93.3%)	5	4 (80.0%)
Cycle 34	17	15 (88.2%)	3	3 (100.0%)
Cycle 35	11	10 (90.9%)	2	2 (100.0%)
Cycle 36	8	7 (87.5%)	2	2 (100.0%)

Table 8.1 Return rates for EORTC QLQ-C30 Questionnaire: eCOA-ITT Population

	KdD		Kd	
Timepoint	**Patients under treatment (n)[a] at time of assessment**	**Number of patients assessed at the respective time point**	**Patients under treatment (n)[a] at time of assessment**	**Number of patients assessed at the respective time point**

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
[a] Number of patients with a baseline value and at least one post-baseline value

Table 8.2 Return rates for EORTC QLQ-MY20 Questionnaire: eCOA-ITT Population

	KdD		Kd	
Timepoint	**Patients under treatment (n)[a] at time of assessment**	**Number of patients assessed at the respective time point**	**Patients under treatment (n)[a] at time of assessment**	**Number of patients assessed at the respective time point**
Baseline	312	287 (92.0%)	154	139 (90.3%)
Baseline + at least one post-baseline value	302	275 (91.1%)	145	123 (84.8%)
Cycle 2	302	275 (91.1%)	145	123 (84.8%)
Cycle 3	295	261 (88.5%)	136	122 (89.7%)
Cycle 4	286	255 (89.2%)	128	112 (87.5%)
Cycle 5	274	249 (90.9%)	115	104 (90.4%)
Cycle 6	264	243 (92.0%)	109	94 (86.2%)
Cycle 7	245	223 (91.0%)	102	93 (91.2%)
Cycle 8	234	206 (88.0%)	97	87 (89.7%)
Cycle 9	225	202 (89.8%)	91	78 (85.7%)
Cycle 10	214	195 (91.1%)	83	73 (88.0%)
Cycle 11	206	188 (91.3%)	78	66 (84.6%)
Cycle 12	200	188 (94.0%)	73	63 (86.3%)
Cycle 13	194	175 (90.2%)	68	61 (89.7%)
Cycle 14	189	169 (89.4%)	65	59 (90.8%)
Cycle 15	183	167 (91.3%)	62	52 (83.9%)
Cycle 16	179	164 (91.6%)	60	54 (90.0%)
Cycle 17	176	159 (90.3%)	59	54 (91.5%)

Table 8.2 Return rates for EORTC QLQ-MY20 Questionnaire: eCOA-ITT Population

	KdD		Kd	
Timepoint	**Patients under treatment (n)[a] at time of assessment**	**Number of patients assessed at the respective time point**	**Patients under treatment (n)[a] at time of assessment**	**Number of patients assessed at the respective time point**
Cycle 18	169	155 (91.7%)	55	50 (90.9%)
Cycle 19	162	150 (92.6%)	49	47 (95.9%)
Cycle 20	158	142 (89.9%)	43	40 (93.0%)
Cycle 21	152	143 (94.1%)	42	39 (92.9%)
Cycle 22	149	139 (93.3%)	39	36 (92.3%)
Cycle 23	141	131 (92.9%)	39	35 (89.7%)
Cycle 24	137	125 (91.2%)	38	35 (92.1%)
Cycle 25	136	127 (93.4%)	37	33 (89.2%)
Cycle 26	132	120 (90.9%)	35	31 (88.6%)
Cycle 27	122	108 (88.5%)	32	28 (87.5%)
Cycle 28	116	102 (87.9%)	30	27 (90.0%)
Cycle 29	110	96 (87.3%)	26	21 (80.8%)
Cycle 30	96	83 (86.5%)	20	16 (80.0%)
Cycle 31	66	59 (89.4%)	13	11 (84.6%)
Cycle 32	41	37 (90.2%)	9	7 (77.8%)
Cycle 33	30	28 (93.3%)	5	4 (80.0%)
Cycle 34	17	15 (88.2%)	3	3 (100.0%)
Cycle 35	11	10 (90.9%)	2	2 (100.0%)
Cycle 36	8	7 (87.5%)	2	2 (100.0%)

Table 8.2 Return rates for EORTC QLQ-MY20 Questionnaire: eCOA-ITT Population

	KdD		Kd	
Timepoint	**Patients under treatment (n)[a] at time of assessment**	**Number of patients assessed at the respective time point**	**Patients under treatment (n)[a] at time of assessment**	**Number of patients assessed at the respective time point**

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
[a] Number of patients with a baseline value and at least one post-baseline value

Table 8.3 Return rates for EQ-5D VAS: eCOA-ITT Population

	KdD		Kd	
Timepoint	**Patients under treatment (n)[a] at time of assessment**	**Number of patients assessed at the respective time point**	**Patients under treatment (n)[a] at time of assessment**	**Number of patients assessed at the respective time point**
Baseline	312	287 (92.0%)	154	138 (89.6%)
Baseline + at least one post-baseline value	302	274 (90.7%)	145	123 (84.8%)
Cycle 2	302	274 (90.7%)	145	123 (84.8%)
Cycle 3	295	261 (88.5%)	136	122 (89.7%)
Cycle 4	286	255 (89.2%)	128	111 (86.7%)
Cycle 5	274	249 (90.9%)	115	103 (89.6%)
Cycle 6	264	243 (92.0%)	109	94 (86.2%)
Cycle 7	245	223 (91.0%)	102	93 (91.2%)
Cycle 8	234	206 (88.0%)	97	86 (88.7%)
Cycle 9	225	202 (89.8%)	91	77 (84.6%)
Cycle 10	214	194 (90.7%)	83	73 (88.0%)
Cycle 11	206	189 (91.7%)	78	66 (84.6%)
Cycle 12	200	188 (94.0%)	73	63 (86.3%)
Cycle 13	194	174 (89.7%)	68	61 (89.7%)
Cycle 14	189	169 (89.4%)	65	58 (89.2%)
Cycle 15	183	166 (90.7%)	62	52 (83.9%)
Cycle 16	179	163 (91.1%)	60	53 (88.3%)
Cycle 17	176	159 (90.3%)	59	54 (91.5%)

Table 8.3 Return rates for EQ-5D VAS: eCOA-ITT Population

	KdD		Kd	
Timepoint	**Patients under treatment (n)[a] at time of assessment**	**Number of patients assessed at the respective time point**	**Patients under treatment (n)[a] at time of assessment**	**Number of patients assessed at the respective time point**
Cycle 18	169	154 (91.1%)	55	50 (90.9%)
Cycle 19	162	150 (92.6%)	49	47 (95.9%)
Cycle 20	158	141 (89.2%)	43	40 (93.0%)
Cycle 21	152	143 (94.1%)	42	39 (92.9%)
Cycle 22	149	139 (93.3%)	39	36 (92.3%)
Cycle 23	141	131 (92.9%)	39	35 (89.7%)
Cycle 24	137	125 (91.2%)	38	35 (92.1%)
Cycle 25	136	127 (93.4%)	37	33 (89.2%)
Cycle 26	132	120 (90.9%)	35	31 (88.6%)
Cycle 27	122	108 (88.5%)	32	27 (84.4%)
Cycle 28	116	102 (87.9%)	30	27 (90.0%)
Cycle 29	110	96 (87.3%)	26	22 (84.6%)
Cycle 30	96	83 (86.5%)	20	16 (80.0%)
Cycle 31	66	59 (89.4%)	13	11 (84.6%)
Cycle 32	41	37 (90.2%)	9	7 (77.8%)
Cycle 33	30	28 (93.3%)	5	4 (80.0%)
Cycle 34	17	15 (88.2%)	3	3 (100.0%)
Cycle 35	11	10 (90.9%)	2	2 (100.0%)
Cycle 36	8	7 (87.5%)	2	2 (100.0%)

Table 8.3 Return rates for EQ-5D VAS: eCOA-ITT Population

	KdD		Kd	
Timepoint	**Patients under treatment (n)[a] at time of assessment**	**Number of patients assessed at the respective time point**	**Patients under treatment (n)[a] at time of assessment**	**Number of patients assessed at the respective time point**

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
[a] Number of patients with a baseline value and at least one post-baseline value

Table 1. EORTC-QLQ C30 Time to deterioration by at least 10 points
eCOA-ITT Population

EORTC	KdD (N=281)		Kd (N=128)		Treatment Comparison KdD vs. Kd:	
QLQ C30 Scale	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value
Global Health Status	172 (61.2%)	6.5 [4.7, 10.9]	78 (60.9%)	4.0 [2.8, 7.5]	0.83 [0.63, 1.08]	0.1462
Physical Functioning	177 (63.0%)	6.2 [4.7, 9.6]	81 (63.3%)	4.7 [3.1, 5.8]	0.86 [0.66, 1.12]	0.2377
Role Functioning	212 (75.4%)	2.8 [1.9, 3.8]	92 (71.9%)	2.8 [1.9, 3.8]	0.94 [0.74, 1.20]	0.6116
Emotional Functioning	159 (56.6%)	8.7 [6.6, 14.5]	58 (45.3%)	10.8 [6.6, 21.7]	1.10 [0.82, 1.49]	0.5142
Cognitive Functioning	195 (69.4%)	5.2 [3.8, 7.5]	81 (63.3%)	4.7 [2.9, 7.5]	0.93 [0.72, 1.21]	0.5988
Social Functioning	183 (65.1%)	3.8 [2.8, 4.7]	95 (74.2%)	2.8 [1.9, 4.0]	0.76 [0.59, 0.97]	0.0208
Fatigue	213 (75.8%)	2.8 [1.9, 2.9]	91 (71.1%)	2.8 [1.9, 2.9]	0.98 [0.77, 1.25]	0.8614
Nausea/Vomiting	148 (52.7%)	12.9 [8.4, 16.1]	51 (39.8%)	18.2 [14.0, NA]	1.31 [0.95, 1.80]	0.0948
Pain	167 (59.4%)	8.4 [5.6, 12.4]	79 (61.7%)	4.9 [3.8, 8.4]	0.77 [0.59, 1.01]	0.0503
Dyspnea	185 (65.8%)	3.8 [2.8, 5.6]	86 (67.2%)	3.7 [2.1, 5.0]	0.83 [0.64, 1.07]	0.1425
Insomnia	172 (61.2%)	4.8 [3.7, 7.5]	79 (61.7%)	3.8 [2.8, 6.6]	0.84 [0.64, 1.09]	0.1757
Appetite Loss	161 (57.3%)	9.4 [5.6, 12.2]	62 (48.4%)	10.6 [4.9, 18.5]	1.05 [0.78, 1.41]	0.7376
Constipation	117 (41.6%)	22.8 [15.4, NA]	45 (35.2%)	NA [10.0, NA]	1.06 [0.75, 1.49]	0.7473
Diarrhea	162 (57.7%)	9.8 [7.5, 12.4]	58 (45.3%)	15.2 [9.4, 24.3]	1.22 [0.90, 1.65]	0.1861
Financial Difficulties	126 (44.8%)	19.2 [11.3, NA]	59 (46.1%)	13.1 [6.8, 25.4]	0.83 [0.61, 1.13]	0.2281

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
NA denotes that the median time (and 95% CI) were not estimable
[a]From Kaplan–Meier estimate
[b]HR: hazard ratio

Table 2 QLQ MY-20 Time to deterioration by at least 10 points
eCOA-ITT Population

EORTC	KdD (N=278)		Kd (N=133)		Treatment Comparison KdD vs. Kd:	
QLQ-MY20 Scale	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value
Disease Symptoms	174 (62.6%)	2.8 [2.0, 4.7]	74 (55.6%)	4.7 [2.8, 14.5]	1.11 [0.85, 1.46]	0.4317
Side-effects	94 (33.8%)	NA [, NA]	34 (25.6%)	NA [, NA]	1.27 [0.86, 1.89]	0.2185
Body Image	149 (53.6%)	10.3 [7.6, 17.1]	74 (55.6%)	5.6 [3.8, 13.3]	0.85 [0.64, 1.12]	0.2375
Future Perspective	168 (60.4%)	7.5 [5.2, 12.1]	77 (57.9%)	7.5 [4.7, 14.0]	0.93 [0.71, 1.22]	0.6002

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
NA denotes that the median time (and 95% CI) were not estimable
[a]From Kaplan–Meier estimate
[b]HR: hazard ratio

Table 3 EQ-5D VAS Time to deterioration
eCOA-ITT Population

EQ-5D	KdD (N=278)		Kd (N=132)		Treatment Comparison KdD vs. Kd:	
VAS Scale	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value
10-point deterioration	175 (62.9%)	6.6 [3.8, 10.3]	90 (68.2%)	4.7 [2.8, 7.5]	0.77 [0.59, 0.99]	0.0366
7-point deterioration	199 (71.6%)	3.8 [2.8, 6.6]	96 (72.7%)	2.8 [1.9, 4.7]	0.80 [0.62, 1.02]	0.0547

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
[a]From Kaplan–Meier estimate
[b]HR: hazard ratio

Figure 1.1. Time to First 10-Point Deterioration in QLQ-C30 Global Health Status/QOL With Number of Subjects at Risk

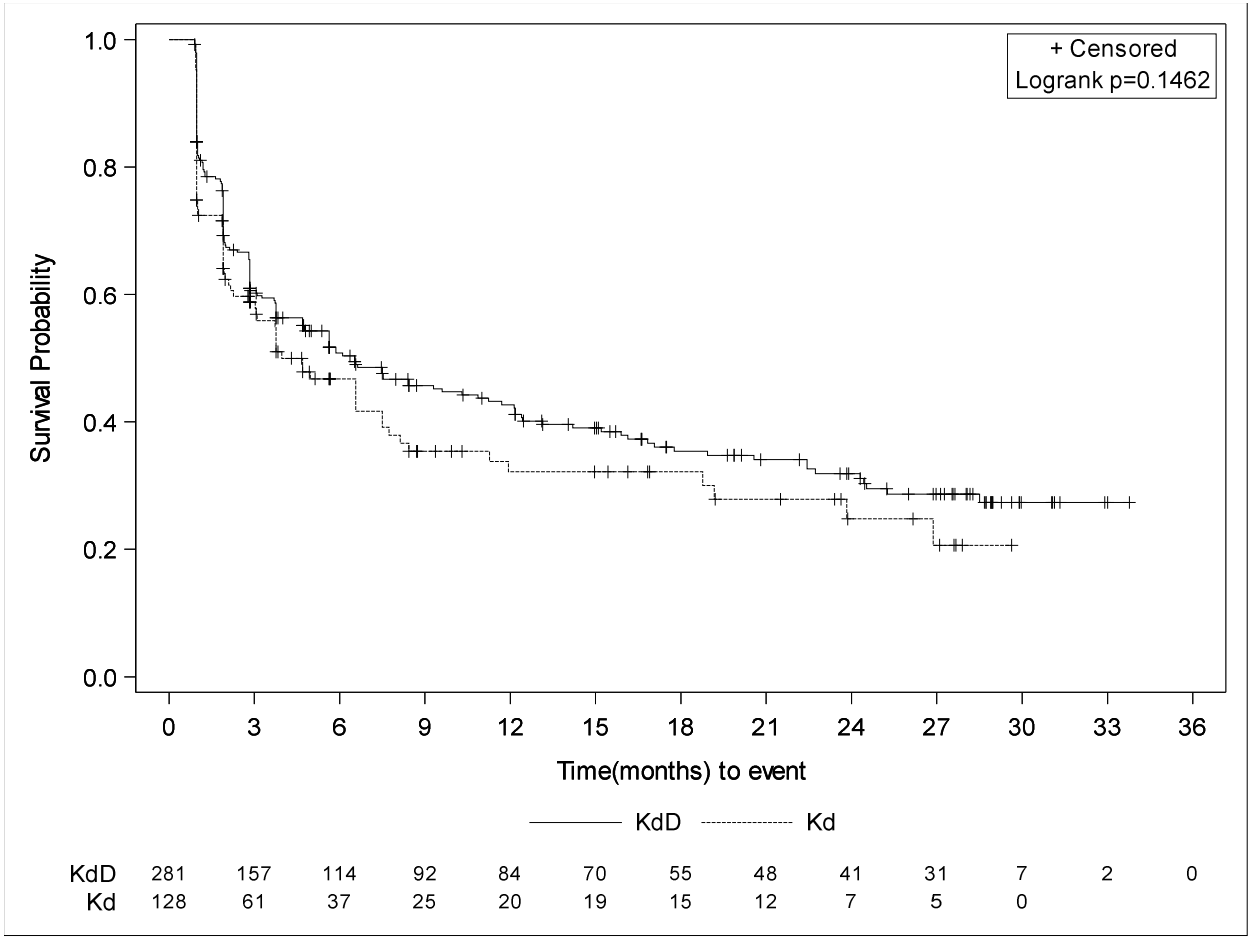


Figure 1.2. Time to First 10-Point Deterioration in QLQ-C30 Physical Functioning With Number of Subjects at Risk

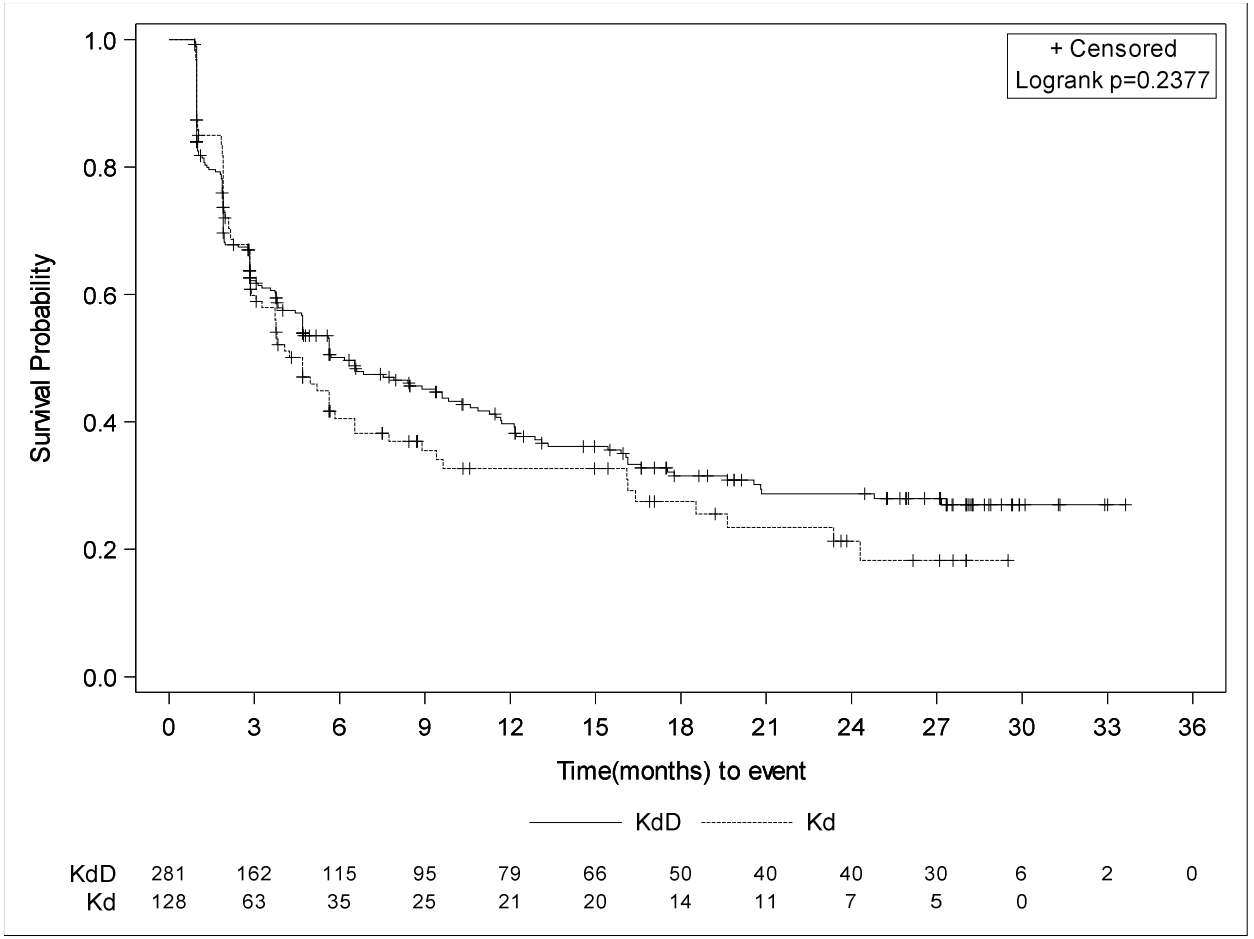


Figure 1.3. Time to First 10-Point Deterioration in QLQ-C30 Role Functioning With Number of Subjects at Risk

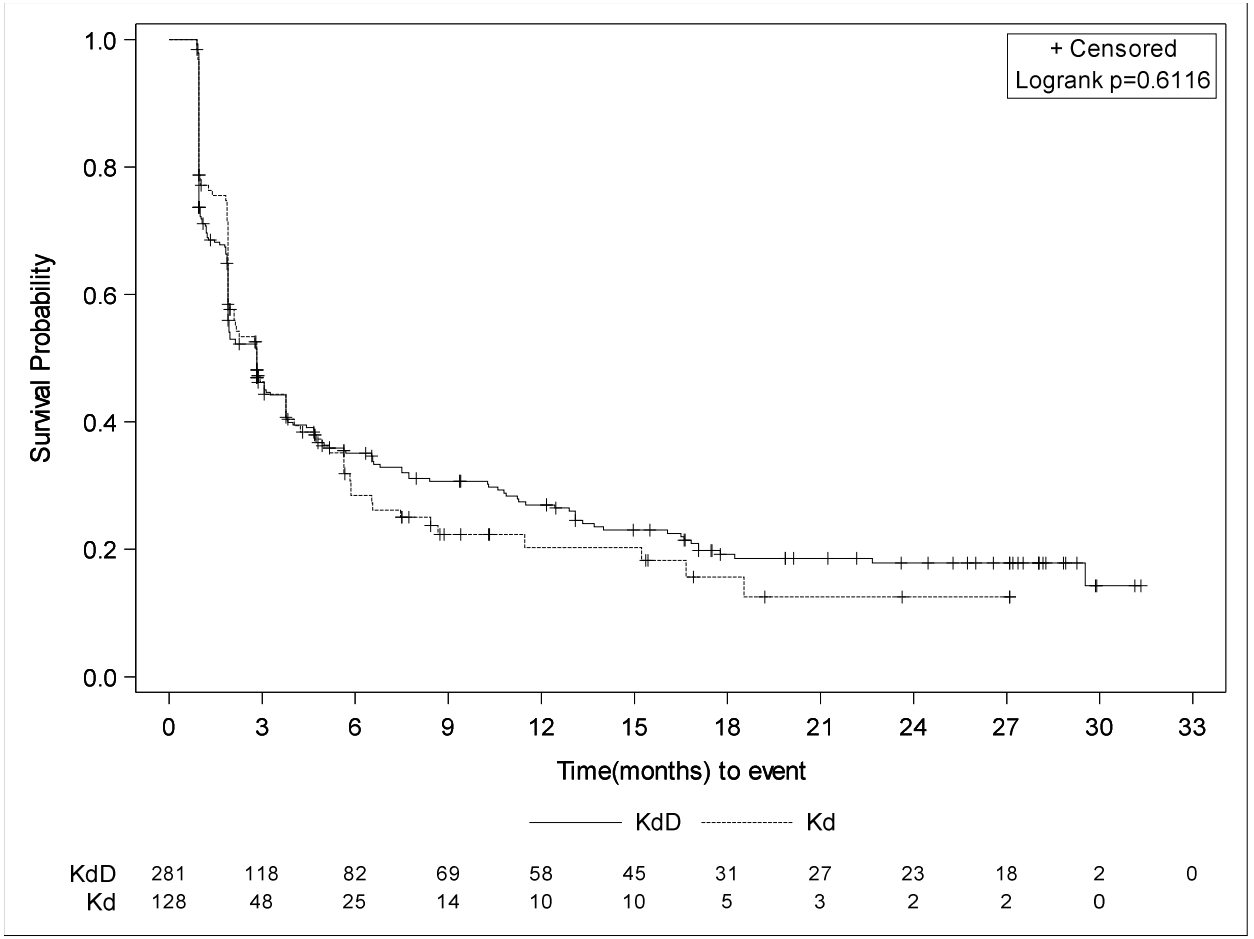


Figure 1.4. Time to First 10-Point Deterioration in QLQ-C30 Emotional Functioning With Number of Subjects at Risk

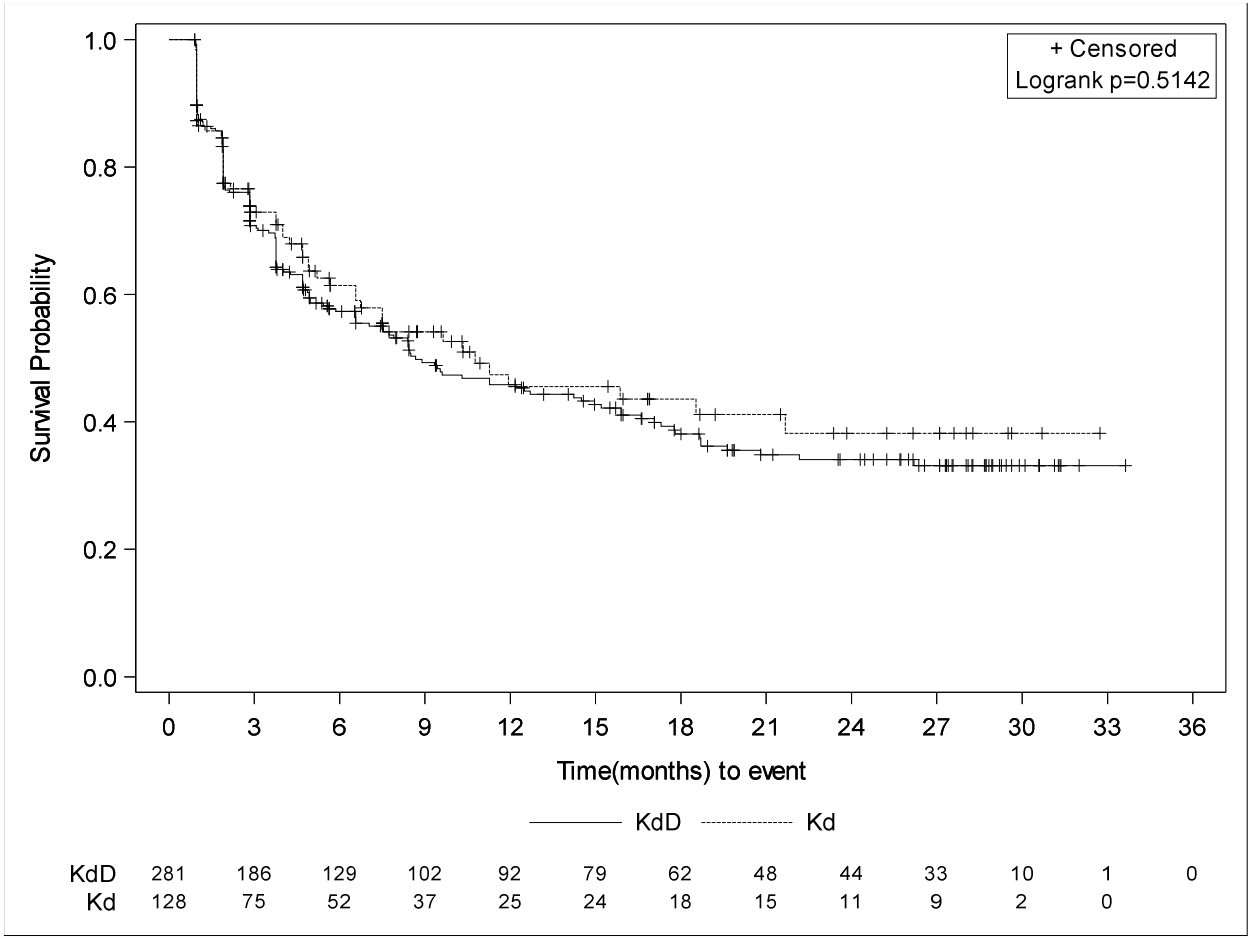


Figure 1.5. Time to First 10-Point Deterioration in QLQ-C30 Cognitive Functioning With Number of Subjects at Risk

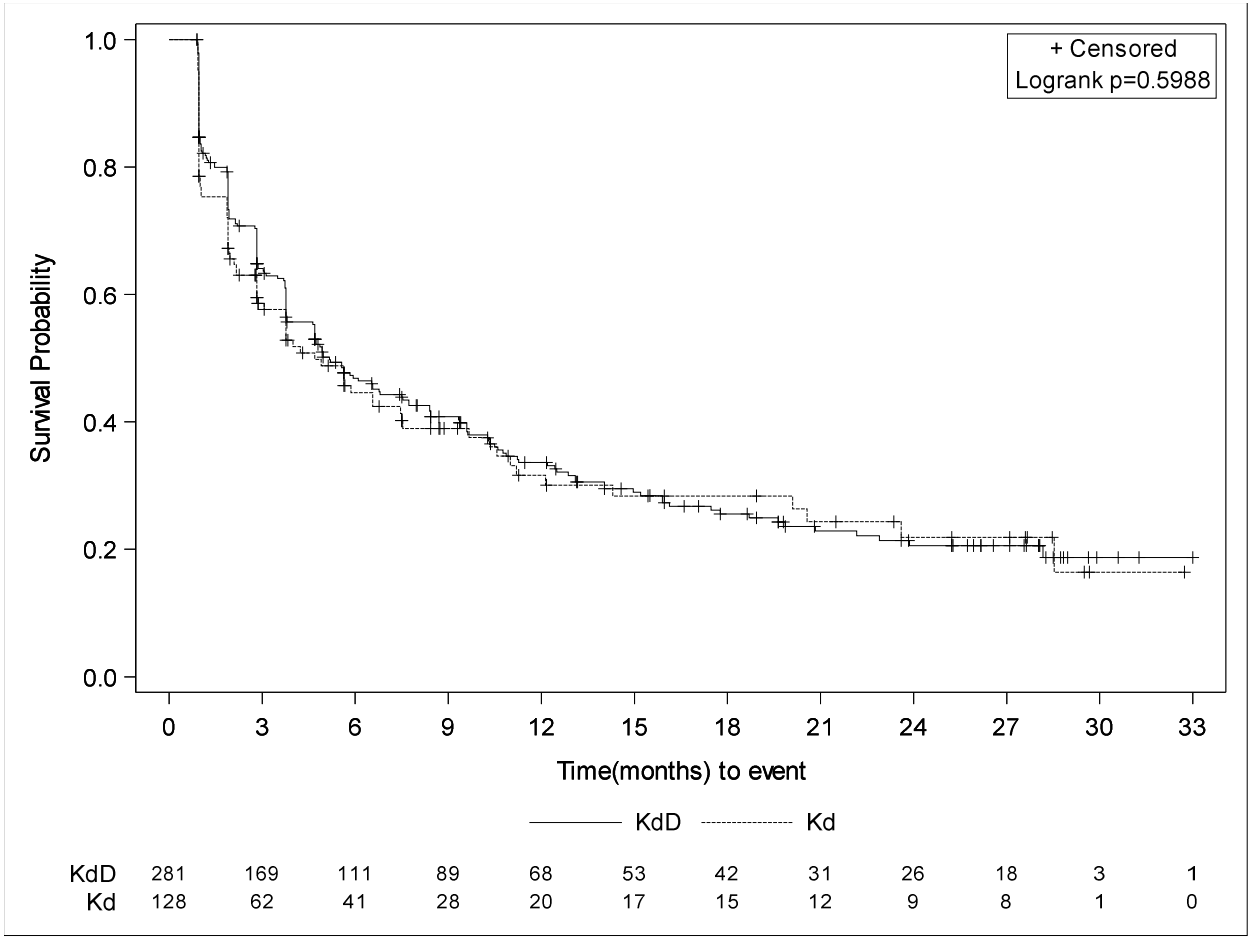


Figure 1.6. Time to First 10-Point Deterioration in QLQ-C30 Social Functioning With Number of Subjects at Risk

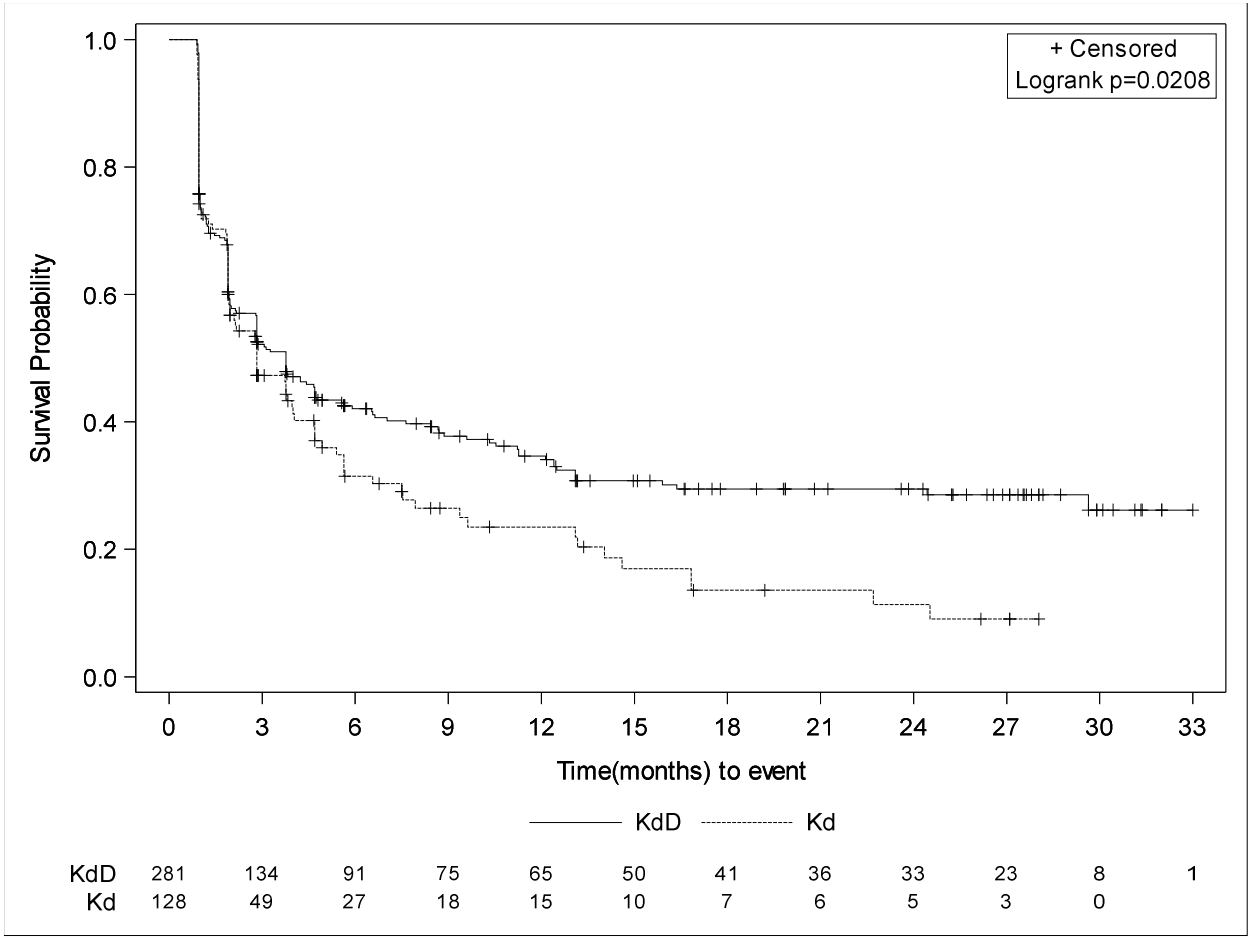


Figure 1.7. Time to First 10-Point Deterioration in QLQ-C30 Fatigue With Number of Subjects at Risk

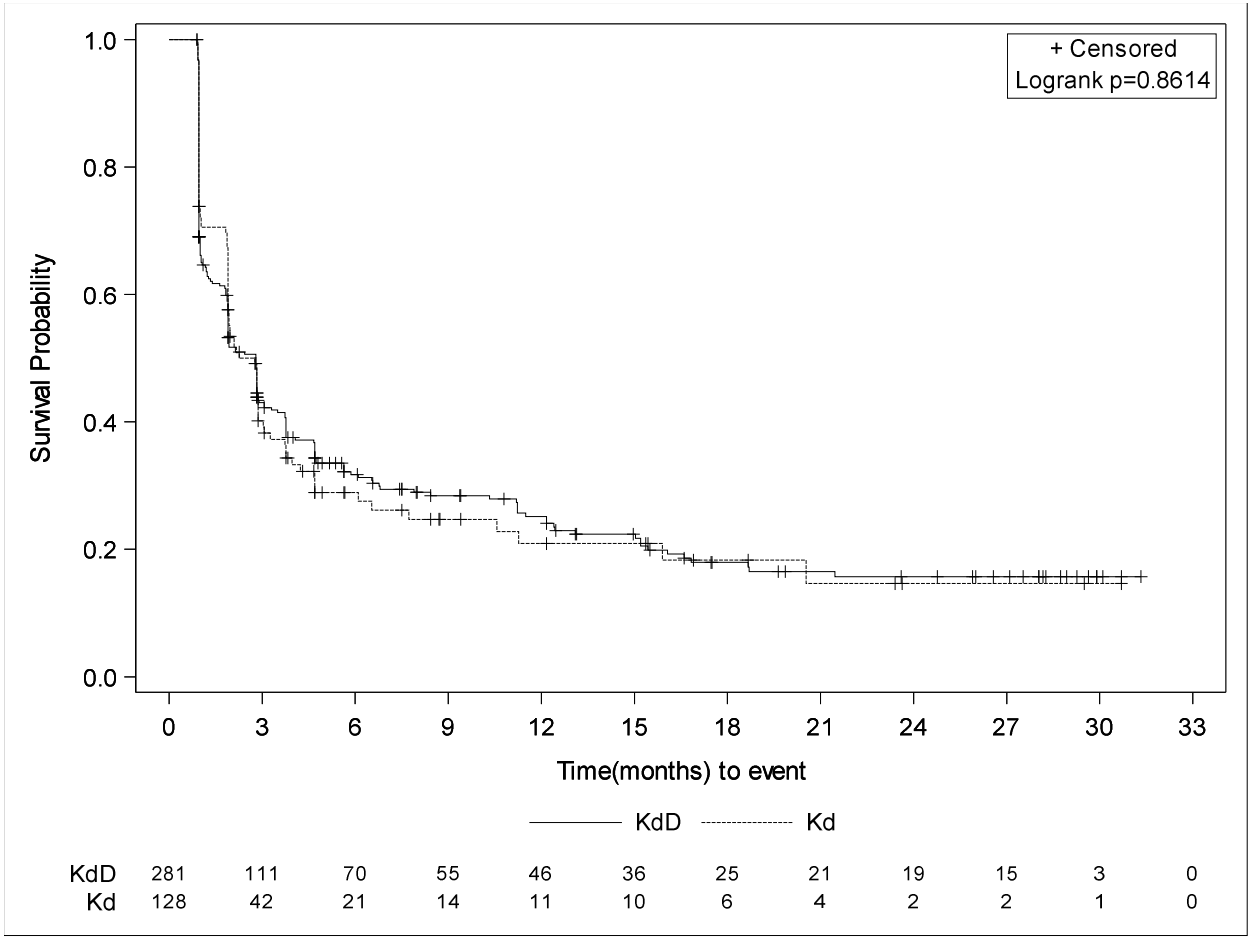


Figure 1.8. Time to First 10-Point Deterioration in QLQ-C30 Nausea & Vomiting With Number of Subjects at Risk

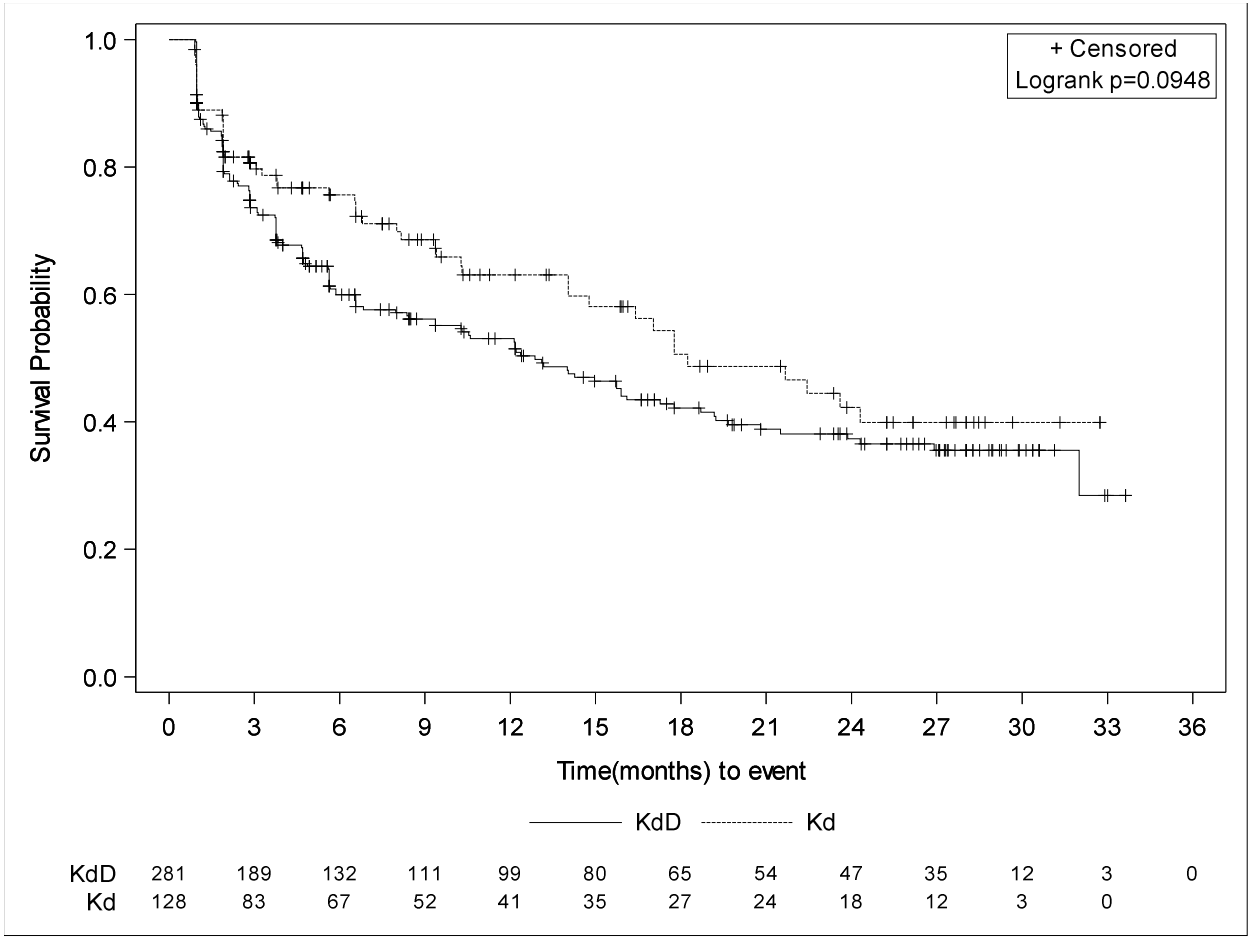


Figure 1.9. Time to First 10-Point Deterioration in QLQ-C30 Pain With Number of Subjects at Risk

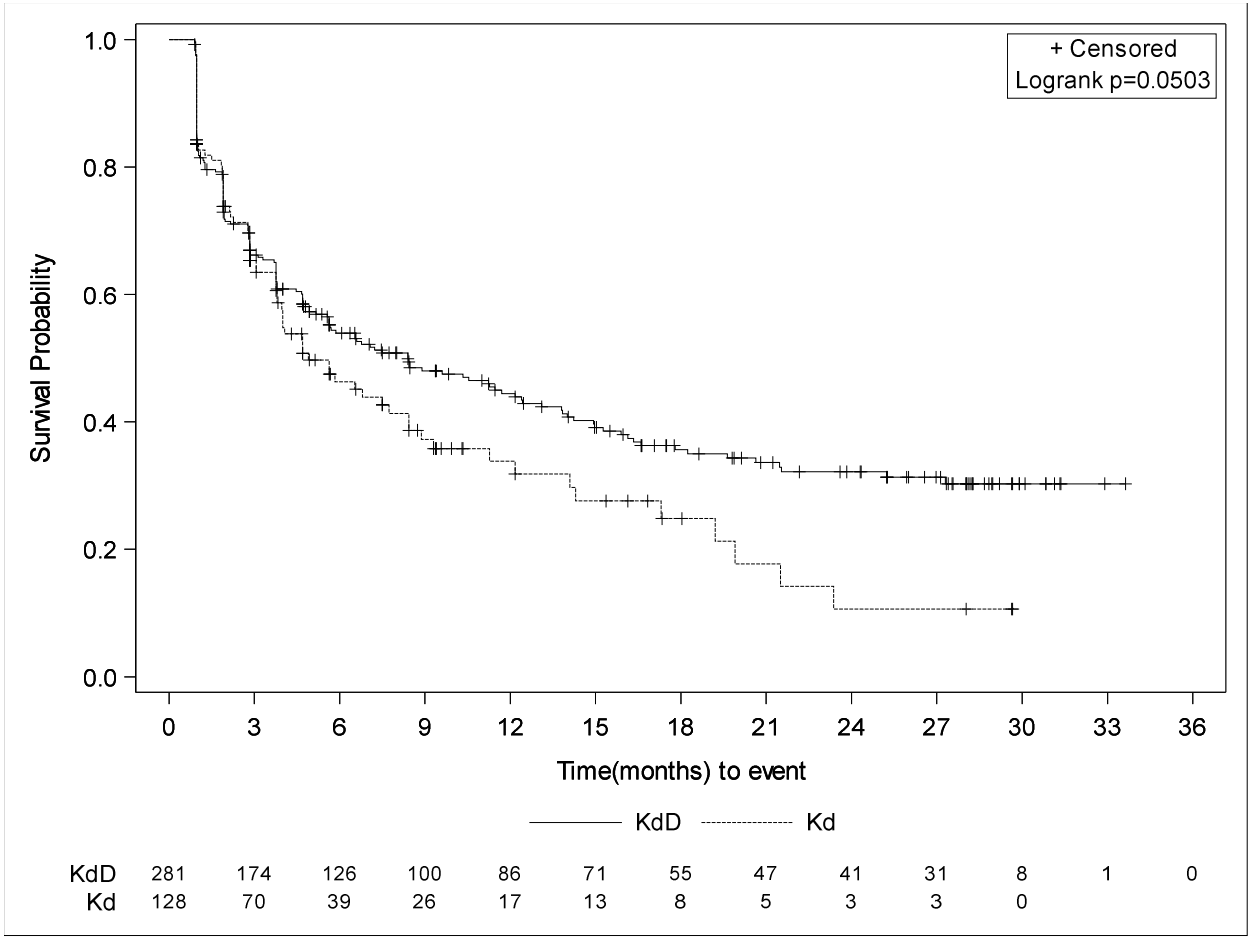


Figure 1.10. Time to First 10-Point Deterioration in QLQ-C30 Dyspnea With Number of Subjects at Risk

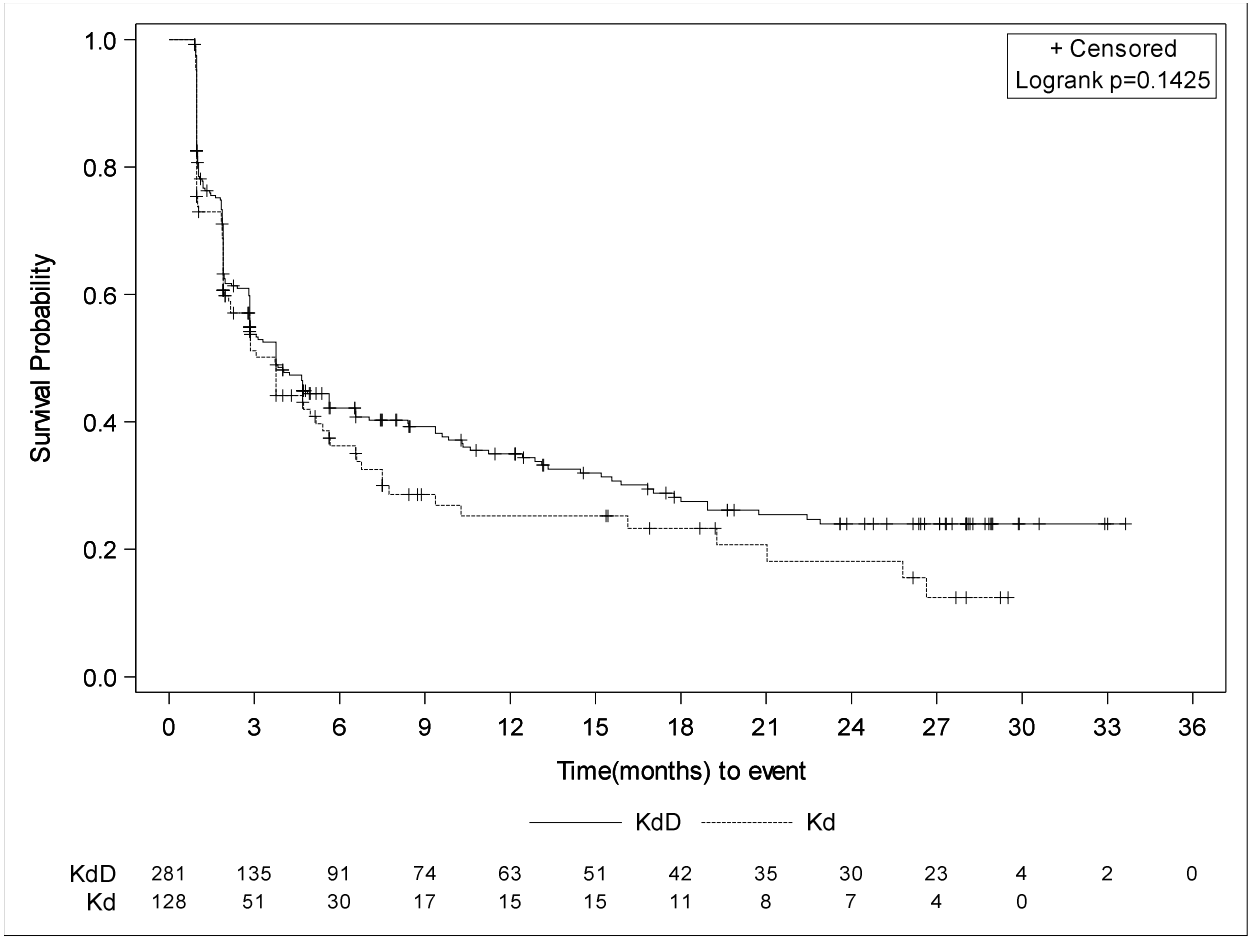


Figure 1.11. Time to First 10-Point Deterioration in QLQ-C30 Insomnia With Number of Subjects at Risk

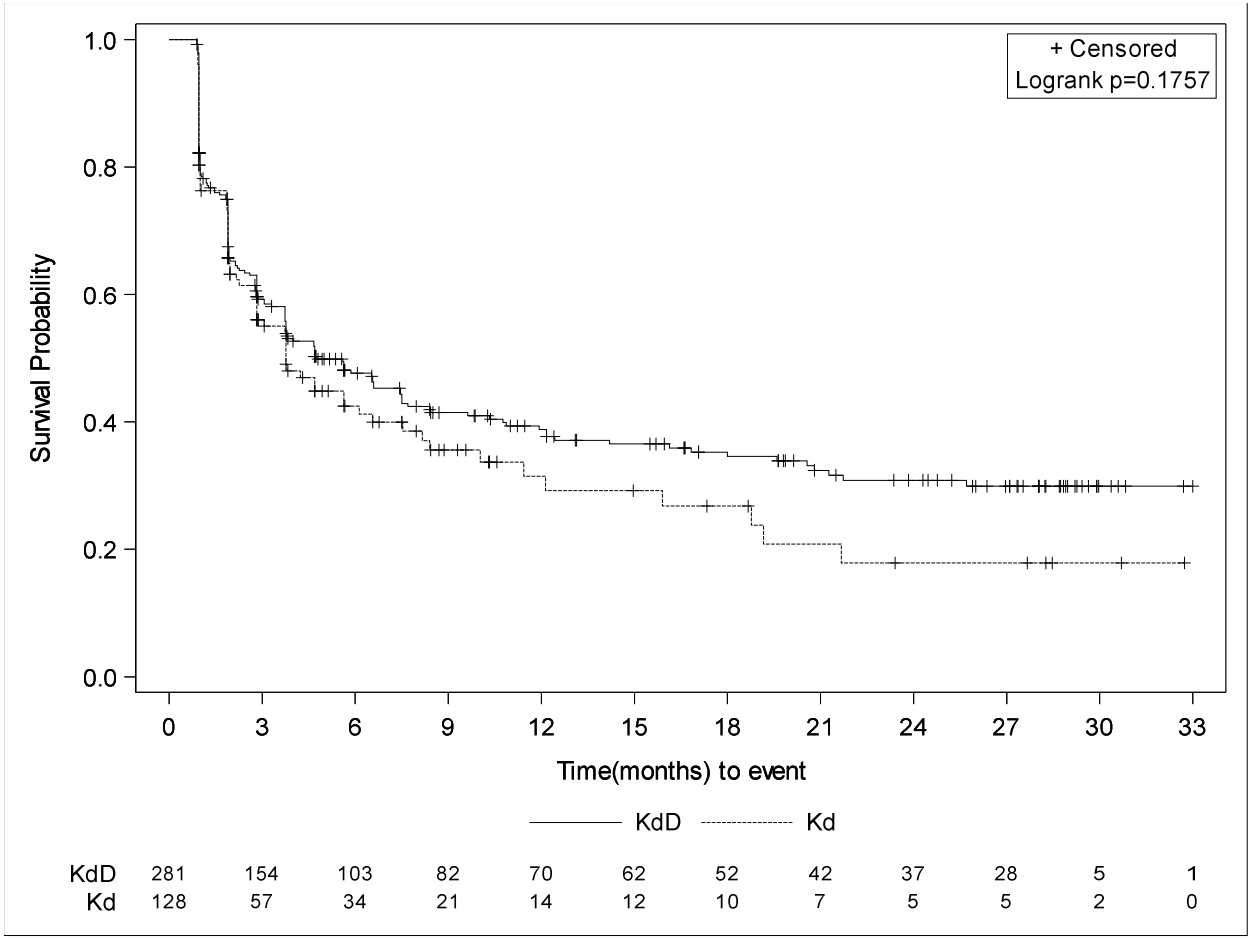


Figure 1.12. Time to First 10-Point Deterioration in QLQ-C30 Appetite Loss With Number of Subjects at Risk

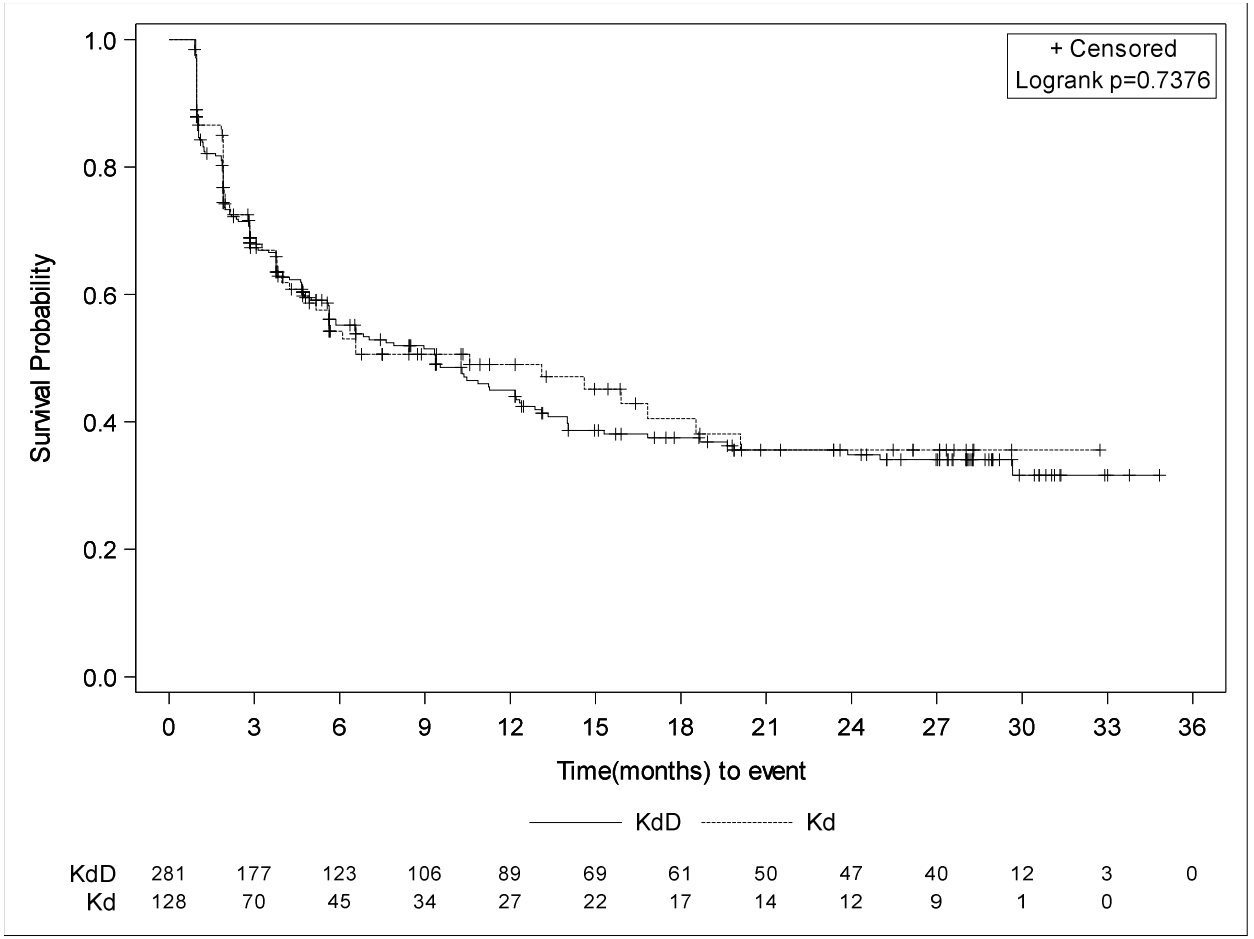


Figure 1.13. Time to First 10-Point Deterioration in QLQ-C30 Constipation With Number of Subjects at Risk

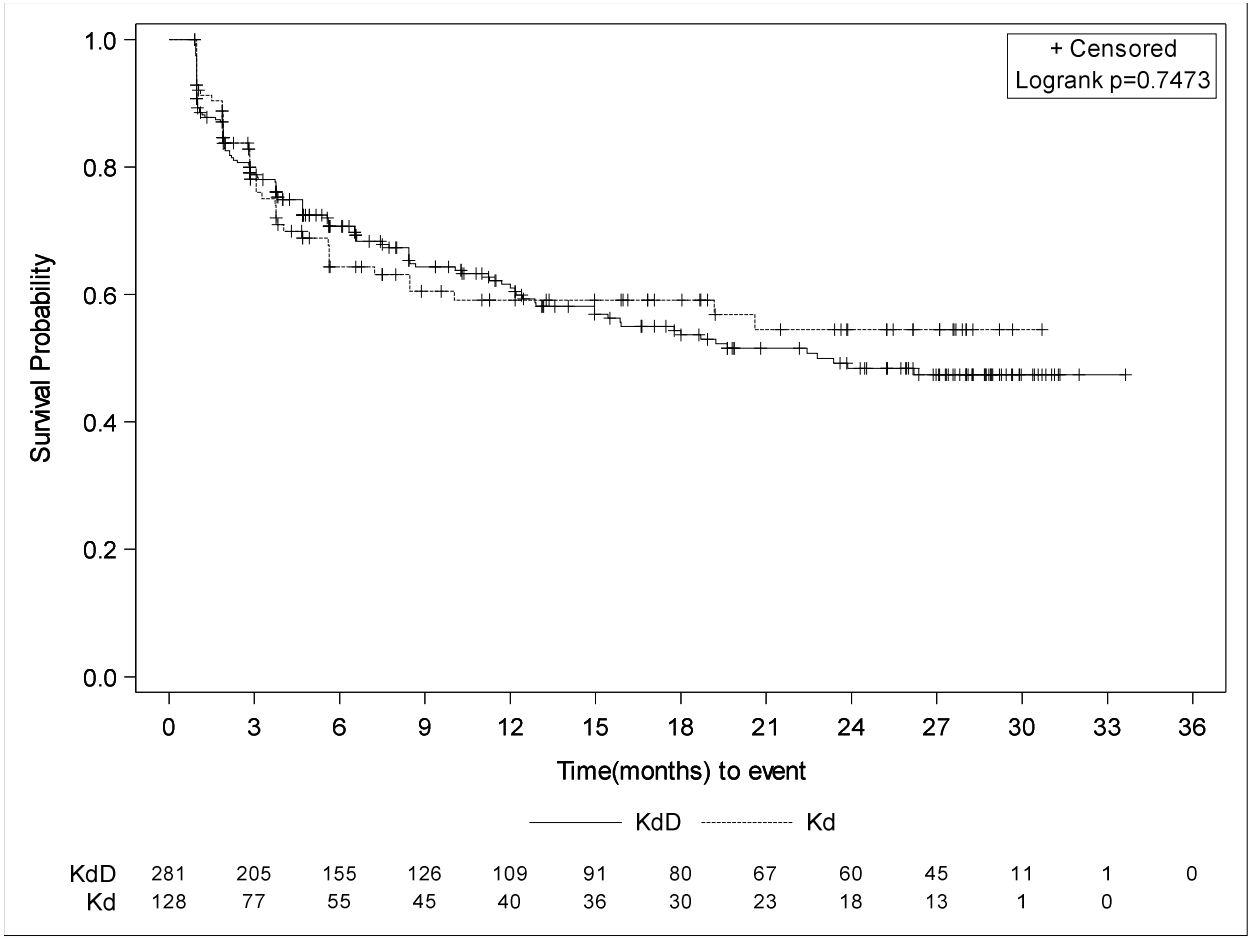


Figure 1.14. Time to First 10-Point Deterioration in QLQ-C30 Diarrhea With Number of Subjects at Risk

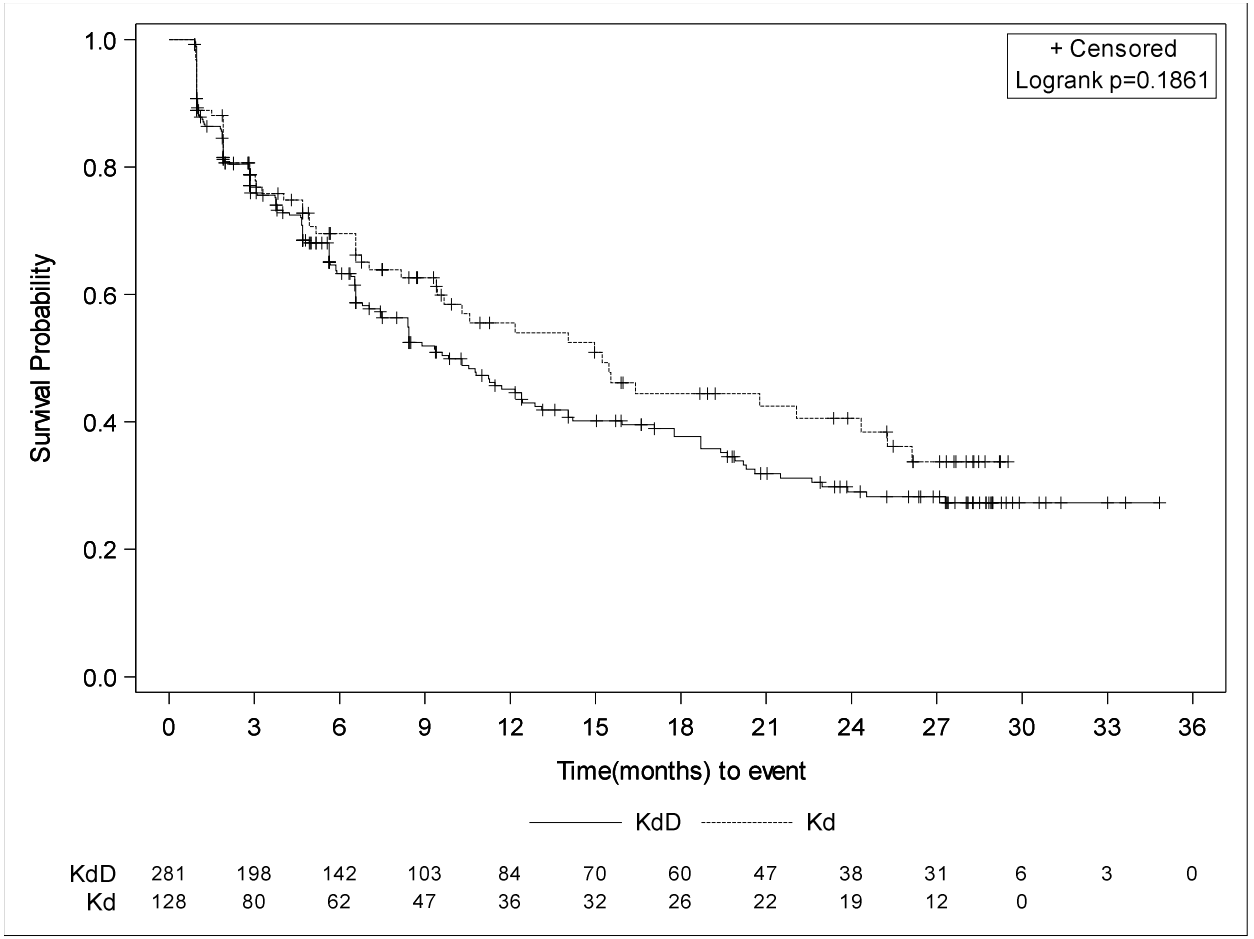


Figure 1.15. Time to First 10-Point Deterioration in QLQ-C30 Financial Difficulties With Number of Subjects at Risk

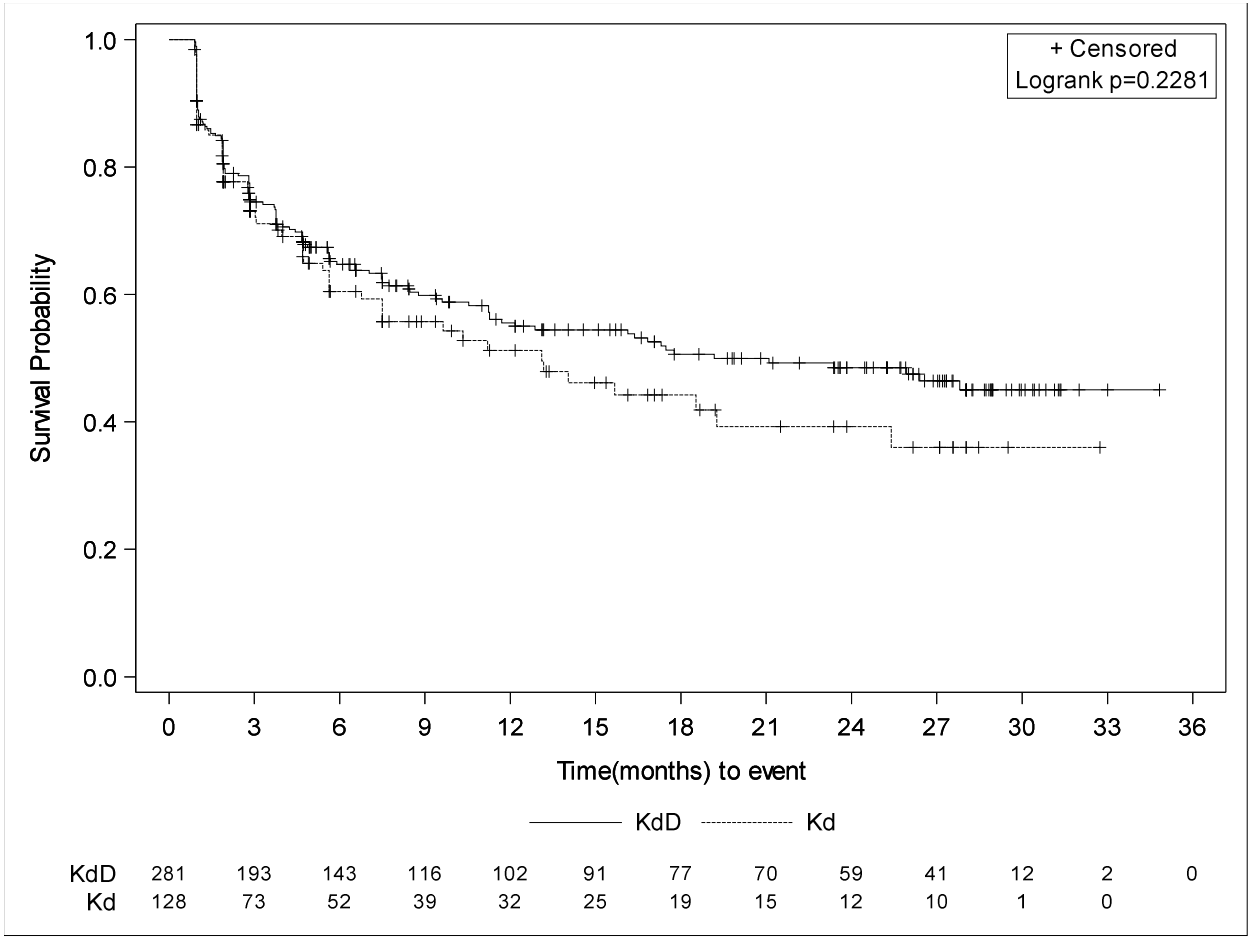


Figure 2.1. Time to First 10-Point Deterioration in QLQ MY-20 Disease Symptoms With Number of Subjects at Risk

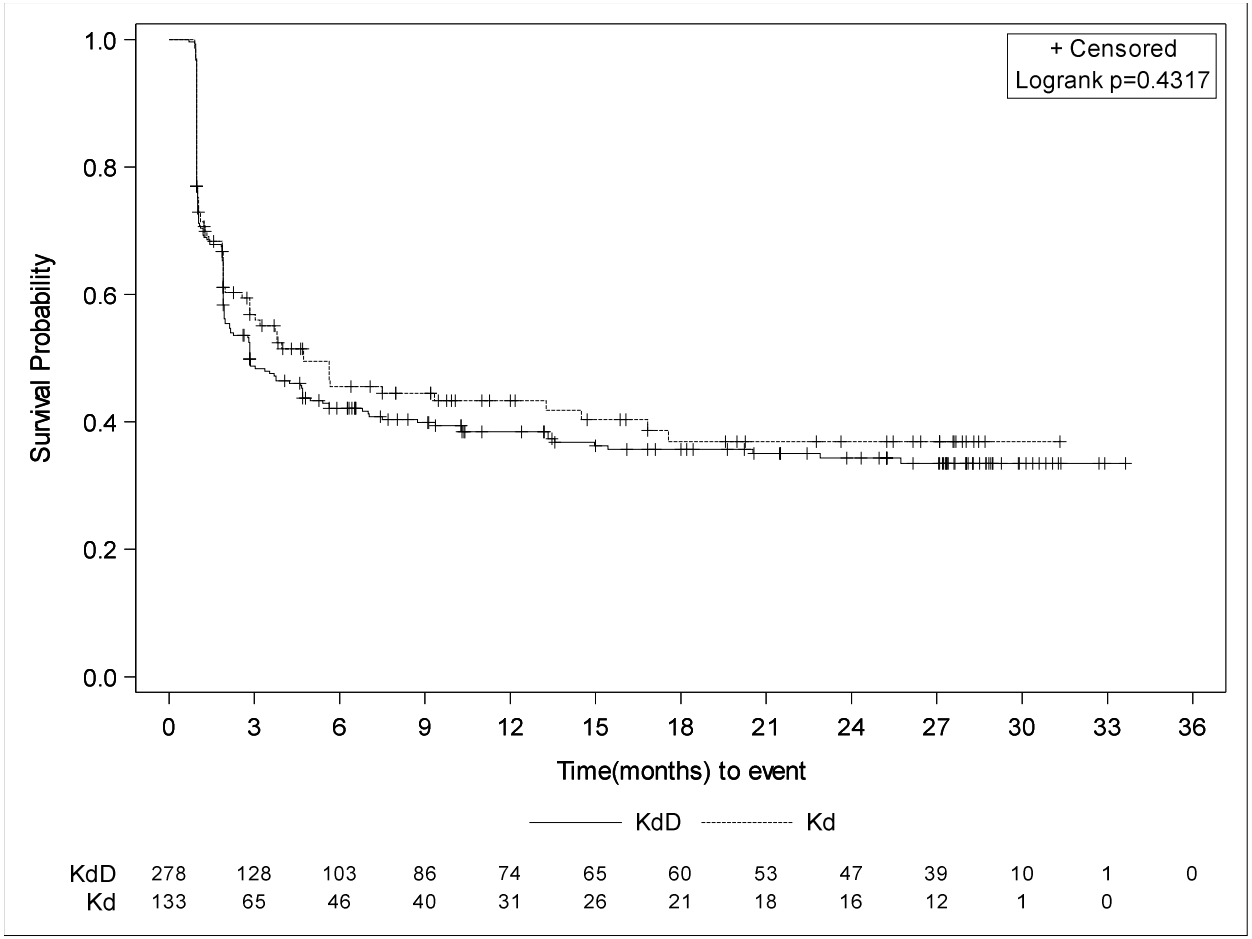


Figure 2.2. Time to First 10-Point Deterioration in QLQ MY-20 Side-effects With Number of Subjects at Risk

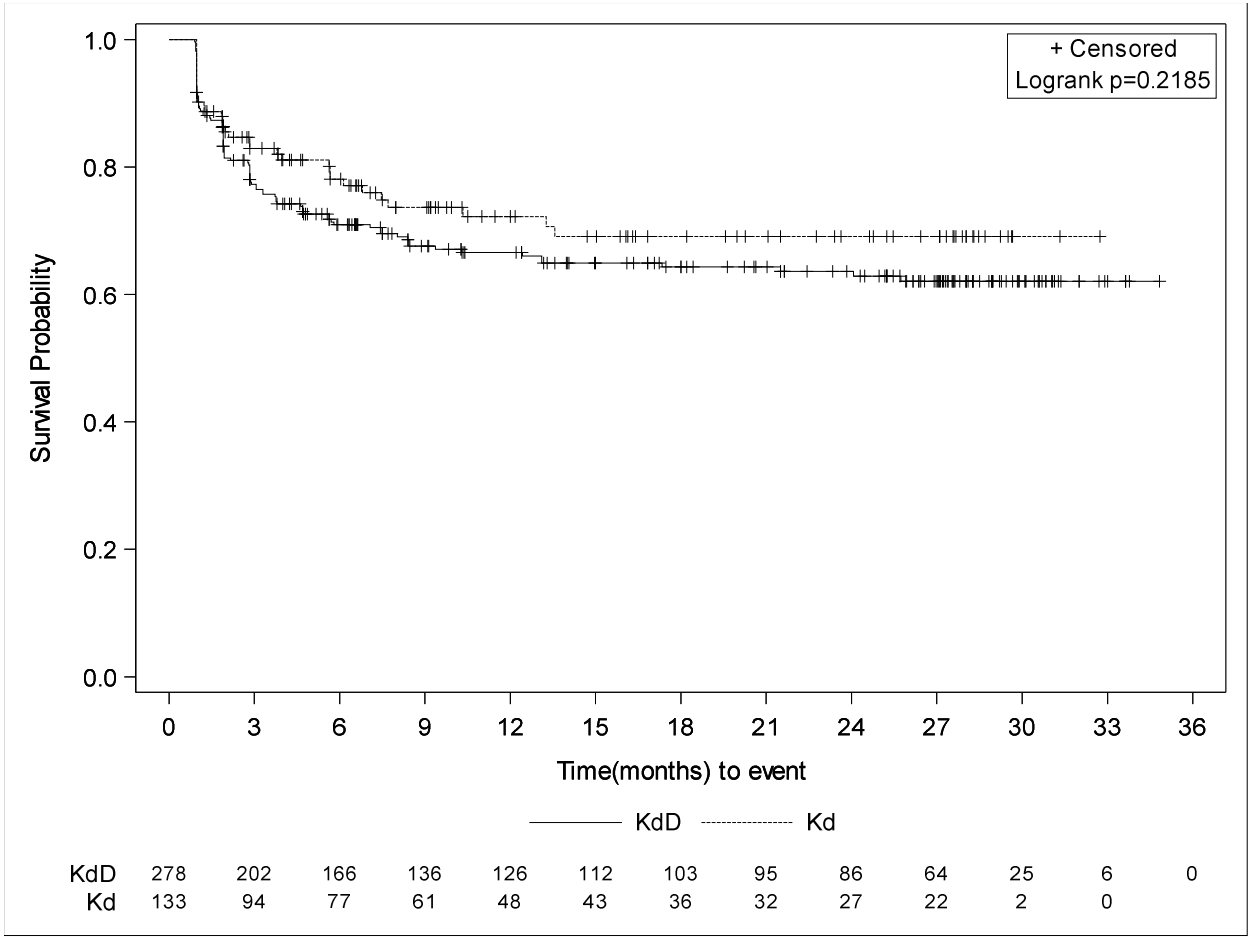


Figure 2.3. Time to First 10-Point Deterioration in QLQ MY-20 Body Image With Number of Subjects at Risk

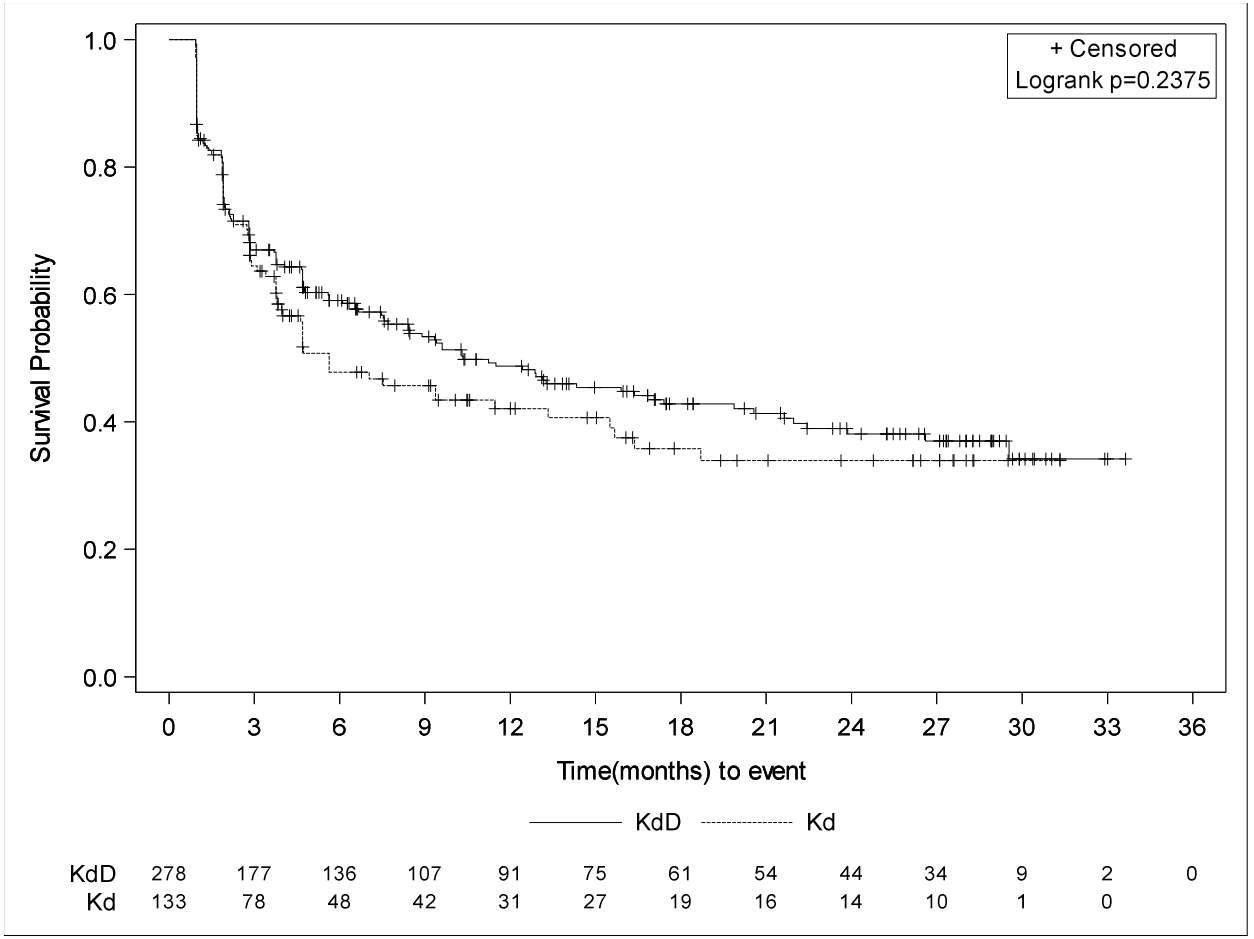


Figure 2.4. Time to First 10-Point Deterioration in QLQ MY-20 Future Perspective With Number of Subjects at Risk

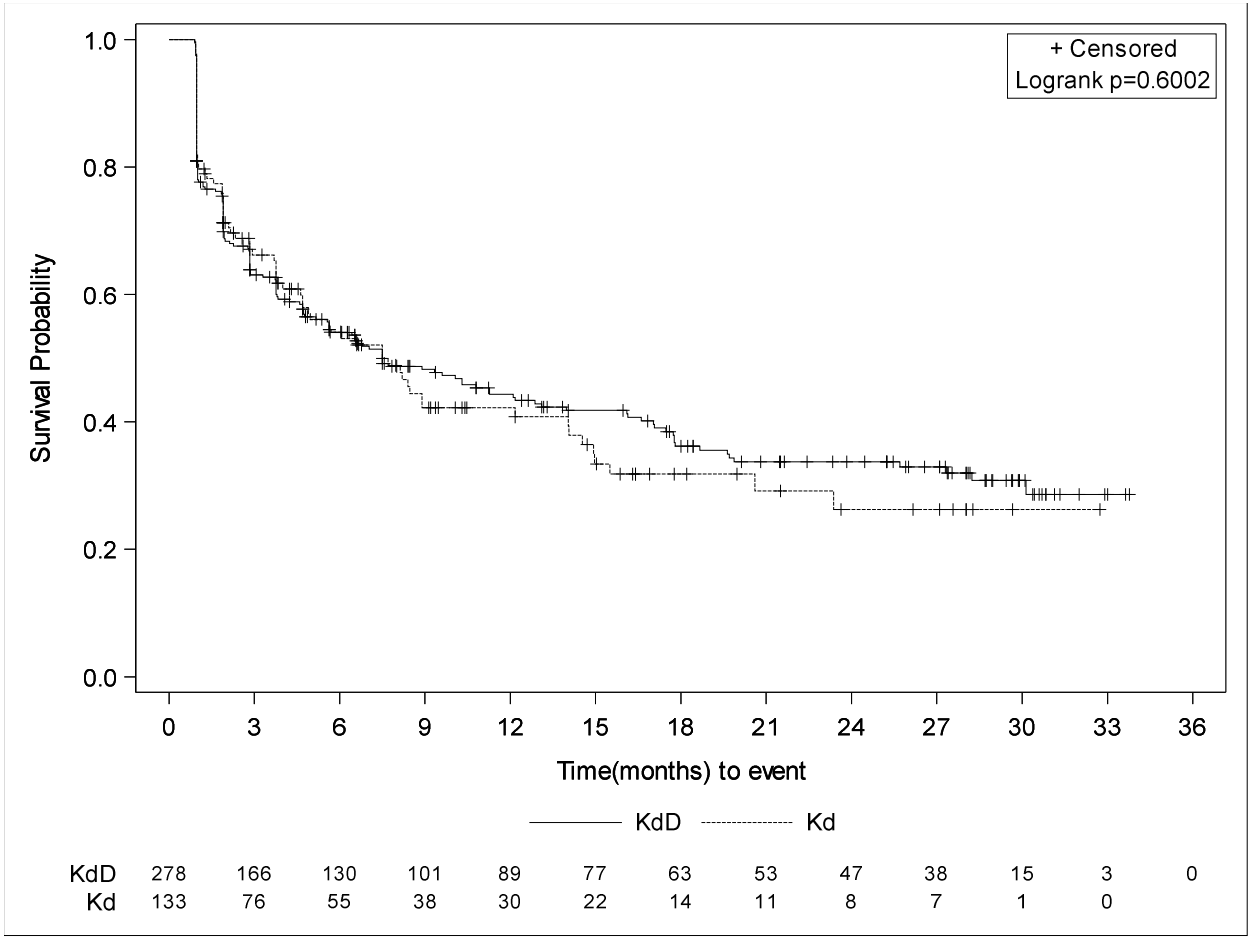


Figure 3.1. Time to First 10-point Deterioration in EQ-5D VAS Scale With Number of Subjects at Risk

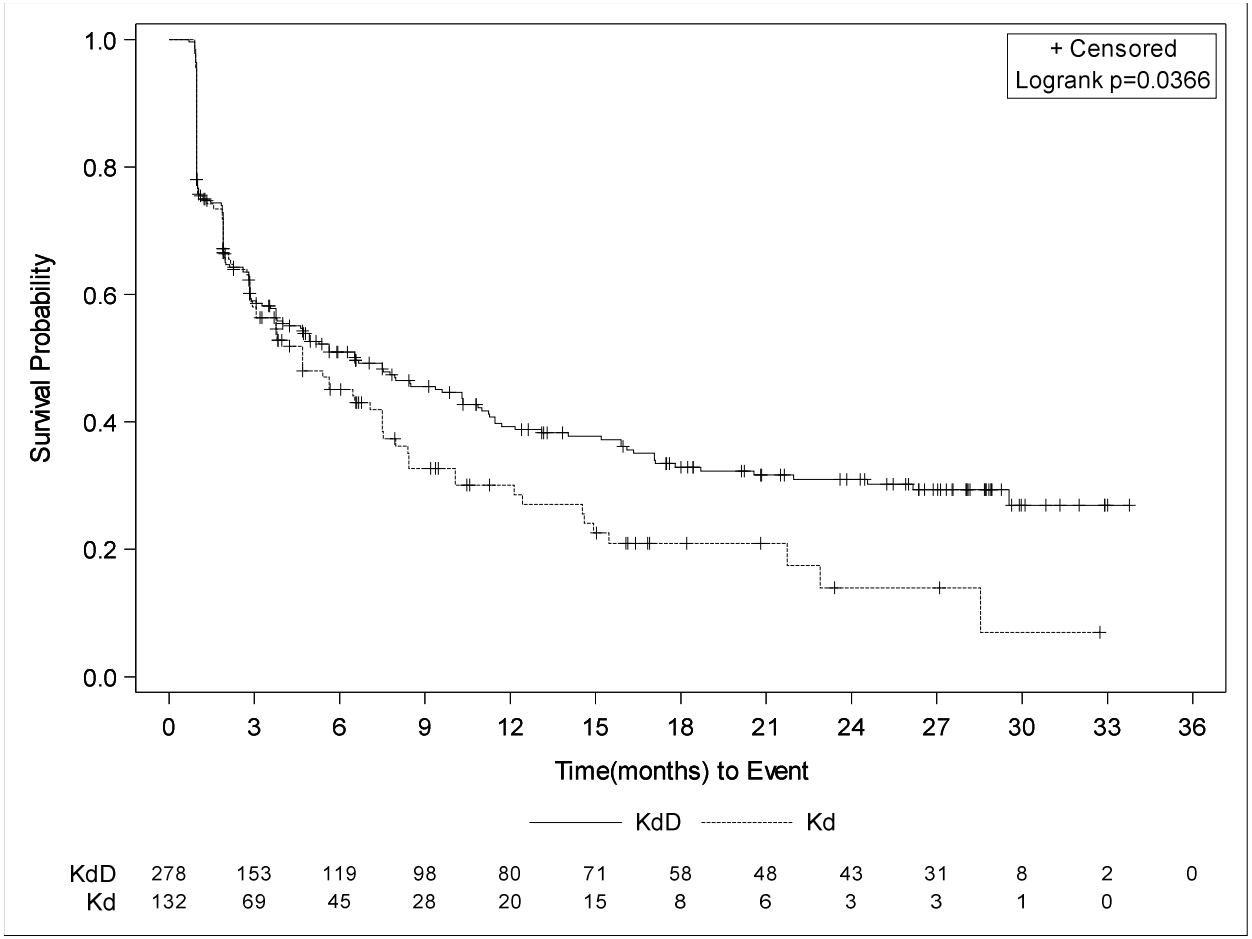


Figure 3.2. Time to First 7-point Deterioration in EQ-5D VAS Scale With Number of Subjects at Risk

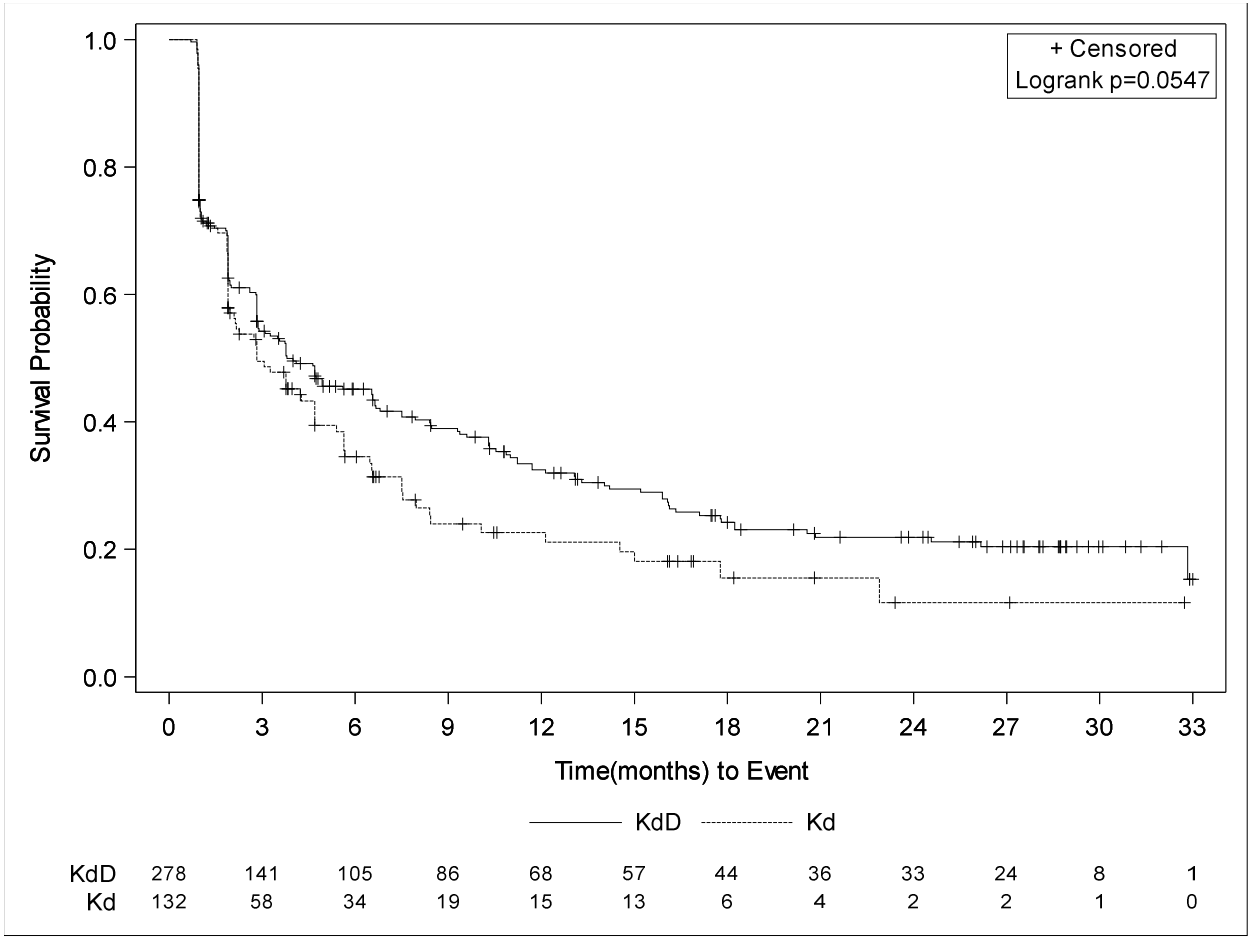


Table 4 Change from Baseline in EORTC QLQ-C30 over time
eCOA-ITT Population

QLQ-C30 Scale	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd	
	N	Baseline Mean (SD)	Change from BL LSMean(SE)	N	Baseline Mean (SD)	Change from BL LSMean(SE)	Difference in LSMean [95%-Cl]; p-value	Hedges'g [95%-Cl]
Global Health Status	281	61.9 (20.12)	0.3 (0.74)	128	66.9 (17.73)	-0.4 (1.18)	0.6 [-2.11, 3.37]; 0.6522	0.0 [-0.16; 0.26]
Physical Functioning	281	76.8 (21.73)	-2.3 (0.74)	128	82.2 (17.19)	-3.4 (1.15)	1.0 [-1.67, 3.73]; 0.4536	0.1 [-0.13; 0.29]
Role Functioning	281	75.3 (27.43)	-4.5 (1.03)	128	78.3 (27.15)	-6.6 (1.62)	2.1 [-1.65, 5.90]; 0.2693	0.1 [-0.09; 0.33]
Emotional Functioning	281	81.3 (19.64)	-0.2 (0.75)	128	82.1 (16.67)	0.1 (1.18)	-0.3 [-3.03, 2.45]; 0.8355	-0.0 [-0.23; 0.19]
Cognitive Functioning	281	85.8 (17.81)	-4.0 (0.77)	128	87.6 (17.15)	-3.2 (1.22)	-0.8 [-3.62, 2.06]; 0.5903	-0.1 [-0.27; 0.15]
Social Functioning	281	77.9 (26.83)	-4.5 (0.95)	128	83.2 (23.71)	-6.2 (1.50)	1.7 [-1.77, 5.22]; 0.3338	0.1 [-0.10; 0.32]
Fatigue	281	31.5 (24.19)	2.8 (0.90)	128	29.1 (23.46)	2.6 (1.43)	0.1 [-3.19, 3.45]; 0.9392	0.0 [-0.20; 0.22]
Nausea/Vomiting	281	3.2 (10.62)	1.6 (0.28)	128	2.1 (7.25)	0.7 (0.56)	0.9 [-0.31, 2.14]; 0.1422	0.2 [-0.03; 0.38]
Pain	281	29.6 (28.43)	-3.0 (0.94)	128	25.8 (27.34)	-2.7 (1.50)	-0.2 [-3.70, 3.25]; 0.8970	-0.0 [-0.22; 0.19]
Dyspnea	281	12.6 (20.51)	8.2 (1.00)	128	12.5 (20.06)	11.4 (1.61)	-3.3 [-6.97, 0.47]; 0.0863	-0.2 [-0.40; 0.02]
Insomnia	281	19.3 (26.16)	4.5 (1.10)	128	17.7 (27.09)	2.3 (1.76)	2.3 [-1.81, 6.36]; 0.2751	0.1 [-0.09; 0.33]
Appetite Loss	281	11.4 (20.43)	-0.7 (0.46)	128	7.3 (19.14)	0.6 (0.86)	-1.3 [-3.18, 0.68]; 0.2036	-0.1 [-0.36; 0.06]
Constipation	281	11.2 (22.41)	-1.5 (0.81)	128	5.5 (14.36)	-2.3 (1.28)	0.8 [-2.17, 3.82]; 0.5886	0.1 [-0.15; 0.27]
Diarrhea	281	6.2 (15.98)	3.3 (0.75)	128	4.7 (13.05)	2.8 (1.25)	0.5 [-2.38, 3.35]; 0.7412	0.0 [-0.17; 0.25]
Financial Difficulties	281	16.6 (25.22)	2.8 (0.69)	128	14.6 (24.66)	-0.4 (1.43)	3.2 [0.02, 6.29]; 0.0482	0.2 [0.03; 0.45]

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
Mixed Model Repeated Measurement for change from baseline score, with time, treatment and interaction of time and treatment as independent variables, and baseline score included as a covariate. Models used a structured covariance matrix (compound symmetry for all models except for nausea/vomiting score [autoregressive(1)], appetite loss score [heterogeneous AR(1)], and financial difficulties score [heterogeneous AR(1)].

Table 5 Change from Baseline in EORTC MY-20 over time
eCOA-ITT Population

MY-20 Scale	KdD (N=278)			Kd (N=128)			Treatment Comparison KdD vs. Kd	
	N	Baseline Mean (SD)	Change from BL LSMean(SE)	N	Baseline Mean (SD)	Change from BL LSMean(SE)	Difference in LSMean [95%-CI]; p-value	Hedges'g [95%-CI]
Disease Symptoms	278	77.3 (19.58)	3.8 (0.68)	128	78.6 (19.97)	3.1 (0.99)	0.7 [-1.51, 2.99]; 0.5173	0.1 [-0.14; 0.27]
Side-effects	278	85.8 (13.17)	-3.3 (0.57)	128	88.8 (11.87)	-2.6 (0.82)	-0.7 [-2.56, 1.22]; 0.4877	-0.1 [-0.28; 0.14]
Body Image	278	81.4 (27.21)	-2.0 (1.15)	128	86.5 (20.25)	-2.7 (1.67)	0.7 [-3.18, 4.50]; 0.7346	0.0 [-0.17; 0.24]
Future Perspective	278	66.0 (26.55)	7.3 (0.94)	128	67.1 (26.47)	6.7 (1.37)	0.6 [-2.52, 3.69]; 0.7095	0.0 [-0.17; 0.25]

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
Mixed Model Repeated Measurement for change from baseline score, with time and treatment as independent variables, and baseline score included as a covariate. Models used a structured covariance matrix (compound symmetry for all models).

Table 6 Change from Baseline in EQ-5D VAS over time
eCOA-ITT Population

	KdD (N=278)			Kd (N=127)			Treatment Comparison KdD vs. Kd	
	N	Baseline Mean (SD)	Change from BL LSMean(SE)	N	Baseline Mean (SD)	Change from BL LSMean(SE)	Difference in LSMean [95%-CI]; p-value	Hedges'g [95%-CI]
EQ-5D VAS	278	67.26 (18.88)	-0.33 (0.73)	127	72.93 (16.64)	-0.93 (1.06)	0.60 [-1.85, 3.05]; 0.6318	0.05 [-0.16; 0.26]

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
Mixed Model Repeated Measurement for change from baseline score, with time and treatment as independent variables, and baseline score included as a covariate. Model used a structured covariance matrix (compound symmetry).

Table 1.9 Change from Baseline in EORTC QLQ-C30 over time - Pain Symptom Score
eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd	
Time	N	Baseline Mean (SD)	Change from BL LSMean(SE)	N	Baseline Mean (SD)	Change from BL LSMean(SE)	Difference in LSMean [95%-CI]; p-value	Hedges'g [95%-CI]
Cycle 2, Day 1	271	29.9 (28.62)	-3.6 (1.20)	119	25.6 (27.77)	-2.5 (1.79)	-1.1 [-5.30; 3.15]; 0.6187	-0.1 [-0.27; 0.16]
Cycle 3, Day 1	254	29.4 (28.42)	-6.3 (1.22)	117	25.2 (27.30)	-1.4 (1.80)	-5.0 [-9.24; -0.70]; 0.0226	-0.3 [-0.47; -0.03]
Cycle 4, Day 1	249	29.1 (28.65)	-6.8 (1.23)	106	27.2 (27.63)	-3.9 (1.86)	-2.8 [-7.18; 1.57]; 0.2092	-0.1 [-0.37; 0.08]
Cycle 5, Day 1	245	29.7 (28.74)	-5.9 (1.24)	99	25.4 (26.87)	-4.1 (1.91)	-1.8 [-6.26; 2.66]; 0.4285	-0.1 [-0.33; 0.14]
Cycle 6, Day 1	237	29.0 (28.16)	-6.1 (1.25)	90	25.4 (25.87)	-3.1 (1.96)	-2.9 [-7.50; 1.63]; 0.2078	-0.2 [-0.40; 0.09]
Cycle 7, Day 1	216	29.6 (28.48)	-4.8 (1.29)	89	23.0 (24.55)	-6.8 (1.97)	2.0 [-2.64; 6.59]; 0.4018	0.1 [-0.14; 0.35]
Cycle 8, Day 1	201	28.9 (28.16)	-4.7 (1.31)	84	22.4 (24.20)	-4.5 (2.01)	-0.1 [-4.85; 4.56]; 0.9523	-0.0 [-0.26; 0.25]
Cycle 9, Day 1	197	28.4 (28.59)	-7.4 (1.32)	77	22.3 (24.27)	-4.1 (2.06)	-3.3 [-8.11; 1.50]; 0.1779	-0.2 [-0.44; 0.09]
Cycle 10, Day 1	193	28.2 (27.98)	-4.7 (1.33)	71	22.8 (24.92)	-4.0 (2.12)	-0.8 [-5.67; 4.14]; 0.7604	-0.0 [-0.31; 0.23]
Cycle 11, Day 1	185	27.9 (27.49)	-6.8 (1.35)	64	24.2 (25.01)	-4.3 (2.19)	-2.5 [-7.54; 2.55]; 0.3321	-0.1 [-0.42; 0.15]
Cycle 12, Day 1	183	27.2 (27.53)	-7.1 (1.35)	62	21.0 (23.36)	-1.4 (2.22)	-5.6 [-10.7; -0.53]; 0.0304	-0.3 [-0.60; -0.02]
Cycle 13, Day 1	171	27.1 (27.36)	-4.2 (1.38)	58	18.7 (23.38)	-2.3 (2.27)	-2.0 [-7.16; 3.26]; 0.4625	-0.1 [-0.41; 0.19]
Cycle 14, Day 1	167	26.1 (27.29)	-5.6 (1.39)	57	18.7 (23.58)	-2.1 (2.28)	-3.6 [-8.81; 1.68]; 0.1828	-0.2 [-0.50; 0.10]
Cycle 15, Day 1	165	25.9 (26.51)	-5.6 (1.40)	52	17.3 (23.33)	-5.5 (2.35)	-0.1 [-5.44; 5.30]; 0.9804	-0.0 [-0.32; 0.31]
Cycle 16, Day 1	163	25.9 (26.85)	-4.3 (1.40)	53	19.5 (23.96)	-0.7 (2.34)	-3.6 [-8.92; 1.78]; 0.1909	-0.2 [-0.51; 0.11]
Cycle 17, Day 1	157	25.8 (26.52)	-4.9 (1.42)	54	19.4 (23.74)	-4.5 (2.33)	-0.4 [-5.76; 4.93]; 0.8794	-0.0 [-0.33; 0.29]
Cycle 18, Day 1	153	26.8 (27.39)	-3.9 (1.43)	52	19.6 (23.96)	-2.2 (2.36)	-1.6 [-7.02; 3.79]; 0.5586	-0.1 [-0.41; 0.22]
Cycle 19, Day 1	148	25.3 (26.83)	-4.1 (1.45)	47	19.5 (24.41)	-5.2 (2.44)	1.1 [-4.43; 6.70]; 0.6897	0.1 [-0.26; 0.39]
Cycle 20, Day 1	139	23.0 (24.69)	-2.5 (1.48)	40	17.1 (23.11)	-4.5 (2.59)	2.0 [-3.80; 7.90]; 0.4919	0.1 [-0.23; 0.47]
Cycle 21, Day 1	141	24.8 (26.55)	-3.2 (1.47)	39	15.4 (22.09)	-5.1 (2.61)	1.9 [-3.94; 7.82]; 0.5183	0.1 [-0.24; 0.47]

Table 1.9 Change from Baseline in EORTC QLQ-C30 over time - Pain Symptom Score eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd	
Time	N	Baseline Mean (SD)	Change from BL LSMean(SE)	N	Baseline Mean (SD)	Change from BL LSMean(SE)	Difference in LSMean [95%-CI]; p-value	Hedges'g [95%-CI]
Cycle 22, Day 1	137	24.9 (26.59)	-4.7 (1.48)	36	16.2 (22.71)	-3.3 (2.70)	-1.4 [-7.47; 4.59]; 0.6398	-0.1 [-0.45; 0.28]
Cycle 23, Day 1	129	24.5 (25.18)	-2.5 (1.51)	35	15.7 (22.85)	1.0 (2.72)	-3.5 [-9.58; 2.65]; 0.2662	-0.2 [-0.58; 0.17]
Cycle 24, Day 1	123	24.9 (26.17)	-2.1 (1.54)	35	15.2 (23.00)	4.5 (2.72)	-6.5 [-12.7; -0.40]; 0.0369	-0.4 [-0.76; -0.01]
Cycle 25, Day 1	125	25.1 (25.98)	-2.0 (1.53)	33	16.2 (23.38)	-4.7 (2.79)	2.7 [-3.56; 8.91]; 0.4009	0.2 [-0.23; 0.54]
Cycle 26, Day 1	118	24.7 (26.31)	-0.8 (1.56)	32	17.7 (23.16)	-1.9 (2.82)	1.2 [-5.17; 7.47]; 0.7206	0.1 [-0.32; 0.46]
Cycle 27, Day 1	107	24.8 (26.24)	-2.8 (1.61)	28	17.9 (23.54)	-6.3 (2.97)	3.6 [-3.04; 10.23]; 0.2882	0.2 [-0.20; 0.63]
Cycle 28, Day 1	100	25.7 (26.42)	-1.9 (1.65)	27	18.5 (23.72)	1.4 (3.02)	-3.3 [-10.1; 3.43]; 0.3352	-0.2 [-0.63; 0.22]
Cycle 29, Day 1	94	25.7 (25.48)	-3.7 (1.69)	22	18.9 (23.17)	-1.6 (3.28)	-2.2 [-9.40; 5.07]; 0.5576	-0.1 [-0.60; 0.33]
Cycle 30, Day 1	81	25.7 (26.49)	-2.0 (1.79)	16	21.9 (25.62)	3.5 (3.76)	-5.5 [-13.6; 2.67]; 0.1875	-0.3 [-0.88; 0.20]
Cycle 31, Day 1	58	25.6 (25.02)	-2.6 (2.04)	11	25.8 (31.06)	-2.4 (4.45)	-0.2 [-9.78; 9.40]; 0.9687	-0.0 [-0.66; 0.63]
Cycle 32, Day 1	36	25.9 (25.02)	1.2 (2.50)	7	21.4 (23.00)	1.4 (5.47)	-0.3 [-12.1; 11.52]; 0.9645	-0.0 [-0.83; 0.79]
Cycle 33, Day 1	27	21.0 (22.45)	1.4 (2.84)	4	25.0 (28.87)	-9.2 (7.13)	10.6 [-4.49; 25.61]; 0.1691	0.7 [-0.37; 1.77]
Cycle 34, Day 1	14	21.4 (20.07)	2.2 (3.85)	3	27.8 (34.69)	-2.5 (8.20)	4.8 [-13.0; 22.51]; 0.5994	0.3 [-0.94; 1.57]
Cycle 35, Day 1	9	25.9 (18.84)	8.4 (4.75)	2	41.7 (35.36)	6.9 (9.99)	1.5 [-20.2; 23.21]; 0.8907	0.1 [-1.44; 1.63]
Cycle 36, Day 1	6	36.1 (12.55)	10.8 (5.78)	2	41.7 (35.36)	-9.8 (9.99)	20.6 [-2.04; 43.23]; 0.0745	1.3 [-0.56; 3.09]

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
Mixed Model Repeated Measurement for change from baseline score, with time, treatment and interaction of time and treatment as independent variables, and baseline score included as a covariate. Due to non-convergence with an unstructured covariance matrix, the model was modified to use a structured covariance matrix (compound symmetry).

Table 1.10 Change from Baseline in EORTC QLQ-C30 over time - Dyspnea Symptom Score
eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd	
Time	N	Baseline Mean (SD)	Change from BL LSMean(SE)	N	Baseline Mean (SD)	Change from BL LSMean(SE)	Difference in LSMean [95%-CI]; p-value	Hedges'g [95%-CI]
Cycle 2, Day 1	271	12.7 (20.67)	6.8 (1.31)	119	11.5 (19.13)	6.8 (1.97)	0.0 [-4.58; 4.68]; 0.9846	0.0 [-0.21; 0.22]
Cycle 3, Day 1	254	12.7 (20.74)	7.5 (1.34)	117	11.7 (18.73)	8.9 (1.98)	-1.4 [-6.08; 3.29]; 0.5597	-0.1 [-0.28; 0.15]
Cycle 4, Day 1	249	12.0 (19.80)	9.8 (1.35)	106	11.0 (17.65)	8.1 (2.05)	1.7 [-3.10; 6.52]; 0.4857	0.1 [-0.15; 0.31]
Cycle 5, Day 1	245	13.2 (20.97)	9.0 (1.36)	99	10.8 (17.71)	8.7 (2.10)	0.3 [-4.63; 5.18]; 0.9114	0.0 [-0.22; 0.25]
Cycle 6, Day 1	237	12.9 (20.62)	7.2 (1.37)	90	8.9 (16.42)	11.0 (2.17)	-3.8 [-8.83; 1.23]; 0.1387	-0.2 [-0.42; 0.06]
Cycle 7, Day 1	216	13.0 (21.00)	6.8 (1.42)	89	9.7 (16.82)	8.2 (2.18)	-1.4 [-6.46; 3.72]; 0.5977	-0.1 [-0.31; 0.18]
Cycle 8, Day 1	201	12.9 (20.78)	7.4 (1.45)	84	9.5 (16.82)	8.3 (2.22)	-0.9 [-6.06; 4.33]; 0.7441	-0.0 [-0.30; 0.21]
Cycle 9, Day 1	197	11.8 (19.80)	5.5 (1.46)	77	8.7 (16.58)	12.1 (2.29)	-6.5 [-11.8; -1.21]; 0.0162	-0.3 [-0.58; -0.05]
Cycle 10, Day 1	193	11.4 (20.04)	6.1 (1.47)	71	8.9 (16.86)	9.1 (2.35)	-3.0 [-8.41; 2.46]; 0.2836	-0.1 [-0.42; 0.13]
Cycle 11, Day 1	185	10.8 (19.12)	7.0 (1.49)	64	8.3 (16.80)	6.9 (2.44)	0.0 [-5.55; 5.65]; 0.9864	0.0 [-0.28; 0.29]
Cycle 12, Day 1	183	11.1 (20.17)	7.9 (1.50)	62	9.1 (17.25)	10.7 (2.47)	-2.9 [-8.54; 2.77]; 0.3179	-0.1 [-0.43; 0.14]
Cycle 13, Day 1	171	9.6 (17.52)	7.1 (1.53)	58	9.8 (17.67)	8.1 (2.53)	-1.1 [-6.85; 4.73]; 0.7200	-0.1 [-0.35; 0.24]
Cycle 14, Day 1	167	9.4 (17.88)	8.4 (1.54)	57	9.4 (17.54)	9.0 (2.54)	-0.6 [-6.38; 5.28]; 0.8528	-0.0 [-0.33; 0.27]
Cycle 15, Day 1	165	9.5 (17.96)	6.0 (1.55)	52	9.0 (17.61)	10.5 (2.63)	-4.5 [-10.5; 1.44]; 0.1367	-0.2 [-0.54; 0.08]
Cycle 16, Day 1	163	9.6 (18.04)	8.2 (1.55)	53	10.1 (18.00)	11.6 (2.61)	-3.3 [-9.26; 2.65]; 0.2767	-0.2 [-0.48; 0.14]
Cycle 17, Day 1	157	9.8 (18.20)	6.4 (1.57)	54	9.3 (17.63)	12.2 (2.59)	-5.8 [-11.7; 0.16]; 0.0567	-0.3 [-0.61; 0.02]
Cycle 18, Day 1	153	9.4 (17.71)	6.7 (1.59)	52	9.0 (16.32)	10.9 (2.63)	-4.2 [-10.2; 1.83]; 0.1729	-0.2 [-0.53; 0.10]
Cycle 19, Day 1	148	10.1 (18.51)	7.9 (1.61)	47	9.9 (16.90)	9.4 (2.73)	-1.5 [-7.71; 4.71]; 0.6365	-0.1 [-0.41; 0.25]
Cycle 20, Day 1	139	8.9 (17.30)	8.3 (1.64)	40	9.2 (16.86)	7.6 (2.90)	0.7 [-5.81; 7.27]; 0.8270	0.0 [-0.31; 0.39]
Cycle 21, Day 1	141	9.9 (18.58)	6.5 (1.63)	39	8.5 (16.61)	9.0 (2.93)	-2.5 [-9.09; 4.07]; 0.4543	-0.1 [-0.49; 0.22]

Table 1.10 Change from Baseline in EORTC QLQ-C30 over time - Dyspnea Symptom Score
eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd	
Time	N	Baseline Mean (SD)	Change from BL LSMean(SE)	N	Baseline Mean (SD)	Change from BL LSMean(SE)	Difference in LSMean [95%-CI]; p-value	Hedges'g [95%-CI]
Cycle 22, Day 1	137	9.5 (18.05)	7.8 (1.65)	36	8.3 (16.67)	7.4 (3.03)	0.4 [-6.39; 7.12]; 0.9156	0.0 [-0.35; 0.39]
Cycle 23, Day 1	129	9.8 (18.35)	8.7 (1.68)	35	8.6 (16.85)	11.1 (3.06)	-2.3 [-9.19; 4.50]; 0.5023	-0.1 [-0.50; 0.25]
Cycle 24, Day 1	123	10.3 (18.67)	8.3 (1.71)	35	7.6 (16.34)	15.8 (3.06)	-7.5 [-14.4; -0.61]; 0.0328	-0.4 [-0.77; -0.02]
Cycle 25, Day 1	125	9.9 (18.46)	9.1 (1.70)	33	7.1 (16.15)	11.0 (3.13)	-1.9 [-8.85; 5.13]; 0.6017	-0.1 [-0.48; 0.29]
Cycle 26, Day 1	118	9.9 (18.65)	11.7 (1.74)	32	6.2 (13.22)	8.6 (3.17)	3.1 [-3.97; 10.21]; 0.3877	0.2 [-0.22; 0.56]
Cycle 27, Day 1	107	9.0 (16.87)	10.4 (1.80)	28	7.1 (13.93)	9.5 (3.35)	0.9 [-6.56; 8.35]; 0.8131	0.0 [-0.37; 0.46]
Cycle 28, Day 1	100	9.0 (16.31)	7.2 (1.85)	27	7.4 (14.12)	13.7 (3.40)	-6.5 [-14.1; 1.06]; 0.0920	-0.4 [-0.78; 0.07]
Cycle 29, Day 1	94	9.2 (16.51)	7.1 (1.89)	22	6.1 (13.16)	5.9 (3.70)	1.2 [-6.92; 9.38]; 0.7680	0.1 [-0.40; 0.53]
Cycle 30, Day 1	81	8.6 (16.48)	6.2 (2.01)	16	8.3 (14.91)	14.3 (4.26)	-8.1 [-17.3; 1.11]; 0.0848	-0.4 [-0.99; 0.09]
Cycle 31, Day 1	58	8.6 (15.99)	10.2 (2.30)	11	12.1 (16.82)	14.4 (5.05)	-4.2 [-15.1; 6.63]; 0.4446	-0.2 [-0.89; 0.40]
Cycle 32, Day 1	36	10.2 (15.57)	6.9 (2.83)	7	9.5 (16.27)	24.3 (6.23)	-17.4 [-30.8; -4.01]; 0.0109	-1.0 [-1.85; -0.17]
Cycle 33, Day 1	27	11.1 (16.01)	11.9 (3.22)	4	8.3 (16.67)	20.7 (8.13)	-8.8 [-25.9; 8.36]; 0.3149	-0.5 [-1.57; 0.55]
Cycle 34, Day 1	14	14.3 (17.12)	9.0 (4.38)	3	11.1 (19.25)	-8.7 (9.36)	17.7 [-2.50; 38.00]; 0.0858	1.0 [-0.28; 2.34]
Cycle 35, Day 1	9	14.8 (17.57)	8.4 (5.42)	2	16.7 (23.57)	24.2 (11.41)	-15.8 [-40.6; 8.96]; 0.2109	-0.9 [-2.49; 0.71]
Cycle 36, Day 1	6	22.2 (17.21)	16.7 (6.60)	2	16.7 (23.57)	40.9 (11.41)	-24.2 [-50.1; 1.61]; 0.0661	-1.3 [-3.14; 0.53]

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
Mixed Model Repeated Measurement for change from baseline score, with time, treatment and interaction of time and treatment as independent variables, and baseline score included as a covariate. Due to non-convergence with an unstructured covariance matrix, the model was modified to use a structured covariance matrix (compound symmetry).

Table 1.11 Change from Baseline in EORTC QLQ-C30 over time - Insomnia Symptom Score
eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd	
Time	N	Baseline Mean (SD)	Change from BL LSMean(SE)	N	Baseline Mean (SD)	Change from BL LSMean(SE)	Difference in LSMean [95%-CI]; p-value	Hedges'g [95%-CI]
Cycle 2, Day 1	271	19.9 (26.38)	4.8 (1.43)	119	17.6 (27.39)	1.7 (2.14)	3.1 [-1.95; 8.13]; 0.2298	0.1 [-0.08; 0.35]
Cycle 3, Day 1	254	19.7 (26.46)	4.9 (1.46)	117	17.9 (26.46)	7.1 (2.15)	-2.2 [-7.31; 2.89]; 0.3947	-0.1 [-0.31; 0.12]
Cycle 4, Day 1	249	19.3 (26.33)	4.1 (1.47)	106	18.2 (27.27)	1.5 (2.23)	2.6 [-2.62; 7.85]; 0.3275	0.1 [-0.11; 0.34]
Cycle 5, Day 1	245	19.3 (26.11)	3.8 (1.48)	99	18.5 (27.86)	4.1 (2.28)	-0.3 [-5.64; 5.03]; 0.9108	-0.0 [-0.25; 0.22]
Cycle 6, Day 1	237	19.4 (26.54)	2.2 (1.49)	90	18.5 (28.32)	1.1 (2.36)	1.1 [-4.39; 6.55]; 0.6997	0.0 [-0.20; 0.29]
Cycle 7, Day 1	216	19.8 (26.91)	0.9 (1.54)	89	16.9 (26.65)	0.3 (2.37)	0.6 [-4.96; 6.11]; 0.8379	0.0 [-0.22; 0.27]
Cycle 8, Day 1	201	19.7 (27.34)	0.3 (1.57)	84	17.1 (27.13)	1.5 (2.41)	-1.1 [-6.78; 4.51]; 0.6946	-0.1 [-0.31; 0.20]
Cycle 9, Day 1	197	20.0 (27.49)	4.5 (1.58)	77	15.6 (25.70)	3.9 (2.48)	0.6 [-5.21; 6.33]; 0.8502	0.0 [-0.24; 0.29]
Cycle 10, Day 1	193	19.7 (27.07)	2.0 (1.59)	71	16.9 (26.35)	-0.5 (2.55)	2.6 [-3.32; 8.47]; 0.3922	0.1 [-0.16; 0.39]
Cycle 11, Day 1	185	18.4 (25.75)	4.1 (1.62)	64	16.7 (25.20)	2.1 (2.64)	2.0 [-4.08; 8.06]; 0.5204	0.1 [-0.19; 0.38]
Cycle 12, Day 1	183	18.0 (25.13)	4.4 (1.62)	62	15.1 (25.38)	-0.1 (2.67)	4.5 [-1.64; 10.62]; 0.1506	0.2 [-0.08; 0.49]
Cycle 13, Day 1	171	18.1 (25.87)	4.6 (1.66)	58	13.2 (22.46)	-1.4 (2.74)	6.0 [-0.31; 12.23]; 0.0626	0.3 [-0.02; 0.58]
Cycle 14, Day 1	167	19.0 (26.25)	2.6 (1.67)	57	14.0 (22.67)	5.1 (2.75)	-2.6 [-8.87; 3.76]; 0.4278	-0.1 [-0.42; 0.18]
Cycle 15, Day 1	165	18.8 (26.36)	4.4 (1.68)	52	12.8 (23.01)	2.0 (2.84)	2.3 [-4.15; 8.80]; 0.4814	0.1 [-0.20; 0.42]
Cycle 16, Day 1	163	19.2 (26.42)	4.1 (1.68)	53	13.2 (22.96)	1.5 (2.82)	2.6 [-3.90; 9.00]; 0.4378	0.1 [-0.19; 0.43]
Cycle 17, Day 1	157	18.9 (26.49)	2.8 (1.70)	54	12.3 (22.71)	4.2 (2.81)	-1.4 [-7.88; 5.00]; 0.6604	-0.1 [-0.38; 0.24]
Cycle 18, Day 1	153	20.0 (26.86)	6.7 (1.72)	52	13.5 (23.11)	1.4 (2.84)	5.3 [-1.20; 11.84]; 0.1097	0.3 [-0.06; 0.57]
Cycle 19, Day 1	148	17.8 (25.32)	5.7 (1.74)	47	14.2 (23.82)	0.3 (2.95)	5.4 [-1.31; 12.12]; 0.1146	0.3 [-0.07; 0.59]
Cycle 20, Day 1	139	17.3 (25.49)	4.8 (1.78)	40	12.5 (24.68)	3.5 (3.14)	1.3 [-5.81; 8.32]; 0.7271	0.1 [-0.29; 0.41]
Cycle 21, Day 1	141	18.9 (25.91)	3.1 (1.77)	39	12.8 (24.92)	3.4 (3.17)	-0.4 [-7.49; 6.73]; 0.9164	-0.0 [-0.37; 0.34]

Table 1.11 Change from Baseline in EORTC QLQ-C30 over time - Insomnia Symptom Score
eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd	
Time	N	Baseline Mean (SD)	Change from BL LSMean(SE)	N	Baseline Mean (SD)	Change from BL LSMean(SE)	Difference in LSMean [95%-CI]; p-value	Hedges'g [95%-CI]
Cycle 22, Day 1	137	18.7 (26.15)	4.1 (1.79)	36	12.0 (24.11)	-0.1 (3.27)	4.3 [-3.04; 11.56]; 0.2524	0.2 [-0.16; 0.57]
Cycle 23, Day 1	129	19.4 (26.25)	5.5 (1.82)	35	11.4 (24.18)	1.4 (3.30)	4.0 [-3.35; 11.44]; 0.2835	0.2 [-0.18; 0.57]
Cycle 24, Day 1	123	18.4 (25.68)	2.6 (1.85)	35	11.4 (24.18)	7.9 (3.30)	-5.3 [-12.7; 2.16]; 0.1642	-0.3 [-0.63; 0.12]
Cycle 25, Day 1	125	18.9 (25.87)	5.8 (1.84)	33	11.1 (24.53)	3.7 (3.38)	2.1 [-5.45; 9.65]; 0.5854	0.1 [-0.28; 0.49]
Cycle 26, Day 1	118	19.8 (26.23)	5.7 (1.88)	32	12.5 (25.04)	-0.2 (3.42)	6.0 [-1.70; 13.60]; 0.1275	0.3 [-0.10; 0.69]
Cycle 27, Day 1	107	18.7 (25.57)	6.6 (1.95)	28	14.3 (26.34)	1.9 (3.61)	4.7 [-3.32; 12.77]; 0.2495	0.2 [-0.18; 0.65]
Cycle 28, Day 1	100	19.7 (27.26)	4.8 (2.00)	27	14.8 (26.69)	5.8 (3.66)	-1.0 [-9.19; 7.17]; 0.8094	-0.1 [-0.48; 0.37]
Cycle 29, Day 1	94	19.9 (27.36)	5.1 (2.04)	22	12.1 (26.32)	2.9 (3.99)	2.2 [-6.61; 10.96]; 0.6277	0.1 [-0.35; 0.57]
Cycle 30, Day 1	81	21.4 (27.54)	5.8 (2.16)	16	18.8 (29.74)	3.8 (4.58)	2.0 [-7.95; 11.91]; 0.6957	0.1 [-0.43; 0.64]
Cycle 31, Day 1	58	20.7 (27.09)	3.8 (2.48)	11	30.3 (34.82)	10.1 (5.43)	-6.4 [-18.1; 5.33]; 0.2860	-0.3 [-0.98; 0.31]
Cycle 32, Day 1	36	18.5 (23.16)	1.0 (3.04)	7	33.3 (38.49)	5.3 (6.69)	-4.3 [-18.7; 10.10]; 0.5580	-0.2 [-1.04; 0.58]
Cycle 33, Day 1	27	18.5 (23.27)	7.6 (3.46)	4	50.0 (43.03)	14.8 (8.73)	-7.3 [-25.7; 11.15]; 0.4397	-0.4 [-1.45; 0.66]
Cycle 34, Day 1	14	16.7 (21.68)	1.6 (4.70)	3	33.3 (33.33)	-15.1 (10.04)	16.7 [-4.99; 38.46]; 0.1311	0.9 [-0.39; 2.20]
Cycle 35, Day 1	9	11.1 (16.67)	7.1 (5.81)	2	50.0 (23.57)	-19.3 (12.24)	26.4 [-0.11; 53.00]; 0.0510	1.4 [-0.31; 3.08]
Cycle 36, Day 1	6	11.1 (17.21)	17.6 (7.08)	2	50.0 (23.57)	14.0 (12.24)	3.6 [-24.1; 31.32]; 0.7988	0.2 [-1.42; 1.79]

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
Mixed Model Repeated Measurement for change from baseline score, with time, treatment and interaction of time and treatment as independent variables, and baseline score included as a covariate. Due to non-convergence with an unstructured covariance matrix, the model was modified to use a structured covariance matrix (compound symmetry).

Table 1.12 Change from Baseline in EORTC QLQ-C30 over time - Appetite Loss Symptom Score
eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd	
Time	N	Baseline Mean (SD)	Change from BL LSMean(SE)	N	Baseline Mean (SD)	Change from BL LSMean(SE)	Difference in LSMean [95%-CI]; p-value	Hedges'g [95%-CI]
Cycle 2, Day 1	271	11.3 (20.36)	5.0 (1.35)	119	6.7 (18.20)	0.2 (2.02)	4.8 [-0.00; 9.56]; 0.0502	0.2 [-0.00; 0.43]
Cycle 3, Day 1	254	11.2 (20.38)	3.9 (1.33)	117	6.3 (17.47)	4.8 (1.96)	-0.8 [-5.49; 3.83]; 0.7271	-0.0 [-0.26; 0.18]
Cycle 4, Day 1	249	10.7 (20.11)	-0.1 (1.18)	106	7.2 (18.97)	1.1 (1.80)	-1.2 [-5.42; 3.05]; 0.5816	-0.1 [-0.29; 0.16]
Cycle 5, Day 1	245	10.3 (19.84)	1.1 (1.12)	99	7.7 (19.53)	0.9 (1.75)	0.2 [-3.87; 4.31]; 0.9155	0.0 [-0.22; 0.25]
Cycle 6, Day 1	237	10.1 (19.18)	-0.7 (1.12)	90	7.0 (17.66)	1.4 (1.79)	-2.1 [-6.26; 2.04]; 0.3183	-0.1 [-0.37; 0.12]
Cycle 7, Day 1	216	9.4 (17.58)	1.5 (1.22)	89	6.0 (16.33)	0.8 (1.87)	0.6 [-3.76; 5.00]; 0.7812	0.0 [-0.21; 0.28]
Cycle 8, Day 1	201	9.3 (18.01)	0.9 (1.20)	84	5.2 (15.08)	1.9 (1.86)	-1.0 [-5.37; 3.35]; 0.6491	-0.1 [-0.31; 0.20]
Cycle 9, Day 1	197	9.3 (17.76)	-0.5 (1.03)	77	4.8 (11.74)	-0.2 (1.65)	-0.3 [-4.11; 3.53]; 0.8828	-0.0 [-0.28; 0.24]
Cycle 10, Day 1	193	9.8 (18.66)	-1.1 (1.12)	71	4.2 (11.17)	-0.2 (1.79)	-0.9 [-5.11; 3.22]; 0.6556	-0.1 [-0.33; 0.21]
Cycle 11, Day 1	185	9.5 (18.36)	-0.5 (1.10)	64	5.2 (12.20)	-0.6 (1.82)	0.1 [-4.07; 4.29]; 0.9586	0.0 [-0.28; 0.29]
Cycle 12, Day 1	183	9.7 (18.76)	-0.1 (1.14)	62	4.8 (11.84)	0.9 (1.91)	-1.0 [-5.32; 3.42]; 0.6692	-0.1 [-0.35; 0.23]
Cycle 13, Day 1	171	9.9 (19.10)	-1.0 (1.12)	58	4.6 (11.59)	4.2 (1.88)	-5.2 [-9.48; -0.89]; 0.0181	-0.4 [-0.66; -0.06]
Cycle 14, Day 1	167	9.8 (19.12)	0.4 (1.16)	57	4.7 (11.68)	0.2 (1.95)	0.2 [-4.27; 4.65]; 0.9339	0.0 [-0.29; 0.31]
Cycle 15, Day 1	165	10.5 (19.41)	-1.5 (1.17)	52	4.5 (11.49)	0.9 (2.02)	-2.4 [-6.96; 2.22]; 0.3104	-0.2 [-0.47; 0.15]
Cycle 16, Day 1	163	10.4 (19.43)	0.9 (1.38)	53	5.0 (12.05)	2.3 (2.28)	-1.4 [-6.65; 3.83]; 0.5962	-0.1 [-0.39; 0.23]
Cycle 17, Day 1	157	10.4 (19.56)	-0.8 (1.26)	54	5.6 (12.54)	-0.7 (2.08)	-0.1 [-4.86; 4.68]; 0.9696	-0.0 [-0.32; 0.30]
Cycle 18, Day 1	153	9.8 (18.29)	-0.6 (1.26)	52	5.1 (12.14)	4.6 (2.11)	-5.3 [-10.1; -0.44]; 0.0326	-0.3 [-0.65; -0.02]
Cycle 19, Day 1	148	9.9 (18.43)	-1.4 (1.27)	47	5.7 (12.66)	4.8 (2.20)	-6.2 [-11.2; -1.23]; 0.0147	-0.4 [-0.73; -0.07]
Cycle 20, Day 1	139	9.4 (17.96)	-1.3 (1.18)	40	5.0 (12.05)	1.7 (2.14)	-3.0 [-7.86; 1.77]; 0.2148	-0.2 [-0.57; 0.13]
Cycle 21, Day 1	141	9.5 (17.96)	-1.5 (1.34)	39	3.4 (10.25)	4.3 (2.52)	-5.7 [-11.4; -0.12]; 0.0452	-0.4 [-0.72; -0.00]

Table 1.12 Change from Baseline in EORTC QLQ-C30 over time - Appetite Loss Symptom Score eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd	
Time	N	Baseline Mean (SD)	Change from BL LSMean(SE)	N	Baseline Mean (SD)	Change from BL LSMean(SE)	Difference in LSMean [95%-CI]; p-value	Hedges'g [95%-CI]
Cycle 22, Day 1	137	9.7 (18.15)	-0.1 (1.24)	36	4.6 (11.69)	2.8 (2.29)	-2.9 [-8.03; 2.21]; 0.2641	-0.2 [-0.57; 0.17]
Cycle 23, Day 1	129	9.0 (17.56)	-2.0 (1.23)	35	4.8 (11.83)	0.5 (2.30)	-2.5 [-7.64; 2.60]; 0.3343	-0.2 [-0.55; 0.19]
Cycle 24, Day 1	123	8.9 (17.11)	-2.2 (1.35)	35	2.9 (9.47)	7.5 (2.49)	-9.7 [-15.3; -4.15]; 0.0007	-0.6 [-1.03; -0.27]
Cycle 25, Day 1	125	8.8 (17.01)	-0.1 (1.29)	33	3.0 (9.73)	0.7 (2.36)	-0.9 [-6.16; 4.43]; 0.7489	-0.1 [-0.44; 0.32]
Cycle 26, Day 1	118	9.3 (17.37)	-0.0 (1.36)	32	4.2 (11.20)	8.9 (2.54)	-8.9 [-14.6; -3.26]; 0.0021	-0.6 [-1.00; -0.21]
Cycle 27, Day 1	107	9.0 (16.87)	-1.1 (1.45)	28	3.6 (10.50)	2.5 (2.70)	-3.6 [-9.62; 2.44]; 0.2426	-0.2 [-0.66; 0.18]
Cycle 28, Day 1	100	9.0 (16.99)	-0.5 (1.49)	27	3.7 (10.68)	3.4 (2.76)	-3.9 [-10.1; 2.28]; 0.2158	-0.3 [-0.69; 0.16]
Cycle 29, Day 1	94	9.2 (17.22)	-1.4 (1.42)	22	3.0 (9.81)	6.3 (2.79)	-7.7 [-13.9; -1.54]; 0.0145	-0.6 [-1.03; -0.09]
Cycle 30, Day 1	81	9.5 (16.86)	-1.1 (1.74)	16	4.2 (11.39)	1.1 (4.04)	-2.2 [-10.8; 6.47]; 0.6213	-0.1 [-0.67; 0.40]
Cycle 31, Day 1	58	8.6 (17.17)	-0.0 (2.10)	11	3.0 (10.05)	-3.0 (4.32)	3.0 [-6.53; 12.45]; 0.5386	0.2 [-0.46; 0.83]
Cycle 32, Day 1	36	6.5 (13.38)	-3.4 (2.31)	7	0.0 (0.00)	-4.5 (5.10)	1.0 [-10.1; 12.15]; 0.8544	0.1 [-0.74; 0.88]
Cycle 33, Day 1	27	3.7 (10.68)	-3.0 (2.25)	4	0.0 (0.00)	2.5 (5.19)	-5.5 [-17.1; 6.07]; 0.3389	-0.5 [-1.52; 0.59]
Cycle 34, Day 1	14	0.0 (0.00)	-2.8 (3.03)	3	0.0 (0.00)	-0.6 (6.81)	-2.2 [-17.5; 13.16]; 0.7716	-0.2 [-1.43; 1.07]
Cycle 35, Day 1	9	0.0 (0.00)	7.2 (4.78)	2	0.0 (0.00)	-1.0 (8.35)	8.2 [-11.3; 27.75]; 0.3994	0.5 [-1.02; 2.09]
Cycle 36, Day 1	6	0.0 (0.00)	5.6 (5.95)	2	0.0 (0.00)	-0.7 (9.21)	6.2 [-17.0; 29.51]; 0.5775	0.4 [-1.24; 2.00]

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
Mixed Model Repeated Measurement for change from baseline score, with time, treatment and interaction of time and treatment as independent variables, and baseline score included as a covariate. Due to non-convergence with an unstructured covariance matrix, the model was modified to use a structured covariance matrix (heterogeneous compound symmetry).

Table 1.13 Change from Baseline in EORTC QLQ-C30 over time - Constipation Symptom Score
eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd	
Time	N	Baseline Mean (SD)	Change from BL LSMean(SE)	N	Baseline Mean (SD)	Change from BL LSMean(SE)	Difference in LSMean [95%-CI]; p-value	Hedges'g [95%-CI]
Cycle 2, Day 1	271	11.6 (22.72)	1.3 (1.02)	119	5.3 (14.38)	-2.2 (1.52)	3.5 [-0.09; 7.12]; 0.0557	0.2 [-0.01; 0.43]
Cycle 3, Day 1	254	11.8 (22.97)	-0.1 (1.04)	117	5.7 (14.71)	-0.1 (1.53)	0.0 [-3.60; 3.68]; 0.9846	0.0 [-0.22; 0.22]
Cycle 4, Day 1	249	11.8 (22.49)	-3.0 (1.05)	106	5.3 (14.65)	0.9 (1.58)	-3.8 [-7.57; -0.11]; 0.0436	-0.2 [-0.46; -0.01]
Cycle 5, Day 1	245	12.1 (23.25)	-1.1 (1.05)	99	5.7 (14.32)	-0.9 (1.62)	-0.2 [-3.99; 3.60]; 0.9211	-0.0 [-0.25; 0.22]
Cycle 6, Day 1	237	12.4 (23.30)	0.3 (1.06)	90	5.2 (13.14)	-0.1 (1.67)	0.4 [-3.47; 4.30]; 0.8342	0.0 [-0.22; 0.27]
Cycle 7, Day 1	216	11.6 (22.61)	-2.0 (1.09)	89	3.4 (10.11)	-0.7 (1.67)	-1.3 [-5.26; 2.60]; 0.5072	-0.1 [-0.33; 0.16]
Cycle 8, Day 1	201	10.8 (21.34)	-1.9 (1.11)	84	3.6 (10.37)	-2.0 (1.70)	0.1 [-3.87; 4.13]; 0.9492	0.0 [-0.25; 0.26]
Cycle 9, Day 1	197	10.7 (20.60)	-1.9 (1.12)	77	3.5 (10.24)	-2.3 (1.75)	0.4 [-3.71; 4.46]; 0.8568	0.0 [-0.24; 0.29]
Cycle 10, Day 1	193	10.2 (20.55)	-1.5 (1.13)	71	3.3 (10.01)	-1.4 (1.79)	-0.1 [-4.28; 4.05]; 0.9572	-0.0 [-0.28; 0.26]
Cycle 11, Day 1	185	9.7 (19.70)	-0.9 (1.14)	64	2.6 (9.02)	-1.9 (1.85)	1.0 [-3.30; 5.26]; 0.6531	0.1 [-0.22; 0.35]
Cycle 12, Day 1	183	10.2 (20.80)	-1.7 (1.15)	62	2.7 (9.15)	-3.2 (1.88)	1.5 [-2.83; 5.80]; 0.5000	0.1 [-0.19; 0.38]
Cycle 13, Day 1	171	9.2 (18.45)	0.4 (1.17)	58	3.4 (10.24)	-2.6 (1.92)	3.0 [-1.40; 7.43]; 0.1808	0.2 [-0.10; 0.50]
Cycle 14, Day 1	167	9.4 (18.97)	-1.8 (1.18)	57	3.5 (10.32)	-3.7 (1.93)	1.8 [-2.62; 6.26]; 0.4208	0.1 [-0.18; 0.42]
Cycle 15, Day 1	165	9.3 (18.98)	-1.7 (1.18)	52	3.8 (10.75)	-2.0 (1.99)	0.3 [-4.27; 4.82]; 0.9041	0.0 [-0.29; 0.33]
Cycle 16, Day 1	163	9.4 (19.07)	-1.9 (1.19)	53	3.8 (10.66)	-3.4 (1.98)	1.5 [-3.02; 6.04]; 0.5129	0.1 [-0.21; 0.41]
Cycle 17, Day 1	157	9.8 (19.34)	0.4 (1.20)	54	3.1 (9.75)	-3.8 (1.97)	4.2 [-0.30; 8.75]; 0.0670	0.3 [-0.03; 0.59]
Cycle 18, Day 1	153	9.8 (19.45)	-2.8 (1.21)	52	3.8 (10.75)	-1.8 (1.99)	-1.0 [-5.60; 3.55]; 0.6612	-0.1 [-0.38; 0.25]
Cycle 19, Day 1	148	8.8 (18.79)	-0.8 (1.22)	47	5.0 (12.00)	-3.0 (2.06)	2.2 [-2.53; 6.89]; 0.3641	0.1 [-0.18; 0.48]
Cycle 20, Day 1	139	8.2 (18.32)	-1.2 (1.25)	40	3.3 (10.13)	-3.5 (2.18)	2.4 [-2.59; 7.29]; 0.3507	0.2 [-0.19; 0.51]
Cycle 21, Day 1	141	8.7 (18.96)	-0.5 (1.24)	39	3.4 (10.25)	-0.0 (2.20)	-0.5 [-5.47; 4.47]; 0.8438	-0.0 [-0.39; 0.32]

Table 1.13 Change from Baseline in EORTC QLQ-C30 over time - Constipation Symptom Score eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd	
Time	N	Baseline Mean (SD)	Change from BL LSMean(SE)	N	Baseline Mean (SD)	Change from BL LSMean(SE)	Difference in LSMean [95%-CI]; p-value	Hedges'g [95%-CI]
Cycle 22, Day 1	137	9.0 (19.18)	-0.9 (1.25)	36	2.8 (9.34)	-2.6 (2.27)	1.6 [-3.45; 6.73]; 0.5282	0.1 [-0.25; 0.48]
Cycle 23, Day 1	129	8.5 (18.76)	-2.5 (1.28)	35	2.9 (9.47)	-1.7 (2.29)	-0.8 [-5.93; 4.39]; 0.7702	-0.1 [-0.43; 0.32]
Cycle 24, Day 1	123	9.2 (19.70)	-2.7 (1.30)	35	1.9 (7.85)	-3.4 (2.30)	0.7 [-4.47; 5.88]; 0.7900	0.0 [-0.33; 0.42]
Cycle 25, Day 1	125	9.1 (19.57)	-2.4 (1.29)	33	1.0 (5.80)	-1.3 (2.35)	-1.1 [-6.39; 4.13]; 0.6729	-0.1 [-0.46; 0.30]
Cycle 26, Day 1	118	9.6 (20.02)	-1.8 (1.32)	32	2.1 (8.20)	1.6 (2.37)	-3.4 [-8.70; 1.96]; 0.2147	-0.2 [-0.63; 0.15]
Cycle 27, Day 1	107	9.7 (20.48)	-3.2 (1.36)	28	2.4 (8.74)	-1.3 (2.50)	-1.9 [-7.51; 3.67]; 0.5000	-0.1 [-0.55; 0.28]
Cycle 28, Day 1	100	8.7 (19.89)	-1.3 (1.39)	27	2.5 (8.90)	-1.3 (2.54)	-0.0 [-5.71; 5.65]; 0.9919	-0.0 [-0.43; 0.42]
Cycle 29, Day 1	94	8.5 (19.51)	-1.1 (1.43)	22	0.0 (0.00)	-1.8 (2.75)	0.7 [-5.37; 6.80]; 0.8179	0.1 [-0.41; 0.52]
Cycle 30, Day 1	81	9.5 (20.57)	-2.0 (1.51)	16	2.1 (8.33)	-1.4 (3.15)	-0.6 [-7.48; 6.24]; 0.8591	-0.0 [-0.58; 0.49]
Cycle 31, Day 1	58	8.0 (20.05)	-1.8 (1.71)	11	6.1 (13.48)	-3.2 (3.73)	1.4 [-6.64; 9.45]; 0.7325	0.1 [-0.54; 0.75]
Cycle 32, Day 1	36	5.6 (16.90)	-1.6 (2.09)	7	4.8 (12.60)	-4.4 (4.58)	2.8 [-7.12; 12.63]; 0.5848	0.2 [-0.59; 1.03]
Cycle 33, Day 1	27	3.7 (14.12)	-1.6 (2.38)	4	8.3 (16.67)	2.5 (5.97)	-4.2 [-16.8; 8.41]; 0.5147	-0.3 [-1.38; 0.72]
Cycle 34, Day 1	14	2.4 (8.91)	-1.5 (3.22)	3	11.1 (19.25)	-7.1 (6.86)	5.6 [-9.22; 20.47]; 0.4576	0.4 [-0.81; 1.70]
Cycle 35, Day 1	9	0.0 (0.00)	-0.6 (3.97)	2	16.7 (23.57)	-9.1 (8.35)	8.5 [-9.62; 26.65]; 0.3572	0.7 [-0.92; 2.22]
Cycle 36, Day 1	6	0.0 (0.00)	-4.9 (4.83)	2	16.7 (23.57)	-9.1 (8.35)	4.2 [-14.7; 23.13]; 0.6628	0.3 [-1.31; 1.92]

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
Mixed Model Repeated Measurement for change from baseline score, with time, treatment and interaction of time and treatment as independent variables, and baseline score included as a covariate. Due to non-convergence with an unstructured covariance matrix, the model was modified to use a structured covariance matrix (compound symmetry).

Table 1.8 Change from Baseline in EORTC QLQ-C30 over time - Nausea/Vomiting Symptom Score
eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd	
Time	N	Baseline Mean (SD)	Change from BL LSMean(SE)	N	Baseline Mean (SD)	Change from BL LSMean(SE)	Difference in LSMean [95%-CI]; p-value	Hedges'g [95%-CI]
Cycle 2, Day 1	271	3.3 (10.79)	1.8 (0.55)	119	2.0 (7.25)	1.8 (0.83)	-0.0 [-1.96; 1.93]; 0.9865	-0.0 [-0.22; 0.21]
Cycle 3, Day 1	254	3.0 (10.00)	2.1 (0.56)	117	1.7 (5.95)	2.3 (0.83)	-0.2 [-2.12; 1.81]; 0.8785	-0.0 [-0.24; 0.20]
Cycle 4, Day 1	249	2.8 (9.87)	1.7 (0.57)	106	2.4 (7.78)	0.9 (0.87)	0.8 [-1.20; 2.87]; 0.4211	0.1 [-0.13; 0.32]
Cycle 5, Day 1	245	2.9 (10.09)	1.9 (0.58)	99	2.5 (8.03)	0.5 (0.90)	1.4 [-0.66; 3.52]; 0.1801	0.2 [-0.07; 0.39]
Cycle 6, Day 1	237	2.4 (7.91)	0.8 (0.59)	90	2.2 (7.58)	-1.0 (0.94)	1.8 [-0.42; 3.93]; 0.1131	0.2 [-0.05; 0.44]
Cycle 7, Day 1	216	2.1 (7.16)	2.1 (0.61)	89	2.2 (7.62)	0.0 (0.95)	2.1 [-0.11; 4.33]; 0.0619	0.2 [-0.01; 0.48]
Cycle 8, Day 1	201	1.7 (6.46)	1.3 (0.63)	84	2.2 (7.67)	1.1 (0.98)	0.2 [-2.08; 2.50]; 0.8590	0.0 [-0.23; 0.28]
Cycle 9, Day 1	197	1.9 (6.89)	0.5 (0.64)	77	1.7 (5.79)	-0.3 (1.02)	0.9 [-1.51; 3.21]; 0.4801	0.1 [-0.17; 0.36]
Cycle 10, Day 1	193	1.7 (6.58)	0.3 (0.65)	71	1.9 (6.01)	-0.6 (1.05)	0.9 [-1.55; 3.30]; 0.4804	0.1 [-0.17; 0.37]
Cycle 11, Day 1	185	1.8 (6.71)	1.3 (0.66)	64	2.1 (6.30)	1.6 (1.11)	-0.2 [-2.75; 2.31]; 0.8650	-0.0 [-0.31; 0.26]
Cycle 12, Day 1	183	1.7 (6.66)	1.2 (0.67)	62	1.9 (6.11)	2.4 (1.13)	-1.2 [-3.77; 1.37]; 0.3581	-0.1 [-0.42; 0.15]
Cycle 13, Day 1	171	1.7 (6.43)	0.6 (0.69)	58	2.0 (6.30)	-0.9 (1.17)	1.4 [-1.24; 4.08]; 0.2963	0.2 [-0.14; 0.46]
Cycle 14, Day 1	167	1.8 (6.85)	1.6 (0.70)	57	2.0 (6.35)	-0.2 (1.19)	1.7 [-0.95; 4.44]; 0.2052	0.2 [-0.11; 0.49]
Cycle 15, Day 1	165	1.8 (6.89)	1.1 (0.70)	52	1.9 (6.31)	-0.5 (1.24)	1.6 [-1.20; 4.38]; 0.2631	0.2 [-0.14; 0.49]
Cycle 16, Day 1	163	1.8 (6.93)	0.7 (0.71)	53	2.2 (6.57)	3.7 (1.23)	-3.0 [-5.83; -0.27]; 0.0316	-0.3 [-0.65; -0.03]
Cycle 17, Day 1	157	1.8 (6.95)	1.5 (0.72)	54	2.2 (6.51)	-0.4 (1.22)	1.9 [-0.87; 4.69]; 0.1780	0.2 [-0.10; 0.52]
Cycle 18, Day 1	153	2.0 (7.14)	0.7 (0.73)	52	2.2 (6.62)	2.5 (1.25)	-1.8 [-4.66; 1.00]; 0.2046	-0.2 [-0.52; 0.11]
Cycle 19, Day 1	148	2.0 (7.25)	0.6 (0.74)	47	2.1 (6.61)	1.4 (1.30)	-0.8 [-3.75; 2.12]; 0.5848	-0.1 [-0.42; 0.24]
Cycle 20, Day 1	139	1.8 (6.86)	-0.4 (0.76)	40	1.7 (6.32)	1.1 (1.40)	-1.4 [-4.56; 1.70]; 0.3699	-0.2 [-0.51; 0.19]
Cycle 21, Day 1	141	2.1 (7.41)	1.3 (0.76)	39	1.3 (5.90)	-0.4 (1.43)	1.7 [-1.51; 4.86]; 0.3029	0.2 [-0.17; 0.54]

Table 1.8 Change from Baseline in EORTC QLQ-C30 over time - Nausea/Vomiting Symptom Score
eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd	
Time	N	Baseline Mean (SD)	Change from BL LSMean(SE)	N	Baseline Mean (SD)	Change from BL LSMean(SE)	Difference in LSMean [95%-CI]; p-value	Hedges'g [95%-CI]
Cycle 22, Day 1	137	2.2 (7.51)	1.2 (0.77)	36	1.4 (6.14)	-0.8 (1.49)	2.0 [-1.28; 5.30]; 0.2310	0.2 [-0.15; 0.59]
Cycle 23, Day 1	129	1.7 (5.84)	1.5 (0.79)	35	1.4 (6.22)	0.1 (1.52)	1.5 [-1.87; 4.84]; 0.3862	0.2 [-0.21; 0.54]
Cycle 24, Day 1	123	1.8 (5.96)	0.6 (0.81)	35	0.5 (2.82)	1.9 (1.52)	-1.3 [-4.69; 2.07]; 0.4475	-0.1 [-0.52; 0.23]
Cycle 25, Day 1	125	1.7 (5.92)	1.6 (0.81)	33	0.5 (2.90)	-0.7 (1.56)	2.3 [-1.17; 5.71]; 0.1956	0.3 [-0.13; 0.64]
Cycle 26, Day 1	118	1.8 (6.08)	1.5 (0.83)	32	0.5 (2.95)	-0.4 (1.57)	1.9 [-1.58; 5.39]; 0.2840	0.2 [-0.18; 0.60]
Cycle 27, Day 1	107	1.7 (6.03)	2.7 (0.86)	28	0.6 (3.15)	0.4 (1.68)	2.4 [-1.34; 6.05]; 0.2117	0.3 [-0.15; 0.68]
Cycle 28, Day 1	100	1.3 (5.12)	1.2 (0.89)	27	0.6 (3.21)	0.4 (1.72)	0.8 [-2.96; 4.63]; 0.6665	0.1 [-0.33; 0.52]
Cycle 29, Day 1	94	1.4 (5.28)	1.4 (0.92)	22	0.8 (3.55)	0.6 (1.89)	0.8 [-3.36; 4.89]; 0.7177	0.1 [-0.38; 0.55]
Cycle 30, Day 1	81	1.6 (5.65)	1.4 (0.99)	16	1.0 (4.17)	3.9 (2.18)	-2.5 [-7.15; 2.23]; 0.3038	-0.3 [-0.81; 0.26]
Cycle 31, Day 1	58	2.0 (6.30)	1.8 (1.16)	11	1.5 (5.03)	3.1 (2.60)	-1.3 [-6.88; 4.29]; 0.6502	-0.1 [-0.79; 0.50]
Cycle 32, Day 1	36	1.4 (4.67)	1.6 (1.45)	7	0.0 (0.00)	1.7 (3.30)	-0.1 [-7.21; 6.93]; 0.9693	-0.0 [-0.83; 0.79]
Cycle 33, Day 1	27	0.6 (3.21)	3.7 (1.69)	4	0.0 (0.00)	2.2 (4.35)	1.5 [-7.67; 10.61]; 0.7523	0.2 [-0.89; 1.21]
Cycle 34, Day 1	14	0.0 (0.00)	5.5 (2.31)	3	0.0 (0.00)	-0.0 (5.10)	5.6 [-5.40; 16.54]; 0.3198	0.6 [-0.66; 1.88]
Cycle 35, Day 1	9	0.0 (0.00)	7.2 (2.91)	2	0.0 (0.00)	-1.0 (6.21)	8.2 [-5.25; 21.64]; 0.2321	0.9 [-0.74; 2.45]
Cycle 36, Day 1	6	0.0 (0.00)	1.3 (3.58)	2	0.0 (0.00)	-1.4 (6.39)	2.7 [-11.6; 17.07]; 0.7103	0.3 [-1.34; 1.88]

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
Mixed Model Repeated Measurement for change from baseline score, with time, treatment and interaction of time and treatment as independent variables, and baseline score included as a covariate. Due to non-convergence with an unstructured covariance matrix, the model was modified to use a structured covariance matrix [autoregressive(1)].

Table 1.14 Change from Baseline in EORTC QLQ-C30 over time - Diarrhea Symptom Score
eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd	
Time	N	Baseline Mean (SD)	Change from BL LSMean(SE)	N	Baseline Mean (SD)	Change from BL LSMean(SE)	Difference in LSMean [95%-CI]; p-value	Hedges'g [95%-CI]
Cycle 2, Day 1	271	6.2 (15.81)	1.8 (1.08)	119	4.8 (13.22)	2.3 (1.62)	-0.6 [-4.38; 3.25]; 0.7704	-0.0 [-0.25; 0.18]
Cycle 3, Day 1	254	6.3 (16.36)	1.4 (1.10)	117	4.8 (13.32)	0.6 (1.63)	0.9 [-2.98; 4.75]; 0.6542	0.1 [-0.17; 0.27]
Cycle 4, Day 1	249	6.3 (16.14)	0.7 (1.11)	106	5.0 (13.64)	0.4 (1.70)	0.3 [-3.71; 4.25]; 0.8935	0.0 [-0.21; 0.24]
Cycle 5, Day 1	245	6.8 (16.78)	2.1 (1.12)	99	5.4 (14.05)	-0.8 (1.75)	2.9 [-1.21; 6.93]; 0.1683	0.2 [-0.07; 0.40]
Cycle 6, Day 1	237	6.6 (16.76)	2.3 (1.14)	90	4.8 (13.74)	2.3 (1.81)	-0.0 [-4.21; 4.18]; 0.9955	-0.0 [-0.24; 0.24]
Cycle 7, Day 1	216	6.9 (17.26)	3.3 (1.18)	89	4.9 (13.81)	-0.4 (1.82)	3.7 [-0.56; 7.95]; 0.0884	0.2 [-0.03; 0.46]
Cycle 8, Day 1	201	6.5 (17.23)	3.6 (1.21)	84	5.2 (14.16)	2.4 (1.86)	1.3 [-3.10; 5.61]; 0.5723	0.1 [-0.18; 0.33]
Cycle 9, Day 1	197	6.3 (16.16)	2.2 (1.22)	77	5.6 (14.71)	3.1 (1.93)	-1.0 [-5.45; 3.49]; 0.6686	-0.1 [-0.32; 0.21]
Cycle 10, Day 1	193	6.0 (16.08)	5.7 (1.23)	71	5.6 (14.89)	2.2 (1.99)	3.5 [-1.08; 8.08]; 0.1343	0.2 [-0.07; 0.48]
Cycle 11, Day 1	185	6.1 (16.25)	2.0 (1.25)	64	6.8 (15.91)	4.6 (2.07)	-2.6 [-7.38; 2.11]; 0.2761	-0.2 [-0.44; 0.13]
Cycle 12, Day 1	183	5.6 (15.58)	1.5 (1.25)	62	5.9 (14.19)	4.3 (2.10)	-2.7 [-7.51; 2.08]; 0.2673	-0.2 [-0.45; 0.13]
Cycle 13, Day 1	171	5.7 (15.36)	3.3 (1.29)	58	5.7 (14.15)	-0.1 (2.16)	3.4 [-1.52; 8.32]; 0.1760	0.2 [-0.10; 0.50]
Cycle 14, Day 1	167	6.4 (16.34)	2.4 (1.30)	57	5.8 (14.26)	1.0 (2.17)	1.4 [-3.58; 6.34]; 0.5860	0.1 [-0.22; 0.38]
Cycle 15, Day 1	165	5.7 (15.45)	3.2 (1.30)	52	6.4 (14.82)	0.8 (2.25)	2.4 [-2.73; 7.47]; 0.3628	0.1 [-0.17; 0.45]
Cycle 16, Day 1	163	6.3 (16.38)	2.5 (1.31)	53	6.3 (14.70)	5.4 (2.24)	-2.9 [-7.97; 2.19]; 0.2649	-0.2 [-0.48; 0.14]
Cycle 17, Day 1	157	5.3 (13.87)	1.0 (1.33)	54	6.2 (14.59)	2.4 (2.22)	-1.4 [-6.45; 3.70]; 0.5959	-0.1 [-0.39; 0.23]
Cycle 18, Day 1	153	6.5 (16.69)	6.5 (1.34)	52	6.4 (14.82)	5.6 (2.25)	0.9 [-4.25; 6.04]; 0.7327	0.1 [-0.26; 0.37]
Cycle 19, Day 1	148	6.1 (16.05)	1.9 (1.36)	47	7.1 (15.44)	5.5 (2.35)	-3.6 [-8.95; 1.70]; 0.1820	-0.2 [-0.55; 0.11]
Cycle 20, Day 1	139	6.7 (17.11)	2.8 (1.39)	40	6.7 (15.47)	1.9 (2.51)	0.9 [-4.71; 6.56]; 0.7471	0.1 [-0.30; 0.41]
Cycle 21, Day 1	141	6.9 (17.14)	3.9 (1.39)	39	7.7 (16.15)	-0.2 (2.54)	4.2 [-1.52; 9.82]; 0.1515	0.3 [-0.10; 0.61]

Table 1.14 Change from Baseline in EORTC QLQ-C30 over time - Diarrhea Symptom Score eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd	
Time	N	Baseline Mean (SD)	Change from BL LSMean(SE)	N	Baseline Mean (SD)	Change from BL LSMean(SE)	Difference in LSMean [95%-CI]; p-value	Hedges'g [95%-CI]
Cycle 22, Day 1	137	7.1 (17.35)	3.2 (1.40)	36	7.4 (16.16)	3.8 (2.63)	-0.6 [-6.45; 5.22]; 0.8364	-0.0 [-0.40; 0.33]
Cycle 23, Day 1	129	7.5 (17.80)	5.0 (1.44)	35	7.6 (16.34)	2.6 (2.66)	2.4 [-3.53; 8.32]; 0.4275	0.1 [-0.23; 0.52]
Cycle 24, Day 1	123	7.3 (17.36)	3.6 (1.46)	35	6.7 (15.76)	4.9 (2.66)	-1.4 [-7.33; 4.57]; 0.6493	-0.1 [-0.46; 0.29]
Cycle 25, Day 1	125	7.7 (18.03)	4.0 (1.45)	33	7.1 (16.15)	-0.5 (2.73)	4.5 [-1.55; 10.57]; 0.1443	0.3 [-0.11; 0.66]
Cycle 26, Day 1	118	7.1 (17.89)	4.5 (1.49)	32	7.3 (16.36)	2.5 (2.76)	2.0 [-4.15; 8.16]; 0.5235	0.1 [-0.27; 0.51]
Cycle 27, Day 1	107	5.9 (15.06)	2.7 (1.55)	28	8.3 (17.27)	1.9 (2.93)	0.9 [-5.64; 7.35]; 0.7962	0.1 [-0.36; 0.47]
Cycle 28, Day 1	100	6.7 (18.35)	2.8 (1.59)	27	8.6 (17.52)	3.4 (2.98)	-0.7 [-7.27; 5.96]; 0.8457	-0.0 [-0.47; 0.38]
Cycle 29, Day 1	94	7.1 (18.85)	4.1 (1.63)	22	9.1 (18.35)	3.0 (3.26)	1.1 [-6.00; 8.29]; 0.7536	0.1 [-0.39; 0.54]
Cycle 30, Day 1	81	6.6 (18.57)	1.1 (1.74)	16	8.3 (14.91)	2.6 (3.77)	-1.6 [-9.72; 6.56]; 0.7035	-0.1 [-0.64; 0.44]
Cycle 31, Day 1	58	6.9 (20.48)	0.8 (2.01)	11	9.1 (15.57)	4.4 (4.50)	-3.6 [-13.3; 6.06]; 0.4652	-0.2 [-0.88; 0.41]
Cycle 32, Day 1	36	5.6 (18.69)	8.2 (2.50)	7	9.5 (16.27)	13.6 (5.57)	-5.4 [-17.4; 6.55]; 0.3744	-0.4 [-1.17; 0.46]
Cycle 33, Day 1	27	2.5 (8.90)	3.8 (2.86)	4	16.7 (19.25)	9.0 (7.30)	-5.2 [-20.6; 10.18]; 0.5076	-0.3 [-1.39; 0.71]
Cycle 34, Day 1	14	2.4 (8.91)	7.1 (3.92)	3	11.1 (19.25)	-15.4 (8.41)	22.6 [4.38; 40.76]; 0.0150	1.5 [0.09; 2.83]
Cycle 35, Day 1	9	3.7 (11.11)	6.3 (4.86)	2	16.7 (23.57)	26.3 (10.27)	-20.0 [-42.3; 2.29]; 0.0786	-1.3 [-2.92; 0.41]
Cycle 36, Day 1	6	5.6 (13.61)	4.0 (5.94)	2	16.7 (23.57)	-7.0 (10.27)	11.0 [-12.2; 34.29]; 0.3527	0.7 [-1.00; 2.32]

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
Mixed Model Repeated Measurement for change from baseline score, with time, treatment and interaction of time and treatment as independent variables, and baseline score included as a covariate. Due to non-convergence with an unstructured covariance matrix, the model was modified to use a structured covariance matrix (compound symmetry).

Table 1.7 Change from Baseline in EORTC QLQ-C30 over time - Fatigue Symptom Score
eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd	
Time	N	Baseline Mean (SD)	Change from BL LSMean(SE)	N	Baseline Mean (SD)	Change from BL LSMean(SE)	Difference in LSMean [95%-CI]; p-value	Hedges'g [95%-CI]
Cycle 2, Day 1	271	31.6 (24.33)	6.0 (1.13)	119	28.6 (23.13)	0.6 (1.69)	5.4 [1.43; 9.41]; 0.0078	0.3 [0.07; 0.51]
Cycle 3, Day 1	254	31.1 (23.90)	3.9 (1.16)	117	28.3 (22.91)	3.1 (1.70)	0.8 [-3.24; 4.83]; 0.6993	0.0 [-0.18; 0.26]
Cycle 4, Day 1	249	30.4 (24.18)	3.3 (1.16)	106	28.4 (22.12)	2.3 (1.76)	0.9 [-3.18; 5.07]; 0.6534	0.1 [-0.18; 0.28]
Cycle 5, Day 1	245	31.0 (24.21)	3.1 (1.17)	99	28.1 (23.13)	-0.1 (1.80)	3.3 [-0.95; 7.45]; 0.1291	0.2 [-0.06; 0.41]
Cycle 6, Day 1	237	30.7 (23.73)	2.2 (1.18)	90	27.3 (22.29)	1.2 (1.85)	1.0 [-3.31; 5.29]; 0.6511	0.1 [-0.19; 0.30]
Cycle 7, Day 1	216	30.5 (23.59)	2.3 (1.21)	89	25.1 (20.00)	1.9 (1.86)	0.4 [-3.91; 4.78]; 0.8453	0.0 [-0.22; 0.27]
Cycle 8, Day 1	201	30.3 (23.14)	0.4 (1.24)	84	24.6 (19.82)	1.1 (1.89)	-0.7 [-5.10; 3.76]; 0.7671	-0.0 [-0.29; 0.22]
Cycle 9, Day 1	197	30.0 (22.86)	-0.1 (1.25)	77	24.4 (20.24)	2.2 (1.94)	-2.3 [-6.85; 2.19]; 0.3127	-0.1 [-0.40; 0.13]
Cycle 10, Day 1	193	29.6 (23.47)	0.4 (1.25)	71	25.7 (20.45)	0.6 (1.99)	-0.2 [-4.80; 4.42]; 0.9343	-0.0 [-0.28; 0.26]
Cycle 11, Day 1	185	29.3 (23.03)	1.4 (1.27)	64	24.7 (18.83)	-0.9 (2.06)	2.3 [-2.44; 7.03]; 0.3428	0.1 [-0.15; 0.42]
Cycle 12, Day 1	183	28.7 (23.39)	1.5 (1.27)	62	23.3 (19.16)	4.5 (2.08)	-3.0 [-7.77; 1.78]; 0.2193	-0.2 [-0.46; 0.11]
Cycle 13, Day 1	171	27.9 (23.29)	1.7 (1.30)	58	23.6 (20.72)	1.6 (2.13)	0.1 [-4.74; 5.03]; 0.9551	0.0 [-0.29; 0.31]
Cycle 14, Day 1	167	28.2 (23.16)	1.6 (1.31)	57	24.0 (20.98)	2.5 (2.14)	-0.9 [-5.87; 3.97]; 0.7048	-0.1 [-0.36; 0.24]
Cycle 15, Day 1	165	27.6 (22.81)	1.8 (1.31)	52	22.0 (21.16)	0.8 (2.20)	1.0 [-4.04; 6.02]; 0.7004	0.1 [-0.25; 0.37]
Cycle 16, Day 1	163	28.1 (23.30)	2.1 (1.32)	53	23.9 (21.62)	3.4 (2.19)	-1.3 [-6.32; 3.71]; 0.6092	-0.1 [-0.39; 0.23]
Cycle 17, Day 1	157	27.7 (22.67)	0.2 (1.33)	54	22.6 (19.90)	1.4 (2.18)	-1.2 [-6.23; 3.79]; 0.6330	-0.1 [-0.38; 0.24]
Cycle 18, Day 1	153	28.5 (23.14)	1.4 (1.34)	52	24.1 (20.84)	2.8 (2.21)	-1.4 [-6.44; 3.69]; 0.5950	-0.1 [-0.40; 0.23]
Cycle 19, Day 1	148	27.3 (22.83)	2.7 (1.36)	47	23.9 (21.61)	2.8 (2.28)	-0.1 [-5.30; 5.12]; 0.9729	-0.0 [-0.33; 0.32]
Cycle 20, Day 1	139	25.7 (21.77)	2.6 (1.39)	40	20.8 (20.16)	0.9 (2.42)	1.8 [-3.70; 7.23]; 0.5275	0.1 [-0.24; 0.46]
Cycle 21, Day 1	141	27.0 (22.39)	3.4 (1.38)	39	21.4 (21.69)	2.7 (2.44)	0.7 [-4.77; 6.23]; 0.7946	0.0 [-0.31; 0.40]

Table 1.7 Change from Baseline in EORTC QLQ-C30 over time - Fatigue Symptom Score
eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd	
Time	N	Baseline Mean (SD)	Change from BL LSMean(SE)	N	Baseline Mean (SD)	Change from BL LSMean(SE)	Difference in LSMean [95%-CI]; p-value	Hedges'g [95%-CI]
Cycle 22, Day 1	137	27.2 (22.26)	2.2 (1.39)	36	21.0 (21.38)	2.1 (2.51)	0.1 [-5.55; 5.73]; 0.9751	0.0 [-0.36; 0.37]
Cycle 23, Day 1	129	26.6 (21.80)	2.2 (1.42)	35	20.6 (21.58)	2.9 (2.54)	-0.7 [-6.42; 4.99]; 0.8065	-0.0 [-0.42; 0.33]
Cycle 24, Day 1	123	26.5 (21.55)	2.4 (1.44)	35	20.0 (21.86)	5.6 (2.54)	-3.1 [-8.87; 2.58]; 0.2818	-0.2 [-0.57; 0.18]
Cycle 25, Day 1	125	26.8 (21.54)	4.0 (1.43)	33	17.8 (19.83)	4.6 (2.60)	-0.6 [-6.46; 5.18]; 0.8284	-0.0 [-0.42; 0.34]
Cycle 26, Day 1	118	26.3 (21.63)	3.7 (1.46)	32	20.1 (19.44)	5.2 (2.63)	-1.5 [-7.37; 4.43]; 0.6255	-0.1 [-0.48; 0.30]
Cycle 27, Day 1	107	26.0 (21.58)	3.1 (1.51)	28	20.6 (20.22)	3.0 (2.77)	0.1 [-6.07; 6.30]; 0.9700	0.0 [-0.41; 0.42]
Cycle 28, Day 1	100	27.2 (22.30)	1.1 (1.55)	27	21.4 (20.19)	6.0 (2.81)	-4.8 [-11.1; 1.46]; 0.1322	-0.3 [-0.74; 0.11]
Cycle 29, Day 1	94	27.5 (22.03)	2.2 (1.58)	22	21.2 (20.55)	0.0 (3.05)	2.2 [-4.58; 8.89]; 0.5298	0.1 [-0.32; 0.61]
Cycle 30, Day 1	81	28.1 (22.71)	1.0 (1.67)	16	24.3 (22.67)	7.0 (3.49)	-6.0 [-13.6; 1.56]; 0.1197	-0.4 [-0.94; 0.14]
Cycle 31, Day 1	58	28.7 (23.92)	1.6 (1.90)	11	30.3 (26.34)	5.5 (4.12)	-4.0 [-12.9; 4.94]; 0.3835	-0.3 [-0.92; 0.37]
Cycle 32, Day 1	36	28.1 (20.31)	2.1 (2.32)	7	34.9 (31.05)	4.1 (5.07)	-2.0 [-12.9; 8.96]; 0.7245	-0.1 [-0.95; 0.67]
Cycle 33, Day 1	27	23.5 (21.20)	3.8 (2.63)	4	44.4 (37.41)	11.6 (6.60)	-7.7 [-21.7; 6.20]; 0.2766	-0.6 [-1.61; 0.51]
Cycle 34, Day 1	14	19.0 (13.38)	4.9 (3.56)	3	29.6 (27.96)	-2.3 (7.58)	7.2 [-9.22; 23.62]; 0.3898	0.5 [-0.75; 1.78]
Cycle 35, Day 1	9	18.5 (13.61)	7.9 (4.39)	2	44.4 (15.71)	0.8 (9.24)	7.1 [-12.9; 27.17]; 0.4869	0.5 [-1.06; 2.05]
Cycle 36, Day 1	6	25.9 (9.07)	12.5 (5.35)	2	44.4 (15.71)	0.8 (9.24)	11.7 [-9.25; 32.60]; 0.2742	0.8 [-0.91; 2.46]

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
Mixed Model Repeated Measurement for change from baseline score, with time, treatment and interaction of time and treatment as independent variables, and baseline score included as a covariate. Due to non-convergence with an unstructured covariance matrix, the model was modified to use a structured covariance matrix (compound symmetry).

Table 1.15 Change from Baseline in EORTC QLQ-C30 over time - Financial Difficulty Score
eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd	
Time	N	Baseline Mean (SD)	Change from BL LSMean(SE)	N	Baseline Mean (SD)	Change from BL LSMean(SE)	Difference in LSMean [95%-CI]; p-value	Hedges'g [95%-CI]
Cycle 2, Day 1	271	16.4 (24.82)	1.0 (1.29)	119	15.1 (25.21)	1.0 (1.93)	0.1 [-4.49; 4.61]; 0.9781	0.0 [-0.21; 0.22]
Cycle 3, Day 1	254	16.4 (25.45)	1.6 (1.32)	117	14.2 (24.49)	0.2 (1.95)	1.3 [-3.29; 5.97]; 0.5701	0.1 [-0.16; 0.28]
Cycle 4, Day 1	249	16.2 (25.06)	2.0 (1.23)	106	15.4 (25.69)	-0.2 (1.85)	2.3 [-2.11; 6.62]; 0.3113	0.1 [-0.11; 0.34]
Cycle 5, Day 1	245	16.3 (25.00)	2.4 (1.33)	99	14.1 (24.79)	-0.8 (2.04)	3.2 [-1.54; 8.03]; 0.1835	0.2 [-0.08; 0.39]
Cycle 6, Day 1	237	16.6 (25.23)	1.8 (1.33)	90	13.7 (24.43)	2.4 (2.11)	-0.6 [-5.51; 4.29]; 0.8069	-0.0 [-0.27; 0.21]
Cycle 7, Day 1	216	16.7 (25.92)	3.1 (1.37)	89	12.4 (22.12)	1.5 (2.14)	1.6 [-3.39; 6.58]; 0.5301	0.1 [-0.17; 0.33]
Cycle 8, Day 1	201	16.3 (25.41)	0.6 (1.37)	84	11.9 (21.73)	-0.2 (2.14)	0.7 [-4.28; 5.72]; 0.7778	0.0 [-0.22; 0.29]
Cycle 9, Day 1	197	15.4 (25.08)	2.0 (1.35)	77	12.6 (22.32)	2.9 (2.15)	-0.9 [-5.90; 4.10]; 0.7236	-0.0 [-0.31; 0.22]
Cycle 10, Day 1	193	15.0 (24.97)	1.3 (1.44)	71	13.1 (22.87)	-0.9 (2.31)	2.3 [-3.09; 7.59]; 0.4076	0.1 [-0.16; 0.39]
Cycle 11, Day 1	185	14.8 (24.28)	-0.2 (1.47)	64	14.6 (22.91)	0.6 (2.42)	-0.8 [-6.40; 4.70]; 0.7643	-0.0 [-0.33; 0.24]
Cycle 12, Day 1	183	14.9 (24.37)	1.6 (1.42)	62	13.4 (22.14)	-2.2 (2.39)	3.9 [-1.61; 9.31]; 0.1662	0.2 [-0.09; 0.49]
Cycle 13, Day 1	171	14.4 (23.98)	1.6 (1.41)	58	12.6 (21.47)	-2.1 (2.39)	3.6 [-1.81; 9.10]; 0.1902	0.2 [-0.10; 0.50]
Cycle 14, Day 1	167	14.4 (24.13)	0.6 (1.39)	57	12.9 (21.60)	-1.8 (2.38)	2.4 [-3.01; 7.83]; 0.3832	0.1 [-0.17; 0.43]
Cycle 15, Day 1	165	14.7 (24.24)	1.2 (1.34)	52	12.8 (22.05)	0.2 (2.36)	1.1 [-4.28; 6.41]; 0.6955	0.1 [-0.25; 0.37]
Cycle 16, Day 1	163	15.1 (24.90)	1.7 (1.37)	53	15.1 (23.17)	-2.2 (2.38)	3.9 [-1.51; 9.26]; 0.1585	0.2 [-0.09; 0.53]
Cycle 17, Day 1	157	14.6 (23.37)	2.8 (1.40)	54	13.6 (21.98)	-1.4 (2.39)	4.1 [-1.34; 9.55]; 0.1393	0.2 [-0.08; 0.54]
Cycle 18, Day 1	153	15.3 (23.57)	1.3 (1.42)	52	14.1 (22.23)	-0.0 (2.43)	1.4 [-4.17; 6.89]; 0.6299	0.1 [-0.24; 0.39]
Cycle 19, Day 1	148	14.2 (22.37)	2.0 (1.50)	47	12.1 (20.17)	-1.3 (2.59)	3.3 [-2.54; 9.22]; 0.2646	0.2 [-0.14; 0.51]
Cycle 20, Day 1	139	14.6 (23.44)	3.0 (1.51)	40	10.0 (17.21)	-3.1 (2.70)	6.1 [0.01; 12.16]; 0.0495	0.3 [-0.01; 0.70]
Cycle 21, Day 1	141	14.4 (23.34)	1.9 (1.55)	39	9.4 (17.01)	1.0 (2.89)	0.9 [-5.54; 7.32]; 0.7856	0.0 [-0.31; 0.40]

Table 1.15 Change from Baseline in EORTC QLQ-C30 over time - Financial Difficulty Score
eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd	
Time	N	Baseline Mean (SD)	Change from BL LSMean(SE)	N	Baseline Mean (SD)	Change from BL LSMean(SE)	Difference in LSMean [95%-CI]; p-value	Hedges'g [95%-CI]
Cycle 22, Day 1	137	14.8 (23.54)	0.8 (1.52)	36	9.3 (17.11)	-2.4 (2.89)	3.1 [-3.27; 9.56]; 0.3358	0.2 [-0.19; 0.54]
Cycle 23, Day 1	129	15.0 (23.56)	3.8 (1.58)	35	9.5 (17.29)	-1.4 (3.03)	5.2 [-1.48; 11.96]; 0.1261	0.3 [-0.08; 0.66]
Cycle 24, Day 1	123	14.1 (21.34)	2.5 (1.64)	35	8.6 (16.85)	2.6 (3.07)	-0.1 [-6.91; 6.77]; 0.9846	-0.0 [-0.38; 0.37]
Cycle 25, Day 1	125	14.7 (22.56)	3.2 (1.55)	33	9.1 (17.23)	0.6 (2.94)	2.6 [-3.92; 9.15]; 0.4324	0.2 [-0.23; 0.53]
Cycle 26, Day 1	118	14.4 (22.43)	4.0 (1.61)	32	8.3 (16.93)	1.9 (3.07)	2.0 [-4.78; 8.85]; 0.5580	0.1 [-0.28; 0.51]
Cycle 27, Day 1	107	15.0 (22.07)	4.3 (1.75)	28	10.7 (18.27)	-0.2 (3.34)	4.5 [-2.88; 11.92]; 0.2308	0.3 [-0.17; 0.67]
Cycle 28, Day 1	100	15.0 (23.87)	3.4 (1.77)	27	11.1 (18.49)	3.6 (3.39)	-0.3 [-7.79; 7.23]; 0.9424	-0.0 [-0.44; 0.41]
Cycle 29, Day 1	94	15.6 (24.30)	2.8 (1.82)	22	9.1 (15.19)	2.1 (3.68)	0.7 [-7.41; 8.73]; 0.8727	0.0 [-0.43; 0.50]
Cycle 30, Day 1	81	14.0 (21.64)	3.7 (1.93)	16	8.3 (14.91)	3.3 (4.12)	0.4 [-8.53; 9.38]; 0.9255	0.0 [-0.51; 0.56]
Cycle 31, Day 1	58	13.8 (21.66)	4.8 (2.28)	11	15.2 (22.92)	2.6 (5.05)	2.2 [-8.74; 13.07]; 0.6960	0.1 [-0.52; 0.77]
Cycle 32, Day 1	36	14.8 (23.16)	4.2 (2.85)	7	14.3 (26.23)	-0.8 (6.33)	5.0 [-8.65; 18.75]; 0.4680	0.3 [-0.52; 1.10]
Cycle 33, Day 1	27	16.0 (25.10)	5.4 (3.29)	4	16.7 (33.33)	6.5 (8.31)	-1.1 [-18.9; 16.71]; 0.9019	-0.1 [-1.11; 0.99]
Cycle 34, Day 1	14	11.9 (16.57)	6.1 (4.70)	3	22.2 (38.49)	-16.4 (10.87)	22.4 [-1.35; 46.19]; 0.0640	1.2 [-0.13; 2.53]
Cycle 35, Day 1	9	7.4 (14.70)	5.5 (4.75)	2	33.3 (47.14)	-3.9 (10.86)	9.3 [-14.9; 33.60]; 0.4371	0.6 [-0.97; 2.16]
Cycle 36, Day 1	6	5.6 (13.61)	9.9 (6.24)	2	33.3 (47.14)	-4.7 (13.91)	14.7 [-17.4; 46.72]; 0.3492	0.8 [-0.90; 2.48]

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
Mixed Model Repeated Measurement for change from baseline score, with time, treatment and interaction of time and treatment as independent variables, and baseline score included as a covariate. Due to non-convergence with an unstructured covariance matrix, the model was modified to use a structured covariance matrix [heterogeneous autoregressive(1)].

Table 1.1 Change from Baseline in EORTC QLQ-C30 over time - Global Health Status Score
eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd	
Time	N	Baseline Mean (SD)	Change from BL LSMean(SE)	N	Baseline Mean (SD)	Change from BL LSMean(SE)	Difference in LSMean [95%-CI]; p-value	Hedges'g [95%-CI]
Cycle 2, Day 1	271	61.7 (20.12)	-3.0 (0.95)	119	67.1 (18.05)	-2.5 (1.42)	-0.5 [-3.86; 2.86]; 0.7695	-0.0 [-0.25; 0.18]
Cycle 3, Day 1	254	62.6 (19.77)	-1.6 (0.97)	117	67.7 (17.68)	-0.2 (1.43)	-1.4 [-4.80; 2.00]; 0.4197	-0.1 [-0.31; 0.13]
Cycle 4, Day 1	249	62.4 (20.19)	-1.5 (0.98)	106	67.6 (17.79)	0.3 (1.48)	-1.8 [-5.32; 1.66]; 0.3029	-0.1 [-0.35; 0.11]
Cycle 5, Day 1	245	62.7 (20.08)	-0.4 (0.99)	99	68.5 (18.27)	-0.2 (1.52)	-0.2 [-3.78; 3.32]; 0.8991	-0.0 [-0.25; 0.22]
Cycle 6, Day 1	237	62.9 (19.86)	1.0 (1.00)	90	68.3 (17.98)	0.1 (1.56)	0.9 [-2.73; 4.56]; 0.6227	0.1 [-0.18; 0.30]
Cycle 7, Day 1	216	63.0 (20.07)	0.6 (1.02)	89	70.2 (17.31)	1.5 (1.57)	-1.0 [-4.64; 2.73]; 0.6130	-0.1 [-0.31; 0.18]
Cycle 8, Day 1	201	62.8 (19.81)	1.2 (1.05)	84	71.3 (16.28)	2.1 (1.60)	-0.9 [-4.66; 2.85]; 0.6370	-0.1 [-0.32; 0.19]
Cycle 9, Day 1	197	63.8 (20.03)	1.7 (1.05)	77	71.4 (16.41)	-2.8 (1.65)	4.5 [0.70; 8.38]; 0.0205	0.3 [0.04; 0.57]
Cycle 10, Day 1	193	64.0 (19.65)	1.8 (1.06)	71	70.3 (16.77)	0.9 (1.69)	0.8 [-3.08; 4.77]; 0.6727	0.1 [-0.21; 0.33]
Cycle 11, Day 1	185	63.9 (19.20)	2.3 (1.08)	64	69.8 (16.16)	0.3 (1.75)	2.0 [-2.05; 6.02]; 0.3349	0.1 [-0.15; 0.42]
Cycle 12, Day 1	183	64.6 (19.89)	0.9 (1.08)	62	71.1 (16.65)	-2.2 (1.77)	3.1 [-0.99; 7.15]; 0.1382	0.2 [-0.08; 0.50]
Cycle 13, Day 1	171	64.2 (19.46)	0.3 (1.10)	58	71.8 (16.80)	0.1 (1.81)	0.2 [-3.97; 4.37]; 0.9264	0.0 [-0.28; 0.31]
Cycle 14, Day 1	167	64.6 (19.03)	-0.7 (1.11)	57	71.5 (16.74)	0.2 (1.82)	-0.8 [-5.05; 3.35]; 0.6913	-0.1 [-0.36; 0.24]
Cycle 15, Day 1	165	64.2 (19.40)	0.8 (1.12)	52	71.6 (16.77)	0.6 (1.88)	0.2 [-4.08; 4.52]; 0.9200	0.0 [-0.30; 0.33]
Cycle 16, Day 1	163	64.1 (19.58)	-0.2 (1.12)	53	71.7 (17.09)	-0.1 (1.87)	-0.1 [-4.36; 4.21]; 0.9737	-0.0 [-0.31; 0.30]
Cycle 17, Day 1	157	64.5 (19.15)	3.0 (1.13)	54	71.3 (17.33)	1.2 (1.86)	1.8 [-2.48; 6.08]; 0.4099	0.1 [-0.18; 0.44]
Cycle 18, Day 1	153	64.2 (19.07)	0.1 (1.14)	52	72.3 (16.89)	-2.1 (1.88)	2.2 [-2.09; 6.57]; 0.3105	0.2 [-0.16; 0.47]
Cycle 19, Day 1	148	65.4 (18.58)	1.5 (1.16)	47	72.0 (17.06)	0.9 (1.96)	0.6 [-3.87; 5.05]; 0.7952	0.0 [-0.29; 0.37]
Cycle 20, Day 1	139	66.1 (18.45)	-0.1 (1.18)	40	73.3 (16.90)	2.0 (2.08)	-2.2 [-6.85; 2.53]; 0.3661	-0.2 [-0.51; 0.20]
Cycle 21, Day 1	141	65.2 (18.42)	0.8 (1.17)	39	73.7 (17.05)	1.2 (2.10)	-0.4 [-5.15; 4.28]; 0.8559	-0.0 [-0.39; 0.32]

Table 1.1 Change from Baseline in EORTC QLQ-C30 over time - Global Health Status Score
eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd	
Time	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**
Cycle 22, Day 1	137	64.9 (18.54)	1.2 (1.19)	36	72.9 (16.83)	-1.4 (2.16)	2.6 [-2.23; 7.45]; 0.2913	0.2 [-0.18; 0.56]
Cycle 23, Day 1	129	65.4 (18.00)	0.1 (1.21)	35	73.1 (16.05)	-0.9 (2.19)	1.0 [-3.86; 5.95]; 0.6760	0.1 [-0.30; 0.45]
Cycle 24, Day 1	123	65.6 (17.98)	1.4 (1.23)	35	74.3 (16.47)	-2.1 (2.19)	3.5 [-1.42; 8.43]; 0.1631	0.3 [-0.12; 0.63]
Cycle 25, Day 1	125	65.2 (17.71)	-0.3 (1.22)	33	74.7 (16.86)	-1.8 (2.24)	1.5 [-3.53; 6.47]; 0.5646	0.1 [-0.28; 0.49]
Cycle 26, Day 1	118	65.0 (17.69)	-0.8 (1.25)	32	73.7 (16.41)	1.0 (2.26)	-1.7 [-6.81; 3.34]; 0.5019	-0.1 [-0.52; 0.26]
Cycle 27, Day 1	107	65.7 (17.91)	-0.5 (1.29)	28	74.1 (16.87)	-2.3 (2.39)	1.8 [-3.57; 7.08]; 0.5187	0.1 [-0.28; 0.55]
Cycle 28, Day 1	100	65.1 (17.64)	0.7 (1.33)	27	73.1 (16.40)	-4.6 (2.42)	5.3 [-0.12; 10.72]; 0.0551	0.4 [-0.03; 0.83]
Cycle 29, Day 1	94	64.7 (17.69)	0.9 (1.36)	22	71.2 (16.21)	-1.8 (2.64)	2.7 [-3.11; 8.53]; 0.3611	0.2 [-0.26; 0.67]
Cycle 30, Day 1	81	64.6 (18.19)	-0.6 (1.43)	16	72.9 (17.35)	-2.4 (3.03)	1.9 [-4.70; 8.44]; 0.5773	0.1 [-0.39; 0.68]
Cycle 31, Day 1	58	65.1 (17.97)	0.1 (1.64)	11	72.0 (18.36)	-3.4 (3.58)	3.5 [-4.24; 11.22]; 0.3761	0.3 [-0.37; 0.92]
Cycle 32, Day 1	36	64.8 (17.72)	1.0 (2.01)	7	69.0 (17.82)	3.2 (4.42)	-2.3 [-11.8; 7.24]; 0.6389	-0.2 [-1.00; 0.62]
Cycle 33, Day 1	27	67.6 (17.04)	-0.6 (2.29)	4	70.8 (20.97)	-2.3 (5.76)	1.7 [-10.4; 13.89]; 0.7788	0.1 [-0.91; 1.19]
Cycle 34, Day 1	14	67.9 (13.81)	2.9 (3.10)	3	72.2 (25.46)	-3.1 (6.62)	6.0 [-8.33; 20.34]; 0.4118	0.5 [-0.77; 1.75]
Cycle 35, Day 1	9	64.8 (12.34)	0.1 (3.84)	2	58.3 (11.79)	3.7 (8.07)	-3.6 [-21.1; 13.96]; 0.6904	-0.3 [-1.82; 1.26]
Cycle 36, Day 1	6	59.7 (11.08)	-5.3 (4.67)	2	58.3 (11.79)	3.7 (8.07)	-8.9 [-27.2; 9.34]; 0.3376	-0.7 [-2.35; 0.99]

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
Mixed Model Repeated Measurement for change from baseline score, with time, treatment and interaction of time and treatment as independent variables, and baseline score included as a covariate. Due to non-convergence with an unstructured covariance matrix, the model was modified to use a structured covariance matrix (compound symmetry).

Table 1.2 Change from Baseline in EORTC QLQ-C30 over time - Physical Functioning Score
eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd	
Time	N	Baseline Mean (SD)	Change from BL LSMean(SE)	N	Baseline Mean (SD)	Change from BL LSMean(SE)	Difference in LSMean [95%-CI]; p-value	Hedges'g [95%-CI]
Cycle 2, Day 1	271	76.6 (21.98)	-2.6 (0.89)	119	82.7 (17.17)	-0.4 (1.32)	-2.2 [-5.31; 0.95]; 0.1716	-0.1 [-0.37; 0.07]
Cycle 3, Day 1	254	77.7 (21.00)	-2.6 (0.90)	117	82.7 (16.31)	-3.1 (1.33)	0.5 [-2.65; 3.67]; 0.7517	0.0 [-0.18; 0.25]
Cycle 4, Day 1	249	77.8 (21.41)	-2.1 (0.91)	106	83.0 (16.67)	-0.2 (1.36)	-1.9 [-5.16; 1.28]; 0.2380	-0.1 [-0.36; 0.09]
Cycle 5, Day 1	245	77.6 (21.26)	-1.2 (0.91)	99	83.7 (17.15)	-1.0 (1.39)	-0.2 [-3.52; 3.03]; 0.8829	-0.0 [-0.25; 0.22]
Cycle 6, Day 1	237	77.8 (21.10)	-0.9 (0.92)	90	83.6 (16.37)	-1.3 (1.43)	0.3 [-3.01; 3.67]; 0.8462	0.0 [-0.22; 0.27]
Cycle 7, Day 1	216	78.1 (21.18)	-1.1 (0.94)	89	84.9 (15.19)	-2.1 (1.43)	1.0 [-2.35; 4.39]; 0.5526	0.1 [-0.17; 0.32]
Cycle 8, Day 1	201	78.1 (21.00)	-0.9 (0.96)	84	85.5 (14.38)	-0.4 (1.45)	-0.5 [-3.95; 2.90]; 0.7627	-0.0 [-0.29; 0.22]
Cycle 9, Day 1	197	78.4 (21.21)	1.1 (0.96)	77	85.7 (14.17)	-1.6 (1.49)	2.7 [-0.82; 6.15]; 0.1340	0.2 [-0.07; 0.46]
Cycle 10, Day 1	193	78.6 (20.82)	0.2 (0.97)	71	85.1 (14.32)	-1.2 (1.52)	1.4 [-2.18; 4.92]; 0.4487	0.1 [-0.17; 0.37]
Cycle 11, Day 1	185	79.0 (20.82)	-0.1 (0.98)	64	85.5 (13.42)	-1.0 (1.57)	0.9 [-2.70; 4.56]; 0.6161	0.1 [-0.21; 0.35]
Cycle 12, Day 1	183	79.0 (21.06)	-0.6 (0.98)	62	86.6 (13.14)	-1.7 (1.58)	1.1 [-2.54; 4.78]; 0.5490	0.1 [-0.20; 0.37]
Cycle 13, Day 1	171	80.2 (20.22)	-0.8 (1.00)	58	86.3 (14.69)	-0.2 (1.62)	-0.5 [-4.26; 3.21]; 0.7830	-0.0 [-0.34; 0.26]
Cycle 14, Day 1	167	80.2 (20.22)	-1.5 (1.01)	57	86.5 (14.72)	-2.9 (1.62)	1.4 [-2.40; 5.11]; 0.4788	0.1 [-0.20; 0.41]
Cycle 15, Day 1	165	80.1 (21.16)	-0.7 (1.01)	52	87.1 (14.96)	-1.8 (1.67)	1.1 [-2.73; 4.94]; 0.5719	0.1 [-0.23; 0.40]
Cycle 16, Day 1	163	79.6 (21.19)	-1.6 (1.01)	53	85.8 (14.97)	-2.4 (1.66)	0.8 [-3.06; 4.59]; 0.6943	0.1 [-0.25; 0.37]
Cycle 17, Day 1	157	80.2 (20.77)	-0.7 (1.02)	54	86.9 (13.52)	-1.8 (1.65)	1.1 [-2.73; 4.90]; 0.5776	0.1 [-0.22; 0.39]
Cycle 18, Day 1	153	80.0 (20.93)	-1.6 (1.03)	52	86.2 (14.87)	-4.1 (1.67)	2.5 [-1.35; 6.36]; 0.2029	0.2 [-0.12; 0.51]
Cycle 19, Day 1	148	80.6 (20.70)	-1.4 (1.04)	47	85.7 (15.03)	-2.2 (1.72)	0.8 [-3.12; 4.79]; 0.6783	0.1 [-0.26; 0.40]
Cycle 20, Day 1	139	81.4 (20.82)	-2.7 (1.06)	40	88.2 (12.31)	-1.5 (1.82)	-1.1 [-5.28; 2.98]; 0.5864	-0.1 [-0.44; 0.26]
Cycle 21, Day 1	141	80.5 (20.60)	-2.9 (1.05)	39	87.5 (14.28)	-3.8 (1.83)	0.9 [-3.23; 5.07]; 0.6645	0.1 [-0.28; 0.43]

Table 1.2 Change from Baseline in EORTC QLQ-C30 over time - Physical Functioning Score
eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd	
Time	N	Baseline Mean (SD)	Change from BL LSMean(SE)	N	Baseline Mean (SD)	Change from BL LSMean(SE)	Difference in LSMean [95%-CI]; p-value	Hedges'g [95%-CI]
Cycle 22, Day 1	137	80.5 (20.24)	-1.9 (1.06)	36	86.9 (14.65)	-2.0 (1.88)	0.1 [-4.19; 4.30]; 0.9809	0.0 [-0.36; 0.37]
Cycle 23, Day 1	129	81.0 (19.43)	-2.2 (1.08)	35	86.5 (14.68)	-3.2 (1.90)	1.0 [-3.30; 5.29]; 0.6494	0.1 [-0.29; 0.46]
Cycle 24, Day 1	123	81.0 (19.47)	-2.5 (1.10)	35	87.6 (14.47)	-6.7 (1.90)	4.2 [-0.15; 8.47]; 0.0588	0.3 [-0.03; 0.72]
Cycle 25, Day 1	125	80.9 (19.40)	-2.4 (1.09)	33	89.1 (12.23)	-3.2 (1.94)	0.8 [-3.60; 5.14]; 0.7295	0.1 [-0.32; 0.45]
Cycle 26, Day 1	118	81.1 (18.66)	-3.1 (1.11)	32	88.1 (11.94)	-4.6 (1.96)	1.6 [-2.87; 5.98]; 0.4905	0.1 [-0.26; 0.52]
Cycle 27, Day 1	107	80.6 (19.93)	-3.1 (1.14)	28	88.1 (12.22)	-2.7 (2.06)	-0.3 [-4.95; 4.30]; 0.8909	-0.0 [-0.44; 0.39]
Cycle 28, Day 1	100	80.8 (20.81)	-2.3 (1.17)	27	87.7 (12.22)	-6.3 (2.09)	4.0 [-0.67; 8.72]; 0.0930	0.3 [-0.08; 0.77]
Cycle 29, Day 1	94	80.9 (20.79)	-2.7 (1.19)	22	87.9 (11.75)	-5.5 (2.26)	2.8 [-2.22; 7.79]; 0.2752	0.2 [-0.22; 0.71]
Cycle 30, Day 1	81	79.9 (19.79)	-2.9 (1.25)	16	85.8 (12.85)	-9.6 (2.57)	6.7 [1.10; 12.30]; 0.0191	0.6 [0.05; 1.14]
Cycle 31, Day 1	58	79.3 (20.43)	-4.4 (1.41)	11	81.8 (14.93)	-7.1 (3.01)	2.6 [-3.88; 9.17]; 0.4274	0.2 [-0.40; 0.89]
Cycle 32, Day 1	36	79.1 (21.68)	-3.2 (1.71)	7	81.0 (14.62)	-7.2 (3.68)	4.0 [-3.93; 12.00]; 0.3204	0.4 [-0.42; 1.20]
Cycle 33, Day 1	27	81.5 (22.75)	-5.9 (1.93)	4	80.0 (17.21)	-9.3 (4.78)	3.4 [-6.74; 13.46]; 0.5140	0.3 [-0.73; 1.38]
Cycle 34, Day 1	14	85.7 (14.05)	-6.0 (2.59)	3	82.2 (20.37)	7.0 (5.48)	-12.9 [-24.8; -1.06]; 0.0328	-1.3 [-2.61; 0.07]
Cycle 35, Day 1	9	85.2 (14.82)	-7.7 (3.18)	2	73.3 (18.86)	-13.1 (6.67)	5.5 [-9.02; 19.96]; 0.4591	0.5 [-1.03; 2.08]
Cycle 36, Day 1	6	78.9 (14.25)	-7.0 (3.87)	2	73.3 (18.86)	-9.8 (6.67)	2.8 [-12.3; 17.91]; 0.7171	0.3 [-1.35; 1.87]

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
Mixed Model Repeated Measurement for change from baseline score, with time, treatment and interaction of time and treatment as independent variables, and baseline score included as a covariate. Due to non-convergence with an unstructured covariance matrix, the model was modified to use a structured covariance matrix (compound symmetry).

Table 1.3 Change from Baseline in EORTC QLQ-C30 over time - Role Functioning Score
eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd	
Time	N	Baseline Mean (SD)	Change from BL LSMean(SE)	N	Baseline Mean (SD)	Change from BL LSMean(SE)	Difference in LSMean [95%-CI]; p-value	Hedges'g [95%-CI]
Cycle 2, Day 1	271	75.4 (27.55)	-5.7 (1.29)	119	79.3 (26.57)	-1.7 (1.93)	-4.0 [-8.55; 0.56]; 0.0859	-0.2 [-0.40; 0.03]
Cycle 3, Day 1	254	76.1 (26.64)	-5.8 (1.32)	117	79.3 (25.39)	-7.5 (1.94)	1.7 [-2.89; 6.32]; 0.4647	0.1 [-0.14; 0.30]
Cycle 4, Day 1	249	76.2 (27.09)	-4.4 (1.33)	106	79.4 (25.26)	-2.6 (2.01)	-1.8 [-6.53; 2.91]; 0.4512	-0.1 [-0.31; 0.14]
Cycle 5, Day 1	245	76.4 (26.51)	-4.8 (1.34)	99	80.0 (24.86)	-4.4 (2.05)	-0.4 [-5.22; 4.39]; 0.8662	-0.0 [-0.25; 0.21]
Cycle 6, Day 1	237	76.9 (26.18)	-4.9 (1.35)	90	79.8 (25.29)	-4.1 (2.11)	-0.7 [-5.66; 4.18]; 0.7686	-0.0 [-0.28; 0.21]
Cycle 7, Day 1	216	77.0 (26.63)	-1.3 (1.39)	89	82.4 (22.38)	-5.2 (2.12)	3.9 [-1.11; 8.83]; 0.1279	0.2 [-0.06; 0.44]
Cycle 8, Day 1	201	76.6 (26.36)	-1.7 (1.42)	84	82.9 (22.10)	-3.1 (2.16)	1.3 [-3.73; 6.41]; 0.6038	0.1 [-0.19; 0.32]
Cycle 9, Day 1	197	77.3 (25.90)	-1.4 (1.42)	77	82.0 (22.74)	-5.0 (2.22)	3.6 [-1.60; 8.74]; 0.1757	0.2 [-0.08; 0.44]
Cycle 10, Day 1	193	77.3 (25.76)	-2.1 (1.43)	71	81.0 (22.94)	-4.3 (2.28)	2.1 [-3.14; 7.41]; 0.4280	0.1 [-0.16; 0.38]
Cycle 11, Day 1	185	77.7 (25.93)	-2.3 (1.45)	64	81.8 (22.56)	-1.6 (2.35)	-0.7 [-6.11; 4.73]; 0.8026	-0.0 [-0.32; 0.25]
Cycle 12, Day 1	183	78.1 (26.07)	-2.0 (1.46)	62	83.1 (22.28)	-7.2 (2.38)	5.2 [-0.25; 10.69]; 0.0615	0.3 [-0.02; 0.56]
Cycle 13, Day 1	171	79.5 (25.50)	-4.6 (1.49)	58	83.3 (22.73)	-3.9 (2.43)	-0.7 [-6.32; 4.87]; 0.7995	-0.0 [-0.34; 0.26]
Cycle 14, Day 1	167	78.8 (25.90)	-3.8 (1.50)	57	82.5 (22.80)	-7.5 (2.45)	3.6 [-1.99; 9.27]; 0.2052	0.2 [-0.11; 0.49]
Cycle 15, Day 1	165	79.3 (26.10)	-4.5 (1.50)	52	83.7 (22.98)	-5.4 (2.53)	1.0 [-4.81; 6.72]; 0.7451	0.0 [-0.26; 0.36]
Cycle 16, Day 1	163	78.9 (26.11)	-5.0 (1.51)	53	81.8 (23.40)	-7.3 (2.51)	2.3 [-3.41; 8.08]; 0.4252	0.1 [-0.19; 0.43]
Cycle 17, Day 1	157	79.6 (25.85)	-2.1 (1.53)	54	84.0 (22.42)	-5.4 (2.49)	3.3 [-2.45; 9.02]; 0.2614	0.2 [-0.14; 0.48]
Cycle 18, Day 1	153	78.9 (25.93)	-3.6 (1.54)	52	83.7 (21.77)	-9.1 (2.53)	5.5 [-0.34; 11.26]; 0.0650	0.3 [-0.03; 0.60]
Cycle 19, Day 1	148	80.2 (25.15)	-2.7 (1.56)	47	82.6 (22.24)	-5.8 (2.62)	3.1 [-2.84; 9.11]; 0.3033	0.2 [-0.16; 0.50]
Cycle 20, Day 1	139	81.7 (24.19)	-3.6 (1.59)	40	87.1 (17.08)	-4.1 (2.77)	0.5 [-5.76; 6.78]; 0.8734	0.0 [-0.32; 0.38]
Cycle 21, Day 1	141	79.9 (25.00)	-4.2 (1.58)	39	86.3 (18.29)	-6.1 (2.80)	1.9 [-4.43; 8.17]; 0.5610	0.1 [-0.25; 0.46]

Table 1.3 Change from Baseline in EORTC QLQ-C30 over time - Role Functioning Score eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd	
Time	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**
Cycle 22, Day 1	137	79.9 (24.60)	-3.8 (1.59)	36	87.0 (18.31)	-6.0 (2.89)	2.2 [-4.26; 8.66]; 0.5046	0.1 [-0.25; 0.49]
Cycle 23, Day 1	129	81.0 (23.82)	-5.9 (1.63)	35	86.7 (18.44)	-6.7 (2.92)	0.8 [-5.76; 7.33]; 0.8133	0.0 [-0.33; 0.42]
Cycle 24, Day 1	123	81.2 (23.85)	-5.7 (1.65)	35	87.6 (18.23)	-10.1 (2.92)	4.4 [-2.20; 10.95]; 0.1918	0.2 [-0.14; 0.62]
Cycle 25, Day 1	125	80.8 (24.05)	-5.3 (1.64)	33	89.9 (15.56)	-5.6 (2.98)	0.4 [-6.31; 7.04]; 0.9156	0.0 [-0.36; 0.40]
Cycle 26, Day 1	118	80.9 (23.80)	-6.5 (1.67)	32	88.5 (16.09)	-7.9 (3.02)	1.4 [-5.37; 8.17]; 0.6850	0.1 [-0.31; 0.47]
Cycle 27, Day 1	107	80.8 (24.31)	-5.8 (1.73)	28	89.9 (14.59)	-3.0 (3.18)	-2.8 [-9.90; 4.29]; 0.4388	-0.2 [-0.57; 0.26]
Cycle 28, Day 1	100	80.3 (24.78)	-5.7 (1.77)	27	89.5 (14.73)	-11.0 (3.23)	5.3 [-1.92; 12.51]; 0.1506	0.3 [-0.13; 0.73]
Cycle 29, Day 1	94	80.3 (24.80)	-6.1 (1.81)	22	89.4 (15.04)	-7.8 (3.50)	1.7 [-6.05; 9.41]; 0.6699	0.1 [-0.37; 0.56]
Cycle 30, Day 1	81	80.2 (24.02)	-4.8 (1.92)	16	89.6 (14.75)	-15.3 (4.01)	10.6 [1.88; 19.30]; 0.0172	0.6 [0.07; 1.16]
Cycle 31, Day 1	58	79.9 (24.93)	-3.2 (2.18)	11	89.4 (15.41)	-15.7 (4.74)	12.5 [2.27; 22.72]; 0.0167	0.7 [0.09; 1.41]
Cycle 32, Day 1	36	78.7 (24.43)	-4.9 (2.66)	7	88.1 (15.85)	-13.7 (5.83)	8.9 [-3.70; 21.43]; 0.1667	0.5 [-0.27; 1.37]
Cycle 33, Day 1	27	84.6 (25.29)	-6.2 (3.03)	4	83.3 (19.25)	-16.4 (7.59)	10.2 [-5.84; 26.21]; 0.2128	0.6 [-0.43; 1.70]
Cycle 34, Day 1	14	88.1 (13.76)	-7.8 (4.10)	3	88.9 (19.25)	-0.1 (8.73)	-7.6 [-26.5; 11.26]; 0.4281	-0.5 [-1.73; 0.79]
Cycle 35, Day 1	9	88.9 (11.79)	-4.7 (5.06)	2	83.3 (23.57)	-5.4 (10.63)	0.7 [-22.3; 23.82]; 0.9501	0.0 [-1.49; 1.58]
Cycle 36, Day 1	6	83.3 (10.54)	-10.3 (6.16)	2	83.3 (23.57)	-5.4 (10.63)	-4.8 [-28.9; 19.26]; 0.6943	-0.3 [-1.89; 1.33]

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
Mixed Model Repeated Measurement for change from baseline score, with time, treatment and interaction of time and treatment as independent variables, and baseline score included as a covariate. Due to non-convergence with an unstructured covariance matrix, the model was modified to use a structured covariance matrix (compound symmetry).

Table 1.4 Change from Baseline in EORTC QLQ-C30 over time - Emotional Functioning Score
eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd	
Time	N	Baseline Mean (SD)	Change from BL LSMean(SE)	N	Baseline Mean (SD)	Change from BL LSMean(SE)	Difference in LSMean [95%-CI]; p-value	Hedges'g [95%-CI]
Cycle 2, Day 1	271	81.1 (19.69)	0.7 (0.93)	119	81.7 (16.85)	0.1 (1.40)	0.6 [-2.67; 3.92]; 0.7095	0.0 [-0.17; 0.26]
Cycle 3, Day 1	254	81.7 (19.23)	1.6 (0.95)	117	82.8 (16.58)	0.1 (1.40)	1.5 [-1.79; 4.86]; 0.3663	0.1 [-0.12; 0.32]
Cycle 4, Day 1	249	81.4 (19.81)	1.7 (0.96)	106	82.5 (16.94)	0.6 (1.45)	1.1 [-2.34; 4.47]; 0.5397	0.1 [-0.16; 0.30]
Cycle 5, Day 1	245	81.5 (19.40)	0.2 (0.96)	99	82.2 (17.07)	-0.0 (1.48)	0.2 [-3.25; 3.68]; 0.9029	0.0 [-0.22; 0.25]
Cycle 6, Day 1	237	81.6 (19.36)	0.8 (0.97)	90	83.1 (16.07)	0.5 (1.52)	0.4 [-3.18; 3.91]; 0.8405	0.0 [-0.22; 0.27]
Cycle 7, Day 1	216	81.0 (19.68)	1.5 (1.00)	89	83.8 (15.56)	2.1 (1.53)	-0.5 [-4.12; 3.04]; 0.7669	-0.0 [-0.28; 0.21]
Cycle 8, Day 1	201	81.4 (19.66)	0.5 (1.02)	84	83.8 (15.65)	0.6 (1.56)	-0.1 [-3.72; 3.57]; 0.9676	-0.0 [-0.26; 0.25]
Cycle 9, Day 1	197	81.7 (19.11)	1.2 (1.02)	77	83.9 (15.73)	-2.8 (1.60)	4.0 [0.23; 7.68]; 0.0374	0.3 [0.01; 0.54]
Cycle 10, Day 1	193	81.6 (19.50)	0.3 (1.03)	71	83.6 (14.64)	0.7 (1.64)	-0.4 [-4.18; 3.41]; 0.8414	-0.0 [-0.30; 0.24]
Cycle 11, Day 1	185	82.0 (19.11)	1.1 (1.04)	64	83.3 (14.32)	0.5 (1.69)	0.6 [-3.34; 4.46]; 0.7769	0.0 [-0.24; 0.32]
Cycle 12, Day 1	183	82.2 (19.37)	0.9 (1.05)	62	84.3 (14.32)	-2.3 (1.71)	3.2 [-0.71; 7.16]; 0.1081	0.2 [-0.06; 0.52]
Cycle 13, Day 1	171	81.8 (19.27)	-0.3 (1.07)	58	85.2 (13.43)	-1.0 (1.75)	0.7 [-3.35; 4.69]; 0.7439	0.0 [-0.25; 0.35]
Cycle 14, Day 1	167	81.4 (19.80)	0.9 (1.08)	57	84.8 (14.01)	0.1 (1.76)	0.9 [-3.19; 4.90]; 0.6784	0.1 [-0.24; 0.36]
Cycle 15, Day 1	165	81.6 (19.98)	1.6 (1.08)	52	85.3 (13.57)	-0.8 (1.81)	2.4 [-1.77; 6.51]; 0.2619	0.2 [-0.14; 0.48]
Cycle 16, Day 1	163	81.7 (19.86)	1.6 (1.08)	53	84.7 (14.22)	-0.7 (1.80)	2.2 [-1.91; 6.34]; 0.2927	0.2 [-0.15; 0.47]
Cycle 17, Day 1	157	81.6 (19.94)	2.7 (1.10)	54	85.6 (13.39)	1.2 (1.79)	1.4 [-2.69; 5.55]; 0.4957	0.1 [-0.20; 0.41]
Cycle 18, Day 1	153	81.5 (20.10)	0.6 (1.11)	52	84.6 (13.84)	-1.9 (1.82)	2.5 [-1.67; 6.66]; 0.2402	0.2 [-0.13; 0.50]
Cycle 19, Day 1	148	82.4 (19.81)	0.5 (1.12)	47	85.5 (13.51)	0.1 (1.88)	0.4 [-3.89; 4.69]; 0.8556	0.0 [-0.30; 0.36]
Cycle 20, Day 1	139	83.3 (19.26)	0.1 (1.14)	40	87.1 (12.51)	1.6 (1.99)	-1.5 [-5.99; 3.00]; 0.5153	-0.1 [-0.46; 0.24]
Cycle 21, Day 1	141	82.5 (19.37)	0.4 (1.13)	39	87.6 (12.95)	-1.7 (2.01)	2.1 [-2.38; 6.67]; 0.3525	0.2 [-0.19; 0.52]

Table 1.4 Change from Baseline in EORTC QLQ-C30 over time - Emotional Functioning Score
eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd	
Time	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**
Cycle 22, Day 1	137	82.4 (19.44)	-1.3 (1.14)	36	86.8 (12.81)	1.4 (2.07)	-2.7 [-7.30; 1.97]; 0.2589	-0.2 [-0.57; 0.17]
Cycle 23, Day 1	129	82.2 (18.97)	-0.6 (1.17)	35	86.9 (12.99)	-0.0 (2.09)	-0.6 [-5.26; 4.13]; 0.8130	-0.0 [-0.42; 0.33]
Cycle 24, Day 1	123	82.3 (18.65)	-1.0 (1.19)	35	87.9 (12.68)	-1.0 (2.09)	-0.1 [-4.77; 4.66]; 0.9819	-0.0 [-0.38; 0.37]
Cycle 25, Day 1	125	82.3 (18.74)	-1.6 (1.18)	33	88.4 (12.49)	0.4 (2.14)	-2.0 [-6.79; 2.78]; 0.4120	-0.2 [-0.54; 0.23]
Cycle 26, Day 1	118	81.6 (19.21)	-0.9 (1.20)	32	88.0 (12.15)	1.0 (2.16)	-1.8 [-6.70; 3.00]; 0.4553	-0.1 [-0.53; 0.25]
Cycle 27, Day 1	107	81.4 (19.31)	-1.7 (1.24)	28	87.8 (12.31)	0.2 (2.28)	-1.9 [-6.96; 3.20]; 0.4687	-0.1 [-0.56; 0.27]
Cycle 28, Day 1	100	82.1 (19.15)	0.7 (1.27)	27	87.3 (12.31)	-1.4 (2.31)	2.1 [-3.02; 7.31]; 0.4161	0.2 [-0.26; 0.60]
Cycle 29, Day 1	94	83.8 (17.51)	-2.4 (1.30)	22	88.3 (13.03)	-0.5 (2.51)	-1.9 [-7.43; 3.63]; 0.5007	-0.2 [-0.62; 0.31]
Cycle 30, Day 1	81	82.9 (18.16)	-0.4 (1.37)	16	85.4 (13.09)	-1.2 (2.87)	0.8 [-5.44; 7.02]; 0.8028	0.1 [-0.47; 0.60]
Cycle 31, Day 1	58	84.2 (18.45)	-1.5 (1.56)	11	84.1 (13.15)	1.7 (3.38)	-3.2 [-10.5; 4.12]; 0.3933	-0.3 [-0.91; 0.38]
Cycle 32, Day 1	36	84.3 (18.98)	-4.5 (1.90)	7	84.5 (13.11)	1.3 (4.16)	-5.9 [-14.8; 3.11]; 0.2002	-0.5 [-1.32; 0.31]
Cycle 33, Day 1	27	83.3 (19.61)	-3.2 (2.16)	4	91.7 (11.79)	-1.4 (5.41)	-1.7 [-13.1; 9.70]; 0.7679	-0.1 [-1.20; 0.90]
Cycle 34, Day 1	14	89.9 (12.73)	-3.5 (2.92)	3	97.2 (4.81)	-3.2 (6.22)	-0.2 [-13.7; 13.23]; 0.9731	-0.0 [-1.27; 1.23]
Cycle 35, Day 1	9	92.6 (11.37)	-1.0 (3.60)	2	95.8 (5.89)	4.0 (7.58)	-5.0 [-21.4; 11.45]; 0.5513	-0.4 [-1.97; 1.12]
Cycle 36, Day 1	6	90.3 (13.35)	-3.9 (4.39)	2	95.8 (5.89)	4.0 (7.58)	-7.8 [-25.0; 9.34]; 0.3719	-0.6 [-2.29; 1.03]

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
Mixed Model Repeated Measurement for change from baseline score, with time, treatment and interaction of time and treatment as independent variables, and baseline score included as a covariate. Due to non-convergence with an unstructured covariance matrix, the model was modified to use a structured covariance matrix (compound symmetry).

Table 1.5 Change from Baseline in EORTC QLQ-C30 over time - Cognitive Functioning Score
eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd	
Time	N	Baseline Mean (SD)	Change from BL LSMean(SE)	N	Baseline Mean (SD)	Change from BL LSMean(SE)	Difference in LSMean [95%-CI]; p-value	Hedges'g [95%-CI]
Cycle 2, Day 1	271	85.9 (17.77)	-0.2 (0.96)	119	87.5 (17.25)	-2.2 (1.44)	2.0 [-1.40; 5.40]; 0.2491	0.1 [-0.09; 0.34]
Cycle 3, Day 1	254	86.2 (16.97)	0.1 (0.98)	117	88.0 (16.64)	-1.3 (1.45)	1.3 [-2.09; 4.78]; 0.4435	0.1 [-0.13; 0.30]
Cycle 4, Day 1	249	86.3 (17.01)	-1.5 (0.99)	106	87.6 (17.83)	-0.9 (1.50)	-0.6 [-4.16; 2.87]; 0.7202	-0.0 [-0.27; 0.19]
Cycle 5, Day 1	245	86.3 (16.74)	-2.2 (0.99)	99	87.5 (17.87)	-3.0 (1.53)	0.8 [-2.82; 4.33]; 0.6787	0.0 [-0.18; 0.28]
Cycle 6, Day 1	237	86.2 (16.87)	-2.7 (1.00)	90	88.5 (15.73)	-1.5 (1.57)	-1.2 [-4.85; 2.47]; 0.5223	-0.1 [-0.32; 0.16]
Cycle 7, Day 1	216	86.0 (17.49)	-1.1 (1.03)	89	88.6 (15.81)	-0.2 (1.58)	-0.9 [-4.57; 2.83]; 0.6457	-0.1 [-0.30; 0.19]
Cycle 8, Day 1	201	86.0 (17.12)	-3.4 (1.05)	84	88.7 (15.77)	-1.2 (1.61)	-2.2 [-5.99; 1.54]; 0.2471	-0.1 [-0.40; 0.11]
Cycle 9, Day 1	197	86.2 (16.67)	-1.4 (1.06)	77	88.7 (15.16)	-2.5 (1.65)	1.2 [-2.69; 4.99]; 0.5572	0.1 [-0.19; 0.34]
Cycle 10, Day 1	193	86.4 (16.95)	-2.1 (1.06)	71	88.0 (15.48)	-0.2 (1.69)	-1.9 [-5.86; 1.97]; 0.3299	-0.1 [-0.40; 0.14]
Cycle 11, Day 1	185	86.9 (16.27)	-2.5 (1.08)	64	87.8 (14.32)	-1.1 (1.75)	-1.4 [-5.43; 2.61]; 0.4921	-0.1 [-0.38; 0.19]
Cycle 12, Day 1	183	87.3 (16.27)	-2.7 (1.08)	62	89.0 (13.48)	-3.1 (1.77)	0.4 [-3.70; 4.42]; 0.8618	0.0 [-0.26; 0.31]
Cycle 13, Day 1	171	86.8 (16.69)	-2.0 (1.10)	58	88.8 (13.39)	-4.8 (1.80)	2.8 [-1.32; 6.98]; 0.1816	0.2 [-0.10; 0.50]
Cycle 14, Day 1	167	87.3 (16.59)	-2.5 (1.11)	57	88.9 (13.49)	-2.9 (1.82)	0.5 [-3.70; 4.65]; 0.8228	0.0 [-0.27; 0.33]
Cycle 15, Day 1	165	86.8 (16.92)	-2.7 (1.11)	52	88.8 (13.50)	-2.8 (1.87)	0.1 [-4.18; 4.36]; 0.9658	0.0 [-0.31; 0.32]
Cycle 16, Day 1	163	86.5 (16.93)	-2.7 (1.12)	53	88.7 (13.39)	-4.2 (1.86)	1.4 [-2.83; 5.69]; 0.5103	0.1 [-0.21; 0.41]
Cycle 17, Day 1	157	86.7 (16.53)	-2.6 (1.13)	54	89.2 (13.41)	-3.6 (1.85)	1.0 [-3.23; 5.27]; 0.6378	0.1 [-0.24; 0.38]
Cycle 18, Day 1	153	86.7 (16.71)	-3.1 (1.14)	52	89.1 (13.15)	-2.9 (1.87)	-0.2 [-4.49; 4.10]; 0.9287	-0.0 [-0.33; 0.30]
Cycle 19, Day 1	148	87.3 (16.54)	-3.6 (1.15)	47	89.4 (12.73)	-2.4 (1.94)	-1.3 [-5.70; 3.14]; 0.5714	-0.1 [-0.42; 0.24]
Cycle 20, Day 1	139	88.1 (16.08)	-5.3 (1.17)	40	90.0 (11.20)	-2.0 (2.05)	-3.3 [-7.96; 1.31]; 0.1594	-0.2 [-0.60; 0.11]
Cycle 21, Day 1	141	87.7 (15.51)	-3.7 (1.17)	39	90.2 (11.29)	-4.0 (2.07)	0.2 [-4.43; 4.90]; 0.9217	0.0 [-0.34; 0.37]

Table 1.5 Change from Baseline in EORTC QLQ-C30 over time - Cognitive Functioning Score
eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd	
Time	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**
Cycle 22, Day 1	137	87.7 (15.69)	-4.3 (1.18)	36	89.8 (11.46)	-4.1 (2.13)	-0.2 [-4.96; 4.60]; 0.9417	-0.0 [-0.38; 0.35]
Cycle 23, Day 1	129	87.3 (15.84)	-5.0 (1.20)	35	89.5 (11.49)	-1.8 (2.15)	-3.2 [-7.99; 1.68]; 0.2010	-0.2 [-0.61; 0.14]
Cycle 24, Day 1	123	87.4 (15.29)	-4.5 (1.22)	35	90.5 (10.91)	-5.0 (2.15)	0.4 [-4.44; 5.28]; 0.8654	0.0 [-0.34; 0.41]
Cycle 25, Day 1	125	87.5 (15.21)	-4.9 (1.22)	33	90.4 (11.05)	-3.2 (2.20)	-1.7 [-6.64; 3.22]; 0.4956	-0.1 [-0.51; 0.26]
Cycle 26, Day 1	118	87.6 (15.59)	-5.9 (1.24)	32	90.6 (11.15)	-5.7 (2.23)	-0.2 [-5.20; 4.79]; 0.9352	-0.0 [-0.41; 0.38]
Cycle 27, Day 1	107	88.2 (15.19)	-6.1 (1.28)	28	89.3 (11.31)	-1.0 (2.34)	-5.1 [-10.4; 0.12]; 0.0557	-0.4 [-0.81; 0.03]
Cycle 28, Day 1	100	87.7 (15.65)	-3.2 (1.31)	27	88.9 (11.32)	-3.0 (2.38)	-0.3 [-5.59; 5.06]; 0.9221	-0.0 [-0.45; 0.40]
Cycle 29, Day 1	94	88.5 (15.46)	-4.7 (1.34)	22	89.4 (12.11)	-4.2 (2.58)	-0.5 [-6.22; 5.18]; 0.8572	-0.0 [-0.50; 0.42]
Cycle 30, Day 1	81	89.1 (14.94)	-5.4 (1.41)	16	87.5 (12.91)	-3.1 (2.95)	-2.3 [-8.75; 4.08]; 0.4757	-0.2 [-0.72; 0.35]
Cycle 31, Day 1	58	88.8 (15.73)	-5.9 (1.61)	11	84.8 (11.68)	-6.6 (3.48)	0.8 [-6.76; 8.28]; 0.8426	0.1 [-0.58; 0.71]
Cycle 32, Day 1	36	89.4 (15.51)	-5.3 (1.96)	7	85.7 (11.50)	-3.5 (4.28)	-1.9 [-11.1; 7.36]; 0.6915	-0.2 [-0.97; 0.65]
Cycle 33, Day 1	27	91.4 (13.37)	-9.4 (2.22)	4	83.3 (13.61)	-9.9 (5.57)	0.5 [-11.2; 12.26]; 0.9320	0.0 [-1.01; 1.09]
Cycle 34, Day 1	14	92.9 (10.77)	-5.5 (3.00)	3	83.3 (16.67)	2.1 (6.39)	-7.6 [-21.5; 6.23]; 0.2807	-0.6 [-1.92; 0.63]
Cycle 35, Day 1	9	94.4 (8.33)	-8.0 (3.71)	2	75.0 (11.79)	-12.5 (7.79)	4.4 [-12.5; 21.34]; 0.6082	0.4 [-1.18; 1.91]
Cycle 36, Day 1	6	94.4 (8.61)	-13.1 (4.51)	2	75.0 (11.79)	-4.1 (7.79)	-9.0 [-26.7; 8.64]; 0.3171	-0.7 [-2.38; 0.96]

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
Mixed Model Repeated Measurement for change from baseline score, with time, treatment and interaction of time and treatment as independent variables, and baseline score included as a covariate. Due to non-convergence with an unstructured covariance matrix, the model was modified to use a structured covariance matrix (compound symmetry).

Table 1.6 Change from Baseline in EORTC QLQ-C30 over time - Social Functioning Score
eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd	
Time	N	Baseline Mean (SD)	Change from BL LSMean(SE)	N	Baseline Mean (SD)	Change from BL LSMean(SE)	Difference in LSMean [95%-CI]; p-value	Hedges'g [95%-CI]
Cycle 2, Day 1	271	77.8 (26.76)	-5.4 (1.22)	119	83.8 (23.01)	-6.0 (1.82)	0.6 [-3.68; 4.91]; 0.7784	0.0 [-0.18; 0.25]
Cycle 3, Day 1	254	78.9 (26.04)	-4.4 (1.24)	117	83.0 (24.17)	-4.2 (1.83)	-0.2 [-4.50; 4.19]; 0.9440	-0.0 [-0.23; 0.21]
Cycle 4, Day 1	249	78.8 (26.13)	-3.7 (1.25)	106	83.3 (23.68)	-2.7 (1.89)	-1.0 [-5.43; 3.48]; 0.6663	-0.0 [-0.28; 0.18]
Cycle 5, Day 1	245	78.9 (26.22)	-3.9 (1.26)	99	84.8 (22.47)	-3.7 (1.94)	-0.2 [-4.69; 4.39]; 0.9470	-0.0 [-0.24; 0.23]
Cycle 6, Day 1	237	79.7 (25.49)	-4.4 (1.27)	90	85.2 (20.97)	-1.6 (2.00)	-2.8 [-7.44; 1.86]; 0.2399	-0.1 [-0.39; 0.10]
Cycle 7, Day 1	216	79.2 (26.27)	-3.9 (1.31)	89	86.9 (19.05)	-5.3 (2.01)	1.4 [-3.32; 6.09]; 0.5642	0.1 [-0.17; 0.32]
Cycle 8, Day 1	201	80.5 (25.61)	-2.5 (1.34)	84	87.7 (18.32)	-2.8 (2.05)	0.3 [-4.48; 5.12]; 0.8955	0.0 [-0.24; 0.27]
Cycle 9, Day 1	197	80.5 (25.01)	-2.9 (1.35)	77	87.2 (18.32)	-4.1 (2.11)	1.1 [-3.77; 6.05]; 0.6486	0.1 [-0.20; 0.32]
Cycle 10, Day 1	193	80.7 (25.67)	-3.3 (1.36)	71	86.6 (18.61)	-2.8 (2.16)	-0.5 [-5.48; 4.55]; 0.8552	-0.0 [-0.30; 0.25]
Cycle 11, Day 1	185	81.3 (24.58)	-2.4 (1.38)	64	85.9 (19.07)	-3.6 (2.24)	1.1 [-4.02; 6.30]; 0.6652	0.1 [-0.22; 0.35]
Cycle 12, Day 1	183	81.4 (25.15)	-2.4 (1.38)	62	86.6 (18.56)	-1.2 (2.27)	-1.3 [-6.48; 3.94]; 0.6335	-0.1 [-0.36; 0.22]
Cycle 13, Day 1	171	81.6 (24.46)	-4.7 (1.41)	58	88.5 (16.87)	-5.9 (2.32)	1.2 [-4.08; 6.58]; 0.6462	0.1 [-0.23; 0.37]
Cycle 14, Day 1	167	81.5 (24.06)	-4.6 (1.42)	57	88.0 (17.47)	-2.9 (2.34)	-1.6 [-7.01; 3.72]; 0.5476	-0.1 [-0.39; 0.21]
Cycle 15, Day 1	165	81.4 (24.58)	-5.1 (1.43)	52	88.5 (17.00)	-4.3 (2.41)	-0.8 [-6.27; 4.73]; 0.7836	-0.0 [-0.35; 0.27]
Cycle 16, Day 1	163	81.5 (24.71)	-3.6 (1.43)	53	87.1 (18.09)	-3.2 (2.40)	-0.4 [-5.92; 5.04]; 0.8741	-0.0 [-0.33; 0.29]
Cycle 17, Day 1	157	82.0 (24.31)	-3.3 (1.45)	54	88.9 (17.13)	-7.3 (2.38)	4.0 [-1.51; 9.44]; 0.1555	0.2 [-0.09; 0.53]
Cycle 18, Day 1	153	81.8 (24.21)	-3.1 (1.46)	52	87.8 (17.50)	-6.0 (2.41)	2.8 [-2.70; 8.37]; 0.3153	0.2 [-0.16; 0.47]
Cycle 19, Day 1	148	82.8 (23.20)	-4.9 (1.48)	47	88.3 (16.99)	-6.6 (2.50)	1.7 [-3.96; 7.45]; 0.5492	0.1 [-0.23; 0.43]
Cycle 20, Day 1	139	83.6 (22.70)	-3.8 (1.51)	40	92.9 (12.45)	-2.6 (2.66)	-1.2 [-7.24; 4.76]; 0.6845	-0.1 [-0.42; 0.28]
Cycle 21, Day 1	141	83.0 (22.84)	-4.7 (1.50)	39	91.9 (13.17)	-3.8 (2.68)	-0.9 [-6.99; 5.09]; 0.7580	-0.1 [-0.41; 0.30]

Table 1.6 Change from Baseline in EORTC QLQ-C30 over time - Social Functioning Score
eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd	
Time	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**
Cycle 22, Day 1	137	83.0 (22.64)	-4.3 (1.52)	36	92.6 (12.88)	-8.6 (2.77)	4.3 [-1.89; 10.50]; 0.1732	0.2 [-0.12; 0.61]
Cycle 23, Day 1	129	82.4 (23.04)	-4.8 (1.55)	35	92.4 (13.00)	-8.4 (2.80)	3.5 [-2.74; 9.82]; 0.2687	0.2 [-0.17; 0.58]
Cycle 24, Day 1	123	83.1 (21.76)	-6.1 (1.58)	35	93.3 (12.26)	-12.9 (2.80)	6.8 [0.48; 13.08]; 0.0350	0.4 [0.01; 0.77]
Cycle 25, Day 1	125	82.8 (22.09)	-6.8 (1.57)	33	93.9 (11.65)	-7.7 (2.86)	0.9 [-5.51; 7.30]; 0.7832	0.1 [-0.33; 0.44]
Cycle 26, Day 1	118	83.5 (21.18)	-6.3 (1.60)	32	93.8 (11.79)	-9.0 (2.90)	2.7 [-3.80; 9.19]; 0.4151	0.2 [-0.23; 0.55]
Cycle 27, Day 1	107	83.3 (22.31)	-7.2 (1.66)	28	92.9 (12.36)	-4.2 (3.06)	-3.0 [-9.78; 3.87]; 0.3963	-0.2 [-0.59; 0.24]
Cycle 28, Day 1	100	83.3 (23.09)	-4.0 (1.70)	27	92.6 (12.52)	-11.3 (3.10)	7.3 [0.36; 14.24]; 0.0394	0.4 [0.00; 0.86]
Cycle 29, Day 1	94	83.3 (23.57)	-5.2 (1.74)	22	92.4 (13.34)	-10.1 (3.38)	4.9 [-2.51; 12.39]; 0.1935	0.3 [-0.17; 0.76]
Cycle 30, Day 1	81	83.7 (23.42)	-5.5 (1.84)	16	90.6 (14.87)	-13.0 (3.88)	7.5 [-0.96; 15.87]; 0.0825	0.5 [-0.09; 0.99]
Cycle 31, Day 1	58	82.8 (24.97)	-6.8 (2.10)	11	93.9 (11.24)	-13.4 (4.59)	6.6 [-3.35; 16.46]; 0.1944	0.4 [-0.24; 1.06]
Cycle 32, Day 1	36	80.1 (27.26)	-4.0 (2.58)	7	95.2 (8.13)	-15.1 (5.66)	11.2 [-1.02; 23.37]; 0.0725	0.7 [-0.11; 1.54]
Cycle 33, Day 1	27	80.9 (29.49)	-6.6 (2.93)	4	95.8 (8.33)	-12.2 (7.39)	5.7 [-9.90; 21.26]; 0.4748	0.4 [-0.69; 1.42]
Cycle 34, Day 1	14	86.9 (16.25)	-6.8 (3.98)	3	94.4 (9.62)	-2.7 (8.49)	-4.0 [-22.4; 14.34]; 0.6664	-0.3 [-1.51; 0.99]
Cycle 35, Day 1	9	87.0 (16.20)	-5.5 (4.92)	2	91.7 (11.79)	-7.5 (10.36)	2.0 [-20.4; 24.51]; 0.8595	0.1 [-1.41; 1.66]
Cycle 36, Day 1	6	88.9 (17.21)	1.2 (5.99)	2	91.7 (11.79)	0.8 (10.36)	0.4 [-23.1; 23.81]; 0.9766	0.0 [-1.58; 1.62]

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
Mixed Model Repeated Measurement for change from baseline score, with time, treatment and interaction of time and treatment as independent variables, and baseline score included as a covariate. Due to non-convergence with an unstructured covariance matrix, the model was modified to use a structured covariance matrix (compound symmetry).

Table 4.10 EORTC-QLQ C30 Dyspnoea Symptom: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EORTC	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Age									0.0184
<= 75	257	171 (66.5%)	3.8 [2.8, 5.6]	112	72 (64.3%)	3.8 [2.2, 6.6]	0.92 [0.70, 1.22]	0.5583	
> 75	24	14 (58.3%)	4.7 [1.9, NA]	16	14 (87.5%)	1.9 [1.0, 3.7]	0.37 [0.17, 0.80]	0.0068	
Sex									0.4380
Male	161	107 (66.5%)	3.8 [2.8, 5.6]	78	49 (62.8%)	3.8 [2.8, 5.4]	0.91 [0.65, 1.28]	0.5667	
Female	120	78 (65.0%)	3.8 [2.8, 7.0]	50	37 (74.0%)	2.2 [1.9, 5.7]	0.73 [0.49, 1.08]	0.1010	
Race									0.8779
White	220	144 (65.5%)	4.7 [3.8, 6.6]	104	68 (65.4%)	3.7 [2.1, 5.2]	0.81 [0.60, 1.08]	0.1294	
Non-White	61	41 (67.2%)	1.9 [1.8, 3.1]	24	18 (75.0%)	2.9 [1.0, 7.5]	0.89 [0.51, 1.55]	0.6696	
Geographic region									0.0045
Europe	182	116 (63.7%)	5.6 [3.8, 9.8]	84	51 (60.7%)	4.7 [2.8, 7.5]	0.88 [0.63, 1.22]	0.4178	
Asia Pacific	81	59 (72.8%)	1.9 [1.9, 2.8]	34	25 (73.5%)	1.9 [1.0, 5.0]	0.92 [0.58, 1.47]	0.7169	
North America	18	10 (55.6%)	9.4 [1.9, NA]	10	10 (100.0%)	1.5 [0.9, 2.2]	0.25 [0.10, 0.64]	0.0014	
ECOG performance status									0.9691
0-1	268	176 (65.7%)	3.8 [2.8, 5.6]	125	86 (68.8%)	3.1 [1.9, 5.0]	0.82 [0.63, 1.06]	0.1163	
2	12	8 (66.7%)	4.7 [1.9, 22.4]	3	0 (0.0%)	NA [NA, NA]	NA [NA, NA]	0.2931	
Prior bortezomib or ixazomib exposure									0.2524
Yes	259	167 (64.5%)	4.0 [2.9, 6.6]	113	74 (65.5%)	3.1 [2.1, 5.4]	0.81 [0.62, 1.07]	0.1276	
No	22	18 (81.8%)	1.9 [1.0, 3.8]	15	12 (80.0%)	4.7 [1.0, 7.5]	1.36 [0.65, 2.87]	0.3799	

Table 4.10 EORTC-QLQ C30 Dyspnoea Symptom: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EORTC	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Refractory to bortezomib									0.8832
Yes	89	48 (53.9%)	5.6 [2.8, 15.9]	48	28 (58.3%)	3.8 [1.9, 25.8]	0.83 [0.52, 1.33]	0.4157	
No	192	137 (71.4%)	3.1 [2.8, 4.7]	80	58 (72.5%)	3.1 [2.1, 5.0]	0.82 [0.60, 1.12]	0.1915	
Prior lenalidomide exposure									0.7486
Yes	112	70 (62.5%)	3.8 [2.8, 11.2]	61	38 (62.3%)	2.9 [1.9, 6.6]	0.80 [0.53, 1.19]	0.2503	
No	169	115 (68.0%)	3.8 [2.8, 5.6]	67	48 (71.6%)	3.7 [1.9, 5.4]	0.85 [0.61, 1.20]	0.3360	
Refractory to lenalidomide									0.6336
Yes	89	53 (59.6%)	5.6 [2.8, 17.0]	46	27 (58.7%)	2.9 [1.9, 6.6]	0.78 [0.48, 1.24]	0.2766	
No	192	132 (68.8%)	3.8 [2.8, 4.7]	82	59 (72.0%)	3.8 [1.9, 5.2]	0.86 [0.63, 1.17]	0.3228	
Prior IMiD exposure									0.3505
Yes	186	124 (66.7%)	2.8 [2.0, 4.0]	90	60 (66.7%)	3.8 [1.9, 5.6]	0.93 [0.68, 1.26]	0.6145	
No	95	61 (64.2%)	6.6 [3.8, 12.4]	38	26 (68.4%)	3.1 [1.9, 9.4]	0.69 [0.43, 1.09]	0.1009	
Refractory to IMiD									0.9487
Yes	117	73 (62.4%)	4.0 [2.8, 11.2]	54	32 (59.3%)	2.9 [1.9, 6.6]	0.83 [0.55, 1.27]	0.3789	
No	164	112 (68.3%)	3.8 [2.8, 5.6]	74	54 (73.0%)	3.8 [1.9, 5.4]	0.83 [0.60, 1.16]	0.2569	
International Staging System (ISS)									0.1587
Stage I or II	229	154 (67.2%)	3.8 [2.8, 4.7]	107	79 (73.8%)	2.9 [1.9, 3.8]	0.79 [0.60, 1.03]	0.0726	
Stage III	51	30 (58.8%)	8.4 [2.9, 18.9]	21	7 (33.3%)	19.3 [1.9, 19.3]	1.33 [0.58, 3.05]	0.5010	

Table 4.10 EORTC-QLQ C30 Dyspnoea Symptom: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EORTC	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Prior proteasome inhibitor exposure									0.2158
Yes	260	168 (64.6%)	4.0 [2.9, 5.6]	114	75 (65.8%)	2.9 [1.9, 5.4]	0.81 [0.62, 1.06]	0.1132	
No	21	17 (81.0%)	1.9 [1.0, 3.8]	14	11 (78.6%)	4.7 [1.0, 7.5]	1.46 [0.67, 3.15]	0.3051	
Number of prior lines of therapy									0.2747
1	130	95 (73.1%)	2.9 [2.8, 4.7]	57	47 (82.5%)	3.1 [1.9, 4.7]	0.69 [0.48, 0.98]	0.0288	
>= 2	151	90 (59.6%)	4.7 [2.9, 9.6]	71	39 (54.9%)	3.8 [1.9, 21.0]	0.97 [0.67, 1.41]	0.8679	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
[a]From Kaplan–Meier estimate
[b]HR: hazard ratio
NA denotes that the median time (and 95% CI) were not estimable

Table 4.11 EORTC-QLQ C30 Insomnia Symptom: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EORTC	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Age									0.2273
<= 75	257	157 (61.1%)	4.8 [3.7, 7.5]	112	68 (60.7%)	3.8 [2.8, 7.5]	0.89 [0.67, 1.18]	0.3931	
> 75	24	15 (62.5%)	5.6 [2.8, 20.6]	16	11 (68.8%)	2.0 [1.0, 10.0]	0.49 [0.22, 1.10]	0.0695	
Sex									0.2486
Male	161	105 (65.2%)	3.8 [2.8, 7.5]	78	47 (60.3%)	4.7 [2.8, 11.4]	0.94 [0.66, 1.33]	0.7054	
Female	120	67 (55.8%)	6.6 [3.3, 12.2]	50	32 (64.0%)	3.8 [1.9, 5.6]	0.70 [0.46, 1.08]	0.0924	
Race									0.3926
White	220	131 (59.5%)	5.6 [3.7, 9.6]	104	62 (59.6%)	4.2 [2.8, 8.2]	0.88 [0.65, 1.19]	0.3741	
Non-White	61	41 (67.2%)	4.0 [2.8, 7.5]	24	17 (70.8%)	1.9 [1.0, 6.6]	0.66 [0.37, 1.17]	0.1348	
Geographic region									0.7211
Europe	182	102 (56.0%)	6.6 [3.8, 12.2]	84	53 (63.1%)	3.8 [2.8, 6.1]	0.70 [0.50, 0.98]	0.0310	
Asia Pacific	81	56 (69.1%)	3.7 [1.9, 6.5]	34	20 (58.8%)	3.8 [1.9, 19.2]	1.06 [0.64, 1.78]	0.8007	
North America	18	14 (77.8%)	2.4 [1.0, 7.7]	10	6 (60.0%)	6.8 [1.0, NA]	1.33 [0.51, 3.51]	0.5446	
ECOG performance status									0.7251
0-1	268	166 (61.9%)	4.7 [3.7, 7.5]	125	78 (62.4%)	3.8 [2.8, 6.6]	0.85 [0.65, 1.12]	0.2281	
2	12	5 (41.7%)	7.5 [1.0, NA]	3	1 (33.3%)	NA [0.9, NA]	0.33 [0.03, 3.77]	0.3487	
Prior bortezomib or ixazomib exposure									0.4194
Yes	259	157 (60.6%)	5.6 [3.8, 7.7]	113	70 (61.9%)	3.8 [2.8, 7.5]	0.81 [0.61, 1.08]	0.1380	
No	22	15 (68.2%)	2.8 [1.0, 7.5]	15	9 (60.0%)	4.2 [1.0, 19.2]	1.10 [0.48, 2.55]	0.8118	

Table 4.11 EORTC-QLQ C30 Insomnia Symptom: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EORTC	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	N	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Refractory to bortezomib									0.5481
Yes	89	46 (51.7%)	8.4 [3.8, 20.6]	48	27 (56.3%)	6.6 [1.9, 12.1]	0.73 [0.45, 1.18]	0.1861	
No	192	126 (65.6%)	3.8 [2.8, 6.5]	80	52 (65.0%)	3.8 [2.3, 5.6]	0.88 [0.64, 1.22]	0.4149	
Prior lenalidomide exposure									0.6769
Yes	112	61 (54.5%)	7.7 [3.7, 21.3]	61	32 (52.5%)	6.1 [2.8, 18.8]	0.87 [0.57, 1.35]	0.5297	
No	169	111 (65.7%)	3.8 [2.8, 6.6]	67	47 (70.1%)	3.1 [1.9, 4.7]	0.77 [0.55, 1.09]	0.1261	
Refractory to lenalidomide									0.7580
Yes	89	47 (52.8%)	11.9 [4.7, NA]	46	22 (47.8%)	12.1 [2.3, NA]	0.89 [0.53, 1.49]	0.6541	
No	192	125 (65.1%)	3.8 [2.8, 6.6]	82	57 (69.5%)	3.8 [1.9, 4.7]	0.80 [0.59, 1.10]	0.1495	
Prior IMiD exposure									0.7284
Yes	186	111 (59.7%)	4.0 [3.1, 7.5]	90	56 (62.2%)	3.8 [2.2, 6.1]	0.83 [0.60, 1.14]	0.2323	
No	95	61 (64.2%)	6.6 [3.7, 10.9]	38	23 (60.5%)	4.2 [2.0, 15.9]	0.87 [0.54, 1.41]	0.5609	
Refractory to IMiD									0.2949
Yes	117	67 (57.3%)	4.8 [3.3, 19.6]	54	27 (50.0%)	6.6 [2.8, NA]	1.03 [0.66, 1.61]	0.9005	
No	164	105 (64.0%)	4.7 [2.9, 7.5]	74	52 (70.3%)	3.8 [1.9, 4.7]	0.73 [0.52, 1.02]	0.0544	
International Staging System (ISS)									0.1318
Stage I or II	229	145 (63.3%)	4.7 [3.7, 7.5]	107	67 (62.6%)	4.2 [2.8, 8.2]	0.90 [0.67, 1.21]	0.4695	
Stage III	51	26 (51.0%)	8.4 [3.1, NA]	21	12 (57.1%)	2.0 [1.9, NA]	0.53 [0.25, 1.10]	0.0706	

Table 4.11 EORTC-QLQ C30 Insomnia Symptom: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EORTC	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Prior proteasome inhibitor exposure									0.6909
Yes	260	158 (60.8%)	5.6 [3.8, 7.7]	114	70 (61.4%)	3.8 [2.8, 7.5]	0.83 [0.62, 1.10]	0.1788	
No	21	14 (66.7%)	2.8 [1.6, 25.7]	14	9 (64.3%)	3.8 [1.0, 19.2]	0.91 [0.39, 2.14]	0.8231	
Number of prior lines of therapy									0.9629
1	130	87 (66.9%)	3.7 [2.4, 5.9]	57	39 (68.4%)	3.8 [1.9, 4.7]	0.84 [0.58, 1.23]	0.3522	
>= 2	151	85 (56.3%)	7.5 [4.7, 11.9]	71	40 (56.3%)	6.1 [2.8, 15.9]	0.83 [0.57, 1.21]	0.3193	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
[a]From Kaplan–Meier estimate
[b]HR: hazard ratio
NA denotes that the median time (and 95% CI) were not estimable

Table 4.12 EORTC-QLQ C30 Appetite Loss Symptom: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EORTC	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Age									0.9519
<= 75	257	143 (55.6%)	10.3 [6.6, 13.3]	112	52 (46.4%)	14.6 [4.7, NA]	1.07 [0.78, 1.48]	0.6506	
> 75	24	18 (75.0%)	3.8 [1.9, 5.6]	16	10 (62.5%)	5.2 [1.9, 6.6]	1.09 [0.50, 2.38]	0.8315	
Sex									0.6619
Male	161	94 (58.4%)	10.3 [6.6, 12.3]	78	36 (46.2%)	6.6 [4.7, NA]	1.10 [0.74, 1.61]	0.6369	
Female	120	67 (55.8%)	6.6 [4.7, 16.8]	50	26 (52.0%)	13.1 [3.1, 20.1]	0.98 [0.62, 1.54]	0.9170	
Race									0.2056
White	220	121 (55.0%)	10.9 [7.6, 13.3]	104	51 (49.0%)	6.6 [4.2, 18.5]	0.94 [0.67, 1.30]	0.6945	
Non-White	61	40 (65.6%)	3.8 [1.9, 7.0]	24	11 (45.8%)	10.6 [3.3, NA]	1.57 [0.81, 3.07]	0.1698	
Geographic region									0.4949
Europe	182	105 (57.7%)	9.4 [5.6, 12.2]	84	40 (47.6%)	6.6 [4.0, NA]	1.06 [0.74, 1.53]	0.7391	
Asia Pacific	81	46 (56.8%)	5.6 [3.8, 25.0]	34	18 (52.9%)	13.1 [3.3, 20.1]	0.99 [0.57, 1.71]	0.9671	
North America	18	10 (55.6%)	18.7 [4.7, NA]	10	4 (40.0%)	NA [1.9, NA]	0.95 [0.28, 3.22]	0.9389	
ECOG performance status									0.9750
0-1	268	155 (57.8%)	9.3 [5.6, 12.2]	125	62 (49.6%)	6.6 [4.7, 18.5]	1.05 [0.78, 1.42]	0.7227	
2	12	6 (50.0%)	14.0 [1.9, NA]	3	0 (0.0%)	NA [NA, NA]	NA [NA, NA]	0.3483	
Prior bortezomib or ixazomib exposure									0.3709
Yes	259	148 (57.1%)	9.4 [5.9, 12.4]	113	56 (49.6%)	6.6 [4.0, 18.5]	1.00 [0.73, 1.36]	0.9984	
No	22	13 (59.1%)	5.6 [1.0, NA]	15	6 (40.0%)	15.9 [2.8, NA]	1.63 [0.62, 4.31]	0.3059	

Table 4.12 EORTC-QLQ C30 Appetite Loss Symptom: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EORTC	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	N	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Refractory to bortezomib									0.8328
Yes	89	52 (58.4%)	5.6 [2.8, 12.2]	48	24 (50.0%)	5.2 [2.0, NA]	1.02 [0.63, 1.65]	0.9456	
No	192	109 (56.8%)	10.3 [6.6, 14.0]	80	38 (47.5%)	13.1 [5.6, NA]	1.08 [0.74, 1.56]	0.6870	
Prior lenalidomide exposure									0.1205
Yes	112	69 (61.6%)	7.0 [3.8, 13.3]	61	24 (39.3%)	NA [4.0, NA]	1.39 [0.87, 2.21]	0.1614	
No	169	92 (54.4%)	10.3 [5.6, 13.1]	67	38 (56.7%)	6.6 [3.8, 16.8]	0.87 [0.59, 1.26]	0.4479	
Refractory to lenalidomide									0.6003
Yes	89	54 (60.7%)	5.9 [3.8, 15.3]	46	19 (41.3%)	10.6 [3.3, NA]	1.20 [0.71, 2.02]	0.4965	
No	192	107 (55.7%)	9.5 [6.6, 12.9]	82	43 (52.4%)	6.6 [4.7, 18.5]	0.99 [0.70, 1.41]	0.9644	
Prior IMiD exposure									0.0215
Yes	186	111 (59.7%)	6.6 [4.2, 11.3]	90	39 (43.3%)	15.9 [5.6, NA]	1.34 [0.93, 1.93]	0.1104	
No	95	50 (52.6%)	12.2 [9.3, NA]	38	23 (60.5%)	5.2 [2.8, 16.8]	0.61 [0.37, 1.01]	0.0494	
Refractory to IMiD									0.3168
Yes	117	69 (59.0%)	5.9 [4.0, 14.0]	54	21 (38.9%)	10.6 [3.3, NA]	1.28 [0.79, 2.09]	0.3109	
No	164	92 (56.1%)	10.3 [6.6, 13.3]	74	41 (55.4%)	6.6 [4.2, 16.8]	0.92 [0.64, 1.34]	0.6700	
International Staging System (ISS)									0.7068
Stage I or II	229	130 (56.8%)	9.3 [5.6, 12.2]	107	53 (49.5%)	10.6 [4.9, 20.1]	1.08 [0.78, 1.49]	0.6332	
Stage III	51	30 (58.8%)	12.2 [5.6, 15.3]	21	9 (42.9%)	3.8 [2.0, NA]	0.90 [0.42, 1.91]	0.7796	

Table 4.12 EORTC-QLQ C30 Appetite Loss Symptom: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EORTC	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Prior proteasome inhibitor exposure									0.3648
Yes	260	149 (57.3%)	9.4 [5.9, 12.2]	114	57 (50.0%)	6.6 [4.7, 18.5]	1.00 [0.74, 1.36]	0.9911	
No	21	12 (57.1%)	9.4 [1.0, NA]	14	5 (35.7%)	15.9 [2.8, NA]	1.70 [0.60, 4.85]	0.3030	
Number of prior lines of therapy									0.3752
1	130	68 (52.3%)	10.4 [6.8, 18.7]	57	24 (42.1%)	15.9 [4.7, NA]	1.23 [0.77, 1.96]	0.3759	
>= 2	151	93 (61.6%)	5.9 [4.0, 11.3]	71	38 (53.5%)	5.6 [3.3, 18.5]	0.94 [0.64, 1.37]	0.7351	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
[a]From Kaplan–Meier estimate
[b]HR: hazard ratio
NA denotes that the median time (and 95% CI) were not estimable

Table 4.13 EORTC-QLQ C30 Constipation Symptom: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EORTC	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Age									0.1948
<= 75	257	103 (40.1%)	26.2 [15.9, NA]	112	40 (35.7%)	NA [8.5, NA]	0.98 [0.68, 1.42]	0.9248	
> 75	24	14 (58.3%)	8.4 [2.8, NA]	16	5 (31.3%)	NA [2.8, NA]	2.01 [0.72, 5.58]	0.1704	
Sex									0.9727
Male	161	69 (42.9%)	22.4 [12.4, NA]	78	28 (35.9%)	NA [8.5, NA]	1.04 [0.67, 1.62]	0.8475	
Female	120	48 (40.0%)	23.9 [12.9, NA]	50	17 (34.0%)	NA [5.6, NA]	1.07 [0.62, 1.87]	0.8003	
Race									0.4992
White	220	84 (38.2%)	NA [17.8, NA]	104	35 (33.7%)	NA [8.5, NA]	0.99 [0.67, 1.47]	0.9573	
Non-White	61	33 (54.1%)	12.2 [4.7, 22.8]	24	10 (41.7%)	19.2 [3.3, NA]	1.28 [0.63, 2.60]	0.4874	
Geographic region									0.1060
Europe	182	65 (35.7%)	NA [18.0, NA]	84	28 (33.3%)	NA [10.0, NA]	0.93 [0.60, 1.46]	0.7614	
Asia Pacific	81	42 (51.9%)	15.0 [4.7, NA]	34	11 (32.4%)	NA [3.8, NA]	1.58 [0.81, 3.07]	0.1677	
North America	18	10 (55.6%)	8.4 [1.9, NA]	10	6 (60.0%)	5.6 [1.1, NA]	0.74 [0.26, 2.11]	0.5737	
ECOG performance status									0.7211
0-1	268	110 (41.0%)	23.9 [15.0, NA]	125	44 (35.2%)	NA [10.0, NA]	1.05 [0.74, 1.49]	0.7708	
2	12	6 (50.0%)	18.7 [1.9, NA]	3	1 (33.3%)	3.8 [, NA]	0.36 [0.03, 4.10]	0.3924	
Prior bortezomib or ixazomib exposure									0.0094
Yes	259	102 (39.4%)	26.2 [18.0, NA]	113	42 (37.2%)	NA [5.6, NA]	0.90 [0.63, 1.29]	0.5659	
No	22	15 (68.2%)	5.6 [1.6, 11.2]	15	3 (20.0%)	NA [8.5, NA]	5.06 [1.46, 17.57]	0.0041	

Table 4.13 EORTC-QLQ C30 Constipation Symptom: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EORTC	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Refractory to bortezomib									0.3381
Yes	89	32 (36.0%)	NA [15.4, NA]	48	17 (35.4%)	NA [3.8, NA]	0.85 [0.47, 1.54]	0.5959	
No	192	85 (44.3%)	19.2 [12.4, NA]	80	28 (35.0%)	NA [8.5, NA]	1.19 [0.77, 1.82]	0.4291	
Prior lenalidomide exposure									0.1096
Yes	112	47 (42.0%)	22.8 [12.2, NA]	61	26 (42.6%)	8.5 [3.8, NA]	0.79 [0.48, 1.28]	0.3231	
No	169	70 (41.4%)	23.4 [12.9, NA]	67	19 (28.4%)	NA [NA, NA]	1.41 [0.85, 2.34]	0.1819	
Refractory to lenalidomide									0.4303
Yes	89	36 (40.4%)	23.9 [12.2, NA]	46	17 (37.0%)	19.2 [3.8, NA]	0.85 [0.47, 1.53]	0.5824	
No	192	81 (42.2%)	19.6 [12.9, NA]	82	28 (34.1%)	NA [8.5, NA]	1.16 [0.76, 1.79]	0.4865	
Prior IMiD exposure									0.5641
Yes	186	78 (41.9%)	22.4 [12.0, NA]	90	34 (37.8%)	20.6 [5.6, NA]	1.01 [0.67, 1.51]	0.9737	
No	95	39 (41.1%)	26.2 [12.9, NA]	38	11 (28.9%)	NA [10.0, NA]	1.25 [0.64, 2.44]	0.5132	
Refractory to IMiD									0.2750
Yes	117	44 (37.6%)	NA [15.4, NA]	54	19 (35.2%)	20.6 [3.8, NA]	0.81 [0.47, 1.40]	0.4417	
No	164	73 (44.5%)	18.0 [12.2, NA]	74	26 (35.1%)	NA [8.5, NA]	1.23 [0.79, 1.93]	0.3582	
International Staging System (ISS)									0.1530
Stage I or II	229	100 (43.7%)	22.4 [12.4, NA]	107	38 (35.5%)	NA [10.0, NA]	1.17 [0.80, 1.70]	0.4098	
Stage III	51	16 (31.4%)	NA [18.0, NA]	21	7 (33.3%)	NA [2.8, NA]	0.54 [0.22, 1.34]	0.1781	

Table 4.13 EORTC-QLQ C30 Constipation Symptom: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EORTC	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Prior proteasome inhibitor exposure									0.0176
Yes	260	103 (39.6%)	26.2 [17.8, NA]	114	42 (36.8%)	NA [7.2, NA]	0.92 [0.64, 1.32]	0.6435	
No	21	14 (66.7%)	5.6 [1.9, 15.9]	14	3 (21.4%)	NA [3.8, NA]	4.61 [1.32, 16.16]	0.0080	
Number of prior lines of therapy									0.3897
1	130	59 (45.4%)	18.7 [11.7, NA]	57	20 (35.1%)	NA [8.5, NA]	1.23 [0.74, 2.04]	0.4239	
>= 2	151	58 (38.4%)	NA [15.9, NA]	71	25 (35.2%)	20.6 [5.6, NA]	0.92 [0.58, 1.48]	0.7294	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
[a]From Kaplan–Meier estimate
[b]HR: hazard ratio
NA denotes that the median time (and 95% CI) were not estimable

Table 4.14 EORTC-QLQ C30 Diarrhoea Symptom: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EORTC	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	N	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Age									0.3845
<= 75	257	146 (56.8%)	10.3 [8.4, 12.4]	112	52 (46.4%)	15.0 [9.4, 24.3]	1.17 [0.85, 1.60]	0.3294	
> 75	24	16 (66.7%)	5.7 [1.9, 17.8]	16	6 (37.5%)	15.2 [4.9, NA]	1.75 [0.68, 4.47]	0.2348	
Sex									0.4793
Male	161	94 (58.4%)	10.3 [7.5, 14.0]	78	32 (41.0%)	15.5 [9.4, NA]	1.34 [0.89, 2.00]	0.1512	
Female	120	68 (56.7%)	9.8 [6.5, 15.9]	50	26 (52.0%)	15.0 [6.8, 24.3]	1.08 [0.68, 1.69]	0.7504	
Race									0.8228
White	220	125 (56.8%)	10.3 [7.0, 12.9]	104	47 (45.2%)	15.5 [9.4, 24.3]	1.20 [0.86, 1.68]	0.2816	
Non-White	61	37 (60.7%)	9.3 [5.9, 18.7]	24	11 (45.8%)	15.2 [3.3, NA]	1.29 [0.66, 2.53]	0.4516	
Geographic region									0.2274
Europe	182	96 (52.7%)	12.2 [9.4, 17.8]	84	38 (45.2%)	15.5 [8.2, 26.1]	1.11 [0.76, 1.61]	0.5866	
Asia Pacific	81	52 (64.2%)	8.4 [4.7, 12.4]	34	14 (41.2%)	14.0 [7.0, NA]	1.58 [0.87, 2.85]	0.1201	
North America	18	14 (77.8%)	5.6 [1.9, 10.3]	10	6 (60.0%)	6.6 [0.9, NA]	1.11 [0.42, 2.92]	0.8315	
ECOG performance status									0.4196
0-1	268	155 (57.8%)	9.8 [7.5, 12.4]	125	57 (45.6%)	15.2 [9.4, 24.3]	1.25 [0.92, 1.69]	0.1427	
2	12	7 (58.3%)	12.4 [4.2, NA]	3	1 (33.3%)	NA [0.9, NA]	0.15 [0.01, 2.63]	0.1405	
Prior bortezomib or ixazomib exposure									0.6496
Yes	259	153 (59.1%)	9.6 [7.0, 12.4]	113	54 (47.8%)	14.0 [9.4, 22.1]	1.17 [0.86, 1.59]	0.3219	
No	22	9 (40.9%)	20.3 [4.7, NA]	15	4 (26.7%)	NA [4.9, NA]	1.54 [0.47, 4.99]	0.4679	

Table 4.14 EORTC-QLQ C30 Diarrhoea Symptom: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EORTC	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Refractory to bortezomib									0.7359
Yes	89	52 (58.4%)	10.8 [5.7, 14.0]	48	23 (47.9%)	20.8 [5.2, 25.3]	1.18 [0.72, 1.93]	0.5031	
No	192	110 (57.3%)	10.3 [7.5, 13.1]	80	35 (43.8%)	15.2 [9.4, NA]	1.28 [0.87, 1.87]	0.2022	
Prior lenalidomide exposure									0.8539
Yes	112	71 (63.4%)	7.4 [4.9, 10.5]	61	28 (45.9%)	15.0 [4.9, 24.3]	1.29 [0.83, 2.00]	0.2488	
No	169	91 (53.8%)	11.7 [8.4, 17.8]	67	30 (44.8%)	15.5 [9.7, NA]	1.21 [0.80, 1.83]	0.3525	
Refractory to lenalidomide									0.5357
Yes	89	56 (62.9%)	6.6 [3.8, 10.8]	46	19 (41.3%)	15.2 [4.9, 26.1]	1.42 [0.84, 2.39]	0.1825	
No	192	106 (55.2%)	11.3 [8.4, 15.9]	82	39 (47.6%)	15.5 [7.0, NA]	1.15 [0.79, 1.65]	0.4627	
Prior IMiD exposure									0.4184
Yes	186	114 (61.3%)	7.4 [5.6, 9.8]	90	43 (47.8%)	14.0 [9.4, 24.3]	1.37 [0.97, 1.95]	0.0729	
No	95	48 (50.5%)	17.8 [11.3, 24.5]	38	15 (39.5%)	22.1 [6.6, NA]	1.03 [0.58, 1.84]	0.9191	
Refractory to IMiD									0.4440
Yes	117	73 (62.4%)	6.6 [4.7, 10.8]	54	23 (42.6%)	15.0 [9.4, 26.1]	1.41 [0.88, 2.25]	0.1447	
No	164	89 (54.3%)	11.7 [9.4, 17.8]	74	35 (47.3%)	15.5 [7.0, NA]	1.10 [0.75, 1.63]	0.6172	
International Staging System (ISS)									0.0312
Stage I or II	229	132 (57.6%)	9.3 [7.4, 12.9]	107	46 (43.0%)	16.4 [10.3, NA]	1.37 [0.98, 1.92]	0.0593	
Stage III	51	29 (56.9%)	11.3 [6.5, 17.1]	21	12 (57.1%)	6.8 [1.9, 15.5]	0.59 [0.30, 1.17]	0.1253	

Table 4.14 EORTC-QLQ C30 Diarrhoea Symptom: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EORTC	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Prior proteasome inhibitor exposure									0.5084
Yes	260	154 (59.2%)	9.6 [7.0, 12.2]	114	55 (48.2%)	14.0 [8.2, 22.1]	1.16 [0.85, 1.58]	0.3447	
No	21	8 (38.1%)	NA [4.7, NA]	14	3 (21.4%)	NA [4.7, NA]	1.82 [0.48, 6.88]	0.3619	
Number of prior lines of therapy									0.4374
1	130	69 (53.1%)	11.7 [8.4, 17.8]	57	22 (38.6%)	16.4 [10.3, NA]	1.41 [0.87, 2.27]	0.1577	
>= 2	151	93 (61.6%)	7.5 [5.9, 11.3]	71	36 (50.7%)	10.6 [4.9, 24.3]	1.11 [0.75, 1.63]	0.5930	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
[a]From Kaplan–Meier estimate
[b]HR: hazard ratio
NA denotes that the median time (and 95% CI) were not estimable

Table 4.15 EORTC-QLQ C30 Financial Difficulties: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EORTC	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Age									0.7803
<= 75	257	117 (45.5%)	17.8 [11.2, NA]	112	54 (48.2%)	13.1 [5.6, 19.3]	0.81 [0.59, 1.12]	0.1951	
> 75	24	9 (37.5%)	NA [5.7, NA]	16	5 (31.3%)	NA [2.8, NA]	0.92 [0.31, 2.75]	0.8764	
Sex									0.8375
Male	161	67 (41.6%)	NA [11.3, NA]	78	34 (43.6%)	13.2 [5.6, NA]	0.85 [0.56, 1.29]	0.4480	
Female	120	59 (49.2%)	16.8 [7.5, 27.8]	50	25 (50.0%)	7.5 [4.0, NA]	0.78 [0.49, 1.24]	0.2858	
Race									0.8295
White	220	102 (46.4%)	16.8 [8.8, NA]	104	50 (48.1%)	10.3 [5.6, 19.3]	0.82 [0.59, 1.16]	0.2571	
Non-White	61	24 (39.3%)	NA [11.3, NA]	24	9 (37.5%)	NA [4.7, NA]	0.90 [0.42, 1.94]	0.7801	
Geographic region									0.1365
Europe	182	91 (50.0%)	12.2 [8.4, 21.1]	84	42 (50.0%)	13.1 [5.4, 19.3]	0.89 [0.62, 1.28]	0.5278	
Asia Pacific	81	30 (37.0%)	NA [16.4, NA]	34	15 (44.1%)	11.2 [3.1, NA]	0.66 [0.35, 1.22]	0.1777	
North America	18	5 (27.8%)	NA [7.5, NA]	10	2 (20.0%)	NA [1.0, NA]	1.20 [0.23, 6.23]	0.8270	
ECOG performance status									0.9204
0-1	268	123 (45.9%)	17.8 [11.2, NA]	125	58 (46.4%)	13.1 [6.8, 25.4]	0.86 [0.63, 1.17]	0.3321	
2	12	3 (25.0%)	NA [4.7, NA]	3	1 (33.3%)	5.6 [, NA]	0.22 [0.02, 2.45]	0.1762	
Prior bortezomib or ixazomib exposure									0.1839
Yes	259	118 (45.6%)	17.8 [11.2, NA]	113	51 (45.1%)	13.2 [7.5, 25.4]	0.88 [0.63, 1.23]	0.4460	
No	22	8 (36.4%)	NA [2.8, NA]	15	8 (53.3%)	3.8 [1.9, NA]	0.58 [0.21, 1.55]	0.2562	

Table 4.15 EORTC-QLQ C30 Financial Difficulties: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EORTC	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Refractory to bortezomib									0.9739
Yes	89	40 (44.9%)	16.8 [5.7, NA]	48	23 (47.9%)	11.2 [4.7, 25.4]	0.85 [0.51, 1.42]	0.5200	
No	192	86 (44.8%)	23.4 [11.3, NA]	80	36 (45.0%)	14.0 [6.8, NA]	0.84 [0.57, 1.24]	0.3807	
Prior lenalidomide exposure									0.9743
Yes	112	44 (39.3%)	27.8 [17.5, NA]	61	24 (39.3%)	13.2 [5.6, NA]	0.84 [0.51, 1.39]	0.4987	
No	169	82 (48.5%)	16.1 [8.5, NA]	67	35 (52.2%)	11.2 [4.7, 25.4]	0.82 [0.55, 1.21]	0.3044	
Refractory to lenalidomide									0.7641
Yes	89	34 (38.2%)	NA [21.1, NA]	46	18 (39.1%)	13.2 [5.6, NA]	0.79 [0.45, 1.42]	0.4288	
No	192	92 (47.9%)	12.9 [8.8, NA]	82	41 (50.0%)	11.2 [5.4, 25.4]	0.85 [0.59, 1.23]	0.3735	
Prior IMiD exposure									0.6270
Yes	186	75 (40.3%)	27.8 [17.3, NA]	90	37 (41.1%)	13.2 [6.8, NA]	0.88 [0.59, 1.31]	0.5256	
No	95	51 (53.7%)	11.3 [6.6, 19.2]	38	22 (57.9%)	7.5 [4.0, 19.3]	0.72 [0.44, 1.19]	0.1925	
Refractory to IMiD									0.5655
Yes	117	44 (37.6%)	NA [23.4, NA]	54	21 (38.9%)	13.1 [5.6, NA]	0.77 [0.46, 1.31]	0.3314	
No	164	82 (50.0%)	11.7 [8.4, 25.9]	74	38 (51.4%)	11.2 [4.7, 25.4]	0.89 [0.61, 1.31]	0.5448	
International Staging System (ISS)									0.5834
Stage I or II	229	97 (42.4%)	26.4 [16.4, NA]	107	49 (45.8%)	13.2 [7.5, NA]	0.79 [0.56, 1.11]	0.1693	
Stage III	51	29 (56.9%)	6.6 [3.8, 16.1]	21	10 (47.6%)	5.6 [2.8, NA]	0.98 [0.47, 2.01]	0.9460	

Table 4.15 EORTC-QLQ C30 Financial Difficulties: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EORTC	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Prior proteasome inhibitor exposure									0.1877
Yes	260	119 (45.8%)	17.5 [11.2, NA]	114	52 (45.6%)	13.2 [6.8, 25.4]	0.88 [0.63, 1.21]	0.4207	
No	21	7 (33.3%)	NA [2.8, NA]	14	7 (50.0%)	3.8 [1.9, NA]	0.55 [0.19, 1.57]	0.2441	
Number of prior lines of therapy									0.9462
1	130	63 (48.5%)	16.1 [6.6, NA]	57	29 (50.9%)	7.5 [4.7, NA]	0.85 [0.55, 1.32]	0.4653	
>= 2	151	63 (41.7%)	26.4 [11.7, NA]	71	30 (42.3%)	13.2 [5.6, NA]	0.82 [0.53, 1.27]	0.3715	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
[a]From Kaplan–Meier estimate
[b]HR: hazard ratio
NA denotes that the median time (and 95% CI) were not estimable

Table 4.1 EORTC-QLQ C30 Global Health status: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EORTC	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Age									0.8656
<= 75	257	155 (60.3%)	6.6 [4.8, 12.1]	112	67 (59.8%)	4.7 [3.1, 7.5]	0.83 [0.62, 1.10]	0.1823	
> 75	24	17 (70.8%)	2.8 [1.9, 10.3]	16	11 (68.8%)	1.9 [1.0, 23.8]	0.92 [0.43, 1.97]	0.8170	
Sex									0.9537
Male	161	99 (61.5%)	7.5 [5.6, 12.4]	78	46 (59.0%)	4.7 [2.8, 8.1]	0.81 [0.57, 1.15]	0.2233	
Female	120	73 (60.8%)	4.7 [2.8, 11.7]	50	32 (64.0%)	3.8 [1.9, 8.4]	0.84 [0.55, 1.27]	0.3914	
Race									0.2560
White	220	132 (60.0%)	6.5 [4.7, 12.1]	104	65 (62.5%)	3.8 [2.2, 6.6]	0.77 [0.57, 1.03]	0.0700	
Non-White	61	40 (65.6%)	6.5 [2.8, 14.2]	24	13 (54.2%)	7.5 [1.9, NA]	1.08 [0.58, 2.03]	0.7993	
Geographic region									0.8181
Europe	182	105 (57.7%)	9.6 [5.6, 16.8]	84	53 (63.1%)	3.8 [2.0, 7.7]	0.70 [0.50, 0.97]	0.0268	
Asia Pacific	81	55 (67.9%)	3.7 [2.0, 7.5]	34	19 (55.9%)	6.6 [1.9, NA]	1.18 [0.70, 1.99]	0.5215	
North America	18	12 (66.7%)	1.9 [1.9, 25.3]	10	6 (60.0%)	6.1 [1.0, NA]	1.08 [0.39, 3.00]	0.8718	
ECOG performance status									0.9727
0-1	268	170 (63.4%)	5.9 [3.8, 9.3]	125	78 (62.4%)	4.0 [2.3, 7.5]	0.85 [0.65, 1.11]	0.2221	
2	12	1 (8.3%)	NA [NA, NA]	3	0 (0.0%)	NA [NA, NA]	NA [NA, NA]	0.7630	
Prior bortezomib or ixazomib exposure									0.9832
Yes	259	158 (61.0%)	6.6 [4.7, 11.7]	113	68 (60.2%)	4.7 [3.0, 7.7]	0.82 [0.62, 1.10]	0.1693	
No	22	14 (63.6%)	1.9 [1.0, NA]	15	10 (66.7%)	1.9 [1.0, NA]	0.88 [0.39, 1.99]	0.7412	

Table 4.1 EORTC-QLQ C30 Global Health status: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EORTC	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Refractory to bortezomib or ixazomib									0.8111
Yes	89	50 (56.2%)	7.5 [3.8, 16.8]	48	27 (56.3%)	4.7 [1.9, 11.3]	0.78 [0.49, 1.25]	0.2826	
No	192	122 (63.5%)	6.1 [3.7, 10.9]	80	51 (63.8%)	4.0 [2.2, 8.1]	0.84 [0.61, 1.17]	0.2862	
Prior lenalidomide exposure									0.1983
Yes	112	64 (57.1%)	6.6 [3.7, 18.9]	61	39 (63.9%)	3.7 [1.9, 6.6]	0.69 [0.46, 1.03]	0.0558	
No	169	108 (63.9%)	6.1 [3.8, 11.2]	67	39 (58.2%)	6.6 [3.1, 11.3]	0.96 [0.67, 1.39]	0.8329	
Refractory to lenalidomide									0.4859
Yes	89	51 (57.3%)	6.6 [3.8, 18.9]	46	27 (58.7%)	4.0 [1.9, 18.8]	0.72 [0.45, 1.15]	0.1552	
No	192	121 (63.0%)	6.1 [3.7, 11.2]	82	51 (62.2%)	4.7 [2.1, 8.1]	0.88 [0.63, 1.22]	0.4239	
Prior IMiD exposure									0.2792
Yes	186	111 (59.7%)	5.6 [3.1, 9.3]	90	58 (64.4%)	3.8 [1.9, 6.6]	0.76 [0.55, 1.04]	0.0762	
No	95	61 (64.2%)	9.6 [4.7, 12.4]	38	20 (52.6%)	7.7 [3.0, NA]	1.02 [0.62, 1.70]	0.9244	
Refractory to IMiD									0.9904
Yes	117	71 (60.7%)	5.6 [2.8, 10.3]	54	31 (57.4%)	4.0 [1.9, 11.3]	0.82 [0.54, 1.26]	0.3586	
No	164	101 (61.6%)	7.5 [4.7, 12.2]	74	47 (63.5%)	4.7 [2.1, 8.1]	0.82 [0.58, 1.16]	0.2475	
International Staging System (ISS)									0.5712
Stage I or II	229	147 (64.2%)	5.9 [3.8, 9.3]	107	71 (66.4%)	3.8 [2.2, 6.6]	0.81 [0.61, 1.08]	0.1334	
Stage III	51	25 (49.0%)	12.4 [2.8, NA]	21	7 (33.3%)	NA [1.9, NA]	1.19 [0.51, 2.78]	0.6704	

Table 4.1 EORTC-QLQ C30 Global Health status: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EORTC	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Prior proteasome inhibitor exposure									0.8932
Yes	260	159 (61.2%)	6.6 [4.7, 11.2]	114	69 (60.5%)	4.7 [3.0, 7.7]	0.82 [0.62, 1.09]	0.1508	
No	21	13 (61.9%)	1.9 [1.6, NA]	14	9 (64.3%)	1.9 [1.0, NA]	0.92 [0.39, 2.16]	0.8434	
Number of prior lines of therapy									0.8871
1	130	86 (66.2%)	5.9 [3.7, 11.7]	57	38 (66.7%)	3.8 [2.1, 7.7]	0.83 [0.56, 1.21]	0.3144	
>= 2	151	86 (57.0%)	7.5 [3.8, 16.1]	71	40 (56.3%)	4.7 [1.9, 18.8]	0.82 [0.56, 1.20]	0.2931	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
[a]From Kaplan–Meier estimate
[b]HR: hazard ratio
NA denotes that the median time (and 95% CI) were not estimable

Table 4.2 EORTC-QLQ C30 Physical Functioning: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EORTC	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Age									0.4590
<= 75	257	162 (63.0%)	6.5 [4.7, 10.6]	112	73 (65.2%)	4.7 [2.9, 5.8]	0.82 [0.62, 1.08]	0.1461	
> 75	24	15 (62.5%)	4.7 [1.9, NA]	16	8 (50.0%)	3.7 [1.9, NA]	1.18 [0.50, 2.81]	0.6926	
Sex									0.8159
Male	161	98 (60.9%)	6.8 [4.7, 11.7]	78	48 (61.5%)	4.1 [2.9, 7.7]	0.83 [0.59, 1.17]	0.2785	
Female	120	79 (65.8%)	5.6 [2.9, 9.8]	50	33 (66.0%)	4.7 [2.2, 8.9]	0.89 [0.59, 1.33]	0.5544	
Race									0.1348
White	220	135 (61.4%)	7.9 [4.7, 11.5]	104	68 (65.4%)	4.7 [2.9, 6.5]	0.76 [0.56, 1.01]	0.0558	
Non-White	61	42 (68.9%)	4.4 [1.9, 6.5]	24	13 (54.2%)	4.1 [1.9, NA]	1.29 [0.69, 2.41]	0.4012	
Geographic region									0.3320
Europe	182	108 (59.3%)	8.4 [4.7, 12.1]	84	54 (64.3%)	4.7 [2.9, 5.8]	0.80 [0.57, 1.11]	0.1641	
Asia Pacific	81	59 (72.8%)	4.4 [2.8, 6.2]	34	19 (55.9%)	4.7 [2.9, 23.4]	1.21 [0.72, 2.04]	0.4508	
North America	18	10 (55.6%)	11.7 [1.8, NA]	10	8 (80.0%)	3.8 [1.0, 9.4]	0.48 [0.18, 1.31]	0.1369	
ECOG performance status									0.9723
0-1	268	171 (63.8%)	6.2 [4.7, 9.6]	125	81 (64.8%)	4.2 [2.9, 5.8]	0.85 [0.65, 1.11]	0.2308	
2	12	5 (41.7%)	NA [1.0, NA]	3	0 (0.0%)	NA [NA, NA]	NA [NA, NA]	0.3062	
Prior bortezomib or ixazomib exposure									0.6739
Yes	259	159 (61.4%)	6.5 [4.7, 10.9]	113	71 (62.8%)	4.7 [3.3, 6.5]	0.85 [0.65, 1.13]	0.2599	
No	22	18 (81.8%)	3.8 [1.6, 9.6]	15	10 (66.7%)	2.8 [1.9, 16.4]	0.86 [0.38, 1.95]	0.7144	

Table 4.2 EORTC-QLQ C30 Physical Functioning: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EORTC	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Refractory to bortezomib or ixazomib									0.4574
Yes	89	50 (56.2%)	5.7 [3.3, 15.9]	48	30 (62.5%)	3.8 [2.8, 5.6]	0.76 [0.49, 1.20]	0.2325	
No	192	127 (66.1%)	6.5 [3.8, 9.6]	80	51 (63.8%)	5.2 [2.9, 8.9]	0.91 [0.65, 1.26]	0.5496	
Prior lenalidomide exposure									0.3307
Yes	112	64 (57.1%)	7.9 [4.7, 16.6]	61	36 (59.0%)	3.8 [2.2, 6.5]	0.77 [0.51, 1.17]	0.2120	
No	169	113 (66.9%)	5.6 [3.8, 9.6]	67	45 (67.2%)	4.7 [3.7, 8.9]	0.94 [0.67, 1.33]	0.7239	
Refractory to lenalidomide									0.3725
Yes	89	48 (53.9%)	11.3 [5.6, 24.8]	46	25 (54.3%)	3.8 [2.3, 16.1]	0.75 [0.46, 1.22]	0.2336	
No	192	129 (67.2%)	4.7 [3.7, 8.4]	82	56 (68.3%)	4.7 [2.9, 5.8]	0.92 [0.67, 1.26]	0.6076	
Prior IMiD exposure									0.7921
Yes	186	113 (60.8%)	6.2 [4.7, 10.6]	90	55 (61.1%)	3.8 [2.8, 5.8]	0.85 [0.61, 1.17]	0.3094	
No	95	64 (67.4%)	6.8 [3.8, 11.7]	38	26 (68.4%)	5.6 [2.9, 16.1]	0.89 [0.56, 1.40]	0.6015	
Refractory to IMiD									0.4292
Yes	117	66 (56.4%)	6.6 [4.7, 16.6]	54	30 (55.6%)	3.8 [2.2, 9.6]	0.78 [0.50, 1.21]	0.2497	
No	164	111 (67.7%)	4.7 [3.6, 9.6]	74	51 (68.9%)	4.7 [2.9, 5.8]	0.93 [0.67, 1.30]	0.6795	
International Staging System (ISS)									0.9079
Stage I or II	229	150 (65.5%)	5.6 [3.8, 8.9]	107	71 (66.4%)	4.1 [2.9, 5.6]	0.86 [0.65, 1.14]	0.2837	
Stage III	51	26 (51.0%)	12.2 [4.0, NA]	21	10 (47.6%)	5.8 [1.9, NA]	0.87 [0.41, 1.81]	0.6934	

Table 4.2 EORTC-QLQ C30 Physical Functioning: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EORTC	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Prior proteasome inhibitor exposure									0.7181
Yes	260	160 (61.5%)	6.5 [4.7, 10.6]	114	72 (63.2%)	4.7 [3.3, 6.5]	0.85 [0.65, 1.13]	0.2549	
No	21	17 (81.0%)	3.8 [1.9, 9.6]	14	9 (64.3%)	2.8 [1.9, 16.4]	0.86 [0.37, 2.02]	0.7260	
Number of prior lines of therapy									0.7623
1	130	89 (68.5%)	5.6 [3.8, 9.8]	57	38 (66.7%)	4.7 [2.8, 5.8]	0.87 [0.59, 1.28]	0.4769	
>= 2	151	88 (58.3%)	6.6 [4.7, 12.2]	71	43 (60.6%)	4.1 [2.8, 9.6]	0.83 [0.58, 1.20]	0.3064	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
[a]From Kaplan–Meier estimate
[b]HR: hazard ratio
NA denotes that the median time (and 95% CI) were not estimable

Table 4.3 EORTC-QLQ C30 Role Functioning: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EORTC	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Age									0.7728
<= 75	257	194 (75.5%)	2.8 [1.9, 3.8]	112	80 (71.4%)	2.8 [1.9, 4.0]	0.95 [0.73, 1.24]	0.7116	
> 75	24	18 (75.0%)	2.8 [1.9, 2.9]	16	12 (75.0%)	2.8 [1.3, 5.2]	0.95 [0.45, 2.00]	0.8940	
Sex									0.8032
Male	161	120 (74.5%)	2.9 [2.0, 4.7]	78	53 (67.9%)	2.8 [1.9, 5.2]	0.95 [0.69, 1.32]	0.7708	
Female	120	92 (76.7%)	1.9 [1.9, 3.1]	50	39 (78.0%)	2.1 [1.9, 3.8]	0.91 [0.62, 1.32]	0.5910	
Race									0.8771
White	220	166 (75.5%)	2.8 [1.9, 3.8]	104	76 (73.1%)	2.8 [1.9, 4.0]	0.93 [0.70, 1.22]	0.5588	
Non-White	61	46 (75.4%)	3.1 [1.9, 5.0]	24	16 (66.7%)	2.8 [1.0, 7.5]	1.02 [0.58, 1.80]	0.9434	
Geographic region									0.1328
Europe	182	136 (74.7%)	2.8 [1.9, 3.8]	84	62 (73.8%)	2.8 [1.9, 3.8]	0.88 [0.65, 1.19]	0.3792	
Asia Pacific	81	62 (76.5%)	1.9 [1.9, 3.8]	34	24 (70.6%)	2.8 [1.4, 4.7]	0.95 [0.59, 1.52]	0.8096	
North America	18	14 (77.8%)	2.1 [1.9, 17.1]	10	6 (60.0%)	7.5 [1.0, NA]	1.48 [0.56, 3.90]	0.4220	
ECOG performance status									0.4675
0-1	268	205 (76.5%)	2.8 [1.9, 3.1]	125	91 (72.8%)	2.8 [1.9, 3.8]	0.96 [0.75, 1.23]	0.7293	
2	12	6 (50.0%)	14.0 [2.8, NA]	3	1 (33.3%)	3.8 [, NA]	0.71 [0.08, 6.43]	0.7493	
Prior bortezomib or ixazomib exposure									0.3938
Yes	259	193 (74.5%)	2.8 [1.9, 3.8]	113	83 (73.5%)	2.8 [1.9, 3.8]	0.92 [0.71, 1.19]	0.4827	
No	22	19 (86.4%)	1.8 [1.0, 2.8]	15	9 (60.0%)	2.8 [1.0, NA]	1.31 [0.58, 2.97]	0.4855	

Table 4.3 EORTC-QLQ C30 Role Functioning: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EORTC	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Refractory to bortezomib or ixazomib									0.3307
Yes	89	63 (70.8%)	2.8 [1.9, 4.7]	48	35 (72.9%)	1.9 [1.9, 3.8]	0.82 [0.54, 1.25]	0.3242	
No	192	149 (77.6%)	2.8 [1.9, 3.8]	80	57 (71.3%)	2.9 [2.1, 5.6]	1.02 [0.75, 1.38]	0.9072	
Prior lenalidomide exposure									0.1948
Yes	112	86 (76.8%)	1.9 [1.9, 3.1]	61	40 (65.6%)	2.9 [2.0, 5.9]	1.14 [0.78, 1.67]	0.4623	
No	169	126 (74.6%)	2.8 [1.9, 3.8]	67	52 (77.6%)	2.1 [1.9, 4.0]	0.81 [0.58, 1.12]	0.1704	
Refractory to lenalidomide									0.1881
Yes	89	66 (74.2%)	2.8 [1.9, 4.7]	46	27 (58.7%)	3.8 [1.9, 16.7]	1.20 [0.76, 1.89]	0.3989	
No	192	146 (76.0%)	2.8 [1.9, 3.8]	82	65 (79.3%)	2.8 [1.9, 3.1]	0.83 [0.62, 1.11]	0.1856	
Prior IMiD exposure									0.0551
Yes	186	144 (77.4%)	1.9 [1.9, 2.8]	90	61 (67.8%)	2.8 [1.9, 4.9]	1.12 [0.83, 1.52]	0.4235	
No	95	68 (71.6%)	3.8 [2.8, 7.5]	38	31 (81.6%)	2.8 [1.9, 3.8]	0.63 [0.41, 0.97]	0.0256	
Refractory to IMiD									0.0683
Yes	117	89 (76.1%)	2.0 [1.9, 3.8]	54	32 (59.3%)	3.8 [1.9, 8.4]	1.27 [0.84, 1.90]	0.2267	
No	164	123 (75.0%)	2.8 [1.9, 3.8]	74	60 (81.1%)	2.8 [1.9, 3.1]	0.77 [0.57, 1.05]	0.0844	
International Staging System (ISS)									0.7766
Stage I or II	229	178 (77.7%)	2.8 [1.9, 3.3]	107	80 (74.8%)	2.8 [2.0, 3.8]	0.91 [0.70, 1.19]	0.4880	
Stage III	51	33 (64.7%)	2.8 [1.2, 13.1]	21	12 (57.1%)	1.9 [1.9, NA]	1.14 [0.59, 2.22]	0.6783	

Table 4.3 EORTC-QLQ C30 Role Functioning: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EORTC	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Prior proteasome inhibitor exposure									0.3111
Yes	260	194 (74.6%)	2.8 [1.9, 3.8]	114	84 (73.7%)	2.8 [1.9, 3.8]	0.91 [0.70, 1.18]	0.4447	
No	21	18 (85.7%)	1.9 [1.0, 2.8]	14	8 (57.1%)	2.8 [1.0, NA]	1.42 [0.60, 3.36]	0.3863	
Number of prior lines of therapy									0.3815
1	130	100 (76.9%)	2.8 [1.9, 4.0]	57	45 (78.9%)	2.8 [1.9, 3.8]	0.83 [0.58, 1.18]	0.2723	
>= 2	151	112 (74.2%)	2.8 [1.9, 3.1]	71	47 (66.2%)	3.8 [1.9, 5.6]	1.05 [0.75, 1.48]	0.7610	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
[a]From Kaplan–Meier estimate
[b]HR: hazard ratio
NA denotes that the median time (and 95% CI) were not estimable

Table 4.4 EORTC-QLQ C30 Emotional Functioning: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EORTC	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	N	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Age									0.9138
<= 75	257	144 (56.0%)	9.3 [6.6, 14.5]	112	51 (45.5%)	10.8 [6.6, 21.7]	1.11 [0.81, 1.53]	0.5109	
> 75	24	15 (62.5%)	7.5 [2.8, 22.2]	16	7 (43.8%)	NA [1.0, NA]	1.13 [0.46, 2.79]	0.7824	
Sex									0.5261
Male	161	93 (57.8%)	8.7 [5.0, 15.2]	78	34 (43.6%)	11.9 [6.6, NA]	1.19 [0.80, 1.76]	0.3820	
Female	120	66 (55.0%)	8.4 [5.9, 17.1]	50	24 (48.0%)	7.5 [4.0, NA]	0.98 [0.61, 1.56]	0.9213	
Race									0.3391
White	220	128 (58.2%)	8.4 [5.0, 11.3]	104	46 (44.2%)	10.8 [5.7, NA]	1.19 [0.85, 1.67]	0.2977	
Non-White	61	31 (50.8%)	15.9 [6.6, NA]	24	12 (50.0%)	11.3 [4.0, NA]	0.83 [0.42, 1.62]	0.5683	
Geographic region									0.7780
Europe	182	108 (59.3%)	7.5 [4.7, 8.9]	84	41 (48.8%)	7.5 [4.2, NA]	1.10 [0.77, 1.58]	0.5803	
Asia Pacific	81	39 (48.1%)	17.8 [8.4, NA]	34	12 (35.3%)	11.3 [7.5, NA]	1.14 [0.59, 2.18]	0.6962	
North America	18	12 (66.7%)	18.7 [4.9, NA]	10	5 (50.0%)	10.3 [1.0, NA]	0.75 [0.25, 2.21]	0.5915	
ECOG performance status									0.7226
0-1	268	153 (57.1%)	8.5 [6.6, 14.2]	125	57 (45.6%)	10.8 [6.6, NA]	1.12 [0.82, 1.52]	0.4651	
2	12	6 (50.0%)	9.4 [1.0, NA]	3	1 (33.3%)	NA [2.8, NA]	0.73 [0.08, 7.01]	0.7793	
Prior bortezomib or ixazomib exposure									0.2904
Yes	259	146 (56.4%)	8.5 [6.6, 12.7]	113	50 (44.2%)	11.3 [6.7, NA]	1.17 [0.85, 1.61]	0.3326	
No	22	13 (59.1%)	15.9 [2.8, NA]	15	8 (53.3%)	5.7 [1.3, NA]	0.70 [0.28, 1.74]	0.4316	

Table 4.4 EORTC-QLQ C30 Emotional Functioning: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EORTC	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Refractory to bortezomib or ixazomib									0.2182
Yes	89	46 (51.7%)	8.4 [3.8, 17.8]	48	18 (37.5%)	21.7 [7.5, NA]	1.43 [0.83, 2.46]	0.1882	
No	192	113 (58.9%)	9.5 [6.6, 15.9]	80	40 (50.0%)	7.5 [4.9, 18.5]	0.95 [0.66, 1.36]	0.7572	
Prior lenalidomide exposure									0.3776
Yes	112	62 (55.4%)	8.4 [5.9, 18.7]	61	28 (45.9%)	7.5 [4.7, NA]	0.96 [0.61, 1.50]	0.8539	
No	169	97 (57.4%)	8.9 [5.0, 15.2]	67	30 (44.8%)	11.9 [4.9, NA]	1.24 [0.83, 1.87]	0.2881	
Refractory to lenalidomide									0.4002
Yes	89	48 (53.9%)	11.3 [6.6, 26.2]	46	20 (43.5%)	7.5 [4.7, NA]	0.94 [0.56, 1.59]	0.8175	
No	192	111 (57.8%)	8.5 [5.0, 14.2]	82	38 (46.3%)	11.9 [6.6, NA]	1.21 [0.83, 1.74]	0.3109	
Prior IMiD exposure									0.6492
Yes	186	105 (56.5%)	7.9 [4.9, 15.9]	90	42 (46.7%)	10.3 [5.2, NA]	1.07 [0.75, 1.54]	0.6868	
No	95	54 (56.8%)	9.6 [6.6, 17.8]	38	16 (42.1%)	18.5 [4.9, NA]	1.22 [0.70, 2.12]	0.4861	
Refractory to IMiD									0.5773
Yes	117	62 (53.0%)	9.4 [6.6, 19.6]	54	23 (42.6%)	9.6 [4.7, NA]	1.00 [0.62, 1.62]	0.9943	
No	164	97 (59.1%)	8.4 [4.9, 14.5]	74	35 (47.3%)	11.9 [5.7, NA]	1.19 [0.81, 1.75]	0.3784	
International Staging System (ISS)									0.6754
Stage I or II	229	130 (56.8%)	8.9 [6.6, 15.0]	107	49 (45.8%)	11.3 [6.6, NA]	1.12 [0.81, 1.56]	0.4754	
Stage III	51	28 (54.9%)	8.4 [3.8, 19.6]	21	9 (42.9%)	7.5 [1.9, NA]	0.92 [0.43, 1.97]	0.8244	

Table 4.4 EORTC-QLQ C30 Emotional Functioning: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EORTC	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Prior proteasome inhibitor exposure									0.3900
Yes	260	147 (56.5%)	8.5 [6.6, 12.7]	114	51 (44.7%)	11.3 [6.6, NA]	1.15 [0.84, 1.59]	0.3707	
No	21	12 (57.1%)	16.6 [2.8, NA]	14	7 (50.0%)	5.7 [1.9, NA]	0.70 [0.27, 1.85]	0.4665	
Number of prior lines of therapy									0.7229
1	130	74 (56.9%)	12.7 [5.6, 17.8]	57	28 (49.1%)	7.5 [4.9, NA]	1.02 [0.66, 1.59]	0.9136	
>= 2	151	85 (56.3%)	8.4 [4.7, 12.2]	71	30 (42.3%)	18.5 [5.2, NA]	1.18 [0.78, 1.79]	0.4290	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
[a]From Kaplan–Meier estimate
[b]HR: hazard ratio
NA denotes that the median time (and 95% CI) were not estimable

Table 4.5 EORTC-QLQ C30 Cognitive Functioning: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EORTC	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	N	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Age									0.6281
<= 75	257	176 (68.5%)	5.0 [3.8, 7.5]	112	70 (62.5%)	5.6 [3.1, 7.5]	0.96 [0.73, 1.27]	0.7729	
> 75	24	19 (79.2%)	6.5 [2.8, 11.3]	16	11 (68.8%)	2.8 [1.0, 11.0]	0.77 [0.36, 1.64]	0.4929	
Sex									0.1679
Male	161	111 (68.9%)	5.8 [3.8, 9.6]	78	44 (56.4%)	7.5 [3.8, 14.3]	1.08 [0.76, 1.53]	0.6588	
Female	120	84 (70.0%)	4.7 [3.8, 6.6]	50	37 (74.0%)	3.1 [1.9, 4.9]	0.74 [0.50, 1.10]	0.1251	
Race									0.7676
White	220	150 (68.2%)	5.2 [3.8, 7.7]	104	64 (61.5%)	4.9 [2.8, 7.5]	0.95 [0.71, 1.28]	0.7346	
Non-White	61	45 (73.8%)	4.7 [2.9, 9.6]	24	17 (70.8%)	3.8 [1.0, 11.2]	0.90 [0.51, 1.57]	0.7005	
Geographic region									0.1232
Europe	182	126 (69.2%)	5.0 [3.8, 7.5]	84	52 (61.9%)	4.7 [2.8, 10.6]	1.04 [0.75, 1.43]	0.8188	
Asia Pacific	81	54 (66.7%)	5.0 [2.9, 11.3]	34	21 (61.8%)	6.6 [2.8, 11.2]	0.89 [0.54, 1.48]	0.6496	
North America	18	15 (83.3%)	8.1 [3.8, 14.0]	10	8 (80.0%)	2.5 [1.0, 10.3]	0.38 [0.15, 0.97]	0.0349	
ECOG performance status									0.9698
0-1	268	186 (69.4%)	5.6 [4.7, 7.5]	125	80 (64.0%)	4.7 [2.9, 7.5]	0.94 [0.72, 1.22]	0.6329	
2	12	8 (66.7%)	3.8 [1.0, NA]	3	1 (33.3%)	NA [0.9, NA]	0.45 [0.05, 4.50]	0.4895	
Prior bortezomib or ixazomib exposure									0.8629
Yes	259	183 (70.7%)	5.0 [3.8, 6.8]	113	73 (64.6%)	3.8 [2.8, 6.6]	0.92 [0.70, 1.21]	0.5403	
No	22	12 (54.5%)	6.6 [2.8, NA]	15	8 (53.3%)	14.3 [1.0, 28.5]	0.87 [0.35, 2.16]	0.7695	

Table 4.5 EORTC-QLQ C30 Cognitive Functioning: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EORTC	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	N	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Refractory to bortezomib									0.7128
Yes	89	64 (71.9%)	4.7 [2.8, 8.4]	48	30 (62.5%)	3.8 [1.9, 11.2]	1.00 [0.65, 1.54]	0.9877	
No	192	131 (68.2%)	5.2 [3.8, 8.4]	80	51 (63.8%)	5.6 [2.9, 10.3]	0.91 [0.66, 1.26]	0.5789	
Prior lenalidomide exposure									0.7180
Yes	112	80 (71.4%)	6.8 [3.8, 10.3]	61	35 (57.4%)	6.6 [2.9, 10.6]	0.95 [0.64, 1.42]	0.8141	
No	169	115 (68.0%)	4.9 [3.8, 6.6]	67	46 (68.7%)	3.8 [1.9, 7.5]	0.89 [0.64, 1.26]	0.5093	
Refractory to lenalidomide									0.7257
Yes	89	62 (69.7%)	7.7 [4.6, 10.8]	46	23 (50.0%)	7.5 [2.8, 12.1]	0.96 [0.59, 1.56]	0.8700	
No	192	133 (69.3%)	4.7 [3.8, 5.9]	82	58 (70.7%)	3.8 [2.0, 6.6]	0.91 [0.67, 1.24]	0.5319	
Prior IMiD exposure									0.8342
Yes	186	131 (70.4%)	4.9 [3.8, 6.8]	90	56 (62.2%)	5.6 [2.8, 9.7]	0.95 [0.70, 1.30]	0.7546	
No	95	64 (67.4%)	5.6 [3.8, 12.2]	38	25 (65.8%)	4.0 [1.9, 20.6]	0.91 [0.57, 1.44]	0.6675	
Refractory to IMiD									0.5736
Yes	117	82 (70.1%)	6.6 [3.8, 9.6]	54	28 (51.9%)	7.5 [2.8, 12.1]	1.02 [0.66, 1.56]	0.9446	
No	164	113 (68.9%)	4.9 [3.8, 7.5]	74	53 (71.6%)	3.8 [2.1, 6.6]	0.89 [0.64, 1.23]	0.4577	
International Staging System (ISS)									0.8924
Stage I or II	229	158 (69.0%)	5.6 [4.7, 8.4]	107	69 (64.5%)	5.6 [3.1, 9.7]	0.93 [0.70, 1.23]	0.6007	
Stage III	51	36 (70.6%)	3.8 [1.9, 10.5]	21	12 (57.1%)	4.9 [1.0, NA]	0.93 [0.48, 1.80]	0.8312	

Table 4.5 EORTC-QLQ C30 Cognitive Functioning: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EORTC	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Prior proteasome inhibitor exposure									0.9662
Yes	260	184 (70.8%)	4.9 [3.8, 6.8]	114	74 (64.9%)	3.8 [2.8, 6.6]	0.91 [0.70, 1.20]	0.5006	
No	21	11 (52.4%)	9.4 [2.8, NA]	14	7 (50.0%)	14.3 [4.2, 28.5]	0.91 [0.35, 2.36]	0.8395	
Number of prior lines of therapy									0.7938
1	130	90 (69.2%)	4.7 [3.8, 5.9]	57	38 (66.7%)	4.2 [2.8, 11.0]	0.97 [0.66, 1.41]	0.8625	
>= 2	151	105 (69.5%)	6.6 [3.8, 9.4]	71	43 (60.6%)	5.6 [2.2, 10.3]	0.88 [0.62, 1.26]	0.4919	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
[a]From Kaplan–Meier estimate
[b]HR: hazard ratio
NA denotes that the median time (and 95% CI) were not estimable

Table 4.6 EORTC-QLQ C30 Social Functioning: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EORTC	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Age									0.2227
<= 75	257	168 (65.4%)	3.3 [2.1, 4.7]	112	82 (73.2%)	2.8 [2.1, 4.7]	0.80 [0.61, 1.04]	0.0837	
> 75	24	15 (62.5%)	5.6 [1.9, 15.9]	16	13 (81.3%)	1.9 [1.0, 4.7]	0.37 [0.16, 0.85]	0.0110	
Sex									0.5734
Male	161	103 (64.0%)	3.3 [1.9, 6.6]	78	57 (73.1%)	2.8 [1.9, 4.0]	0.71 [0.51, 0.99]	0.0324	
Female	120	80 (66.7%)	3.8 [2.1, 5.6]	50	38 (76.0%)	2.1 [1.9, 5.6]	0.83 [0.56, 1.22]	0.3094	
Race									0.6274
White	220	147 (66.8%)	2.8 [2.0, 4.7]	104	78 (75.0%)	2.8 [1.9, 4.0]	0.79 [0.60, 1.04]	0.0738	
Non-White	61	36 (59.0%)	6.5 [3.1, 16.4]	24	17 (70.8%)	2.8 [1.0, 13.1]	0.67 [0.38, 1.21]	0.1655	
Geographic region									0.2812
Europe	182	122 (67.0%)	2.9 [2.0, 4.7]	84	63 (75.0%)	2.8 [1.9, 4.0]	0.76 [0.56, 1.03]	0.0624	
Asia Pacific	81	51 (63.0%)	3.8 [1.9, 10.3]	34	26 (76.5%)	3.3 [1.4, 9.4]	0.75 [0.47, 1.21]	0.2210	
North America	18	10 (55.6%)	11.2 [1.9, NA]	10	6 (60.0%)	4.3 [1.0, NA]	0.65 [0.23, 1.87]	0.4174	
ECOG performance status									0.9522
0-1	268	176 (65.7%)	3.8 [2.8, 4.7]	125	93 (74.4%)	2.8 [1.9, 4.0]	0.76 [0.59, 0.98]	0.0274	
2	12	7 (58.3%)	4.2 [1.0, NA]	3	2 (66.7%)	5.6 [1.0, 5.6]	0.89 [0.18, 4.30]	0.8808	
Prior bortezomib or ixazomib exposure									0.2928
Yes	259	167 (64.5%)	3.8 [2.8, 4.8]	113	86 (76.1%)	2.8 [1.9, 4.0]	0.73 [0.56, 0.94]	0.0110	
No	22	16 (72.7%)	2.8 [1.0, 8.9]	15	9 (60.0%)	3.8 [1.0, 22.7]	1.15 [0.51, 2.62]	0.7216	

Table 4.6 EORTC-QLQ C30 Social Functioning: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EORTC	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Refractory to bortezomib									0.7474
Yes	89	55 (61.8%)	4.2 [2.2, 11.3]	48	32 (66.7%)	3.8 [1.9, 5.6]	0.81 [0.52, 1.25]	0.3084	
No	192	128 (66.7%)	3.1 [2.0, 4.8]	80	63 (78.8%)	2.8 [1.9, 4.0]	0.74 [0.54, 1.00]	0.0379	
Prior lenalidomide exposure									0.9156
Yes	112	71 (63.4%)	3.8 [1.9, 6.6]	61	43 (70.5%)	3.8 [2.0, 5.6]	0.77 [0.53, 1.13]	0.1682	
No	169	112 (66.3%)	3.8 [2.0, 5.9]	67	52 (77.6%)	2.1 [1.9, 4.0]	0.75 [0.54, 1.04]	0.0697	
Refractory to lenalidomide									0.5560
Yes	89	53 (59.6%)	4.7 [2.8, 24.4]	46	31 (67.4%)	3.8 [1.9, 7.5]	0.69 [0.44, 1.08]	0.0935	
No	192	130 (67.7%)	3.1 [1.9, 4.7]	82	64 (78.0%)	2.8 [1.9, 4.0]	0.80 [0.59, 1.08]	0.1183	
Prior IMiD exposure									0.1660
Yes	186	120 (64.5%)	2.8 [1.9, 4.2]	90	64 (71.1%)	3.8 [2.0, 5.6]	0.86 [0.63, 1.16]	0.2916	
No	95	63 (66.3%)	4.7 [2.8, 11.3]	38	31 (81.6%)	1.9 [1.9, 4.0]	0.55 [0.36, 0.86]	0.0047	
Refractory to IMiD									0.9321
Yes	117	71 (60.7%)	4.2 [2.8, 8.7]	54	36 (66.7%)	3.8 [2.0, 7.9]	0.77 [0.51, 1.16]	0.1921	
No	164	112 (68.3%)	2.8 [1.9, 4.7]	74	59 (79.7%)	2.1 [1.9, 4.0]	0.76 [0.55, 1.04]	0.0717	
International Staging System (ISS)									0.7681
Stage I or II	229	150 (65.5%)	3.8 [2.8, 5.6]	107	78 (72.9%)	2.8 [2.0, 4.7]	0.76 [0.58, 1.01]	0.0441	
Stage III	51	32 (62.7%)	2.8 [1.2, 6.5]	21	17 (81.0%)	1.9 [1.0, 5.6]	0.71 [0.39, 1.28]	0.2282	

Table 4.6 EORTC-QLQ C30 Social Functioning: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EORTC	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Prior proteasome inhibitor exposure									0.2433
Yes	260	168 (64.6%)	3.8 [2.8, 4.8]	114	87 (76.3%)	2.8 [1.9, 4.0]	0.72 [0.56, 0.94]	0.0093	
No	21	15 (71.4%)	2.8 [1.0, 8.9]	14	8 (57.1%)	3.8 [1.3, NA]	1.22 [0.52, 2.90]	0.6286	
Number of prior lines of therapy									0.3889
1	130	85 (65.4%)	3.8 [2.0, 8.4]	57	47 (82.5%)	2.8 [1.9, 4.0]	0.67 [0.47, 0.96]	0.0198	
>= 2	151	98 (64.9%)	3.8 [1.9, 4.7]	71	48 (67.6%)	3.7 [1.9, 5.6]	0.84 [0.60, 1.19]	0.3168	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
[a]From Kaplan–Meier estimate
[b]HR: hazard ratio
NA denotes that the median time (and 95% CI) were not estimable

Table 4.7 EORTC-QLQ C30 Fatigue Symptom: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EORTC	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Age									0.1580
<= 75	257	194 (75.5%)	2.8 [1.9, 2.9]	112	77 (68.8%)	2.8 [1.9, 3.3]	1.05 [0.81, 1.37]	0.6941	
> 75	24	19 (79.2%)	2.8 [1.0, 3.8]	16	14 (87.5%)	1.0 [1.0, 2.9]	0.65 [0.32, 1.31]	0.1888	
Sex									0.6358
Male	161	123 (76.4%)	2.8 [1.9, 2.9]	78	53 (67.9%)	2.8 [1.9, 3.8]	1.03 [0.74, 1.42]	0.8482	
Female	120	90 (75.0%)	2.1 [1.3, 3.8]	50	38 (76.0%)	2.1 [1.9, 2.9]	0.91 [0.62, 1.33]	0.5985	
Race									0.3028
White	220	164 (74.5%)	2.8 [1.9, 3.7]	104	73 (70.2%)	2.2 [1.9, 2.9]	0.91 [0.69, 1.20]	0.4705	
Non-White	61	49 (80.3%)	1.0 [1.0, 1.9]	24	18 (75.0%)	2.9 [1.0, 4.7]	1.28 [0.75, 2.21]	0.3262	
Geographic region									0.3598
Europe	182	138 (75.8%)	2.8 [1.9, 3.8]	84	60 (71.4%)	2.8 [1.9, 3.0]	0.95 [0.70, 1.29]	0.7375	
Asia Pacific	81	63 (77.8%)	1.4 [1.0, 1.9]	34	23 (67.6%)	2.8 [1.0, 4.7]	1.16 [0.72, 1.87]	0.5026	
North America	18	12 (66.7%)	4.3 [1.0, 18.7]	10	8 (80.0%)	1.5 [0.9, 6.5]	0.53 [0.20, 1.39]	0.1616	
ECOG performance status									0.5562
0-1	268	202 (75.4%)	2.8 [1.9, 2.8]	125	90 (72.0%)	2.2 [1.9, 2.9]	0.97 [0.75, 1.24]	0.7803	
2	12	10 (83.3%)	3.8 [1.0, 11.2]	3	1 (33.3%)	3.8 [, NA]	1.43 [0.17, 11.68]	0.7025	
Prior bortezomib or ixazomib exposure									0.0955
Yes	259	195 (75.3%)	2.8 [1.9, 3.1]	113	83 (73.5%)	2.2 [1.9, 2.9]	0.92 [0.71, 1.19]	0.4911	
No	22	18 (81.8%)	1.9 [1.0, 2.8]	15	8 (53.3%)	6.1 [1.0, NA]	1.98 [0.85, 4.64]	0.0775	

Table 4.7 EORTC-QLQ C30 Fatigue Symptom: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EORTC	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Refractory to bortezomib									0.8428
Yes	89	62 (69.7%)	2.8 [1.9, 4.7]	48	33 (68.8%)	2.8 [1.9, 4.0]	1.01 [0.66, 1.54]	0.9643	
No	192	151 (78.6%)	2.4 [1.9, 2.8]	80	58 (72.5%)	2.3 [1.9, 2.9]	0.95 [0.70, 1.29]	0.7459	
Prior lenalidomide exposure									0.3998
Yes	112	83 (74.1%)	1.9 [1.2, 3.7]	61	41 (67.2%)	2.9 [2.1, 3.8]	1.11 [0.76, 1.62]	0.5722	
No	169	130 (76.9%)	2.8 [1.9, 3.1]	67	50 (74.6%)	1.9 [1.0, 2.8]	0.87 [0.63, 1.21]	0.3744	
Refractory to lenalidomide									0.3075
Yes	89	64 (71.9%)	2.8 [1.8, 4.1]	46	28 (60.9%)	3.3 [2.2, 7.7]	1.18 [0.76, 1.85]	0.4466	
No	192	149 (77.6%)	2.1 [1.9, 2.8]	82	63 (76.8%)	1.9 [1.8, 2.8]	0.88 [0.65, 1.18]	0.3455	
Prior IMiD exposure									0.5805
Yes	186	137 (73.7%)	1.9 [1.8, 2.8]	90	63 (70.0%)	2.8 [1.9, 3.3]	1.04 [0.77, 1.41]	0.7679	
No	95	76 (80.0%)	2.8 [1.9, 4.7]	38	28 (73.7%)	1.9 [1.0, 3.1]	0.85 [0.55, 1.32]	0.4335	
Refractory to IMiD									0.0882
Yes	117	86 (73.5%)	1.9 [1.2, 3.1]	54	33 (61.1%)	3.0 [2.3, 7.7]	1.29 [0.86, 1.94]	0.1849	
No	164	127 (77.4%)	2.8 [1.9, 3.8]	74	58 (78.4%)	1.9 [1.0, 2.8]	0.80 [0.59, 1.10]	0.1402	
International Staging System (ISS)									0.6804
Stage I or II	229	177 (77.3%)	2.8 [1.9, 2.8]	107	79 (73.8%)	2.3 [1.9, 2.9]	0.97 [0.74, 1.26]	0.7832	
Stage III	51	36 (70.6%)	2.8 [1.2, 10.3]	21	12 (57.1%)	3.3 [1.9, NA]	1.18 [0.61, 2.28]	0.5995	

Table 4.7 EORTC-QLQ C30 Fatigue Symptom: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EORTC	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Prior proteasome inhibitor exposure									0.0701
Yes	260	196 (75.4%)	2.8 [1.9, 3.1]	114	84 (73.7%)	2.2 [1.9, 2.9]	0.91 [0.70, 1.18]	0.4514	
No	21	17 (81.0%)	1.9 [1.0, 2.8]	14	7 (50.0%)	6.1 [1.0, NA]	2.23 [0.91, 5.49]	0.0501	
Number of prior lines of therapy									0.5015
1	130	103 (79.2%)	1.9 [1.2, 2.9]	57	44 (77.2%)	1.9 [1.0, 2.8]	0.89 [0.62, 1.27]	0.4690	
>= 2	151	110 (72.8%)	2.8 [1.9, 3.7]	71	47 (66.2%)	2.8 [1.9, 4.0]	1.07 [0.76, 1.50]	0.7046	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
[a]From Kaplan–Meier estimate
[b]HR: hazard ratio
NA denotes that the median time (and 95% CI) were not estimable

Table 4.8 EORTC-QLQ C30 Nausea/Vomiting Symptom: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EORTC	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Age									0.7736
<= 75	257	136 (52.9%)	12.4 [8.4, 15.9]	112	45 (40.2%)	17.8 [14.0, NA]	1.32 [0.94, 1.85]	0.0978	
> 75	24	12 (50.0%)	18.7 [4.7, 32.0]	16	6 (37.5%)	18.2 [6.8, NA]	1.08 [0.40, 2.92]	0.8846	
Sex									0.4703
Male	161	74 (46.0%)	17.8 [13.1, NA]	78	23 (29.5%)	NA [17.8, NA]	1.47 [0.92, 2.34]	0.1041	
Female	120	74 (61.7%)	6.6 [4.7, 10.3]	50	28 (56.0%)	10.3 [5.6, 18.2]	1.16 [0.75, 1.79]	0.5004	
Race									0.6024
White	220	112 (50.9%)	13.2 [8.4, 19.2]	104	41 (39.4%)	21.7 [14.0, NA]	1.24 [0.87, 1.78]	0.2256	
Non-White	61	36 (59.0%)	10.3 [5.6, 17.3]	24	10 (41.7%)	18.2 [6.6, NA]	1.53 [0.75, 3.08]	0.2290	
Geographic region									0.7840
Europe	182	89 (48.9%)	14.0 [10.3, 21.5]	84	32 (38.1%)	21.7 [10.3, NA]	1.27 [0.85, 1.90]	0.2389	
Asia Pacific	81	47 (58.0%)	9.4 [4.7, 16.1]	34	15 (44.1%)	14.8 [6.6, NA]	1.27 [0.71, 2.29]	0.4094	
North America	18	12 (66.7%)	6.6 [1.9, NA]	10	4 (40.0%)	22.4 [0.9, 22.4]	1.44 [0.46, 4.54]	0.5276	
ECOG performance status									0.7215
0-1	268	139 (51.9%)	13.1 [8.4, 17.8]	125	50 (40.0%)	18.2 [14.0, NA]	1.31 [0.94, 1.80]	0.1009	
2	12	8 (66.7%)	5.6 [2.8, NA]	3	1 (33.3%)	NA [2.8, NA]	0.43 [0.04, 4.77]	0.4675	
Prior bortezomib or ixazomib exposure									0.7465
Yes	259	136 (52.5%)	12.9 [6.8, 16.1]	113	46 (40.7%)	18.2 [14.0, NA]	1.28 [0.91, 1.78]	0.1457	
No	22	12 (54.5%)	15.9 [5.6, NA]	15	5 (33.3%)	NA [6.6, NA]	1.41 [0.49, 4.01]	0.5145	

Table 4.8 EORTC-QLQ C30 Nausea/Vomiting Symptom: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EORTC	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Refractory to bortezomib									0.3914
Yes	89	47 (52.8%)	6.6 [4.7, 23.9]	48	16 (33.3%)	NA [10.3, NA]	1.58 [0.90, 2.80]	0.1041	
No	192	101 (52.6%)	14.0 [9.4, 19.2]	80	35 (43.8%)	17.8 [10.3, NA]	1.18 [0.81, 1.74]	0.3811	
Prior lenalidomide exposure									0.5108
Yes	112	55 (49.1%)	14.0 [6.6, NA]	61	23 (37.7%)	14.8 [9.4, NA]	1.16 [0.71, 1.89]	0.5415	
No	169	93 (55.0%)	12.9 [5.7, 16.1]	67	28 (41.8%)	22.4 [16.4, NA]	1.43 [0.93, 2.18]	0.0943	
Refractory to lenalidomide									0.2977
Yes	89	45 (50.6%)	14.0 [6.6, NA]	46	18 (39.1%)	14.8 [6.6, NA]	1.04 [0.60, 1.81]	0.8732	
No	192	103 (53.6%)	12.9 [6.8, 16.1]	82	33 (40.2%)	23.6 [14.0, NA]	1.46 [0.99, 2.17]	0.0526	
Prior IMiD exposure									0.4916
Yes	186	104 (55.9%)	10.3 [5.6, 14.0]	90	37 (41.1%)	17.0 [10.3, 24.3]	1.44 [0.99, 2.09]	0.0536	
No	95	44 (46.3%)	19.7 [12.2, NA]	38	14 (36.8%)	NA [8.0, NA]	1.14 [0.62, 2.07]	0.6773	
Refractory to IMiD									0.2517
Yes	117	60 (51.3%)	12.4 [6.6, 23.9]	54	22 (40.7%)	14.8 [6.8, 18.2]	1.04 [0.63, 1.69]	0.8845	
No	164	88 (53.7%)	13.1 [6.8, 19.2]	74	29 (39.2%)	24.3 [14.0, NA]	1.51 [0.99, 2.29]	0.0511	
International Staging System (ISS)									0.0359
Stage I or II	229	122 (53.3%)	13.2 [8.0, 18.7]	107	41 (38.3%)	21.7 [16.4, NA]	1.46 [1.02, 2.08]	0.0339	
Stage III	51	25 (49.0%)	12.2 [5.6, 21.5]	21	10 (47.6%)	3.8 [1.9, NA]	0.55 [0.26, 1.17]	0.1088	

Table 4.8 EORTC-QLQ C30 Nausea/Vomiting Symptom: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EORTC	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Prior proteasome inhibitor exposure									0.3945
Yes	260	136 (52.3%)	12.9 [8.0, 17.3]	114	47 (41.2%)	18.2 [14.0, NA]	1.24 [0.89, 1.73]	0.1963	
No	21	12 (57.1%)	15.9 [3.8, NA]	14	4 (28.6%)	NA [6.6, NA]	1.88 [0.60, 5.85]	0.2624	
Number of prior lines of therapy									0.5362
1	130	66 (50.8%)	15.9 [10.5, 21.5]	57	21 (36.8%)	23.6 [14.0, NA]	1.46 [0.89, 2.39]	0.1235	
>= 2	151	82 (54.3%)	9.4 [5.6, 15.7]	71	30 (42.3%)	16.4 [9.4, 24.3]	1.20 [0.79, 1.82]	0.3858	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
[a]From Kaplan–Meier estimate
[b]HR: hazard ratio
NA denotes that the median time (and 95% CI) were not estimable

Table 4.9 EORTC-QLQ C30 Pain Symptom: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EORTC	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Age									0.1316
<= 75	257	153 (59.5%)	8.4 [4.9, 12.2]	112	68 (60.7%)	5.8 [4.0, 8.9]	0.83 [0.62, 1.10]	0.1816	
> 75	24	14 (58.3%)	11.5 [4.7, NA]	16	11 (68.8%)	2.8 [1.3, 9.3]	0.35 [0.14, 0.87]	0.0161	
Sex									0.7439
Male	161	100 (62.1%)	7.5 [3.8, 12.2]	78	47 (60.3%)	4.7 [2.8, 9.3]	0.81 [0.57, 1.15]	0.2268	
Female	120	67 (55.8%)	11.2 [5.6, 16.3]	50	32 (64.0%)	5.6 [4.0, 8.4]	0.73 [0.48, 1.11]	0.1332	
Race									0.7545
White	220	130 (59.1%)	10.3 [5.9, 13.8]	104	64 (61.5%)	4.7 [3.8, 8.4]	0.75 [0.55, 1.01]	0.0505	
Non-White	61	37 (60.7%)	5.6 [3.1, 17.8]	24	15 (62.5%)	6.5 [2.8, 14.3]	0.93 [0.51, 1.71]	0.8229	
Geographic region									0.3444
Europe	182	105 (57.7%)	10.5 [5.9, 14.0]	84	55 (65.5%)	4.0 [3.1, 7.5]	0.66 [0.47, 0.92]	0.0112	
Asia Pacific	81	52 (64.2%)	5.6 [2.8, 12.2]	34	19 (55.9%)	5.6 [3.1, 23.4]	1.01 [0.60, 1.71]	0.9702	
North America	18	10 (55.6%)	7.2 [1.0, NA]	10	5 (50.0%)	6.8 [1.0, NA]	0.97 [0.33, 2.87]	0.9574	
ECOG performance status									0.8603
0-1	268	162 (60.4%)	8.4 [5.6, 11.7]	125	78 (62.4%)	4.9 [3.8, 8.4]	0.79 [0.60, 1.03]	0.0761	
2	12	5 (41.7%)	20.6 [1.0, NA]	3	1 (33.3%)	5.6 [, NA]	0.71 [0.08, 6.45]	0.7524	
Prior bortezomib or ixazomib exposure									0.6389
Yes	259	152 (58.7%)	8.4 [5.2, 12.2]	113	71 (62.8%)	4.9 [3.8, 7.7]	0.76 [0.57, 1.01]	0.0524	
No	22	15 (68.2%)	13.8 [2.8, 17.8]	15	8 (53.3%)	19.2 [1.3, 19.9]	0.85 [0.35, 2.05]	0.7074	

Table 4.9 EORTC-QLQ C30 Pain Symptom: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EORTC	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Refractory to bortezomib									0.1199
Yes	89	49 (55.1%)	7.5 [3.8, 15.9]	48	25 (52.1%)	9.3 [4.0, 14.3]	1.05 [0.65, 1.70]	0.8509	
No	192	118 (61.5%)	8.5 [5.6, 13.1]	80	54 (67.5%)	3.8 [2.8, 6.8]	0.65 [0.47, 0.90]	0.0077	
Prior lenalidomide exposure									0.2473
Yes	112	67 (59.8%)	5.6 [3.8, 12.4]	61	34 (55.7%)	5.6 [4.0, 19.2]	0.94 [0.62, 1.43]	0.7687	
No	169	100 (59.2%)	10.5 [5.7, 14.0]	67	45 (67.2%)	4.1 [3.1, 8.4]	0.66 [0.46, 0.94]	0.0177	
Refractory to lenalidomide									0.0630
Yes	89	55 (61.8%)	5.9 [3.8, 12.4]	46	21 (45.7%)	7.5 [4.0, NA]	1.17 [0.70, 1.95]	0.5350	
No	192	112 (58.3%)	9.6 [5.6, 13.8]	82	58 (70.7%)	4.1 [2.8, 7.7]	0.64 [0.46, 0.88]	0.0042	
Prior IMiD exposure									0.2295
Yes	186	110 (59.1%)	5.9 [3.8, 11.3]	90	54 (60.0%)	6.5 [4.0, 8.9]	0.88 [0.63, 1.22]	0.4298	
No	95	57 (60.0%)	12.2 [7.1, 15.3]	38	25 (65.8%)	3.8 [2.8, 9.3]	0.57 [0.35, 0.92]	0.0176	
Refractory to IMiD									0.0689
Yes	117	71 (60.7%)	5.6 [3.8, 11.5]	54	26 (48.1%)	7.5 [4.0, NA]	1.12 [0.71, 1.76]	0.6274	
No	164	96 (58.5%)	10.5 [5.7, 14.2]	74	53 (71.6%)	4.0 [2.8, 8.4]	0.62 [0.44, 0.87]	0.0038	
International Staging System (ISS)									0.7217
Stage I or II	229	138 (60.3%)	7.1 [4.9, 12.2]	107	67 (62.6%)	5.6 [3.8, 8.9]	0.79 [0.59, 1.07]	0.1165	
Stage III	51	29 (56.9%)	11.2 [4.7, 16.3]	21	12 (57.1%)	4.9 [1.9, 8.4]	0.66 [0.33, 1.31]	0.2162	

Table 4.9 EORTC-QLQ C30 Pain Symptom: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EORTC	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd:		
QLQ C30 Scale	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Prior proteasome inhibitor exposure									0.5407
Yes	260	153 (58.8%)	8.4 [5.2, 11.7]	114	72 (63.2%)	4.9 [3.8, 7.7]	0.76 [0.57, 1.00]	0.0456	
No	21	14 (66.7%)	13.8 [2.8, 25.2]	14	7 (50.0%)	19.2 [1.9, 19.9]	0.88 [0.35, 2.24]	0.7865	
Number of prior lines of therapy									0.3065
1	130	76 (58.5%)	11.7 [5.7, 15.9]	57	38 (66.7%)	4.9 [2.8, 8.4]	0.66 [0.45, 0.99]	0.0347	
>= 2	151	91 (60.3%)	6.6 [4.7, 10.3]	71	41 (57.7%)	5.6 [3.8, 11.3]	0.89 [0.61, 1.28]	0.5101	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
[a]From Kaplan–Meier estimate
[b]HR: hazard ratio
NA denotes that the median time (and 95% CI) were not estimable

Table 5.3 QLQ MY-20 Body image: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EORTC	KdD (N=278)			Kd (N=133)			Treatment Comparison KdD vs. Kd:		
QLQ MY-20	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Age									0.9265
<= 75	254	137 (53.9%)	10.3 [7.6, 17.4]	115	64 (55.7%)	5.6 [3.8, 15.5]	0.85 [0.63, 1.14]	0.2684	
> 75	24	12 (50.0%)	14.3 [1.9, NA]	18	10 (55.6%)	7.0 [1.9, NA]	0.86 [0.37, 2.00]	0.7189	
Sex									0.8569
Male	160	84 (52.5%)	12.9 [7.6, 22.0]	81	43 (53.1%)	9.4 [3.8, 16.4]	0.86 [0.59, 1.24]	0.3972	
Female	118	65 (55.1%)	8.9 [4.7, 21.6]	52	31 (59.6%)	4.7 [2.3, 11.5]	0.82 [0.53, 1.25]	0.3398	
Race									0.5591
White	219	115 (52.5%)	12.4 [8.4, 20.6]	106	59 (55.7%)	5.6 [3.8, 15.7]	0.80 [0.59, 1.10]	0.1652	
Non-White	59	34 (57.6%)	7.5 [2.8, NA]	27	15 (55.6%)	9.4 [2.7, NA]	1.01 [0.55, 1.86]	0.9739	
Geographic region									0.8149
Europe	181	97 (53.6%)	10.3 [8.4, 19.9]	87	50 (57.5%)	4.7 [3.8, 15.5]	0.81 [0.58, 1.14]	0.2184	
Asia Pacific	79	40 (50.6%)	7.5 [2.8, NA]	36	18 (50.0%)	9.4 [2.8, NA]	1.04 [0.60, 1.81]	0.8890	
North America	18	12 (66.7%)	9.4 [2.8, NA]	10	6 (60.0%)	4.7 [0.9, NA]	0.78 [0.29, 2.10]	0.6234	
ECOG performance status									0.2950
0-1	265	142 (53.6%)	10.3 [7.6, 17.1]	129	71 (55.0%)	5.6 [4.0, 15.5]	0.87 [0.65, 1.15]	0.3123	
2	12	6 (50.0%)	21.6 [1.0, NA]	4	3 (75.0%)	1.8 [0.9, NA]	0.34 [0.08, 1.56]	0.1437	
Prior bortezomib or ixazomib exposure									0.1876
Yes	257	139 (54.1%)	10.3 [7.6, 17.4]	118	69 (58.5%)	4.7 [3.8, 9.4]	0.78 [0.58, 1.04]	0.0871	
No	21	10 (47.6%)	13.3 [1.9, NA]	15	5 (33.3%)	NA [2.9, NA]	1.62 [0.55, 4.75]	0.3698	

Table 5.3 QLQ MY-20 Body image: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EORTC	KdD (N=278)			Kd (N=133)			Treatment Comparison KdD vs. Kd:		
QLQ MY-20	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Refractory to bortezomib or ixazomib									0.4256
Yes	89	47 (52.8%)	10.3 [4.8, 23.9]	49	29 (59.2%)	3.8 [2.3, 11.5]	0.72 [0.45, 1.15]	0.1496	
No	189	102 (54.0%)	12.4 [7.5, 21.6]	84	45 (53.6%)	9.4 [4.7, 18.7]	0.93 [0.65, 1.32]	0.6712	
Prior lenalidomide exposure									0.3589
Yes	111	59 (53.2%)	11.5 [4.8, 26.6]	64	37 (57.8%)	4.6 [2.8, 13.3]	0.74 [0.49, 1.12]	0.1506	
No	167	90 (53.9%)	10.3 [6.6, 19.9]	69	37 (53.6%)	9.4 [4.0, 18.7]	0.95 [0.65, 1.40]	0.8066	
Refractory to lenalidomide									0.4238
Yes	88	46 (52.3%)	13.3 [7.5, 26.6]	48	26 (54.2%)	3.8 [2.8, NA]	0.72 [0.44, 1.17]	0.1711	
No	190	103 (54.2%)	9.6 [5.6, 17.4]	85	48 (56.5%)	7.0 [4.0, 15.7]	0.92 [0.65, 1.29]	0.6200	
Prior IMiD exposure									0.1400
Yes	184	93 (50.5%)	9.6 [6.1, 26.6]	95	55 (57.9%)	4.7 [2.9, 9.4]	0.75 [0.54, 1.05]	0.0862	
No	94	56 (59.6%)	10.3 [5.6, 17.4]	38	19 (50.0%)	15.5 [4.7, NA]	1.14 [0.67, 1.91]	0.6242	
Refractory to IMiD									0.3048
Yes	116	60 (51.7%)	12.9 [6.7, 26.6]	56	31 (55.4%)	3.8 [2.8, NA]	0.72 [0.46, 1.11]	0.1312	
No	162	89 (54.9%)	10.3 [5.6, 17.4]	77	43 (55.8%)	7.5 [4.7, 16.4]	0.95 [0.66, 1.37]	0.7920	
International Staging System (ISS)									0.9592
Stage I or II	226	117 (51.8%)	12.9 [7.5, 22.4]	111	62 (55.9%)	5.6 [4.6, 15.7]	0.83 [0.61, 1.13]	0.2201	
Stage III	51	31 (60.8%)	8.4 [2.8, 15.9]	22	12 (54.5%)	3.8 [1.9, NA]	0.85 [0.43, 1.66]	0.6223	

Table 5.3 QLQ MY-20 Body image: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EORTC	KdD (N=278)			Kd (N=133)			Treatment Comparison KdD vs. Kd:		
QLQ MY-20	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Prior proteasome inhibitor exposure									0.1645
Yes	258	140 (54.3%)	10.3 [7.6, 17.1]	119	70 (58.8%)	4.7 [3.8, 9.4]	0.78 [0.58, 1.04]	0.0810	
No	20	9 (45.0%)	13.3 [2.8, NA]	14	4 (28.6%)	NA [3.4, NA]	1.82 [0.56, 5.93]	0.3093	
Number of prior lines of therapy									0.3071
1	128	67 (52.3%)	13.1 [8.5, 22.4]	58	29 (50.0%)	15.7 [4.7, NA]	0.99 [0.64, 1.53]	0.9658	
>= 2	150	82 (54.7%)	8.4 [4.7, 17.4]	75	45 (60.0%)	3.8 [2.8, 7.0]	0.75 [0.52, 1.09]	0.1182	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
[a]From Kaplan–Meier estimate
[b]HR: hazard ratio
NA denotes that the median time (and 95% CI) were not estimable

Table 5.4 QLQ MY-20 Future perspective: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EORTC	KdD (N=278)			Kd (N=133)			Treatment Comparison KdD vs. Kd:		
QLQ MY-20	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Age									0.3526
<= 75	254	154 (60.6%)	7.7 [5.6, 12.2]	115	65 (56.5%)	7.7 [4.7, 14.5]	0.97 [0.73, 1.30]	0.8506	
> 75	24	14 (58.3%)	3.7 [1.0, NA]	18	12 (66.7%)	4.7 [1.3, 8.9]	0.79 [0.36, 1.72]	0.5341	
Sex									0.9287
Male	160	99 (61.9%)	7.5 [4.7, 14.0]	81	47 (58.0%)	8.1 [4.7, 15.0]	0.91 [0.64, 1.30]	0.6037	
Female	118	69 (58.5%)	7.5 [3.8, 17.8]	52	30 (57.7%)	7.5 [3.8, 14.5]	0.95 [0.62, 1.47]	0.8284	
Race									0.7866
White	219	129 (58.9%)	8.9 [4.6, 14.0]	106	62 (58.5%)	7.5 [4.6, 14.1]	0.91 [0.67, 1.24]	0.5489	
Non-White	59	39 (66.1%)	7.0 [4.7, 16.1]	27	15 (55.6%)	8.9 [1.6, NA]	1.02 [0.56, 1.86]	0.9383	
Geographic region									0.0938
Europe	181	106 (58.6%)	7.7 [4.7, 12.9]	87	55 (63.2%)	5.6 [3.8, 8.4]	0.82 [0.59, 1.14]	0.2141	
Asia Pacific	79	54 (68.4%)	5.7 [2.9, 14.0]	36	19 (52.8%)	8.9 [2.9, NA]	1.18 [0.70, 1.99]	0.5296	
North America	18	8 (44.4%)	NA [2.8, NA]	10	3 (30.0%)	NA [1.0, NA]	1.21 [0.31, 4.71]	0.7781	
ECOG performance status									0.5310
0-1	265	160 (60.4%)	7.5 [5.6, 12.2]	129	76 (58.9%)	7.5 [4.6, 14.0]	0.92 [0.70, 1.21]	0.5454	
2	12	7 (58.3%)	7.5 [1.0, NA]	4	1 (25.0%)	5.6 [, NA]	1.57 [0.19, 13.23]	0.6698	
Prior bortezomib or ixazomib exposure									0.5894
Yes	257	155 (60.3%)	7.5 [5.6, 12.2]	118	70 (59.3%)	7.5 [4.6, 12.2]	0.91 [0.68, 1.21]	0.4916	
No	21	13 (61.9%)	3.7 [1.0, NA]	15	7 (46.7%)	NA [1.0, NA]	1.18 [0.46, 3.00]	0.7040	

Table 5.4 QLQ MY-20 Future perspective: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EORTC	KdD (N=278)			Kd (N=133)			Treatment Comparison KdD vs. Kd:		
QLQ MY-20	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Refractory to bortezomib or ixazomib									0.3926
Yes	89	50 (56.2%)	9.3 [3.8, 17.8]	49	30 (61.2%)	4.9 [1.9, 14.1]	0.81 [0.51, 1.27]	0.3367	
No	189	118 (62.4%)	7.5 [4.8, 12.2]	84	47 (56.0%)	8.4 [5.0, 15.0]	1.01 [0.72, 1.42]	0.9410	
Prior lenalidomide exposure									0.9412
Yes	111	66 (59.5%)	7.5 [4.7, 18.7]	64	35 (54.7%)	8.2 [3.8, 20.6]	0.89 [0.59, 1.35]	0.5646	
No	167	102 (61.1%)	7.5 [3.8, 11.3]	69	42 (60.9%)	7.5 [4.0, 12.2]	0.95 [0.66, 1.36]	0.7774	
Refractory to lenalidomide									0.8977
Yes	88	54 (61.4%)	7.5 [4.2, 19.7]	48	26 (54.2%)	8.2 [3.8, 20.6]	0.92 [0.57, 1.48]	0.7344	
No	190	114 (60.0%)	7.5 [4.6, 11.3]	85	51 (60.0%)	7.5 [3.8, 12.2]	0.94 [0.67, 1.30]	0.6840	
Prior IMiD exposure									0.1184
Yes	184	111 (60.3%)	7.5 [4.7, 16.1]	95	49 (51.6%)	8.9 [5.0, 20.6]	1.07 [0.77, 1.50]	0.6739	
No	94	57 (60.6%)	7.7 [3.8, 12.9]	38	28 (73.7%)	4.7 [2.1, 8.1]	0.68 [0.43, 1.07]	0.0795	
Refractory to IMiD									0.5205
Yes	116	73 (62.9%)	6.6 [3.8, 17.1]	56	30 (53.6%)	8.2 [3.8, 20.6]	1.02 [0.66, 1.57]	0.9248	
No	162	95 (58.6%)	8.9 [4.7, 12.9]	77	47 (61.0%)	7.5 [2.9, 14.0]	0.88 [0.62, 1.26]	0.4758	
International Staging System (ISS)									0.7965
Stage I or II	226	137 (60.6%)	7.7 [5.6, 14.0]	111	65 (58.6%)	8.1 [4.7, 14.1]	0.91 [0.68, 1.23]	0.5411	
Stage III	51	31 (60.8%)	4.7 [1.9, 19.6]	22	12 (54.5%)	3.8 [1.9, NA]	1.03 [0.53, 2.02]	0.9270	

Table 5.4 QLQ MY-20 Future perspective: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EORTC	KdD (N=278)			Kd (N=133)			Treatment Comparison KdD vs. Kd:		
QLQ MY-20	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Prior proteasome inhibitor exposure									0.4887
Yes	258	156 (60.5%)	7.5 [5.6, 12.1]	119	71 (59.7%)	7.5 [4.6, 12.2]	0.90 [0.68, 1.19]	0.4552	
No	20	12 (60.0%)	3.7 [1.0, NA]	14	6 (42.9%)	NA [1.0, NA]	1.30 [0.48, 3.51]	0.5755	
Number of prior lines of therapy									0.9244
1	128	80 (62.5%)	7.7 [4.6, 16.1]	58	34 (58.6%)	5.6 [2.8, 15.0]	0.95 [0.63, 1.42]	0.7829	
>= 2	150	88 (58.7%)	7.5 [4.2, 16.1]	75	43 (57.3%)	8.2 [4.6, 14.5]	0.92 [0.64, 1.33]	0.6492	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
[a]From Kaplan–Meier estimate
[b]HR: hazard ratio
NA denotes that the median time (and 95% CI) were not estimable

Table 5.1 QLQ MY-20 Disease Symptoms: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EORTC	KdD (N=278)			Kd (N=133)			Treatment Comparison KdD vs. Kd:		
QLQ MY-20	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Age									0.2881
<= 75	254	158 (62.2%)	2.9 [2.0, 5.0]	115	66 (57.4%)	4.7 [2.0, 13.3]	1.05 [0.79, 1.40]	0.7253	
> 75	24	16 (66.7%)	1.9 [1.0, NA]	18	8 (44.4%)	14.5 [1.3, NA]	1.69 [0.72, 3.95]	0.2058	
Sex									0.9558
Male	160	97 (60.6%)	3.4 [2.1, 8.7]	81	44 (54.3%)	5.7 [2.8, 17.6]	1.11 [0.77, 1.58]	0.5641	
Female	118	77 (65.3%)	2.2 [1.9, 5.6]	52	30 (57.7%)	3.0 [1.3, NA]	1.10 [0.72, 1.67]	0.6529	
Race									0.4861
White	219	132 (60.3%)	2.8 [1.9, 7.0]	106	60 (56.6%)	4.7 [2.6, 14.5]	1.05 [0.78, 1.43]	0.7298	
Non-White	59	42 (71.2%)	2.9 [1.9, 5.6]	27	14 (51.9%)	4.7 [1.1, NA]	1.32 [0.72, 2.43]	0.3510	
Geographic region									0.9939
Europe	181	110 (60.8%)	2.8 [1.9, 5.6]	87	45 (51.7%)	5.7 [2.8, NA]	1.19 [0.84, 1.68]	0.3031	
Asia Pacific	79	52 (65.8%)	3.8 [1.9, 10.3]	36	23 (63.9%)	2.8 [1.2, 17.6]	0.91 [0.56, 1.49]	0.7002	
North America	18	12 (66.7%)	2.8 [1.9, NA]	10	6 (60.0%)	9.0 [0.9, NA]	1.39 [0.52, 3.73]	0.5025	
ECOG performance status									0.2864
0-1	265	162 (61.1%)	3.0 [2.1, 5.6]	129	71 (55.0%)	5.6 [2.8, 16.8]	1.09 [0.83, 1.45]	0.5103	
2	12	12 (100.0%)	1.0 [1.0, 2.8]	4	3 (75.0%)	1.5 [1.0, 1.9]	1.00 [0.26, 3.83]	0.9976	
Prior bortezomib or ixazomib exposure									0.6235
Yes	257	163 (63.4%)	2.8 [1.9, 4.7]	118	68 (57.6%)	4.0 [2.0, 9.3]	1.07 [0.81, 1.42]	0.6242	
No	21	11 (52.4%)	22.9 [1.0, NA]	15	6 (40.0%)	NA [1.0, NA]	1.30 [0.48, 3.54]	0.5878	

Table 5.1 QLQ MY-20 Disease Symptoms: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EORTC	KdD (N=278)			Kd (N=133)			Treatment Comparison KdD vs. Kd:		
QLQ MY-20	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Refractory to bortezomib or ixazomib									0.3498
Yes	89	59 (66.3%)	1.9 [1.8, 4.7]	49	34 (69.4%)	2.8 [1.4, 5.6]	0.96 [0.63, 1.47]	0.8458	
No	189	115 (60.8%)	3.5 [2.8, 7.5]	84	40 (47.6%)	16.8 [3.8, NA]	1.26 [0.88, 1.81]	0.1872	
Prior lenalidomide exposure									0.1528
Yes	111	66 (59.5%)	2.9 [1.9, 9.4]	64	39 (60.9%)	4.0 [1.4, 13.3]	0.90 [0.60, 1.33]	0.5765	
No	167	108 (64.7%)	2.8 [1.9, 5.0]	69	35 (50.7%)	7.5 [2.8, NA]	1.34 [0.92, 1.96]	0.1135	
Refractory to lenalidomide									0.1237
Yes	88	52 (59.1%)	2.9 [1.9, 13.6]	48	30 (62.5%)	3.8 [1.4, 9.3]	0.84 [0.54, 1.32]	0.4396	
No	190	122 (64.2%)	2.8 [1.9, 5.6]	85	44 (51.8%)	7.5 [2.8, NA]	1.30 [0.92, 1.83]	0.1171	
Prior IMiD exposure									0.8279
Yes	184	116 (63.0%)	2.9 [2.0, 4.7]	95	53 (55.8%)	5.6 [1.9, 17.6]	1.10 [0.79, 1.52]	0.5670	
No	94	58 (61.7%)	2.8 [1.9, 15.4]	38	21 (55.3%)	3.8 [2.0, NA]	1.19 [0.72, 1.96]	0.4803	
Refractory to IMiD									0.0932
Yes	116	70 (60.3%)	3.8 [1.9, 13.3]	56	34 (60.7%)	3.7 [1.9, 9.3]	0.84 [0.56, 1.27]	0.3830	
No	162	104 (64.2%)	2.8 [1.9, 5.0]	77	40 (51.9%)	7.5 [2.8, NA]	1.35 [0.94, 1.94]	0.0902	
International Staging System (ISS)									0.6755
Stage I or II	226	138 (61.1%)	2.9 [2.1, 5.4]	111	62 (55.9%)	4.7 [2.0, 17.6]	1.08 [0.80, 1.45]	0.6119	
Stage III	51	35 (68.6%)	2.8 [1.9, 7.5]	22	12 (54.5%)	5.7 [1.4, 16.8]	1.20 [0.62, 2.32]	0.5629	

Table 5.1 QLQ MY-20 Disease Symptoms: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EORTC	KdD (N=278)			Kd (N=133)			Treatment Comparison KdD vs. Kd:		
QLQ MY-20	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Prior proteasome inhibitor exposure									0.7895
Yes	258	164 (63.6%)	2.8 [1.9, 4.7]	119	68 (57.1%)	4.0 [2.6, 9.3]	1.08 [0.82, 1.44]	0.5681	
No	20	10 (50.0%)	2.9 [1.0, NA]	14	6 (42.9%)	17.6 [1.0, NA]	1.23 [0.45, 3.39]	0.6697	
Number of prior lines of therapy									0.4669
1	128	77 (60.2%)	4.6 [2.1, 13.3]	58	29 (50.0%)	13.3 [2.8, NA]	1.25 [0.82, 1.92]	0.2828	
>= 2	150	97 (64.7%)	2.2 [1.9, 4.7]	75	45 (60.0%)	3.8 [1.9, 9.3]	1.02 [0.72, 1.45]	0.9021	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
[a]From Kaplan–Meier estimate
[b]HR: hazard ratio
NA denotes that the median time (and 95% CI) were not estimable

Table 5.2 QLQ MY-20 Side-effects: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EORTC	KdD (N=278)			Kd (N=133)			Treatment Comparison KdD vs. Kd:		
QLQ MY-20	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Age									0.1286
<= 75	254	88 (34.6%)	NA [NA, NA]	115	27 (23.5%)	NA [NA, NA]	1.44 [0.93, 2.21]	0.0940	
> 75	24	6 (25.0%)	NA [24.1, NA]	18	7 (38.9%)	NA [2.0, NA]	0.56 [0.19, 1.68]	0.2944	
Sex									0.2392
Male	160	46 (28.8%)	NA [NA, NA]	81	21 (25.9%)	NA [NA, NA]	1.02 [0.61, 1.71]	0.9441	
Female	118	48 (40.7%)	NA [8.4, NA]	52	13 (25.0%)	NA [NA, NA]	1.67 [0.90, 3.08]	0.0935	
Race									0.1017
White	219	75 (34.2%)	NA [NA, NA]	106	24 (22.6%)	NA [NA, NA]	1.51 [0.95, 2.39]	0.0729	
Non-White	59	19 (32.2%)	NA [NA, NA]	27	10 (37.0%)	NA [5.7, NA]	0.75 [0.35, 1.63]	0.4624	
Geographic region									0.9176
Europe	181	64 (35.4%)	NA [25.7, NA]	87	17 (19.5%)	NA [NA, NA]	1.85 [1.08, 3.16]	0.0206	
Asia Pacific	79	26 (32.9%)	NA [NA, NA]	36	15 (41.7%)	NA [2.8, NA]	0.67 [0.35, 1.26]	0.2030	
North America	18	4 (22.2%)	NA [8.0, NA]	10	2 (20.0%)	NA [3.8, NA]	1.06 [0.19, 5.85]	0.9503	
ECOG performance status									0.6935
0-1	265	90 (34.0%)	NA [NA, NA]	129	33 (25.6%)	NA [NA, NA]	1.28 [0.86, 1.91]	0.2135	
2	12	4 (33.3%)	NA [1.0, NA]	4	1 (25.0%)	NA [1.0, NA]	1.33 [0.15, 11.98]	0.7863	
Prior bortezomib or ixazomib exposure									0.5648
Yes	257	87 (33.9%)	NA [NA, NA]	118	29 (24.6%)	NA [NA, NA]	1.33 [0.87, 2.03]	0.1770	
No	21	7 (33.3%)	NA [2.8, NA]	15	5 (33.3%)	NA [1.0, NA]	0.95 [0.30, 3.00]	0.9305	

Table 5.2 QLQ MY-20 Side-effects: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EORTC	KdD (N=278)			Kd (N=133)			Treatment Comparison KdD vs. Kd:		
QLQ MY-20	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Refractory to bortezomib or ixazomib									0.9459
Yes	89	35 (39.3%)	NA [10.3, NA]	49	15 (30.6%)	NA [10.3, NA]	1.26 [0.69, 2.30]	0.4530	
No	189	59 (31.2%)	NA [NA, NA]	84	19 (22.6%)	NA [NA, NA]	1.32 [0.79, 2.22]	0.2837	
Prior lenalidomide exposure									0.7463
Yes	111	37 (33.3%)	NA [NA, NA]	64	17 (26.6%)	NA [13.3, NA]	1.20 [0.67, 2.12]	0.5384	
No	167	57 (34.1%)	NA [NA, NA]	69	17 (24.6%)	NA [NA, NA]	1.36 [0.79, 2.34]	0.2547	
Refractory to lenalidomide									0.9592
Yes	88	30 (34.1%)	NA [NA, NA]	48	12 (25.0%)	NA [10.3, NA]	1.31 [0.67, 2.56]	0.4288	
No	190	64 (33.7%)	NA [NA, NA]	85	22 (25.9%)	NA [NA, NA]	1.27 [0.78, 2.06]	0.3308	
Prior IMiD exposure									0.3212
Yes	184	66 (35.9%)	NA [NA, NA]	95	23 (24.2%)	NA [NA, NA]	1.47 [0.91, 2.36]	0.1080	
No	94	28 (29.8%)	NA [NA, NA]	38	11 (28.9%)	NA [13.6, NA]	0.97 [0.48, 1.94]	0.9241	
Refractory to IMiD									0.8371
Yes	116	39 (33.6%)	NA [NA, NA]	56	13 (23.2%)	NA [10.3, NA]	1.31 [0.70, 2.47]	0.3903	
No	162	55 (34.0%)	NA [NA, NA]	77	21 (27.3%)	NA [NA, NA]	1.23 [0.75, 2.04]	0.4070	
International Staging System (ISS)									0.7634
Stage I or II	226	76 (33.6%)	NA [NA, NA]	111	28 (25.2%)	NA [NA, NA]	1.31 [0.85, 2.01]	0.2222	
Stage III	51	18 (35.3%)	NA [10.3, NA]	22	6 (27.3%)	NA [5.6, NA]	1.11 [0.44, 2.81]	0.8195	

Table 5.2 QLQ MY-20 Side-effects: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EORTC	KdD (N=278)			Kd (N=133)			Treatment Comparison KdD vs. Kd:		
QLQ MY-20	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Prior proteasome inhibitor exposure									0.5413
Yes	258	87 (33.7%)	NA [NA, NA]	119	29 (24.4%)	NA [NA, NA]	1.34 [0.88, 2.04]	0.1703	
No	20	7 (35.0%)	NA [2.8, NA]	14	5 (35.7%)	NA [1.0, NA]	0.92 [0.29, 2.92]	0.8891	
Number of prior lines of therapy									0.9251
1	128	37 (28.9%)	NA [NA, NA]	58	13 (22.4%)	NA [NA, NA]	1.26 [0.67, 2.37]	0.4704	
>= 2	150	57 (38.0%)	NA [21.5, NA]	75	21 (28.0%)	NA [13.6, NA]	1.30 [0.79, 2.14]	0.2981	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
[a]From Kaplan–Meier estimate
[b]HR: hazard ratio
NA denotes that the median time (and 95% CI) were not estimable

Table 6.2 EQ5D VAS: Time to deterioration by at least 7 points by subgroups. eCOA-ITT Population

EQ5D	KdD (N=278)			Kd (N=132)			Treatment Comparison KdD vs. Kd:		
VAS	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Age									0.8169
<= 75	254	179 (70.5%)	4.7 [2.9, 6.8]	115	81 (70.4%)	3.3 [2.1, 5.6]	0.81 [0.62, 1.06]	0.1109	
> 75	24	20 (83.3%)	2.8 [1.0, 3.8]	17	15 (88.2%)	1.9 [1.0, 4.2]	0.80 [0.41, 1.56]	0.4767	
Sex									0.5716
Male	160	114 (71.3%)	3.8 [2.8, 7.9]	80	58 (72.5%)	2.8 [1.9, 5.4]	0.76 [0.55, 1.05]	0.0840	
Female	118	85 (72.0%)	4.6 [2.8, 6.6]	52	38 (73.1%)	2.8 [1.9, 5.7]	0.85 [0.58, 1.24]	0.3727	
Race									0.6075
White	219	154 (70.3%)	3.8 [2.8, 6.6]	105	76 (72.4%)	2.8 [1.9, 4.3]	0.78 [0.59, 1.03]	0.0637	
Non-White	59	45 (76.3%)	6.5 [1.9, 8.4]	27	20 (74.1%)	6.1 [1.6, 8.4]	0.91 [0.53, 1.54]	0.7070	
Geographic region									0.5262
Europe	181	121 (66.9%)	4.7 [2.8, 9.6]	87	65 (74.7%)	2.8 [1.9, 4.3]	0.67 [0.49, 0.91]	0.0063	
Asia Pacific	79	65 (82.3%)	2.9 [1.8, 5.6]	35	24 (68.6%)	4.7 [1.9, 7.5]	1.14 [0.71, 1.83]	0.5630	
North America	18	13 (72.2%)	4.8 [1.9, 11.2]	10	7 (70.0%)	5.7 [1.0, 14.5]	0.96 [0.38, 2.43]	0.9353	
ECOG performance status									0.3512
0-1	265	192 (72.5%)	4.0 [2.8, 6.6]	128	95 (74.2%)	2.8 [1.9, 4.7]	0.79 [0.62, 1.02]	0.0555	
2	12	6 (50.0%)	NA [1.0, NA]	4	1 (25.0%)	5.6 [, NA]	1.59 [0.19, 13.26]	0.6599	
Prior bortezomib or ixazomib exposure									0.7260
Yes	257	182 (70.8%)	4.0 [2.8, 6.6]	118	84 (71.2%)	2.8 [1.9, 4.7]	0.79 [0.61, 1.03]	0.0690	
No	21	17 (81.0%)	3.8 [1.0, 17.1]	14	12 (85.7%)	4.0 [1.0, 7.5]	0.86 [0.40, 1.84]	0.6752	

Table 6.2 EQ5D VAS: Time to deterioration by at least 7 points by subgroups. eCOA-ITT Population

EQ5D	KdD (N=278)			Kd (N=132)			Treatment Comparison KdD vs. Kd:		
VAS	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Refractory to bortezomib or ixazomib									0.9966
Yes	89	61 (68.5%)	3.6 [2.8, 6.7]	49	34 (69.4%)	2.8 [1.3, 5.6]	0.81 [0.53, 1.23]	0.3009	
No	189	138 (73.0%)	4.7 [2.8, 7.5]	83	62 (74.7%)	3.3 [1.9, 5.4]	0.79 [0.58, 1.07]	0.1128	
Prior lenalidomide exposure									0.1006
Yes	111	78 (70.3%)	2.9 [1.9, 6.6]	63	41 (65.1%)	4.7 [2.7, 7.5]	1.00 [0.69, 1.47]	0.9824	
No	167	121 (72.5%)	4.1 [2.9, 7.5]	69	55 (79.7%)	1.9 [1.9, 3.8]	0.64 [0.46, 0.89]	0.0044	
Refractory to lenalidomide									0.2066
Yes	88	61 (69.3%)	4.7 [2.6, 8.5]	47	29 (61.7%)	5.6 [2.3, 8.4]	0.99 [0.64, 1.55]	0.9773	
No	190	138 (72.6%)	3.8 [2.8, 6.6]	85	67 (78.8%)	2.1 [1.9, 3.8]	0.70 [0.52, 0.94]	0.0114	
Prior IMiD exposure									0.1846
Yes	184	132 (71.7%)	2.9 [1.9, 4.7]	94	68 (72.3%)	3.8 [1.9, 5.6]	0.90 [0.67, 1.21]	0.4759	
No	94	67 (71.3%)	6.6 [3.3, 10.9]	38	28 (73.7%)	2.0 [1.9, 4.2]	0.56 [0.36, 0.89]	0.0097	
Refractory to IMiD									0.0602
Yes	116	86 (74.1%)	2.9 [1.9, 4.7]	55	36 (65.5%)	4.7 [2.3, 7.5]	1.07 [0.72, 1.58]	0.7341	
No	162	113 (69.8%)	4.9 [2.9, 10.3]	77	60 (77.9%)	2.1 [1.9, 3.8]	0.64 [0.46, 0.88]	0.0034	
International Staging System (ISS)									0.7724
Stage I or II	226	166 (73.5%)	3.8 [2.8, 6.5]	110	82 (74.5%)	3.1 [1.9, 4.7]	0.81 [0.62, 1.06]	0.1027	
Stage III	51	32 (62.7%)	6.5 [2.6, 13.3]	22	14 (63.6%)	2.7 [1.3, 17.8]	0.73 [0.38, 1.39]	0.3120	

Table 6.2 EQ5D VAS: Time to deterioration by at least 7 points by subgroups. eCOA-ITT Population

EQ5D	KdD (N=278)			Kd (N=132)			Treatment Comparison KdD vs. Kd:		
VAS	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Prior proteasome inhibitor exposure									0.6598
Yes	258	183 (70.9%)	4.1 [2.8, 6.6]	119	85 (71.4%)	2.8 [1.9, 4.7]	0.79 [0.61, 1.02]	0.0617	
No	20	16 (80.0%)	2.8 [1.0, 17.1]	13	11 (84.6%)	4.2 [1.0, 8.0]	0.87 [0.39, 1.93]	0.7146	
Number of prior lines of therapy									0.3838
1	128	93 (72.7%)	4.7 [2.8, 8.4]	58	46 (79.3%)	2.8 [1.9, 5.4]	0.68 [0.47, 0.97]	0.0277	
>= 2	150	106 (70.7%)	3.5 [2.6, 6.6]	74	50 (67.6%)	2.8 [1.9, 5.6]	0.90 [0.64, 1.26]	0.5028	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
[a]From Kaplan–Meier estimate
[b]HR: hazard ratio
NA denotes that the median time (and 95% CI) were not estimable

Table 6.1 EQ5D VAS: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EQ5D	KdD (N=278)			Kd (N=132)			Treatment Comparison KdD vs. Kd:		
VAS	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Age									0.7487
<= 75	254	155 (61.0%)	7.5 [4.7, 11.2]	115	76 (66.1%)	4.7 [3.1, 7.5]	0.77 [0.59, 1.02]	0.0587	
> 75	24	20 (83.3%)	2.9 [1.0, 3.8]	17	14 (82.4%)	2.9 [1.0, 8.0]	0.90 [0.45, 1.79]	0.7519	
Sex									0.9129
Male	160	100 (62.5%)	7.5 [2.9, 10.9]	80	53 (66.3%)	4.7 [2.7, 7.5]	0.78 [0.56, 1.10]	0.1406	
Female	118	75 (63.6%)	5.6 [3.8, 12.2]	52	37 (71.2%)	4.7 [2.8, 8.4]	0.76 [0.51, 1.13]	0.1537	
Race									0.9170
White	219	135 (61.6%)	6.5 [3.3, 10.3]	105	71 (67.6%)	4.7 [2.8, 6.5]	0.77 [0.58, 1.03]	0.0676	
Non-White	59	40 (67.8%)	7.5 [3.6, 15.9]	27	19 (70.4%)	7.5 [1.6, 12.4]	0.77 [0.44, 1.34]	0.3382	
Geographic region									0.8482
Europe	181	106 (58.6%)	8.5 [4.9, 12.2]	87	62 (71.3%)	4.2 [2.8, 6.5]	0.67 [0.49, 0.92]	0.0087	
Asia Pacific	79	59 (74.7%)	3.8 [1.9, 7.5]	35	21 (60.0%)	6.5 [1.9, 8.4]	1.13 [0.69, 1.87]	0.6130	
North America	18	10 (55.6%)	4.9 [1.9, NA]	10	7 (70.0%)	8.4 [1.0, 14.5]	0.64 [0.23, 1.74]	0.3661	
ECOG performance status									0.4198
0-1	265	168 (63.4%)	6.6 [4.0, 10.3]	128	89 (69.5%)	4.7 [2.8, 7.5]	0.76 [0.59, 0.99]	0.0330	
2	12	6 (50.0%)	NA [1.0, NA]	4	1 (25.0%)	5.6 [, NA]	1.59 [0.19, 13.26]	0.6599	
Prior bortezomib or ixazomib exposure									0.5992
Yes	257	159 (61.9%)	6.6 [3.8, 10.3]	118	79 (66.9%)	4.7 [2.8, 7.5]	0.76 [0.58, 1.00]	0.0409	
No	21	16 (76.2%)	5.6 [1.0, 15.9]	14	11 (78.6%)	4.0 [2.8, 8.0]	0.93 [0.43, 2.05]	0.8615	

Table 6.1 EQ5D VAS: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EQ5D	KdD (N=278)			Kd (N=132)			Treatment Comparison KdD vs. Kd:		
VAS	N	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-CI][a]	HR[b][95% CI]	p-value	Interaction p-values
Refractory to bortezomib or ixazomib									0.9194
Yes	89	53 (59.6%)	5.3 [2.8, 15.9]	49	31 (63.3%)	4.7 [1.9, 8.4]	0.81 [0.52, 1.26]	0.3298	
No	189	122 (64.6%)	7.5 [3.8, 11.2]	83	59 (71.1%)	4.7 [2.8, 7.5]	0.76 [0.55, 1.03]	0.0686	
Prior lenalidomide exposure									0.1659
Yes	111	68 (61.3%)	4.9 [2.8, 11.3]	63	39 (61.9%)	7.5 [4.7, 12.1]	0.94 [0.63, 1.40]	0.7525	
No	167	107 (64.1%)	7.5 [3.8, 11.2]	69	51 (73.9%)	3.1 [1.9, 4.7]	0.64 [0.45, 0.90]	0.0065	
Refractory to lenalidomide									0.2377
Yes	88	52 (59.1%)	6.5 [2.8, 17.1]	47	27 (57.4%)	8.4 [4.7, 14.9]	0.95 [0.60, 1.52]	0.8328	
No	190	123 (64.7%)	6.6 [3.6, 10.3]	85	63 (74.1%)	3.1 [2.1, 5.4]	0.68 [0.50, 0.92]	0.0097	
Prior IMiD exposure									0.2523
Yes	184	115 (62.5%)	4.9 [2.8, 8.5]	94	63 (67.0%)	5.6 [2.8, 8.4]	0.86 [0.63, 1.17]	0.3279	
No	94	60 (63.8%)	9.6 [3.8, 15.9]	38	27 (71.1%)	3.8 [2.1, 6.5]	0.56 [0.35, 0.90]	0.0122	
Refractory to IMiD									0.0704
Yes	116	76 (65.5%)	4.7 [1.9, 7.5]	55	34 (61.8%)	7.5 [3.8, 12.4]	1.03 [0.69, 1.55]	0.8745	
No	162	99 (61.1%)	9.4 [4.0, 13.1]	77	56 (72.7%)	3.8 [2.8, 6.5]	0.62 [0.44, 0.87]	0.0034	
International Staging System (ISS)									0.7349
Stage I or II	226	145 (64.2%)	6.6 [3.8, 10.3]	110	76 (69.1%)	4.7 [2.9, 7.5]	0.78 [0.59, 1.03]	0.0657	
Stage III	51	29 (56.9%)	6.5 [2.6, 14.0]	22	14 (63.6%)	4.7 [1.9, 21.7]	0.73 [0.38, 1.39]	0.3129	

Table 6.1 EQ5D VAS: Time to deterioration by at least 10 points by subgroups. eCOA-ITT Population

EQ5D	KdD (N=278)			Kd (N=132)			Treatment Comparison KdD vs. Kd:		
VAS	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	N	Number (%) of patients with event	Median Time to event[months] [95%-Cl][a]	HR[b][95% Cl]	p-value	Interaction p-values
Prior proteasome inhibitor exposure									0.5412
Yes	258	160 (62.0%)	6.7 [4.0, 10.3]	119	80 (67.2%)	4.7 [2.8, 7.5]	0.76 [0.58, 0.99]	0.0362	
No	20	15 (75.0%)	3.8 [1.0, 17.1]	13	10 (76.9%)	4.2 [2.8, 10.1]	0.99 [0.43, 2.23]	0.9711	
Number of prior lines of therapy									0.2747
1	128	81 (63.3%)	7.9 [4.6, 13.1]	58	43 (74.1%)	3.8 [2.8, 7.5]	0.64 [0.44, 0.93]	0.0154	
>= 2	150	94 (62.7%)	4.9 [2.8, 10.3]	74	47 (63.5%)	5.6 [2.3, 10.1]	0.88 [0.62, 1.26]	0.4713	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
[a]From Kaplan–Meier estimate
[b]HR: hazard ratio
NA denotes that the median time (and 95% CI) were not estimable

Table 7.7 Change from Baseline in EORTC QLQ-C30 - Fatigue Symptom Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
Age									0.8297
<= 75	257	31.6 (24.50)	1.8 (0.91)	112	30.5 (24.18)	0.6 (1.40)	1.2 [-2.05, 4.49]; 0.4632	0.1 [-0.14; 0.30]	
> 75	24	29.6 (20.89)	7.0 (2.54)	16	19.4 (14.91)	6.6 (3.15)	0.4 [-7.84, 8.68]; 0.9188	0.0 [-0.60; 0.67]	
Sex									0.2941
Male	161	28.4 (23.43)	2.1 (1.08)	78	27.8 (23.81)	2.5 (1.57)	-0.4 [-4.16, 3.30]; 0.8210	-0.0 [-0.30; 0.24]	
Female	120	35.6 (24.68)	2.5 (1.40)	50	31.1 (23.00)	-0.6 (2.19)	3.1 [-1.98, 8.26]; 0.2281	0.2 [-0.13; 0.53]	
Race									0.7049
White	220	32.2 (24.72)	1.6 (0.93)	104	28.8 (23.35)	0.9 (1.37)	0.6 [-2.62, 3.87]; 0.7046	0.0 [-0.19; 0.28]	
Non-White	61	28.8 (22.16)	4.8 (2.13)	24	30.1 (24.40)	2.6 (3.43)	2.1 [-5.89, 10.14]; 0.5990	0.1 [-0.35; 0.60]	
Geographic region									0.3220
Europe	182	34.2 (25.36)	0.7 (1.07)	84	29.0 (24.64)	-1.2 (1.60)	1.9 [-1.90, 5.66]; 0.3279	0.1 [-0.13; 0.39]	
Asia Pacific	81	23.6 (19.36)	5.8 (1.58)	34	29.7 (22.51)	5.0 (2.53)	0.8 [-5.07, 6.64]; 0.7917	0.1 [-0.35; 0.45]	
North America	18	39.5 (24.17)	1.2 (3.53)	10	27.8 (17.57)	8.7 (4.76)	-7.5 [-19.8, 4.90]; 0.2256	-0.5 [-1.27; 0.30]	
ECOG performance status									0.6738
0-1	268	31.2 (24.06)	2.7 (0.89)	125	28.1 (22.56)	1.7 (1.31)	1.0 [-2.07, 4.13]; 0.5134	0.1 [-0.14; 0.28]	
2	12	40.7 (25.66)	-9.7 (3.13)	3	70.4 (27.96)	-15.0 (7.95)	5.3 [-12.7, 23.29]; 0.5380	0.4 [-0.84; 1.72]	

Table 7.7 Change from Baseline in EORTC QLQ-C30 - Fatigue Symptom Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	N	Baseline Mean (SD)	Change from BL LSMean(SE)	N	Baseline Mean (SD)	Change from BL LSMean(SE)	Difference in LSMean [95%-CI]; p-value	Hedges'g [95%-CI]	
Prior bortezomib or ixazomib exposure									0.1153
Yes	259	32.2 (24.57)	1.8 (0.90)	113	30.1 (23.41)	1.7 (1.39)	0.1 [-3.18, 3.29]; 0.9717	0.0 [-0.22; 0.22]	
No	22	22.7 (17.31)	7.8 (2.81)	15	21.5 (23.18)	-1.0 (3.48)	8.8 [-0.19, 17.87]; 0.0547	0.7 [-0.02; 1.32]	
Refractory to bortezomib or ixazomib									0.4124
Yes	89	36.2 (24.19)	-1.7 (1.61)	48	39.6 (25.20)	-0.9 (2.22)	-0.8 [-6.13, 4.56]; 0.7717	-0.1 [-0.40; 0.30]	
No	192	29.3 (23.94)	3.8 (1.02)	80	22.8 (19.99)	2.1 (1.60)	1.6 [-2.12, 5.35]; 0.3941	0.1 [-0.15; 0.38]	
Prior lenalidomide exposure									0.7938
Yes	112	32.8 (24.71)	0.9 (1.44)	61	32.1 (22.51)	-0.6 (1.98)	1.6 [-3.24, 6.36]; 0.5214	0.1 [-0.21; 0.41]	
No	169	30.6 (23.87)	3.6 (0.74)	67	26.4 (24.15)	2.2 (1.20)	1.4 [-1.28, 4.04]; 0.3083	0.1 [-0.14; 0.43]	
Refractory to lenalidomide									0.5026
Yes	89	33.8 (25.12)	-0.4 (1.53)	46	32.9 (21.59)	-2.8 (2.18)	2.4 [-2.86, 7.61]; 0.3714	0.2 [-0.19; 0.52]	
No	192	30.4 (23.73)	3.4 (0.68)	82	27.0 (24.32)	2.8 (1.09)	0.6 [-1.85, 3.08]; 0.6227	0.1 [-0.19; 0.32]	
Prior IMiD exposure									0.5532
Yes	186	33.3 (23.72)	1.9 (1.08)	90	29.0 (20.98)	0.2 (1.57)	1.7 [-2.06, 5.40]; 0.3797	0.1 [-0.14; 0.36]	

Table 7.7 Change from Baseline in EORTC QLQ-C30 - Fatigue Symptom Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
No	95	28.0 (24.84)	2.9 (1.42)	38	29.2 (28.81)	3.3 (2.30)	-0.4 [-5.72, 4.93]; 0.8839	-0.0 [-0.40; 0.35]	
Refractory to IMiD									0.3906
Yes	117	32.3 (24.19)	0.8 (1.38)	54	33.7 (21.69)	-2.0 (2.09)	2.8 [-2.09, 7.70]; 0.2597	0.2 [-0.14; 0.51]	
No	164	30.9 (24.24)	3.2 (0.75)	74	25.7 (24.25)	2.2 (1.13)	1.0 [-1.58, 3.56]; 0.4502	0.1 [-0.17; 0.38]	
International Staging System (ISS)									0.3183
Stage I or II	229	30.5 (24.62)	3.4 (0.96)	107	26.7 (21.03)	1.7 (1.41)	1.7 [-1.65, 5.03]; 0.3193	0.1 [-0.11; 0.35]	
Stage III	51	35.7 (22.15)	-3.7 (1.97)	21	41.3 (31.06)	-1.8 (3.26)	-1.9 [-9.40, 5.60]; 0.6138	-0.1 [-0.64; 0.38]	
Prior proteasome inhibitor exposure									0.0701
Yes	260	32.1 (24.56)	1.9 (0.91)	114	29.8 (23.48)	2.0 (1.38)	-0.0 [-3.28, 3.18]; 0.9762	-0.0 [-0.22; 0.22]	
No	21	23.3 (17.53)	6.6 (2.65)	14	23.0 (23.25)	-3.2 (3.32)	9.7 [1.17, 18.31]; 0.0271	0.8 [0.07; 1.48]	
Number of prior lines of therapy									0.3446
1	130	28.4 (23.97)	4.2 (1.14)	57	24.0 (22.60)	1.7 (1.74)	2.5 [-1.58, 6.62]; 0.2268	0.2 [-0.12; 0.50]	
>= 2	151	34.1 (24.14)	0.5 (1.28)	71	33.2 (23.49)	0.8 (1.89)	-0.3 [-4.74, 4.19]; 0.9029	-0.0 [-0.30; 0.26]	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
Mixed Model Repeated Measurement for change from baseline score, with time and treatment as independent variables, and baseline score included as a covariate

Table 7.8 Change from Baseline in EORTC QLQ-C30 - Nausea/Vomiting Symptom Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-Cl]; p-value**	**Hedges'g [95%-Cl]**	
Age									0.6160
<= 75	257	3.4 (11.03)	1.3 (0.36)	112	2.4 (7.70)	1.0 (0.57)	0.4 [-0.93, 1.70]; 0.5649	0.1 [-0.16; 0.29]	
> 75	24	0.7 (3.40)	1.2 (0.63)	16	0.0 (0.00)	2.3 (0.81)	-1.1 [-3.16, 0.96]; 0.2851	-0.3 [-0.98; 0.29]	
Sex									0.6290
Male	161	2.5 (10.24)	0.7 (0.36)	78	2.4 (7.93)	0.7 (0.54)	0.0 [-1.27, 1.28]; 0.9921	0.0 [-0.27; 0.27]	
Female	120	4.2 (11.07)	2.3 (0.61)	50	1.7 (6.07)	1.7 (0.97)	0.5 [-1.70, 2.77]; 0.6377	0.1 [-0.25; 0.41]	
Race									0.8934
White	220	3.3 (11.07)	1.4 (0.36)	104	1.9 (7.09)	1.1 (0.55)	0.3 [-1.03, 1.53]; 0.6998	0.0 [-0.19; 0.28]	
Non-White	61	3.0 (8.88)	1.3 (0.86)	24	2.8 (8.03)	0.9 (1.41)	0.4 [-2.90, 3.66]; 0.8178	0.1 [-0.42; 0.53]	
Geographic region									0.9584
Europe	182	2.7 (9.19)	1.2 (0.40)	84	2.2 (7.67)	0.9 (0.60)	0.3 [-1.10, 1.71]; 0.6721	0.1 [-0.20; 0.31]	
Asia Pacific	81	2.1 (6.66)	2.6 (0.67)	34	2.0 (6.82)	2.1 (1.07)	0.5 [-1.95, 3.02]; 0.6707	0.1 [-0.31; 0.49]	
North America	18	13.0 (25.28)	-1.5 (1.66)	10	1.7 (5.27)	-1.9 (2.27)	0.4 [-5.45, 6.33]; 0.8789	0.1 [-0.71; 0.83]	
ECOG performance status									0.8205
0-1	268	3.2 (10.69)	1.4 (0.34)	125	2.0 (7.21)	1.0 (0.52)	0.3 [-0.88, 1.54]; 0.5870	0.1 [-0.15; 0.27]	
2	12	2.8 (9.62)	0.9 (2.00)	3	5.6 (9.62)	3.6 (5.15)	-2.7 [-14.2, 8.78]; 0.6246	-0.4 [-1.62; 0.92]	

Table 7.8 Change from Baseline in EORTC QLQ-C30 - Nausea/Vomiting Symptom Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
Prior bortezomib or ixazomib exposure									0.6027
Yes	259	3.3 (10.96)	1.3 (0.36)	113	2.4 (7.67)	1.2 (0.56)	0.2 [-1.13, 1.48]; 0.7967	0.0 [-0.19; 0.25]	
No	22	1.5 (4.90)	1.7 (0.73)	15	0.0 (0.00)	0.5 (0.94)	1.2 [-1.20, 3.69]; 0.3051	0.3 [-0.31; 1.01]	
Refractory to bortezomib or ixazomib									0.7466
Yes	89	4.3 (14.11)	0.7 (0.58)	48	3.1 (7.42)	0.5 (0.80)	0.2 [-1.77, 2.08]; 0.8708	0.0 [-0.32; 0.38]	
No	192	2.7 (8.53)	1.6 (0.41)	80	1.5 (7.11)	1.2 (0.66)	0.4 [-1.14, 1.92]; 0.6152	0.1 [-0.19; 0.33]	
Prior lenalidomide exposure									0.9555
Yes	112	4.3 (13.00)	0.4 (0.56)	61	2.2 (7.74)	0.1 (0.79)	0.3 [-1.59, 2.17]; 0.7615	0.0 [-0.26; 0.36]	
No	169	2.5 (8.65)	2.1 (0.42)	67	2.0 (6.82)	1.7 (0.69)	0.4 [-1.18, 1.99]; 0.6137	0.1 [-0.21; 0.36]	
Refractory to lenalidomide									0.0011
Yes	89	4.1 (13.36)	0.9 (0.66)	46	1.4 (4.75)	0.6 (0.97)	0.3 [-2.02, 2.58]; 0.8085	0.0 [-0.31; 0.40]	
No	192	2.8 (9.08)	1.6 (0.39)	82	2.4 (8.33)	1.2 (0.61)	0.5 [-0.95, 1.85]; 0.5262	0.1 [-0.18; 0.34]	
Prior IMiD exposure									0.9143
Yes	186	3.9 (12.20)	1.3 (0.43)	90	2.2 (7.58)	0.9 (0.64)	0.4 [-1.14, 1.86]; 0.6395	0.1 [-0.19; 0.31]	

Table 7.8 Change from Baseline in EORTC QLQ-C30 - Nausea/Vomiting Symptom Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
No	95	1.9 (6.37)	1.5 (0.52)	38	1.8 (6.47)	1.0 (0.85)	0.5 [-1.48, 2.44]; 0.6273	0.1 [-0.28; 0.47]	
Refractory to IMiD									0.3001
Yes	117	3.8 (12.26)	0.9 (0.57)	54	1.5 (4.88)	1.4 (0.89)	-0.4 [-2.50, 1.63]; 0.6796	-0.1 [-0.39; 0.25]	
No	164	2.7 (9.28)	1.7 (0.42)	74	2.5 (8.58)	0.8 (0.63)	0.9 [-0.61, 2.33]; 0.2512	0.2 [-0.11; 0.43]	
International Staging System (ISS)									0.0193
Stage I or II	229	3.0 (10.22)	1.6 (0.37)	107	1.7 (6.84)	0.7 (0.55)	0.9 [-0.44, 2.15]; 0.1936	0.2 [-0.08; 0.38]	
Stage III	51	4.2 (12.40)	0.1 (0.76)	21	4.0 (8.98)	2.7 (1.35)	-2.5 [-5.56, 0.50]; 0.0998	-0.4 [-0.95; 0.07]	
Prior proteasome inhibitor exposure									0.2841
Yes	260	3.4 (10.97)	1.2 (0.36)	114	2.3 (7.64)	1.2 (0.56)	0.1 [-1.23, 1.37]; 0.9159	0.0 [-0.21; 0.23]	
No	21	0.8 (3.64)	2.4 (0.60)	14	0.0 (0.00)	0.4 (0.79)	2.0 [0.00, 4.01]; 0.0498	0.7 [-0.00; 1.39]	
Number of prior lines of therapy									0.3103
1	130	2.8 (11.20)	1.5 (0.45)	57	2.0 (8.38)	0.6 (0.70)	1.0 [-0.64, 2.63]; 0.2329	0.2 [-0.12; 0.50]	
>= 2	151	3.5 (10.11)	1.2 (0.49)	71	2.1 (6.25)	1.4 (0.74)	-0.2 [-1.97, 1.51]; 0.7919	-0.0 [-0.32; 0.24]	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
Mixed Model Repeated Measurement for change from baseline score, with time and treatment as independent variables, and baseline score included as a covariate

Table 7.9 Change from Baseline in EORTC QLQ-C30 - Pain Symptom Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
Age									0.6353
<= 75	257	30.2 (28.48)	-4.8 (0.94)	112	25.9 (26.64)	-3.0 (1.45)	-1.8 [-5.15, 1.60]; 0.3018	-0.1 [-0.34; 0.11]	
> 75	24	23.6 (27.77)	-6.8 (2.88)	16	25.0 (32.77)	-2.4 (3.59)	-4.4 [-13.7, 4.87]; 0.3428	-0.3 [-0.94; 0.33]	
Sex									0.9367
Male	161	24.7 (26.29)	-3.6 (1.09)	78	25.4 (26.55)	-1.6 (1.60)	-1.9 [-5.71, 1.86]; 0.3170	-0.1 [-0.41; 0.13]	
Female	120	36.1 (29.97)	-6.9 (1.50)	50	26.3 (28.79)	-5.1 (2.36)	-1.8 [-7.28, 3.76]; 0.5289	-0.1 [-0.44; 0.22]	
Race									0.6771
White	220	30.1 (28.68)	-5.9 (0.99)	104	26.1 (27.46)	-3.5 (1.46)	-2.4 [-5.84, 1.08]; 0.1763	-0.2 [-0.39; 0.07]	
Non-White	61	27.9 (27.68)	-1.4 (2.07)	24	24.3 (27.35)	-1.2 (3.32)	-0.3 [-8.04, 7.53]; 0.9480	-0.0 [-0.49; 0.46]	
Geographic region									0.7333
Europe	182	32.8 (29.42)	-7.5 (1.07)	84	24.2 (26.94)	-4.9 (1.59)	-2.6 [-6.35, 1.18]; 0.1776	-0.2 [-0.44; 0.08]	
Asia Pacific	81	20.8 (21.49)	0.5 (1.69)	34	28.4 (29.17)	2.2 (2.71)	-1.7 [-7.97, 4.53]; 0.5867	-0.1 [-0.51; 0.29]	
North America	18	37.0 (37.29)	-3.9 (4.59)	10	30.0 (25.82)	-6.2 (6.27)	2.3 [-13.7, 18.27]; 0.7711	0.1 [-0.66; 0.89]	
ECOG performance status									0.8070
0-1	268	29.1 (28.02)	-4.3 (0.92)	125	24.4 (26.06)	-2.5 (1.36)	-1.7 [-4.93, 1.48]; 0.2912	-0.1 [-0.33; 0.10]	
2	12	43.1 (35.15)	-22.5 (3.61)	3	83.3 (16.67)	-13.0 (9.16)	-9.6 [-31.2, 12.04]; 0.3484	-0.7 [-1.99; 0.61]	

Table 7.9 Change from Baseline in EORTC QLQ-C30 - Pain Symptom Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
Prior bortezomib or ixazomib exposure									0.2946
Yes	259	30.2 (29.07)	-5.4 (0.95)	113	27.4 (27.18)	-2.8 (1.46)	-2.6 [-5.98, 0.82]; 0.1363	-0.2 [-0.39; 0.05]	
No	22	22.0 (18.10)	-0.5 (2.37)	15	13.3 (26.13)	-2.8 (2.92)	2.3 [-5.34, 10.04]; 0.5384	0.2 [-0.45; 0.86]	
Refractory to bortezomib or ixazomib									0.3070
Yes	89	33.3 (28.76)	-8.0 (1.76)	48	33.7 (32.16)	-4.1 (2.42)	-4.0 [-9.79, 1.87]; 0.1816	-0.2 [-0.59; 0.12]	
No	192	27.9 (28.19)	-3.8 (1.02)	80	21.0 (22.93)	-2.9 (1.61)	-0.9 [-4.67, 2.85]; 0.6342	-0.1 [-0.32; 0.20]	
Prior lenalidomide exposure									0.8398
Yes	112	31.5 (31.03)	-6.9 (1.41)	61	28.7 (29.21)	-5.5 (1.95)	-1.4 [-6.12, 3.29]; 0.5539	-0.1 [-0.41; 0.22]	
No	169	28.3 (26.59)	-3.7 (1.17)	67	23.1 (25.45)	-1.5 (1.86)	-2.2 [-6.52, 2.12]; 0.3172	-0.1 [-0.43; 0.14]	
Refractory to lenalidomide									0.2001
Yes	89	32.6 (31.37)	-7.5 (1.53)	46	32.6 (30.62)	-8.5 (2.20)	1.0 [-4.20, 6.29]; 0.6946	0.1 [-0.28; 0.43]	
No	192	28.2 (26.94)	-3.8 (1.11)	82	22.0 (24.69)	-0.3 (1.70)	-3.5 [-7.45, 0.53]; 0.0885	-0.2 [-0.48; 0.03]	
Prior IMiD exposure									0.2810
Yes	186	31.5 (29.12)	-4.9 (1.07)	90	24.4 (25.99)	-4.2 (1.57)	-0.7 [-4.41, 3.03]; 0.7152	-0.0 [-0.30; 0.20]	

Table 7.9 Change from Baseline in EORTC QLQ-C30 - Pain Symptom Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
No	95	26.0 (26.82)	-5.1 (1.58)	38	28.9 (30.43)	-0.5 (2.56)	-4.6 [-10.5, 1.27]; 0.1227	-0.3 [-0.68; 0.08]	
Refractory to IMiD									0.8330
Yes	117	31.2 (29.49)	-6.6 (1.33)	54	30.2 (29.15)	-6.4 (2.03)	-0.2 [-4.96, 4.52]; 0.9268	-0.0 [-0.34; 0.31]	
No	164	28.5 (27.69)	-3.9 (1.20)	74	22.5 (25.65)	-0.9 (1.79)	-3.0 [-7.24, 1.26]; 0.1672	-0.2 [-0.47; 0.08]	
International Staging System (ISS)									0.3538
Stage I or II	229	28.3 (28.36)	-4.1 (0.95)	107	24.0 (25.92)	-2.8 (1.40)	-1.3 [-4.63, 1.97]; 0.4292	-0.1 [-0.32; 0.14]	
Stage III	51	35.6 (28.48)	-9.5 (2.55)	21	34.9 (32.87)	-4.0 (4.17)	-5.5 [-15.2, 4.14]; 0.2581	-0.3 [-0.81; 0.22]	
Prior proteasome inhibitor exposure									0.1626
Yes	260	30.3 (29.02)	-5.4 (0.95)	114	27.2 (27.18)	-2.6 (1.46)	-2.8 [-6.16, 0.64]; 0.1107	-0.2 [-0.40; 0.04]	
No	21	21.4 (18.37)	-0.9 (1.96)	14	14.3 (26.84)	-4.6 (2.45)	3.7 [-2.67, 10.14]; 0.2430	0.4 [-0.28; 1.09]	
Number of prior lines of therapy									0.5363
1	130	28.1 (28.31)	-3.2 (1.28)	57	20.5 (22.50)	-2.0 (1.95)	-1.2 [-5.83, 3.38]; 0.6008	-0.1 [-0.39; 0.23]	
>= 2	151	30.9 (28.57)	-6.6 (1.25)	71	30.0 (30.16)	-3.8 (1.86)	-2.8 [-7.19, 1.57]; 0.2070	-0.2 [-0.46; 0.10]	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
Mixed Model Repeated Measurement for change from baseline score, with time and treatment as independent variables, and baseline score included as a covariate

Table 7.10 Change from Baseline in EORTC QLQ-C30 - Dyspnoea Symptom Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
Age									0.3105
<= 75	257	12.8 (20.29)	7.1 (0.35)	112	13.7 (20.77)	9.0 (0.59)	-1.8 [-3.15, -0.52]; 0.0062	-0.3 [-0.54; -0.10]	
> 75	24	9.7 (23.01)	7.3 (3.08)	16	4.2 (11.39)	14.4 (3.86)	-7.1 [-17.2, 2.87]; 0.1570	-0.5 [-1.10; 0.18]	
Sex									0.7873
Male	161	12.2 (18.89)	7.0 (1.23)	78	12.4 (18.69)	8.8 (1.80)	-1.8 [-6.07, 2.46]; 0.4051	-0.1 [-0.39; 0.16]	
Female	120	13.1 (22.58)	8.4 (1.50)	50	12.7 (22.22)	9.4 (2.37)	-1.0 [-6.51, 4.48]; 0.7167	-0.1 [-0.39; 0.27]	
Race									0.0469
White	220	12.0 (19.46)	6.9 (1.02)	104	11.2 (17.75)	10.4 (1.51)	-3.5 [-7.08, 0.03]; 0.0521	-0.2 [-0.47; 0.00]	
Non-White	61	14.8 (23.98)	9.8 (2.26)	24	18.1 (27.77)	4.5 (3.67)	5.3 [-3.23, 13.84]; 0.2199	0.3 [-0.18; 0.77]	
Geographic region									0.4090
Europe	182	13.2 (21.81)	5.5 (1.17)	84	11.1 (18.17)	7.6 (1.75)	-2.1 [-6.20, 2.05]; 0.3227	-0.1 [-0.39; 0.13]	
Asia Pacific	81	9.5 (16.86)	12.4 (1.82)	34	16.7 (24.96)	11.4 (2.93)	1.0 [-5.80, 7.80]; 0.7721	0.1 [-0.34; 0.46]	
North America	18	20.4 (20.26)	6.1 (2.82)	10	10.0 (16.10)	15.2 (3.92)	-9.1 [-19.2, 0.89]; 0.0723	-0.7 [-1.53; 0.07]	
ECOG performance status									0.0719
0-1	268	12.6 (20.70)	7.6 (0.97)	125	11.5 (18.50)	9.5 (1.44)	-1.9 [-5.33, 1.44]; 0.2599	-0.1 [-0.33; 0.09]	
2	12	13.9 (17.16)	6.8 (5.62)	3	55.6 (38.49)	-11.7 (15.22)	18.4 [-17.4, 54.30]; 0.2831	0.8 [-0.47; 2.15]	

Table 7.10 Change from Baseline in EORTC QLQ-C30 - Dyspnoea Symptom Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	N	Baseline Mean (SD)	Change from BL LSMean(SE)	N	Baseline Mean (SD)	Change from BL LSMean(SE)	Difference in LSMean [95%-CI]; p-value	Hedges'g [95%-CI]	
Prior bortezomib or ixazomib exposure									0.0787
Yes	259	13.1 (20.94)	6.9 (0.99)	113	12.7 (20.08)	9.5 (1.53)	-2.5 [-6.10, 1.02]; 0.1609	-0.2 [-0.38; 0.06]	
No	22	6.1 (13.16)	13.3 (3.08)	15	11.1 (20.57)	7.4 (3.84)	5.9 [-4.11, 15.88]; 0.2399	0.4 [-0.27; 1.06]	
Refractory to bortezomib or ixazomib									0.7949
Yes	89	14.6 (21.88)	5.7 (1.90)	48	17.4 (23.81)	7.6 (2.61)	-1.9 [-8.22, 4.39]; 0.5490	-0.1 [-0.46; 0.25]	
No	192	11.6 (19.83)	8.2 (1.08)	80	9.6 (16.93)	9.7 (1.72)	-1.4 [-5.41, 2.54]; 0.4783	-0.1 [-0.36; 0.17]	
Prior lenalidomide exposure									0.5975
Yes	112	17.6 (23.23)	6.2 (1.60)	61	15.3 (21.58)	8.5 (2.22)	-2.3 [-7.66, 3.05]; 0.3962	-0.1 [-0.45; 0.18]	
No	169	9.3 (17.80)	8.5 (1.17)	67	10.0 (18.36)	9.1 (1.89)	-0.6 [-4.97, 3.74]; 0.7817	-0.0 [-0.32; 0.24]	
Refractory to lenalidomide									0.2642
Yes	89	18.0 (24.13)	5.2 (1.74)	46	12.3 (20.32)	9.2 (2.49)	-4.1 [-10.0, 1.92]; 0.1820	-0.2 [-0.60; 0.11]	
No	192	10.1 (18.13)	8.7 (1.13)	82	12.6 (20.04)	8.8 (1.76)	-0.1 [-4.23, 3.97]; 0.9495	-0.0 [-0.27; 0.25]	
Prior IMiD exposure									0.3351
Yes	186	15.4 (21.95)	7.4 (1.20)	90	14.8 (21.27)	7.6 (1.75)	-0.2 [-4.35, 3.94]; 0.9224	-0.0 [-0.26; 0.24]	

Table 7.10 Change from Baseline in EORTC QLQ-C30 - Dyspnoea Symptom Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
No	95	7.0 (16.05)	7.7 (1.51)	38	7.0 (15.80)	11.6 (2.46)	-3.9 [-9.60, 1.76]; 0.1748	-0.3 [-0.64; 0.12]	
Refractory to IMiD									0.6907
Yes	117	16.8 (24.22)	5.5 (1.55)	54	14.2 (22.06)	7.6 (2.36)	-2.1 [-7.61, 3.47]; 0.4612	-0.1 [-0.44; 0.20]	
No	164	9.6 (16.83)	8.9 (1.20)	74	11.3 (18.53)	9.9 (1.81)	-1.0 [-5.21, 3.28]; 0.6557	-0.1 [-0.34; 0.21]	
International Staging System (ISS)									0.2423
Stage I or II	229	11.9 (19.33)	8.3 (1.04)	107	9.7 (15.87)	10.8 (1.53)	-2.4 [-6.07, 1.17]; 0.1841	-0.2 [-0.39; 0.07]	
Stage III	51	15.0 (25.22)	2.8 (2.34)	21	27.0 (30.95)	0.3 (3.94)	2.5 [-6.48, 11.53]; 0.5786	0.1 [-0.36; 0.65]	
Prior proteasome inhibitor exposure									0.0388
Yes	260	13.1 (20.92)	7.0 (0.99)	114	12.6 (20.02)	9.7 (1.52)	-2.7 [-6.24, 0.85]; 0.1353	-0.2 [-0.39; 0.05]	
No	21	6.3 (13.41)	13.3 (3.15)	14	11.9 (21.11)	5.6 (3.96)	7.7 [-2.55, 18.04]; 0.1355	0.5 [-0.17; 1.21]	
Number of prior lines of therapy									0.4690
1	130	10.3 (18.02)	9.9 (1.25)	57	7.0 (13.71)	10.3 (1.92)	-0.4 [-4.92, 4.07]; 0.8517	-0.0 [-0.34; 0.28]	
>= 2	151	14.6 (22.30)	5.4 (1.41)	71	16.9 (23.14)	8.0 (2.10)	-2.5 [-7.49, 2.40]; 0.3119	-0.1 [-0.43; 0.14]	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
Mixed Model Repeated Measurement for change from baseline score, with time and treatment as independent variables, and baseline score included as a covariate

Table 7.11 Change from Baseline in EORTC QLQ-C30 - Insomnia Symptom Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
Age									0.6718
<= 75	257	20.0 (26.66)	3.0 (0.38)	112	19.6 (28.14)	2.5 (0.64)	0.5 [-0.92, 1.95]; 0.4814	0.1 [-0.14; 0.30]	
> 75	24	12.5 (19.19)	9.8 (3.10)	16	4.2 (11.39)	7.1 (3.80)	2.7 [-7.22, 12.66]; 0.5828	0.2 [-0.46; 0.81]	
Sex									0.5834
Male	161	14.5 (22.60)	6.6 (1.44)	78	16.7 (25.62)	4.6 (2.11)	2.0 [-2.97, 7.06]; 0.4219	0.1 [-0.16; 0.38]	
Female	120	25.8 (29.14)	0.2 (1.53)	50	19.3 (29.42)	0.2 (2.43)	0.0 [-5.63, 5.63]; 0.9999	0.0 [-0.33; 0.33]	
Race									0.9674
White	220	19.5 (25.62)	3.0 (1.19)	104	18.9 (27.78)	1.9 (1.77)	1.1 [-3.05, 5.30]; 0.5970	0.1 [-0.17; 0.30]	
Non-White	61	18.6 (28.23)	6.9 (2.20)	24	12.5 (23.70)	5.6 (3.57)	1.3 [-7.06, 9.63]; 0.7604	0.1 [-0.40; 0.55]	
Geographic region									0.3529
Europe	182	19.8 (26.44)	2.7 (1.34)	84	15.5 (26.10)	3.0 (2.02)	-0.4 [-5.12, 4.36]; 0.8752	-0.0 [-0.28; 0.24]	
Asia Pacific	81	16.0 (24.22)	6.0 (1.72)	34	19.6 (28.57)	3.0 (2.74)	3.0 [-3.36, 9.38]; 0.3504	0.2 [-0.21; 0.59]	
North America	18	29.6 (30.01)	7.5 (4.38)	10	30.0 (29.19)	-0.7 (5.99)	8.1 [-7.11, 23.39]; 0.2814	0.4 [-0.36; 1.21]	
ECOG performance status									0.4711
0-1	268	19.2 (25.93)	4.2 (1.07)	125	16.8 (26.31)	2.6 (1.59)	1.6 [-2.12, 5.36]; 0.3958	0.1 [-0.12; 0.30]	
2	12	25.0 (32.18)	-5.2 (6.55)	3	55.6 (38.49)	2.1 (15.02)	-7.3 [-42.7, 28.17]; 0.6609	-0.3 [-1.57; 0.98]	

Table 7.11 Change from Baseline in EORTC QLQ-C30 - Insomnia Symptom Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
Prior bortezomib or ixazomib exposure									0.1617
Yes	259	19.9 (26.60)	3.2 (1.10)	113	18.6 (28.15)	3.0 (1.70)	0.3 [-3.67, 4.23]; 0.8890	0.0 [-0.21; 0.24]	
No	22	12.1 (19.37)	10.8 (3.36)	15	11.1 (16.27)	1.8 (4.15)	9.1 [-1.74, 19.85]; 0.0974	0.6 [-0.11; 1.23]	
Refractory to bortezomib or ixazomib									0.3238
Yes	89	22.5 (28.33)	-1.6 (1.87)	48	27.1 (32.00)	-0.5 (2.59)	-1.0 [-7.29, 5.19]; 0.7403	-0.1 [-0.41; 0.29]	
No	192	17.9 (25.04)	6.0 (1.27)	80	12.1 (22.02)	3.5 (2.01)	2.5 [-2.17, 7.18]; 0.2917	0.1 [-0.12; 0.40]	
Prior lenalidomide exposure									0.7098
Yes	112	20.2 (27.71)	1.7 (1.75)	61	20.8 (27.33)	-0.3 (2.42)	2.0 [-3.84, 7.85]; 0.4998	0.1 [-0.21; 0.42]	
No	169	18.7 (25.14)	5.6 (1.31)	67	14.9 (26.77)	4.8 (2.11)	0.7 [-4.15, 5.60]; 0.7699	0.0 [-0.24; 0.33]	
Refractory to lenalidomide									0.6186
Yes	89	21.3 (28.09)	1.4 (1.98)	46	20.3 (28.53)	-1.2 (2.84)	2.6 [-4.21, 9.39]; 0.4522	0.1 [-0.22; 0.49]	
No	192	18.4 (25.24)	5.2 (1.23)	82	16.3 (26.32)	4.6 (1.91)	0.6 [-3.87, 5.04]; 0.7953	0.0 [-0.22; 0.29]	
Prior IMiD exposure									0.7561
Yes	186	21.7 (28.19)	4.3 (1.41)	90	17.8 (25.58)	2.3 (2.06)	1.9 [-2.96, 6.79]; 0.4407	0.1 [-0.15; 0.35]	

Table 7.11 Change from Baseline in EORTC QLQ-C30 - Insomnia Symptom Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
No	95	14.7 (21.03)	3.3 (1.37)	38	17.5 (30.74)	2.6 (2.25)	0.7 [-4.50, 5.87]; 0.7947	0.1 [-0.33; 0.43]	
Refractory to IMiD									0.6060
Yes	117	20.2 (26.61)	3.6 (1.72)	54	19.8 (27.86)	1.1 (2.62)	2.5 [-3.66, 8.59]; 0.4275	0.1 [-0.19; 0.45]	
No	164	18.7 (25.90)	4.1 (1.32)	74	16.2 (26.60)	3.6 (1.98)	0.5 [-4.20, 5.14]; 0.8432	0.0 [-0.25; 0.30]	
International Staging System (ISS)									0.3795
Stage I or II	229	19.7 (26.98)	4.0 (1.16)	107	17.1 (26.84)	2.1 (1.72)	1.9 [-2.11, 6.00]; 0.3453	0.1 [-0.12; 0.34]	
Stage III	51	18.3 (22.42)	3.8 (2.54)	21	20.6 (28.82)	6.1 (4.16)	-2.3 [-11.9, 7.29]; 0.6349	-0.1 [-0.63; 0.39]	
Prior proteasome inhibitor exposure									0.2593
Yes	260	20.0 (26.56)	3.2 (1.10)	114	18.4 (28.08)	2.7 (1.69)	0.5 [-3.44, 4.43]; 0.8054	0.0 [-0.19; 0.25]	
No	21	11.1 (19.25)	11.0 (3.45)	14	11.9 (16.57)	3.8 (4.31)	7.2 [-3.94, 18.39]; 0.1970	0.4 [-0.24; 1.13]	
Number of prior lines of therapy									0.2024
1	130	18.2 (25.62)	5.9 (1.52)	57	15.2 (25.25)	2.2 (2.34)	3.7 [-1.78, 9.19]; 0.1839	0.2 [-0.10; 0.52]	
>= 2	151	20.3 (26.66)	2.0 (1.43)	71	19.7 (28.50)	3.0 (2.14)	-1.0 [-6.01, 4.06]; 0.7031	-0.1 [-0.34; 0.23]	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
Mixed Model Repeated Measurement for change from baseline score, with time and treatment as independent variables, and baseline score included as a covariate

Table 7.12 Change from Baseline in EORTC QLQ-C30 - Appetite Loss Symptom Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
Age									0.7172
<= 75	257	11.7 (20.88)	-0.7 (0.28)	112	7.7 (20.00)	-0.3 (0.47)	-0.5 [-1.52, 0.58]; 0.3832	-0.1 [-0.32; 0.12]	
> 75	24	8.3 (14.74)	3.7 (2.53)	16	4.2 (11.39)	4.5 (3.21)	-0.8 [-8.98, 7.40]; 0.8462	-0.1 [-0.69; 0.57]	
Sex									0.3697
Male	161	9.7 (19.24)	0.9 (0.96)	78	7.3 (18.33)	0.5 (1.42)	0.4 [-2.94, 3.76]; 0.8093	0.0 [-0.24; 0.30]	
Female	120	13.6 (21.82)	-0.2 (1.16)	50	7.3 (20.53)	1.4 (1.84)	-1.7 [-5.96, 2.61]; 0.4415	-0.1 [-0.46; 0.20]	
Race									0.4115
White	220	11.1 (20.74)	0.2 (0.79)	104	6.7 (19.36)	0.2 (1.18)	0.0 [-2.77, 2.79]; 0.9944	0.0 [-0.23; 0.23]	
Non-White	61	12.6 (19.40)	1.1 (1.83)	24	9.7 (18.33)	3.6 (2.98)	-2.5 [-9.45, 4.46]; 0.4772	-0.2 [-0.64; 0.30]	
Geographic region									0.9819
Europe	182	10.4 (20.00)	0.2 (0.91)	84	7.9 (21.09)	0.7 (1.37)	-0.5 [-3.71, 2.72]; 0.7625	-0.0 [-0.30; 0.22]	
Asia Pacific	81	11.1 (19.00)	2.0 (1.33)	34	6.9 (15.95)	2.0 (2.11)	0.0 [-4.91, 4.98]; 0.9890	0.0 [-0.40; 0.40]	
North America	18	22.2 (28.01)	-3.4 (3.66)	10	3.3 (10.54)	-4.3 (5.08)	1.0 [-12.3, 14.27]; 0.8813	0.1 [-0.71; 0.83]	
ECOG performance status									0.7986
0-1	268	10.9 (20.10)	1.0 (0.76)	125	6.7 (18.45)	1.4 (1.14)	-0.3 [-3.01, 2.35]; 0.8070	-0.0 [-0.24; 0.19]	
2	12	22.2 (25.95)	-19.6 (2.17)	3	33.3 (33.33)	-19.7 (6.34)	0.1 [-13.7, 13.86]; 0.9890	0.0 [-1.25; 1.28]	

Table 7.12 Change from Baseline in EORTC QLQ-C30 - Appetite Loss Symptom Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
Prior bortezomib or ixazomib exposure									0.1334
Yes	259	12.1 (20.95)	-0.3 (0.76)	113	7.4 (19.79)	0.8 (1.18)	-1.1 [-3.86, 1.65]; 0.4315	-0.1 [-0.31; 0.13]	
No	22	3.0 (9.81)	7.0 (2.79)	15	6.7 (13.80)	2.1 (3.54)	4.9 [-4.19, 14.03]; 0.2804	0.4 [-0.30; 1.02]	
Refractory to bortezomib or ixazomib									0.6766
Yes	89	15.0 (22.48)	-0.2 (1.41)	48	9.7 (22.76)	0.7 (1.94)	-0.9 [-5.61, 3.80]; 0.7046	-0.1 [-0.42; 0.28]	
No	192	9.7 (19.25)	0.6 (0.87)	80	5.8 (16.58)	0.6 (1.38)	0.0 [-3.20, 3.21]; 0.9975	0.0 [-0.26; 0.26]	
Prior lenalidomide exposure									0.3418
Yes	112	12.8 (21.10)	-0.2 (1.24)	61	8.2 (19.87)	-0.8 (1.74)	0.6 [-3.62, 4.76]; 0.7886	0.0 [-0.27; 0.35]	
No	169	10.5 (19.98)	0.9 (0.90)	67	6.5 (18.57)	2.1 (1.45)	-1.1 [-4.48, 2.24]; 0.5119	-0.1 [-0.38; 0.19]	
Refractory to lenalidomide									0.5023
Yes	89	13.9 (21.79)	0.2 (1.48)	46	6.5 (15.10)	-0.2 (2.15)	0.4 [-4.76, 5.51]; 0.8856	0.0 [-0.33; 0.38]	
No	192	10.2 (19.72)	0.5 (0.83)	82	7.7 (21.15)	1.3 (1.29)	-0.8 [-3.76, 2.23]; 0.6150	-0.1 [-0.32; 0.19]	
Prior IMiD exposure									0.9510
Yes	186	11.6 (20.55)	0.5 (0.93)	90	7.4 (18.55)	1.1 (1.37)	-0.6 [-3.88, 2.59]; 0.6950	-0.1 [-0.30; 0.20]	

Table 7.12 Change from Baseline in EORTC QLQ-C30 - Appetite Loss Symptom Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
No	95	10.9 (20.31)	0.3 (1.19)	38	7.0 (20.73)	0.1 (1.93)	0.1 [-4.36, 4.59]; 0.9589	0.0 [-0.37; 0.39]	
Refractory to IMiD									0.8541
Yes	117	13.1 (21.42)	-0.0 (1.27)	54	8.0 (18.24)	1.0 (1.94)	-1.0 [-5.58, 3.51]; 0.6534	-0.1 [-0.40; 0.25]	
No	164	10.2 (19.67)	0.7 (0.89)	74	6.8 (19.88)	0.7 (1.34)	0.0 [-3.15, 3.16]; 0.9980	0.0 [-0.27; 0.27]	
International Staging System (ISS)									0.1702
Stage I or II	229	10.9 (20.29)	1.2 (0.80)	107	5.0 (15.05)	0.9 (1.19)	0.2 [-2.58, 3.06]; 0.8672	0.0 [-0.21; 0.25]	
Stage III	51	13.7 (21.27)	-4.6 (1.89)	21	19.0 (30.86)	-0.1 (3.19)	-4.4 [-11.7, 2.87]; 0.2293	-0.3 [-0.83; 0.19]	
Prior proteasome inhibitor exposure									0.1254
Yes	260	12.1 (20.92)	-0.3 (0.76)	114	7.3 (19.71)	0.8 (1.18)	-1.1 [-3.82, 1.65]; 0.4347	-0.1 [-0.31; 0.13]	
No	21	3.2 (10.03)	6.9 (2.91)	14	7.1 (14.19)	1.8 (3.73)	5.1 [-4.50, 14.66]; 0.2890	0.4 [-0.32; 1.05]	
Number of prior lines of therapy									0.8160
1	130	9.2 (20.34)	1.0 (0.97)	57	7.6 (18.92)	1.0 (1.49)	0.0 [-3.47, 3.49]; 0.9944	0.0 [-0.31; 0.31]	
>= 2	151	13.2 (20.40)	-0.2 (1.10)	71	7.0 (19.45)	0.7 (1.66)	-0.8 [-4.75, 3.06]; 0.6701	-0.1 [-0.34; 0.22]	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
Mixed Model Repeated Measurement for change from baseline score, with time and treatment as independent variables, and baseline score included as a covariate

Table 7.13 Change from Baseline in EORTC QLQ-C30 - Constipation Symptom Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
Age									0.0660
<= 75	257	10.8 (22.07)	-1.7 (0.26)	112	5.7 (14.07)	-1.6 (0.45)	-0.1 [-1.15, 0.86]; 0.7773	-0.0 [-0.25; 0.19]	
> 75	24	15.3 (25.97)	2.7 (3.40)	16	4.2 (16.67)	-5.1 (4.24)	7.7 [-3.36, 18.84]; 0.1661	0.5 [-0.19; 1.09]	
Sex									0.1935
Male	161	9.7 (20.29)	-1.9 (0.88)	78	5.6 (14.63)	-1.1 (1.28)	-0.7 [-3.78, 2.33]; 0.6404	-0.1 [-0.33; 0.21]	
Female	120	13.1 (24.94)	-1.0 (1.35)	50	5.3 (14.06)	-3.0 (2.13)	2.0 [-2.97, 7.00]; 0.4269	0.1 [-0.20; 0.46]	
Race									0.4922
White	220	9.8 (21.34)	-1.9 (0.76)	104	5.4 (14.77)	-2.0 (1.13)	0.1 [-2.54, 2.81]; 0.9195	0.0 [-0.22; 0.25]	
Non-White	61	15.8 (25.54)	-0.1 (2.15)	24	5.6 (12.69)	-1.0 (3.51)	0.9 [-7.30, 9.15]; 0.8239	0.1 [-0.42; 0.53]	
Geographic region									0.8884
Europe	182	12.1 (25.03)	-2.8 (0.92)	84	4.4 (13.47)	-2.9 (1.37)	0.0 [-3.20, 3.29]; 0.9798	0.0 [-0.26; 0.26]	
Asia Pacific	81	8.2 (15.39)	1.7 (1.62)	34	8.8 (17.03)	0.4 (2.56)	1.3 [-4.65, 7.32]; 0.6604	0.1 [-0.31; 0.49]	
North America	18	14.8 (20.52)	-0.7 (2.38)	10	3.3 (10.54)	-4.1 (3.38)	3.4 [-5.28, 12.04]; 0.4298	0.3 [-0.46; 1.10]	
ECOG performance status									0.7973
0-1	268	11.1 (22.48)	-1.4 (0.80)	125	5.6 (14.50)	-1.8 (1.19)	0.4 [-2.43, 3.21]; 0.7858	0.0 [-0.18; 0.24]	
2	12	13.9 (22.29)	-5.4 (2.42)	3	0.0 (0.00)	-7.6 (6.40)	2.2 [-11.9, 16.34]; 0.7479	0.2 [-1.03; 1.50]	

Table 7.13 Change from Baseline in EORTC QLQ-C30 - Constipation Symptom Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
Prior bortezomib or ixazomib exposure									0.0511
Yes	259	11.5 (22.96)	-1.7 (0.80)	113	5.0 (13.53)	-1.3 (1.23)	-0.4 [-3.31, 2.47]; 0.7760	-0.0 [-0.25; 0.19]	
No	22	7.6 (14.30)	2.0 (2.92)	15	8.9 (19.79)	-6.8 (3.60)	8.8 [-0.55, 18.18]; 0.0643	0.6 [-0.05; 1.30]	
Refractory to bortezomib or ixazomib									0.0386
Yes	89	10.9 (22.90)	-1.0 (1.22)	48	6.9 (15.31)	1.9 (1.68)	-2.9 [-7.00, 1.11]; 0.1530	-0.3 [-0.61; 0.10]	
No	192	11.3 (22.24)	-1.5 (0.96)	80	4.6 (13.77)	-3.7 (1.53)	2.2 [-1.40, 5.72]; 0.2340	0.2 [-0.10; 0.42]	
Prior lenalidomide exposure									0.6983
Yes	112	10.4 (21.93)	-1.0 (1.12)	61	3.8 (12.32)	-0.3 (1.57)	-0.7 [-4.49, 3.08]; 0.7148	-0.1 [-0.37; 0.25]	
No	169	11.6 (22.77)	-1.8 (1.05)	67	7.0 (15.93)	-3.0 (1.69)	1.2 [-2.67, 5.17]; 0.5314	0.1 [-0.19; 0.37]	
Refractory to lenalidomide									0.0700
Yes	89	9.0 (20.58)	-1.3 (1.01)	46	2.9 (11.81)	1.3 (1.48)	-2.7 [-6.21, 0.85]; 0.1354	-0.3 [-0.63; 0.08]	
No	192	12.2 (23.19)	-1.4 (1.03)	82	6.9 (15.48)	-3.5 (1.59)	2.1 [-1.63, 5.82]; 0.2692	0.1 [-0.11; 0.40]	
Prior IMiD exposure									0.5957
Yes	186	11.8 (23.07)	-1.5 (1.01)	90	5.2 (13.14)	-1.5 (1.47)	0.0 [-3.45, 3.55]; 0.9786	0.0 [-0.25; 0.26]	

Table 7.13 Change from Baseline in EORTC QLQ-C30 - Constipation Symptom Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
No	95	9.8 (21.12)	-1.4 (1.17)	38	6.1 (17.08)	-3.1 (1.89)	1.7 [-2.70, 6.08]; 0.4476	0.1 [-0.23; 0.52]	
Refractory to IMiD									0.0973
Yes	117	8.8 (20.71)	-0.7 (1.01)	54	4.3 (13.03)	1.2 (1.55)	-1.9 [-5.52, 1.74]; 0.3061	-0.2 [-0.49; 0.15]	
No	164	12.8 (23.47)	-1.8 (1.10)	74	6.3 (15.29)	-3.8 (1.65)	2.1 [-1.84, 5.97]; 0.2987	0.1 [-0.13; 0.42]	
International Staging System (ISS)									0.8230
Stage I or II	229	10.2 (21.70)	-0.6 (0.88)	107	5.0 (13.59)	-1.1 (1.29)	0.5 [-2.60, 3.54]; 0.7633	0.0 [-0.19; 0.26]	
Stage III	51	15.0 (25.22)	-6.9 (1.52)	21	7.9 (17.97)	-7.0 (2.58)	0.1 [-5.75, 6.02]; 0.9627	0.0 [-0.50; 0.52]	
Prior proteasome inhibitor exposure									0.1092
Yes	260	11.5 (22.96)	-1.7 (0.80)	114	5.0 (13.47)	-1.4 (1.23)	-0.3 [-3.16, 2.62]; 0.8545	-0.0 [-0.24; 0.20]	
No	21	6.3 (13.41)	1.8 (2.95)	14	9.5 (20.37)	-5.9 (3.69)	7.6 [-1.95, 17.19]; 0.1151	0.5 [-0.14; 1.24]	
Number of prior lines of therapy									0.4196
1	130	12.3 (23.53)	-1.7 (1.27)	57	5.8 (14.26)	-3.2 (1.93)	1.5 [-3.06, 6.06]; 0.5168	0.1 [-0.21; 0.41]	
>= 2	151	10.2 (21.43)	-1.2 (0.95)	71	5.2 (14.53)	-0.8 (1.42)	-0.4 [-3.73, 2.96]; 0.8205	-0.0 [-0.31; 0.25]	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
Mixed Model Repeated Measurement for change from baseline score, with time and treatment as independent variables, and baseline score included as a covariate

Table 7.14 Change from Baseline in EORTC QLQ-C30 - Diarrhoea Symptom Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	N	Baseline Mean (SD)	Change from BL LSMean(SE)	N	Baseline Mean (SD)	Change from BL LSMean(SE)	Difference in LSMean [95%-CI]; p-value	Hedges'g [95%-CI]	
Age									0.4211
<= 75	257	6.5 (16.44)	2.5 (0.29)	112	5.4 (13.83)	1.6 (0.50)	0.9 [-0.26, 1.96]; 0.1317	0.2 [-0.05; 0.40]	
> 75	24	2.8 (9.41)	5.7 (1.65)	16	0.0 (0.00)	3.9 (2.14)	1.8 [-3.66, 7.25]; 0.5089	0.2 [-0.42; 0.85]	
Sex									0.4034
Male	161	5.0 (13.02)	3.2 (0.83)	78	5.6 (14.63)	1.7 (1.24)	1.5 [-1.40, 4.41]; 0.3097	0.1 [-0.13; 0.41]	
Female	120	7.8 (19.20)	2.6 (1.20)	50	3.3 (10.10)	3.3 (1.92)	-0.7 [-5.12, 3.74]; 0.7585	-0.1 [-0.38; 0.28]	
Race									0.5872
White	220	5.0 (13.52)	3.5 (0.77)	104	3.5 (10.30)	2.7 (1.16)	0.8 [-1.88, 3.54]; 0.5479	0.1 [-0.16; 0.30]	
Non-White	61	10.4 (22.39)	0.9 (1.49)	24	9.7 (20.80)	1.6 (2.44)	-0.7 [-6.38, 4.91]; 0.7965	-0.1 [-0.53; 0.41]	
Geographic region									0.1484
Europe	182	5.3 (15.35)	3.0 (0.85)	84	1.6 (7.14)	3.8 (1.29)	-0.7 [-3.75, 2.30]; 0.6379	-0.1 [-0.32; 0.20]	
Asia Pacific	81	6.6 (14.36)	2.8 (1.22)	34	11.8 (19.90)	-0.5 (1.98)	3.2 [-1.35, 7.82]; 0.1646	0.3 [-0.11; 0.69]	
North America	18	13.0 (25.92)	4.9 (2.73)	10	6.7 (14.05)	1.1 (3.89)	3.8 [-5.94, 13.45]; 0.4336	0.3 [-0.47; 1.09]	
ECOG performance status									0.0886
0-1	268	6.3 (16.23)	3.0 (0.71)	125	4.8 (13.19)	2.0 (1.07)	1.0 [-1.51, 3.51]; 0.4345	0.1 [-0.13; 0.30]	
2	12	2.8 (9.62)	1.1 (2.41)	3	0.0 (0.00)	17.4 (6.68)	-16.3 [-30.8, -1.72]; 0.0306	-1.7 [-3.17; -0.26]	

Table 7.14 Change from Baseline in EORTC QLQ-C30 - Diarrhoea Symptom Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
Prior bortezomib or ixazomib exposure									0.9839
Yes	259	6.2 (16.22)	3.3 (0.74)	113	4.4 (12.20)	2.8 (1.16)	0.5 [-2.18, 3.18]; 0.7121	0.0 [-0.18; 0.26]	
No	22	6.1 (13.16)	-0.5 (1.66)	15	6.7 (18.69)	-1.0 (2.11)	0.6 [-4.83, 5.99]; 0.8294	0.1 [-0.59; 0.73]	
Refractory to bortezomib or ixazomib									0.9586
Yes	89	7.1 (14.63)	3.4 (1.55)	48	6.9 (15.31)	2.7 (2.14)	0.8 [-4.36, 5.95]; 0.7600	0.1 [-0.30; 0.40]	
No	192	5.7 (16.59)	2.8 (0.73)	80	3.3 (11.38)	1.9 (1.17)	0.8 [-1.88, 3.53]; 0.5479	0.1 [-0.18; 0.34]	
Prior lenalidomide exposure									0.7884
Yes	112	10.1 (20.43)	2.9 (1.35)	61	6.0 (15.53)	1.8 (1.90)	1.0 [-3.50, 5.60]; 0.6498	0.1 [-0.24; 0.38]	
No	169	3.6 (11.52)	3.0 (0.70)	67	3.5 (10.27)	2.4 (1.14)	0.6 [-1.99, 3.25]; 0.6354	0.1 [-0.21; 0.35]	
Refractory to lenalidomide									0.8326
Yes	89	9.0 (19.31)	2.8 (1.44)	46	7.2 (17.09)	1.6 (2.09)	1.1 [-3.83, 6.12]; 0.6496	0.1 [-0.27; 0.44]	
No	192	4.9 (14.05)	3.1 (0.75)	82	3.3 (9.95)	2.4 (1.18)	0.7 [-2.03, 3.43]; 0.6156	0.1 [-0.19; 0.32]	
Prior IMiD exposure									0.7092
Yes	186	7.5 (17.76)	3.5 (0.96)	90	5.9 (14.63)	2.3 (1.41)	1.2 [-2.15, 4.49]; 0.4886	0.1 [-0.16; 0.34]	

Table 7.14 Change from Baseline in EORTC QLQ-C30 - Diarrhoea Symptom Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
No	95	3.5 (11.38)	1.9 (0.76)	38	1.8 (7.54)	1.5 (1.26)	0.4 [-2.54, 3.24]; 0.8112	0.0 [-0.33; 0.42]	
Refractory to IMiD									0.8641
Yes	117	7.7 (17.72)	3.2 (1.26)	54	6.8 (16.36)	2.2 (1.94)	1.0 [-3.47, 5.53]; 0.6516	0.1 [-0.25; 0.40]	
No	164	5.1 (14.58)	2.7 (0.77)	74	3.2 (9.82)	2.1 (1.16)	0.6 [-2.13, 3.32]; 0.6691	0.1 [-0.21; 0.33]	
International Staging System (ISS)									0.2381
Stage I or II	229	6.8 (17.01)	2.7 (0.76)	107	5.0 (13.59)	1.5 (1.14)	1.2 [-1.47, 3.88]; 0.3761	0.1 [-0.13; 0.33]	
Stage III	51	3.3 (10.01)	3.9 (1.76)	21	3.2 (10.03)	6.7 (2.97)	-2.8 [-9.53, 3.94]; 0.4107	-0.2 [-0.72; 0.29]	
Prior proteasome inhibitor exposure									0.8516
Yes	260	6.3 (16.28)	3.2 (0.74)	114	4.4 (12.16)	2.7 (1.15)	0.4 [-2.23, 3.11]; 0.7458	0.0 [-0.18; 0.26]	
No	21	4.8 (11.95)	0.5 (1.73)	14	7.1 (19.30)	-0.6 (2.23)	1.1 [-4.57, 6.83]; 0.6894	0.1 [-0.54; 0.81]	
Number of prior lines of therapy									0.8591
1	130	5.6 (16.67)	1.8 (0.89)	57	4.7 (13.27)	0.9 (1.38)	0.9 [-2.32, 4.09]; 0.5861	0.1 [-0.23; 0.40]	
>= 2	151	6.6 (15.41)	4.0 (1.05)	71	4.7 (12.97)	3.5 (1.58)	0.5 [-3.16, 4.24]; 0.7753	0.0 [-0.24; 0.32]	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
Mixed Model Repeated Measurement for change from baseline score, with time and treatment as independent variables, and baseline score included as a covariate

Table 7.15 Change from Baseline in EORTC QLQ-C30 - Financial Difficulities Symptom Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
Age									0.3281
<= 75	257	17.1 (25.70)	1.7 (0.31)	112	15.8 (25.29)	-0.8 (0.54)	2.5 [1.27, 3.66]; <.0001	0.5 [0.24; 0.69]	
> 75	24	11.1 (18.82)	1.1 (1.96)	16	6.3 (18.13)	4.0 (2.41)	-2.9 [-9.12, 3.33]; 0.3523	-0.3 [-0.93; 0.34]	
Sex									0.8252
Male	161	15.5 (24.45)	1.9 (1.19)	78	18.8 (26.64)	0.8 (1.74)	1.1 [-3.01, 5.24]; 0.5943	0.1 [-0.20; 0.34]	
Female	120	18.1 (26.25)	2.6 (1.32)	50	8.0 (19.70)	0.5 (2.10)	2.1 [-2.84, 6.99]; 0.4053	0.1 [-0.19; 0.47]	
Race									0.9541
White	220	15.8 (24.35)	2.9 (1.00)	104	15.4 (25.83)	1.4 (1.48)	1.5 [-1.99, 4.98]; 0.3989	0.1 [-0.13; 0.33]	
Non-White	61	19.7 (28.14)	-0.4 (1.93)	24	11.1 (18.82)	-2.3 (3.12)	1.8 [-5.46, 9.13]; 0.6179	0.1 [-0.35; 0.59]	
Geographic region									0.2180
Europe	182	15.6 (24.44)	4.0 (1.08)	84	13.1 (24.28)	0.5 (1.62)	3.5 [-0.28, 7.35]; 0.0691	0.2 [-0.02; 0.50]	
Asia Pacific	81	17.3 (24.78)	-0.7 (1.73)	34	18.6 (26.20)	1.3 (2.72)	-2.0 [-8.36, 4.36]; 0.5342	-0.1 [-0.53; 0.27]	
North America	18	24.1 (33.93)	-2.1 (3.36)	10	13.3 (23.31)	0.8 (4.55)	-2.9 [-14.6, 8.72]; 0.6082	-0.2 [-0.98; 0.58]	
ECOG performance status									0.6517
0-1	268	16.3 (24.73)	2.4 (0.91)	125	14.1 (24.42)	0.9 (1.35)	1.5 [-1.68, 4.68]; 0.3538	0.1 [-0.11; 0.31]	
2	12	25.0 (35.18)	-1.9 (3.67)	3	33.3 (33.33)	-7.9 (8.59)	6.0 [-13.2, 25.26]; 0.5204	0.4 [-0.85; 1.71]	

Table 7.15 Change from Baseline in EORTC QLQ-C30 - Financial Difficulities Symptom Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
Prior bortezomib or ixazomib exposure									0.7673
Yes	259	17.4 (25.81)	2.0 (0.93)	113	15.0 (25.19)	0.8 (1.43)	1.2 [-2.12, 4.54]; 0.4759	0.1 [-0.14; 0.30]	
No	22	7.6 (14.30)	3.2 (2.83)	15	11.1 (20.57)	1.0 (3.52)	2.2 [-6.92, 11.32]; 0.6276	0.2 [-0.50; 0.82]	
Refractory to bortezomib or ixazomib									0.2153
Yes	89	19.5 (26.97)	1.1 (1.67)	48	19.4 (28.21)	2.1 (2.30)	-1.0 [-6.53, 4.56]; 0.7260	-0.1 [-0.41; 0.29]	
No	192	15.3 (24.32)	2.5 (1.03)	80	11.7 (21.93)	-0.5 (1.62)	3.0 [-0.77, 6.79]; 0.1183	0.2 [-0.05; 0.47]	
Prior lenalidomide exposure									0.9636
Yes	112	17.9 (26.06)	-0.6 (1.35)	61	15.8 (24.80)	-2.1 (1.88)	1.5 [-3.02, 6.04]; 0.5116	0.1 [-0.21; 0.42]	
No	169	15.8 (24.68)	3.9 (1.16)	67	13.4 (24.66)	2.7 (1.86)	1.2 [-3.10, 5.50]; 0.5831	0.1 [-0.20; 0.36]	
Refractory to lenalidomide									0.6450
Yes	89	20.6 (27.30)	-2.0 (1.57)	46	17.4 (25.08)	-3.1 (2.23)	1.0 [-4.32, 6.41]; 0.6997	0.1 [-0.29; 0.43]	
No	192	14.8 (24.04)	4.2 (1.06)	82	13.0 (24.43)	2.4 (1.64)	1.8 [-2.05, 5.60]; 0.3610	0.1 [-0.14; 0.38]	
Prior IMiD exposure									0.8689
Yes	186	16.5 (25.29)	0.1 (0.99)	90	14.8 (24.02)	-1.6 (1.44)	1.6 [-1.76, 5.06]; 0.3423	0.1 [-0.13; 0.37]	

Table 7.15 Change from Baseline in EORTC QLQ-C30 - Financial Difficulities Symptom Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
No	95	16.8 (25.21)	5.8 (1.75)	38	14.0 (26.43)	5.4 (2.81)	0.4 [-6.15, 6.92]; 0.9074	0.0 [-0.35; 0.40]	
Refractory to IMiD									0.4528
Yes	117	18.5 (26.42)	-1.6 (1.31)	54	16.0 (24.86)	-2.3 (1.99)	0.6 [-4.02, 5.32]; 0.7840	0.0 [-0.28; 0.37]	
No	164	15.2 (24.31)	4.8 (1.16)	74	13.5 (24.62)	2.4 (1.74)	2.3 [-1.77, 6.46]; 0.2622	0.2 [-0.12; 0.43]	
International Staging System (ISS)									0.5832
Stage I or II	229	16.7 (25.86)	1.1 (0.97)	107	15.6 (25.21)	0.1 (1.44)	1.1 [-2.35, 4.45]; 0.5432	0.1 [-0.16; 0.30]	
Stage III	51	16.3 (22.48)	7.8 (2.09)	21	9.5 (21.46)	4.9 (3.49)	2.8 [-5.16, 10.83]; 0.4817	0.2 [-0.33; 0.69]	
Prior proteasome inhibitor exposure									0.7046
Yes	260	17.4 (25.78)	2.0 (0.92)	114	14.9 (25.12)	0.9 (1.42)	1.2 [-2.15, 4.47]; 0.4924	0.1 [-0.14; 0.30]	
No	21	6.3 (13.41)	3.2 (2.89)	14	11.9 (21.11)	1.2 (3.66)	2.0 [-7.46, 11.43]; 0.6718	0.1 [-0.53; 0.82]	
Number of prior lines of therapy									0.2225
1	130	14.6 (24.20)	4.2 (1.30)	57	12.9 (22.50)	0.6 (1.99)	3.6 [-1.12, 8.24]; 0.1352	0.2 [-0.07; 0.55]	
>= 2	151	18.3 (26.02)	0.4 (1.21)	71	16.0 (26.34)	0.6 (1.79)	-0.2 [-4.43, 4.04]; 0.9287	-0.0 [-0.29; 0.27]	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
Mixed Model Repeated Measurement for change from baseline score, with time and treatment as independent variables, and baseline score included as a covariate

Table 7.1 Change from Baseline in EORTC QLQ-C30 - Global Health Status Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
Age									0.4638
<= 75	257	61.4 (20.15)	0.7 (0.78)	112	66.3 (18.12)	0.3 (1.17)	0.4 [-2.29, 3.09]; 0.7693	0.0 [-0.19; 0.25]	
> 75	24	66.7 (19.66)	-5.4 (2.28)	16	70.8 (14.59)	-3.5 (2.83)	-1.9 [-8.98, 5.14]; 0.5858	-0.2 [-0.80; 0.47]	
Sex									0.2291
Male	161	64.0 (20.21)	0.5 (1.00)	78	67.1 (18.46)	-1.0 (1.44)	1.5 [-1.84, 4.93]; 0.3703	0.1 [-0.15; 0.39]	
Female	120	59.0 (19.73)	-0.2 (1.07)	50	66.5 (16.71)	1.4 (1.62)	-1.6 [-5.31, 2.05]; 0.3822	-0.1 [-0.47; 0.19]	
Race									0.5762
White	220	61.3 (19.89)	0.4 (0.81)	104	67.1 (17.60)	-0.0 (1.18)	0.4 [-2.36, 3.17]; 0.7742	0.0 [-0.20; 0.27]	
Non-White	61	64.2 (20.94)	-0.5 (1.70)	24	65.6 (18.60)	0.6 (2.66)	-1.1 [-7.13, 4.95]; 0.7202	-0.1 [-0.55; 0.39]	
Geographic region									0.8653
Europe	182	58.5 (18.54)	1.7 (0.91)	84	66.4 (18.04)	1.9 (1.33)	-0.2 [-3.31, 2.95]; 0.9111	-0.0 [-0.27; 0.24]	
Asia Pacific	81	69.3 (21.20)	-2.3 (1.34)	34	67.4 (18.04)	-2.2 (2.08)	-0.1 [-4.82, 4.56]; 0.9564	-0.0 [-0.41; 0.39]	
North America	18	62.5 (22.55)	-3.8 (3.21)	10	69.2 (15.24)	-2.9 (4.28)	-0.9 [-11.8, 10.06]; 0.8681	-0.1 [-0.84; 0.71]	
ECOG performance status									0.9229
0-1	268	62.4 (20.01)	-0.3 (0.76)	125	67.6 (17.14)	-0.4 (1.11)	0.1 [-2.49, 2.66]; 0.9500	0.0 [-0.21; 0.22]	
2	12	47.2 (14.79)	15.8 (2.22)	3	36.1 (17.35)	16.4 (5.31)	-0.6 [-12.5, 11.24]; 0.9104	-0.1 [-1.34; 1.19]	

Table 7.1 Change from Baseline in EORTC QLQ-C30 - Global Health Status Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
Prior bortezomib or ixazomib exposure									0.5939
Yes	259	60.7 (19.85)	0.8 (0.77)	113	65.5 (17.71)	0.9 (1.16)	-0.0 [-2.69, 2.66]; 0.9907	-0.0 [-0.22; 0.22]	
No	22	75.4 (18.81)	-5.8 (2.39)	15	77.2 (14.59)	-8.0 (2.94)	2.3 [-5.24, 9.74]; 0.5452	0.2 [-0.46; 0.85]	
Refractory to bortezomib or ixazomib									0.8841
Yes	89	58.0 (19.66)	2.4 (1.36)	48	64.2 (19.67)	2.6 (1.84)	-0.2 [-4.64, 4.22]; 0.9252	-0.0 [-0.37; 0.33]	
No	192	63.7 (20.12)	-0.6 (0.88)	80	68.4 (16.38)	-0.8 (1.34)	0.3 [-2.79, 3.33]; 0.8628	0.0 [-0.24; 0.28]	
Prior lenalidomide exposure									0.6912
Yes	112	59.8 (21.61)	0.3 (1.20)	61	65.6 (18.29)	0.6 (1.63)	-0.3 [-4.21, 3.59]; 0.8754	-0.0 [-0.34; 0.29]	
No	169	63.3 (19.02)	0.1 (0.93)	67	68.0 (17.26)	-0.4 (1.46)	0.5 [-2.86, 3.80]; 0.7809	0.0 [-0.24; 0.32]	
Refractory to lenalidomide									0.4677
Yes	89	59.7 (21.51)	0.8 (1.35)	46	65.4 (18.25)	1.5 (1.90)	-0.7 [-5.20, 3.77]; 0.7533	-0.1 [-0.41; 0.30]	
No	192	62.9 (19.42)	-0.0 (0.87)	82	67.7 (17.49)	-0.8 (1.32)	0.7 [-2.33, 3.76]; 0.6433	0.1 [-0.20; 0.32]	
Prior IMiD exposure									0.2540
Yes	186	60.8 (20.77)	-0.5 (0.91)	90	67.9 (17.11)	0.2 (1.29)	-0.6 [-3.67, 2.38]; 0.6761	-0.1 [-0.30; 0.20]	

Table 7.1 Change from Baseline in EORTC QLQ-C30 - Global Health Status Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
No	95	63.9 (18.73)	1.6 (1.24)	38	64.5 (19.15)	-0.6 (1.98)	2.2 [-2.36, 6.66]; 0.3471	0.2 [-0.20; 0.55]	
Refractory to IMiD									0.1402
Yes	117	61.3 (20.71)	-0.6 (1.17)	54	66.4 (17.88)	1.1 (1.72)	-1.7 [-5.68, 2.27]; 0.3984	-0.1 [-0.46; 0.19]	
No	164	62.3 (19.74)	0.7 (0.94)	74	67.2 (17.74)	-0.7 (1.39)	1.5 [-1.75, 4.72]; 0.3682	0.1 [-0.15; 0.40]	
International Staging System (ISS)									0.9137
Stage I or II	229	63.1 (20.49)	-0.7 (0.80)	107	68.8 (16.88)	-0.9 (1.16)	0.2 [-2.52, 2.92]; 0.8845	0.0 [-0.21; 0.25]	
Stage III	51	56.7 (17.80)	5.2 (1.86)	21	56.7 (18.93)	5.6 (3.00)	-0.4 [-7.18, 6.47]; 0.9172	-0.0 [-0.53; 0.48]	
Prior proteasome inhibitor exposure									0.6080
Yes	260	60.8 (19.81)	0.8 (0.77)	114	65.6 (17.71)	0.8 (1.16)	0.0 [-2.66, 2.67]; 0.9968	0.0 [-0.22; 0.22]	
No	21	75.8 (19.17)	-5.5 (2.44)	14	76.8 (15.04)	-7.9 (3.04)	2.4 [-5.31, 10.13]; 0.5294	0.2 [-0.47; 0.89]	
Number of prior lines of therapy									0.4283
1	130	65.1 (19.68)	-1.8 (1.02)	57	69.7 (16.49)	-3.2 (1.52)	1.4 [-2.08, 4.92]; 0.4244	0.1 [-0.19; 0.43]	
>= 2	151	59.1 (20.15)	2.0 (1.06)	71	64.6 (18.46)	3.0 (1.54)	-0.9 [-4.53, 2.66]; 0.6098	-0.1 [-0.35; 0.21]	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
Mixed Model Repeated Measurement for change from baseline score, with time and treatment as independent variables, and baseline score included as a covariate

Table 7.2 Change from Baseline in EORTC QLQ-C30 - Physical Functioning Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
Age									0.2764
<= 75	257	76.9 (21.70)	-2.3 (0.78)	112	81.9 (17.64)	-3.0 (1.18)	0.7 [-2.06, 3.42]; 0.6253	0.1 [-0.17; 0.28]	
> 75	24	76.4 (22.58)	-4.6 (2.10)	16	84.2 (13.96)	-1.3 (2.58)	-3.4 [-9.96, 3.21]; 0.3056	-0.3 [-0.96; 0.32]	
Sex									0.5425
Male	161	80.2 (20.41)	-2.6 (0.95)	78	82.7 (16.35)	-3.5 (1.36)	0.9 [-2.27, 4.13]; 0.5677	0.1 [-0.19; 0.35]	
Female	120	72.3 (22.71)	-2.3 (1.18)	50	81.3 (18.57)	-1.4 (1.80)	-0.9 [-5.13, 3.24]; 0.6575	-0.1 [-0.40; 0.26]	
Race									0.6038
White	220	75.3 (22.59)	-2.2 (0.82)	104	81.7 (17.55)	-2.3 (1.19)	0.1 [-2.76, 2.86]; 0.9717	0.0 [-0.23; 0.24]	
Non-White	61	82.2 (17.46)	-3.3 (1.65)	24	84.4 (15.69)	-4.3 (2.59)	1.0 [-5.04, 6.96]; 0.7496	0.1 [-0.40; 0.55]	
Geographic region									0.4418
Europe	182	73.6 (23.10)	-2.0 (0.95)	84	81.3 (17.59)	-1.5 (1.39)	-0.6 [-3.84, 2.73]; 0.7398	-0.0 [-0.30; 0.22]	
Asia Pacific	81	84.4 (17.45)	-3.9 (1.21)	34	83.1 (17.00)	-5.0 (1.86)	1.1 [-3.19, 5.35]; 0.6175	0.1 [-0.30; 0.50]	
North America	18	75.2 (16.77)	-0.4 (3.13)	10	86.0 (15.22)	-6.1 (4.30)	5.7 [-5.44, 16.80]; 0.3032	0.4 [-0.37; 1.19]	
ECOG performance status									0.5848
0-1	268	77.5 (21.14)	-3.0 (0.76)	125	83.1 (16.17)	-3.3 (1.10)	0.3 [-2.30, 2.86]; 0.8325	0.0 [-0.19; 0.23]	
2	12	60.6 (28.77)	11.1 (3.15)	3	44.4 (19.25)	14.4 (7.21)	-3.4 [-19.8, 13.02]; 0.6670	-0.3 [-1.56; 0.99]	

Table 7.2 Change from Baseline in EORTC QLQ-C30 - Physical Functioning Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
Prior bortezomib or ixazomib exposure									0.2191
Yes	259	76.1 (22.00)	-2.1 (0.78)	113	81.4 (17.19)	-2.8 (1.18)	0.7 [-1.99, 3.48]; 0.5921	0.1 [-0.16; 0.28]	
No	22	85.2 (16.58)	-6.7 (2.02)	15	88.0 (16.56)	-2.8 (2.48)	-3.9 [-10.2, 2.36]; 0.2127	-0.4 [-1.07; 0.26]	
Refractory to bortezomib or ixazomib									0.1260
Yes	89	72.9 (20.40)	-1.1 (1.44)	48	76.4 (20.81)	-3.9 (1.95)	2.8 [-1.86, 7.54]; 0.2335	0.2 [-0.14; 0.56]	
No	192	78.6 (22.14)	-2.8 (0.85)	80	85.7 (13.59)	-1.3 (1.30)	-1.5 [-4.51, 1.49]; 0.3214	-0.1 [-0.39; 0.13]	
Prior lenalidomide exposure									0.8456
Yes	112	75.6 (22.84)	-1.8 (1.29)	61	81.2 (17.02)	-2.4 (1.76)	0.6 [-3.67, 4.86]; 0.7825	0.0 [-0.27; 0.36]	
No	169	77.6 (21.00)	-3.2 (0.88)	67	83.1 (17.42)	-2.8 (1.37)	-0.4 [-3.51, 2.80]; 0.8231	-0.0 [-0.31; 0.25]	
Refractory to lenalidomide									0.6302
Yes	89	75.7 (22.61)	-1.5 (1.44)	46	80.7 (17.73)	-1.0 (2.02)	-0.5 [-5.38, 4.32]; 0.8285	-0.0 [-0.39; 0.32]	
No	192	77.3 (21.36)	-3.1 (0.85)	82	83.0 (16.93)	-3.5 (1.28)	0.4 [-2.53, 3.40]; 0.7727	0.0 [-0.22; 0.30]	
Prior IMiD exposure									0.9827
Yes	186	76.3 (21.16)	-1.9 (0.95)	90	83.3 (15.43)	-2.1 (1.36)	0.3 [-2.95, 3.49]; 0.8698	0.0 [-0.23; 0.27]	

Table 7.2 Change from Baseline in EORTC QLQ-C30 - Physical Functioning Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
No	95	77.9 (22.89)	-3.5 (1.16)	38	79.6 (20.79)	-3.6 (1.84)	0.1 [-4.10, 4.34]; 0.9538	0.0 [-0.37; 0.39]	
Refractory to IMiD									0.8634
Yes	117	76.9 (21.13)	-1.6 (1.28)	54	80.7 (16.97)	-1.7 (1.89)	0.1 [-4.31, 4.57]; 0.9538	0.0 [-0.31; 0.33]	
No	164	76.8 (22.22)	-3.2 (0.88)	74	83.2 (17.39)	-3.2 (1.29)	-0.0 [-3.05, 2.99]; 0.9847	-0.0 [-0.28; 0.27]	
International Staging System (ISS)									0.0665
Stage I or II	229	78.6 (21.07)	-3.7 (0.77)	107	84.2 (15.12)	-3.1 (1.12)	-0.7 [-3.28, 1.98]; 0.6273	-0.1 [-0.29; 0.17]	
Stage III	51	68.6 (23.18)	5.6 (2.08)	21	72.1 (23.15)	1.4 (3.34)	4.2 [-3.50, 11.85]; 0.2813	0.3 [-0.23; 0.79]	
Prior proteasome inhibitor exposure									0.2609
Yes	260	76.2 (21.96)	-2.1 (0.78)	114	81.6 (17.20)	-2.8 (1.17)	0.7 [-2.04, 3.40]; 0.6234	0.1 [-0.17; 0.27]	
No	21	85.1 (16.98)	-6.3 (2.08)	14	87.1 (16.84)	-2.7 (2.58)	-3.6 [-10.2, 2.93]; 0.2693	-0.4 [-1.05; 0.31]	
Number of prior lines of therapy									0.7167
1	130	79.4 (21.19)	-3.7 (0.94)	57	85.4 (15.40)	-3.1 (1.41)	-0.6 [-3.91, 2.65]; 0.7046	-0.1 [-0.37; 0.25]	
>= 2	151	74.6 (22.03)	-1.5 (1.12)	71	79.6 (18.20)	-2.2 (1.62)	0.8 [-3.07, 4.61]; 0.6934	0.1 [-0.23; 0.34]	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
Mixed Model Repeated Measurement for change from baseline score, with time and treatment as independent variables, and baseline score included as a covariate

Table 7.3 Change from Baseline in EORTC QLQ-C30 - Role Functioning Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
Age									0.8355
<= 75	257	75.1 (27.56)	-5.0 (1.09)	112	78.1 (27.03)	-5.9 (1.64)	0.8 [-2.94, 4.60]; 0.6651	0.0 [-0.17; 0.27]	
> 75	24	77.1 (26.38)	-1.5 (2.79)	16	79.2 (28.87)	-3.6 (3.47)	2.1 [-6.48, 10.73]; 0.6199	0.2 [-0.48; 0.78]	
Sex									0.6205
Male	161	78.6 (25.85)	-3.6 (1.27)	78	77.1 (27.80)	-5.1 (1.84)	1.5 [-2.75, 5.82]; 0.4815	0.1 [-0.18; 0.37]	
Female	120	70.8 (28.93)	-6.3 (1.68)	50	80.0 (26.30)	-6.0 (2.56)	-0.3 [-6.16, 5.61]; 0.9265	-0.0 [-0.34; 0.31]	
Race									0.5226
White	220	74.6 (27.28)	-4.2 (1.12)	104	77.4 (27.67)	-4.5 (1.63)	0.3 [-3.49, 4.11]; 0.8733	0.0 [-0.21; 0.25]	
Non-White	61	77.6 (28.04)	-6.6 (2.40)	24	81.9 (25.02)	-8.7 (3.75)	2.1 [-6.54, 10.77]; 0.6281	0.1 [-0.36; 0.58]	
Geographic region									0.7903
Europe	182	72.4 (28.12)	-3.6 (1.30)	84	79.6 (27.05)	-4.0 (1.90)	0.4 [-4.07, 4.82]; 0.8686	0.0 [-0.24; 0.28]	
Asia Pacific	81	83.7 (24.00)	-8.9 (1.80)	34	77.9 (28.93)	-12.2 (2.81)	3.3 [-3.09, 9.66]; 0.3094	0.2 [-0.20; 0.60]	
North America	18	65.7 (27.10)	0.9 (4.04)	10	68.3 (21.44)	-0.6 (5.50)	1.5 [-12.4, 15.44]; 0.8228	0.1 [-0.69; 0.86]	
ECOG performance status									0.4044
0-1	268	75.8 (27.11)	-5.6 (1.04)	125	79.3 (26.47)	-6.4 (1.52)	0.8 [-2.73, 4.32]; 0.6580	0.0 [-0.17; 0.26]	
2	12	61.1 (32.05)	16.9 (4.80)	3	33.3 (16.67)	22.5 (11.38)	-5.6 [-31.5, 20.33]; 0.6498	-0.3 [-1.58; 0.96]	

Table 7.3 Change from Baseline in EORTC QLQ-C30 - Role Functioning Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
Prior bortezomib or ixazomib exposure									0.5541
Yes	259	73.8 (27.83)	-4.0 (1.08)	113	77.3 (27.46)	-5.2 (1.62)	1.2 [-2.48, 4.98]; 0.5104	0.1 [-0.15; 0.29]	
No	22	92.4 (13.34)	-11.1 (3.19)	15	85.6 (24.29)	-9.1 (4.01)	-2.0 [-12.2, 8.22]; 0.6939	-0.1 [-0.79; 0.53]	
Refractory to bortezomib or ixazomib									0.0441
Yes	89	68.9 (26.26)	-2.1 (1.99)	48	73.6 (29.74)	-7.4 (2.70)	5.3 [-1.18, 11.81]; 0.1080	0.3 [-0.07; 0.63]	
No	192	78.2 (27.52)	-5.6 (1.18)	80	81.0 (25.26)	-3.7 (1.81)	-1.9 [-6.04, 2.19]; 0.3572	-0.1 [-0.38; 0.14]	
Prior lenalidomide exposure									0.5654
Yes	112	72.8 (30.10)	-4.5 (1.65)	61	76.0 (25.91)	-4.1 (2.25)	-0.4 [-5.80, 4.97]; 0.8780	-0.0 [-0.34; 0.29]	
No	169	76.9 (25.46)	-5.0 (1.31)	67	80.3 (28.27)	-6.5 (2.05)	1.5 [-3.20, 6.13]; 0.5360	0.1 [-0.20; 0.37]	
Refractory to lenalidomide									0.5628
Yes	89	71.9 (30.83)	-3.2 (1.89)	46	75.7 (25.51)	-2.6 (2.65)	-0.6 [-6.91, 5.67]; 0.8453	-0.0 [-0.39; 0.32]	
No	192	76.8 (25.63)	-5.5 (1.22)	82	79.7 (28.09)	-6.9 (1.84)	1.5 [-2.77, 5.70]; 0.4962	0.1 [-0.17; 0.35]	
Prior IMiD exposure									0.6426
Yes	186	74.6 (27.79)	-5.0 (1.25)	90	80.7 (24.08)	-5.2 (1.78)	0.2 [-3.97, 4.35]; 0.9278	0.0 [-0.24; 0.26]	

Table 7.3 Change from Baseline in EORTC QLQ-C30 - Role Functioning Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
No	95	76.5 (26.80)	-4.1 (1.79)	38	72.4 (32.94)	-6.1 (2.86)	2.0 [-4.49, 8.51]; 0.5426	0.1 [-0.26; 0.49]	
Refractory to IMiD									0.8664
Yes	117	73.9 (29.39)	-3.9 (1.66)	54	76.9 (26.39)	-4.3 (2.46)	0.4 [-5.29, 6.13]; 0.8845	0.0 [-0.30; 0.35]	
No	164	76.2 (25.98)	-5.3 (1.30)	74	79.3 (27.84)	-6.2 (1.92)	0.9 [-3.53, 5.37]; 0.6840	0.1 [-0.22; 0.33]	
International Staging System (ISS)									0.4275
Stage I or II	229	77.4 (26.08)	-6.1 (1.10)	107	81.3 (24.94)	-6.5 (1.59)	0.3 [-3.38, 4.07]; 0.8561	0.0 [-0.21; 0.25]	
Stage III	51	65.0 (31.14)	5.2 (2.64)	21	62.7 (32.87)	2.6 (4.26)	2.5 [-7.14, 12.15]; 0.6060	0.1 [-0.38; 0.64]	
Prior proteasome inhibitor exposure									0.6877
Yes	260	73.9 (27.82)	-4.1 (1.08)	114	77.5 (27.42)	-5.3 (1.62)	1.1 [-2.59, 4.85]; 0.5496	0.1 [-0.15; 0.29]	
No	21	92.1 (13.56)	-9.6 (3.15)	14	84.5 (24.86)	-8.7 (4.01)	-1.0 [-11.1, 9.24]; 0.8499	-0.1 [-0.74; 0.61]	
Number of prior lines of therapy									0.8113
1	130	79.7 (24.55)	-6.4 (1.38)	57	81.9 (24.25)	-6.6 (2.06)	0.2 [-4.48, 4.97]; 0.9197	0.0 [-0.30; 0.33]	
>= 2	151	71.4 (29.21)	-3.3 (1.51)	71	75.4 (29.12)	-4.4 (2.20)	1.1 [-4.01, 6.26]; 0.6665	0.1 [-0.22; 0.34]	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
Mixed Model Repeated Measurement for change from baseline score, with time and treatment as independent variables, and baseline score included as a covariate

Table 7.4 Change from Baseline in EORTC QLQ-C30 - Emotional Functioning Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
Age									0.6129
<= 75	257	81.2 (19.48)	-0.1 (0.77)	112	81.8 (16.60)	-0.6 (1.16)	0.5 [-2.17, 3.16]; 0.7176	0.0 [-0.18; 0.26]	
> 75	24	83.0 (21.63)	0.5 (2.83)	16	83.9 (17.60)	-2.1 (3.52)	2.6 [-6.26, 11.44]; 0.5574	0.2 [-0.45; 0.82]	
Sex									0.6114
Male	161	85.5 (16.91)	-0.1 (0.91)	78	82.7 (17.08)	-1.3 (1.32)	1.2 [-1.89, 4.27]; 0.4471	0.1 [-0.17; 0.37]	
Female	120	75.8 (21.63)	-0.1 (1.25)	50	81.2 (16.13)	0.0 (1.91)	-0.1 [-4.52, 4.23]; 0.9475	-0.0 [-0.34; 0.32]	
Race									0.4004
White	220	83.0 (18.30)	-1.3 (0.80)	104	82.3 (17.52)	-1.4 (1.16)	0.1 [-2.56, 2.84]; 0.9180	0.0 [-0.22; 0.25]	
Non-White	61	75.5 (23.12)	4.8 (1.85)	24	81.3 (12.59)	2.5 (2.93)	2.3 [-4.42, 9.02]; 0.4976	0.2 [-0.31; 0.63]	
Geographic region									0.8720
Europe	182	81.4 (20.19)	-1.5 (0.92)	84	84.5 (16.92)	-1.5 (1.35)	0.0 [-3.10, 3.16]; 0.9850	0.0 [-0.26; 0.26]	
Asia Pacific	81	82.1 (18.26)	2.8 (1.38)	34	78.7 (15.38)	1.6 (2.14)	1.2 [-3.73, 6.09]; 0.6358	0.1 [-0.31; 0.49]	
North America	18	77.8 (20.61)	0.2 (2.71)	10	73.3 (15.11)	-1.3 (3.73)	1.5 [-7.90, 10.92]; 0.7436	0.1 [-0.65; 0.90]	
ECOG performance status									0.4123
0-1	268	81.1 (19.54)	-0.2 (0.76)	125	82.1 (16.86)	-0.7 (1.11)	0.4 [-2.15, 3.01]; 0.7429	0.0 [-0.18; 0.25]	
2	12	85.4 (22.23)	2.1 (3.28)	3	80.6 (4.81)	-6.5 (7.18)	8.6 [-7.70, 24.95]; 0.2786	0.7 [-0.59; 2.00]	

Table 7.4 Change from Baseline in EORTC QLQ-C30 - Emotional Functioning Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	N	Baseline Mean (SD)	Change from BL LSMean(SE)	N	Baseline Mean (SD)	Change from BL LSMean(SE)	Difference in LSMean [95%-CI]; p-value	Hedges'g [95%-CI]	
Prior bortezomib or ixazomib exposure									0.3897
Yes	259	81.0 (19.83)	-0.2 (0.77)	113	81.4 (17.00)	-0.6 (1.17)	0.4 [-2.24, 3.11]; 0.7492	0.0 [-0.19; 0.26]	
No	22	85.6 (17.09)	1.1 (2.72)	15	87.2 (13.31)	-2.4 (3.33)	3.5 [-5.08, 12.06]; 0.4142	0.3 [-0.39; 0.93]	
Refractory to bortezomib or ixazomib									0.6245
Yes	89	79.6 (20.80)	-0.9 (1.39)	48	77.6 (15.58)	-0.8 (1.90)	-0.2 [-4.72, 4.36]; 0.9375	-0.0 [-0.36; 0.34]	
No	192	82.2 (19.08)	0.6 (0.88)	80	84.8 (16.81)	-0.5 (1.36)	1.1 [-1.98, 4.21]; 0.4778	0.1 [-0.17; 0.35]	
Prior lenalidomide exposure									0.8834
Yes	112	80.8 (20.80)	-0.8 (1.20)	61	81.0 (16.40)	-1.3 (1.63)	0.5 [-3.35, 4.45]; 0.7812	0.0 [-0.27; 0.36]	
No	169	81.7 (18.88)	0.3 (0.94)	67	83.1 (16.98)	-0.3 (1.47)	0.6 [-2.75, 3.95]; 0.7246	0.0 [-0.23; 0.33]	
Refractory to lenalidomide									0.8067
Yes	89	80.4 (22.02)	-0.7 (1.38)	46	80.6 (16.86)	-1.1 (1.94)	0.3 [-4.24, 4.94]; 0.8816	0.0 [-0.33; 0.38]	
No	192	81.8 (18.48)	0.2 (0.87)	82	82.9 (16.61)	-0.6 (1.32)	0.8 [-2.26, 3.82]; 0.6129	0.1 [-0.19; 0.32]	
Prior IMiD exposure									0.6070
Yes	186	81.5 (19.37)	-0.3 (0.92)	90	81.9 (15.57)	-0.5 (1.32)	0.2 [-2.87, 3.28]; 0.8966	0.0 [-0.24; 0.27]	

Table 7.4 Change from Baseline in EORTC QLQ-C30 - Emotional Functioning Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
No	95	81.1 (20.25)	0.4 (1.23)	38	82.5 (19.26)	-1.0 (1.96)	1.4 [-3.10, 5.84]; 0.5451	0.1 [-0.26; 0.49]	
Refractory to IMiD									0.9028
Yes	117	81.4 (20.66)	-0.5 (1.18)	54	80.2 (16.05)	-0.9 (1.76)	0.4 [-3.69, 4.42]; 0.8594	0.0 [-0.29; 0.35]	
No	164	81.3 (18.94)	1.3 (0.75)	74	83.4 (17.09)	0.8 (1.02)	0.5 [-1.52, 2.45]; 0.6443	0.0 [-0.22; 0.32]	
International Staging System (ISS)									0.3825
Stage I or II	229	80.9 (20.09)	-0.0 (0.82)	107	83.0 (15.05)	-0.4 (1.20)	0.4 [-2.43, 3.15]; 0.7991	0.0 [-0.20; 0.26]	
Stage III	51	83.0 (17.71)	-0.4 (1.65)	21	77.4 (23.15)	-4.6 (2.71)	4.1 [-1.93, 10.20]; 0.1779	0.3 [-0.17; 0.85]	
Prior proteasome inhibitor exposure									0.7471
Yes	260	81.0 (19.80)	-0.2 (0.77)	114	81.6 (17.01)	-0.9 (1.17)	0.7 [-1.98, 3.39]; 0.6074	0.1 [-0.16; 0.28]	
No	21	85.3 (17.46)	1.5 (2.60)	14	86.3 (13.32)	-0.2 (3.22)	1.7 [-6.53, 9.98]; 0.6733	0.1 [-0.54; 0.82]	
Number of prior lines of therapy									0.9394
1	130	81.4 (18.89)	0.8 (1.01)	57	84.8 (15.44)	0.0 (1.52)	0.8 [-2.68, 4.29]; 0.6490	0.1 [-0.24; 0.38]	
>= 2	151	81.3 (20.32)	-0.9 (1.08)	71	79.9 (17.40)	-1.5 (1.58)	0.7 [-3.02, 4.34]; 0.7236	0.0 [-0.23; 0.33]	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
Mixed Model Repeated Measurement for change from baseline score, with time and treatment as independent variables, and baseline score included as a covariate

Table 7.5 Change from Baseline in EORTC QLQ-C30 - Cognitive Functioning Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
Age									<.0001
<= 75	257	81.2 (19.48)	-0.1 (0.77)	112	81.8 (16.60)	-0.6 (1.16)	0.5 [-2.17, 3.16]; 0.7176	0.0 [-0.18; 0.26]	
> 75	24	83.0 (21.63)	0.5 (2.83)	16	83.9 (17.60)	-2.1 (3.52)	2.6 [-6.26, 11.44]; 0.5574	0.2 [-0.45; 0.82]	
Sex									0.2129
Male	161	85.5 (16.91)	-0.1 (0.91)	78	82.7 (17.08)	-1.3 (1.32)	1.2 [-1.89, 4.27]; 0.4471	0.1 [-0.17; 0.37]	
Female	120	75.8 (21.63)	-0.1 (1.25)	50	81.2 (16.13)	0.0 (1.91)	-0.1 [-4.52, 4.23]; 0.9475	-0.0 [-0.34; 0.32]	
Race									0.0036
White	220	83.0 (18.30)	-1.3 (0.80)	104	82.3 (17.52)	-1.4 (1.16)	0.1 [-2.56, 2.84]; 0.9180	0.0 [-0.22; 0.25]	
Non-White	61	75.5 (23.12)	4.8 (1.85)	24	81.3 (12.59)	2.5 (2.93)	2.3 [-4.42, 9.02]; 0.4976	0.2 [-0.31; 0.63]	
Geographic region									0.5681
Europe	182	81.4 (20.19)	-1.5 (0.92)	84	84.5 (16.92)	-1.5 (1.35)	0.0 [-3.10, 3.16]; 0.9850	0.0 [-0.26; 0.26]	
Asia Pacific	81	82.1 (18.26)	2.8 (1.38)	34	78.7 (15.38)	1.6 (2.14)	1.2 [-3.73, 6.09]; 0.6358	0.1 [-0.31; 0.49]	
North America	18	77.8 (20.61)	0.2 (2.71)	10	73.3 (15.11)	-1.3 (3.73)	1.5 [-7.90, 10.92]; 0.7436	0.1 [-0.65; 0.90]	
ECOG performance status									0.8101
0-1	268	81.1 (19.54)	-0.2 (0.76)	125	82.1 (16.86)	-0.7 (1.11)	0.4 [-2.15, 3.01]; 0.7429	0.0 [-0.18; 0.25]	
2	12	85.4 (22.23)	2.1 (3.28)	3	80.6 (4.81)	-6.5 (7.18)	8.6 [-7.70, 24.95]; 0.2786	0.7 [-0.59; 2.00]	

Table 7.5 Change from Baseline in EORTC QLQ-C30 - Cognitive Functioning Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
Prior bortezomib or ixazomib exposure									0.9735
Yes	259	81.0 (19.83)	-0.2 (0.77)	113	81.4 (17.00)	-0.6 (1.17)	0.4 [-2.24, 3.11]; 0.7492	0.0 [-0.19; 0.26]	
No	22	85.6 (17.09)	1.1 (2.72)	15	87.2 (13.31)	-2.4 (3.33)	3.5 [-5.08, 12.06]; 0.4142	0.3 [-0.39; 0.93]	
Refractory to bortezomib or ixazomib									0.4813
Yes	89	79.6 (20.80)	-0.9 (1.39)	48	77.6 (15.58)	-0.8 (1.90)	-0.2 [-4.72, 4.36]; 0.9375	-0.0 [-0.36; 0.34]	
No	192	82.2 (19.08)	0.6 (0.88)	80	84.8 (16.81)	-0.5 (1.36)	1.1 [-1.98, 4.21]; 0.4778	0.1 [-0.17; 0.35]	
Prior lenalidomide exposure									0.4046
Yes	112	80.8 (20.80)	-0.8 (1.20)	61	81.0 (16.40)	-1.3 (1.63)	0.5 [-3.35, 4.45]; 0.7812	0.0 [-0.27; 0.36]	
No	169	81.7 (18.88)	0.3 (0.94)	67	83.1 (16.98)	-0.3 (1.47)	0.6 [-2.75, 3.95]; 0.7246	0.0 [-0.23; 0.33]	
Refractory to lenalidomide									0.8910
Yes	89	80.4 (22.02)	-0.7 (1.38)	46	80.6 (16.86)	-1.1 (1.94)	0.3 [-4.24, 4.94]; 0.8816	0.0 [-0.33; 0.38]	
No	192	81.8 (18.48)	0.2 (0.87)	82	82.9 (16.61)	-0.6 (1.32)	0.8 [-2.26, 3.82]; 0.6129	0.1 [-0.19; 0.32]	
Prior IMiD exposure									0.9022
Yes	186	81.5 (19.37)	-0.3 (0.92)	90	81.9 (15.57)	-0.5 (1.32)	0.2 [-2.87, 3.28]; 0.8966	0.0 [-0.24; 0.27]	

Table 7.5 Change from Baseline in EORTC QLQ-C30 - Cognitive Functioning Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
No	95	81.1 (20.25)	0.4 (1.23)	38	82.5 (19.26)	-1.0 (1.96)	1.4 [-3.10, 5.84]; 0.5451	0.1 [-0.26; 0.49]	
Refractory to IMiD									0.8025
Yes	117	81.4 (20.66)	-0.5 (1.18)	54	80.2 (16.05)	-0.9 (1.76)	0.4 [-3.69, 4.42]; 0.8594	0.0 [-0.29; 0.35]	
No	164	81.3 (18.94)	1.3 (0.75)	74	83.4 (17.09)	0.8 (1.02)	0.5 [-1.52, 2.45]; 0.6443	0.0 [-0.22; 0.32]	
International Staging System (ISS)									0.5011
Stage I or II	229	80.9 (20.09)	-0.0 (0.82)	107	83.0 (15.05)	-0.4 (1.20)	0.4 [-2.43, 3.15]; 0.7991	0.0 [-0.20; 0.26]	
Stage III	51	83.0 (17.71)	-0.4 (1.65)	21	77.4 (23.15)	-4.6 (2.71)	4.1 [-1.93, 10.20]; 0.1779	0.3 [-0.17; 0.85]	
Prior proteasome inhibitor exposure									0.5647
Yes	260	81.0 (19.80)	-0.2 (0.77)	114	81.6 (17.01)	-0.9 (1.17)	0.7 [-1.98, 3.39]; 0.6074	0.1 [-0.16; 0.28]	
No	21	85.3 (17.46)	1.5 (2.60)	14	86.3 (13.32)	-0.2 (3.22)	1.7 [-6.53, 9.98]; 0.6733	0.1 [-0.54; 0.82]	
Number of prior lines of therapy									0.4051
1	130	81.4 (18.89)	0.8 (1.01)	57	84.8 (15.44)	0.0 (1.52)	0.8 [-2.68, 4.29]; 0.6490	0.1 [-0.24; 0.38]	
>= 2	151	81.3 (20.32)	-0.9 (1.08)	71	79.9 (17.40)	-1.5 (1.58)	0.7 [-3.02, 4.34]; 0.7236	0.0 [-0.23; 0.33]	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
Mixed Model Repeated Measurement for change from baseline score, with time and treatment as independent variables, and baseline score included as a covariate

Table 7.6 Change from Baseline in EORTC QLQ-C30 - Social Functioning Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
Age									0.0259
<= 75	257	77.4 (27.22)	-4.8 (0.98)	112	82.4 (23.34)	-4.1 (1.48)	-0.7 [-4.07, 2.72]; 0.6972	-0.0 [-0.26; 0.18]	
> 75	24	84.0 (21.69)	-2.4 (2.88)	16	88.5 (26.33)	-13.0 (3.52)	10.6 [1.67, 19.50]; 0.0212	0.7 [0.08; 1.39]	
Sex									0.4841
Male	161	82.2 (24.45)	-4.6 (1.15)	78	81.8 (23.90)	-6.1 (1.66)	1.5 [-2.34, 5.37]; 0.4403	0.1 [-0.17; 0.37]	
Female	120	72.2 (28.85)	-4.7 (1.58)	50	85.3 (23.48)	-3.7 (2.39)	-1.1 [-6.58, 4.45]; 0.7036	-0.1 [-0.39; 0.27]	
Race									0.7781
White	220	78.9 (26.48)	-5.3 (1.05)	104	82.5 (23.73)	-5.4 (1.52)	0.1 [-3.41, 3.67]; 0.9418	0.0 [-0.22; 0.24]	
Non-White	61	74.3 (27.98)	-2.2 (2.05)	24	86.1 (23.91)	-4.7 (3.22)	2.6 [-4.86, 10.00]; 0.4931	0.2 [-0.31; 0.63]	
Geographic region									0.3160
Europe	182	78.7 (27.16)	-6.6 (1.17)	84	84.5 (24.65)	-5.1 (1.71)	-1.5 [-5.46, 2.47]; 0.4590	-0.1 [-0.35; 0.16]	
Asia Pacific	81	79.6 (24.30)	-2.0 (1.66)	34	83.3 (21.71)	-6.0 (2.55)	4.0 [-1.78, 9.87]; 0.1714	0.3 [-0.13; 0.67]	
North America	18	63.0 (31.08)	1.4 (4.12)	10	71.7 (20.86)	-1.1 (5.58)	2.4 [-11.8, 16.67]; 0.7266	0.1 [-0.64; 0.91]	
ECOG performance status									0.9252
0-1	268	78.0 (26.83)	-5.1 (0.96)	125	83.7 (23.52)	-5.5 (1.39)	0.3 [-2.89, 3.56]; 0.8396	0.0 [-0.19; 0.23]	
2	12	73.6 (27.94)	3.5 (5.01)	3	61.1 (25.46)	2.0 (11.85)	1.4 [-25.0, 27.88]; 0.9107	0.1 [-1.19; 1.34]	

Table 7.6 Change from Baseline in EORTC QLQ-C30 - Social Functioning Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
Prior bortezomib or ixazomib exposure									0.9515
Yes	259	76.8 (27.37)	-4.3 (0.99)	113	82.4 (24.07)	-4.9 (1.49)	0.6 [-2.81, 4.03]; 0.7256	0.0 [-0.18; 0.26]	
No	22	91.7 (13.36)	-8.0 (2.82)	15	88.9 (20.57)	-8.2 (3.53)	0.2 [-8.69, 9.16]; 0.9570	0.0 [-0.64; 0.67]	
Refractory to bortezomib or ixazomib									0.9269
Yes	89	74.5 (27.07)	-3.8 (1.69)	48	77.1 (30.10)	-3.9 (2.29)	0.0 [-5.43, 5.48]; 0.9925	0.0 [-0.35; 0.35]	
No	192	79.5 (26.64)	-4.6 (1.14)	80	86.9 (18.12)	-5.3 (1.74)	0.7 [-3.24, 4.68]; 0.7206	0.0 [-0.22; 0.31]	
Prior lenalidomide exposure									0.7378
Yes	112	74.4 (27.58)	-3.0 (1.53)	61	80.6 (23.61)	-3.2 (2.08)	0.2 [-4.80, 5.13]; 0.9468	0.0 [-0.30; 0.32]	
No	169	80.3 (26.14)	-5.8 (1.18)	67	85.6 (23.73)	-6.4 (1.85)	0.6 [-3.57, 4.85]; 0.7638	0.0 [-0.24; 0.32]	
Refractory to lenalidomide									0.8729
Yes	89	72.5 (28.66)	-1.0 (1.72)	46	81.9 (21.61)	-1.7 (2.41)	0.7 [-5.06, 6.41]; 0.8160	0.0 [-0.31; 0.40]	
No	192	80.5 (25.62)	-6.3 (1.11)	82	83.9 (24.91)	-6.8 (1.68)	0.5 [-3.36, 4.32]; 0.8064	0.0 [-0.23; 0.29]	
Prior IMiD exposure									0.3899
Yes	186	76.3 (27.22)	-3.3 (1.14)	90	83.5 (21.56)	-3.0 (1.62)	-0.3 [-4.10, 3.49]; 0.8741	-0.0 [-0.27; 0.23]	

Table 7.6 Change from Baseline in EORTC QLQ-C30 - Social Functioning Score over time by Sub-groups eCOA-ITT Population

	KdD (N=281)			Kd (N=128)			Treatment Comparison KdD vs. Kd		Interaction p-values
Subgroup	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**N**	**Baseline Mean (SD)**	**Change from BL LSMean(SE)**	**Difference in LSMean [95%-CI]; p-value**	**Hedges'g [95%-CI]**	
No	95	81.1 (25.91)	-6.9 (1.63)	38	82.5 (28.46)	-9.4 (2.58)	2.5 [-3.40, 8.37]; 0.4051	0.2 [-0.22; 0.53]	
Refractory to IMiD									0.8837
Yes	117	73.9 (27.19)	-0.7 (1.49)	54	81.8 (23.63)	-2.1 (2.19)	1.4 [-3.71, 6.45]; 0.5945	0.1 [-0.24; 0.41]	
No	164	80.8 (26.28)	-7.0 (1.20)	74	84.2 (23.87)	-7.1 (1.76)	0.0 [-4.04, 4.10]; 0.9890	0.0 [-0.27; 0.28]	
International Staging System (ISS)									0.1418
Stage I or II	229	78.2 (27.10)	-5.1 (1.02)	107	84.6 (21.44)	-4.7 (1.47)	-0.5 [-3.89, 2.99]; 0.7963	-0.0 [-0.26; 0.20]	
Stage III	51	76.5 (26.07)	-2.9 (2.36)	21	76.2 (32.73)	-8.7 (3.81)	5.8 [-2.83, 14.44]; 0.1842	0.3 [-0.17; 0.85]	
Prior proteasome inhibitor exposure									0.7921
Yes	260	76.9 (27.36)	-4.4 (0.99)	114	82.6 (24.02)	-5.1 (1.49)	0.7 [-2.70, 4.15]; 0.6761	0.0 [-0.17; 0.27]	
No	21	91.3 (13.56)	-6.7 (2.44)	14	88.1 (21.11)	-6.1 (3.10)	-0.6 [-8.36, 7.21]; 0.8805	-0.0 [-0.73; 0.63]	
Number of prior lines of therapy									0.6473
1	130	80.8 (26.69)	-5.7 (1.29)	57	85.7 (20.03)	-5.2 (1.93)	-0.6 [-4.99, 3.86]; 0.8018	-0.0 [-0.35; 0.27]	
>= 2	151	75.5 (26.79)	-3.7 (1.36)	71	81.2 (26.27)	-4.9 (1.97)	1.2 [-3.38, 5.81]; 0.6027	0.1 [-0.21; 0.35]	

KdD: 20/56 mg/m^2 twice weekly carfilzomib, dexamethasone, and daratumumab; Kd: 20/56 mg/m^2 twice weekly carfilzomib and dexamethasone
Mixed Model Repeated Measurement for change from baseline score, with time and treatment as independent variables, and baseline score included as a covariate

Figure 4.12. Time to First Deterioration in QLQ-C30 Appetite Loss by Treatment and Prior IMiD exposure With Number of Subjects at Risk

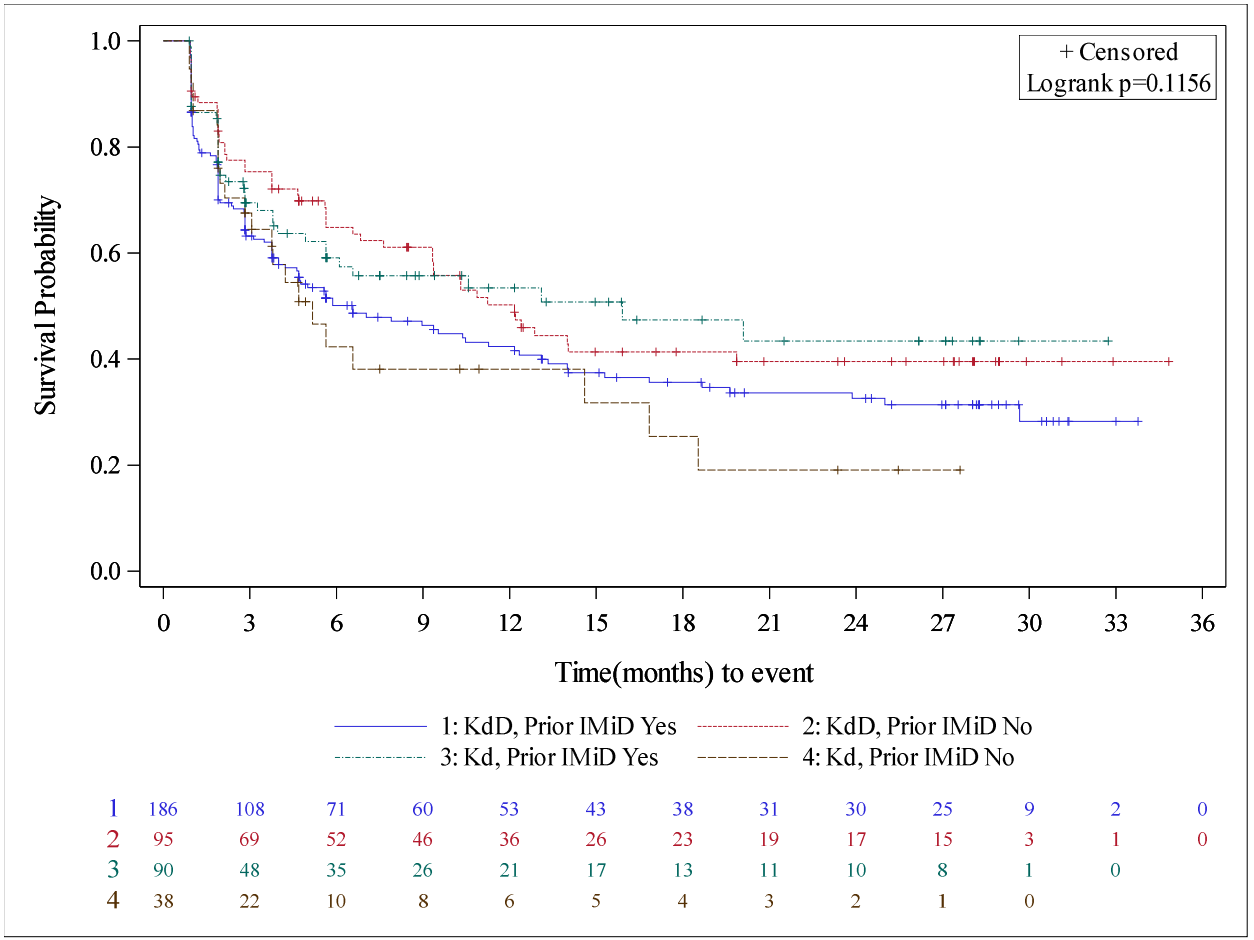


Figure 4.13a. Time to First Deterioration in QLQ-C30 Constipation by Treatment and Prior bortezomib or ixazomib exposure With Number of Subjects at Risk

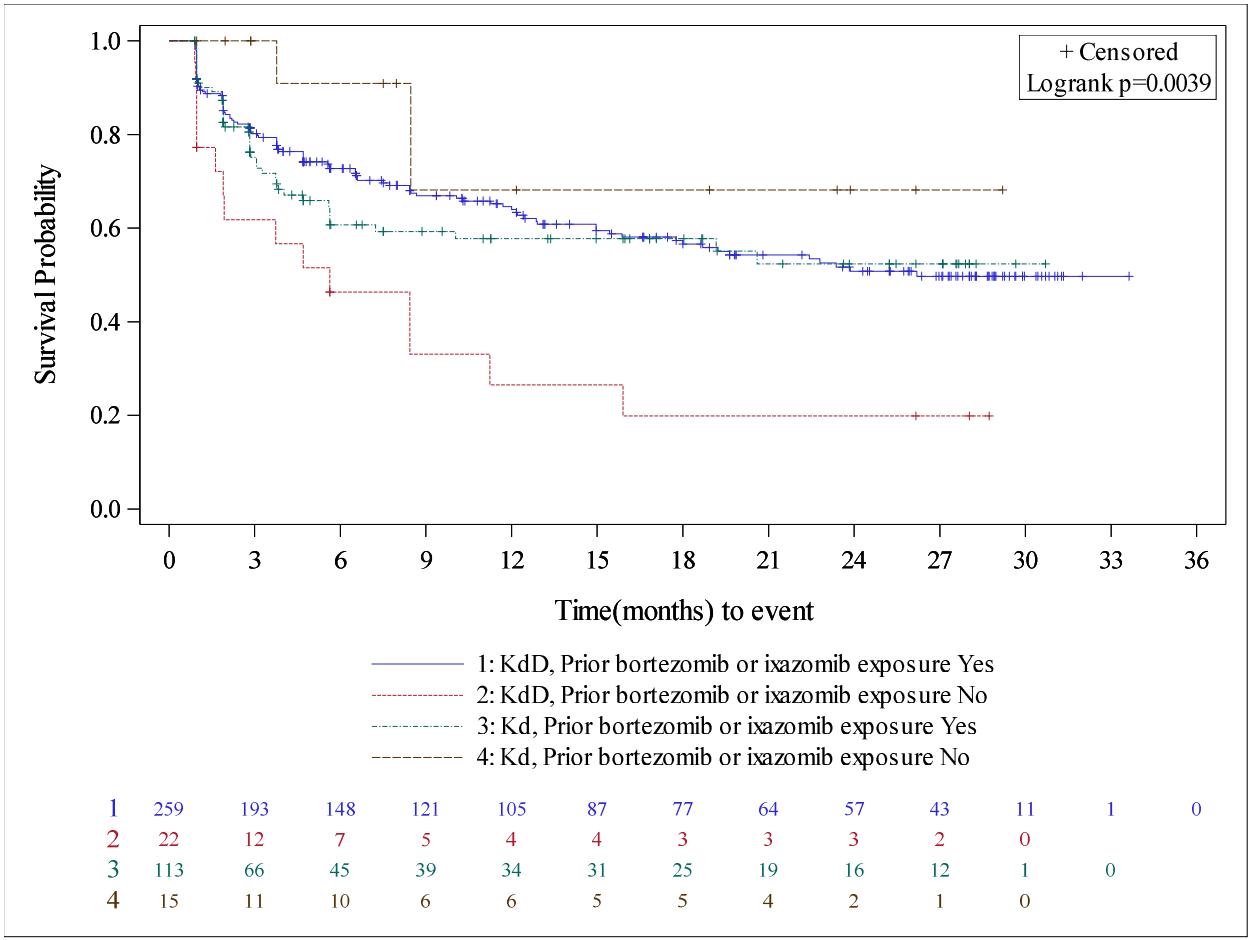


Figure 4.13b. Time to First Deterioration in QLQ-C30 Constipation by Treatment and Prior proteasome inhibitor exposure With Number of Subjects at Risk

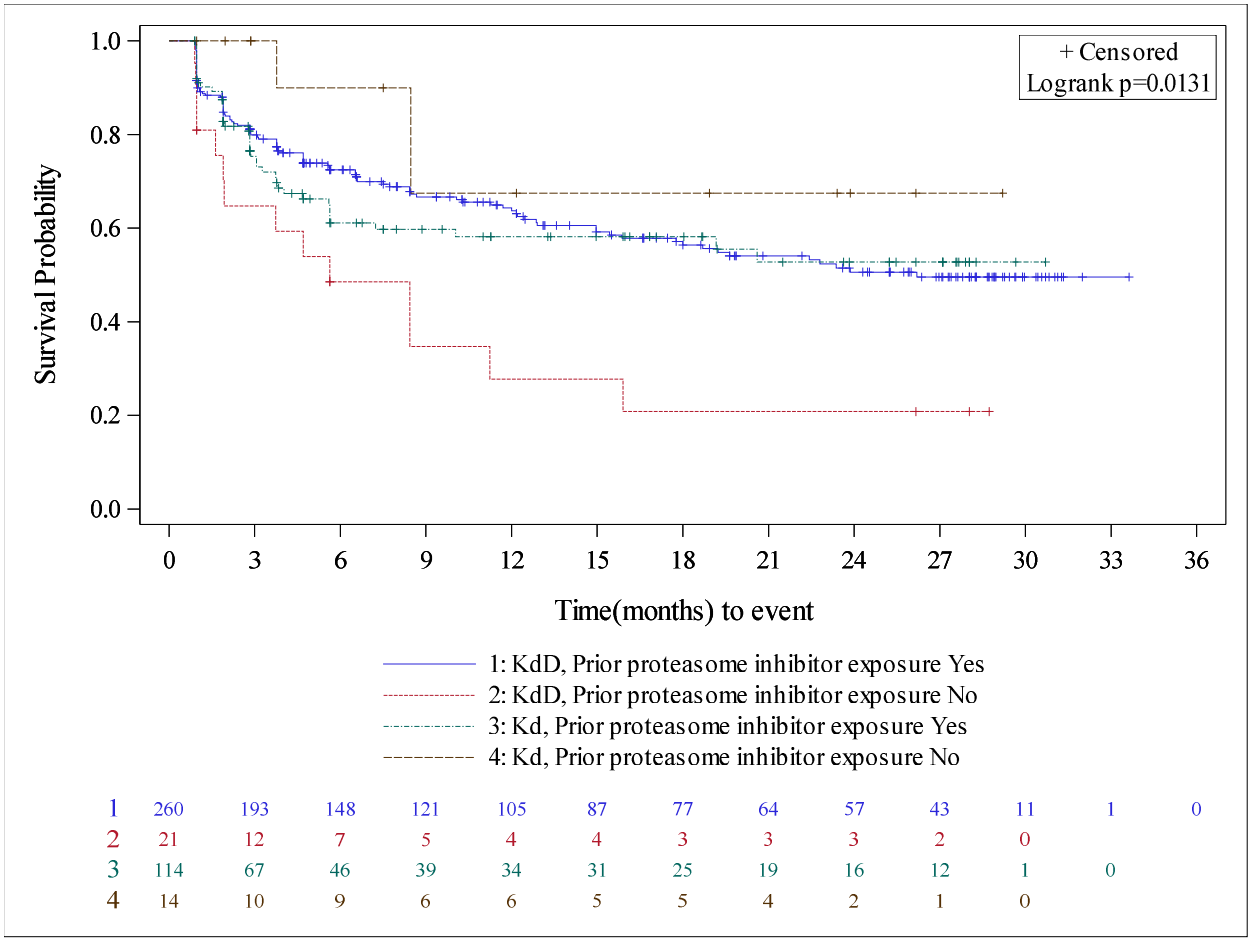


Figure 4.14. Time to First Deterioration in QLQ-C30 Diarrhoea by Treatment and ISS Stage With Number of Subjects at Risk

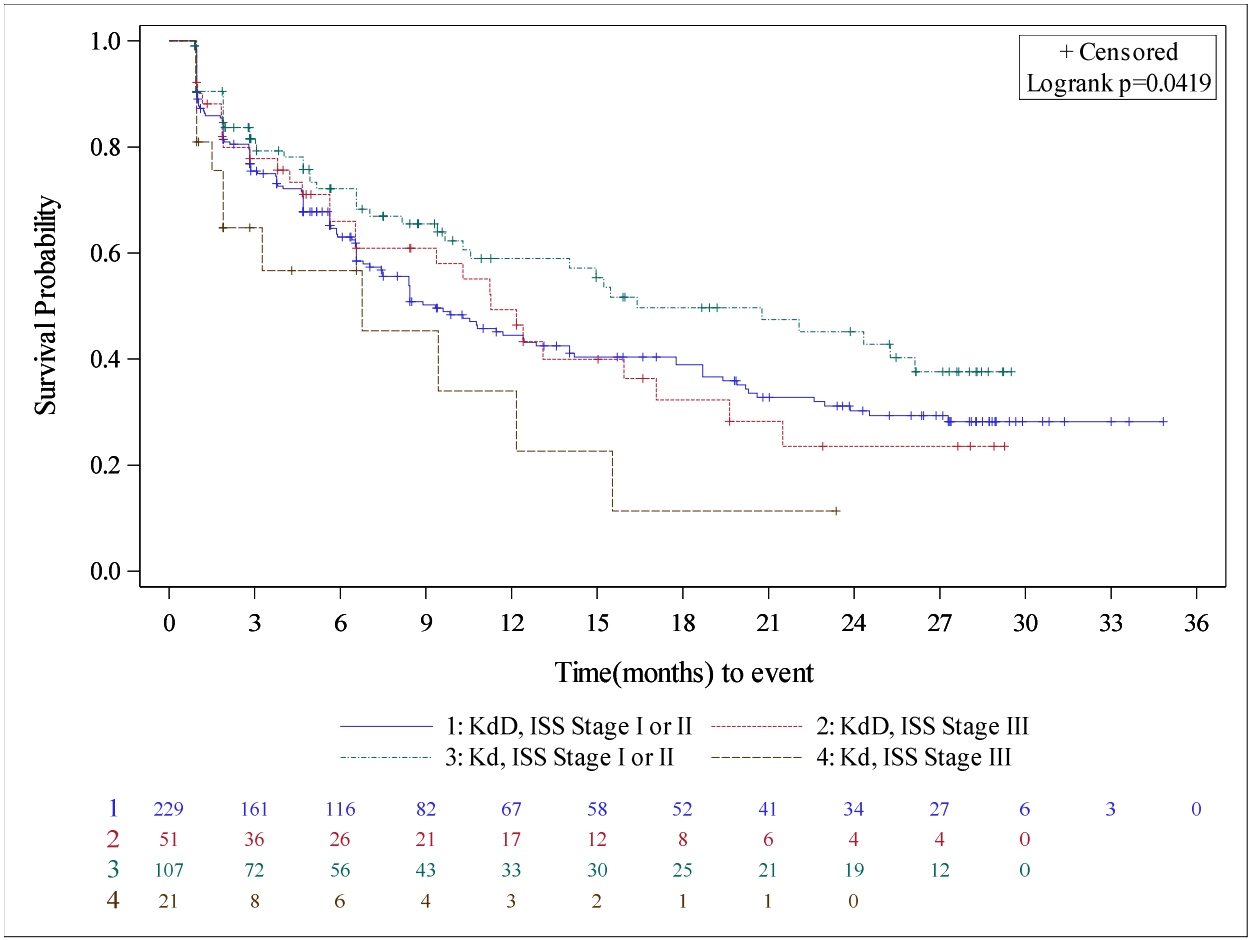


Figure 4.8. Time to First Deterioration in QLQ-C30 Nausea/Vomiting by Treatment and ISS Stage With Number of Subjects at Risk

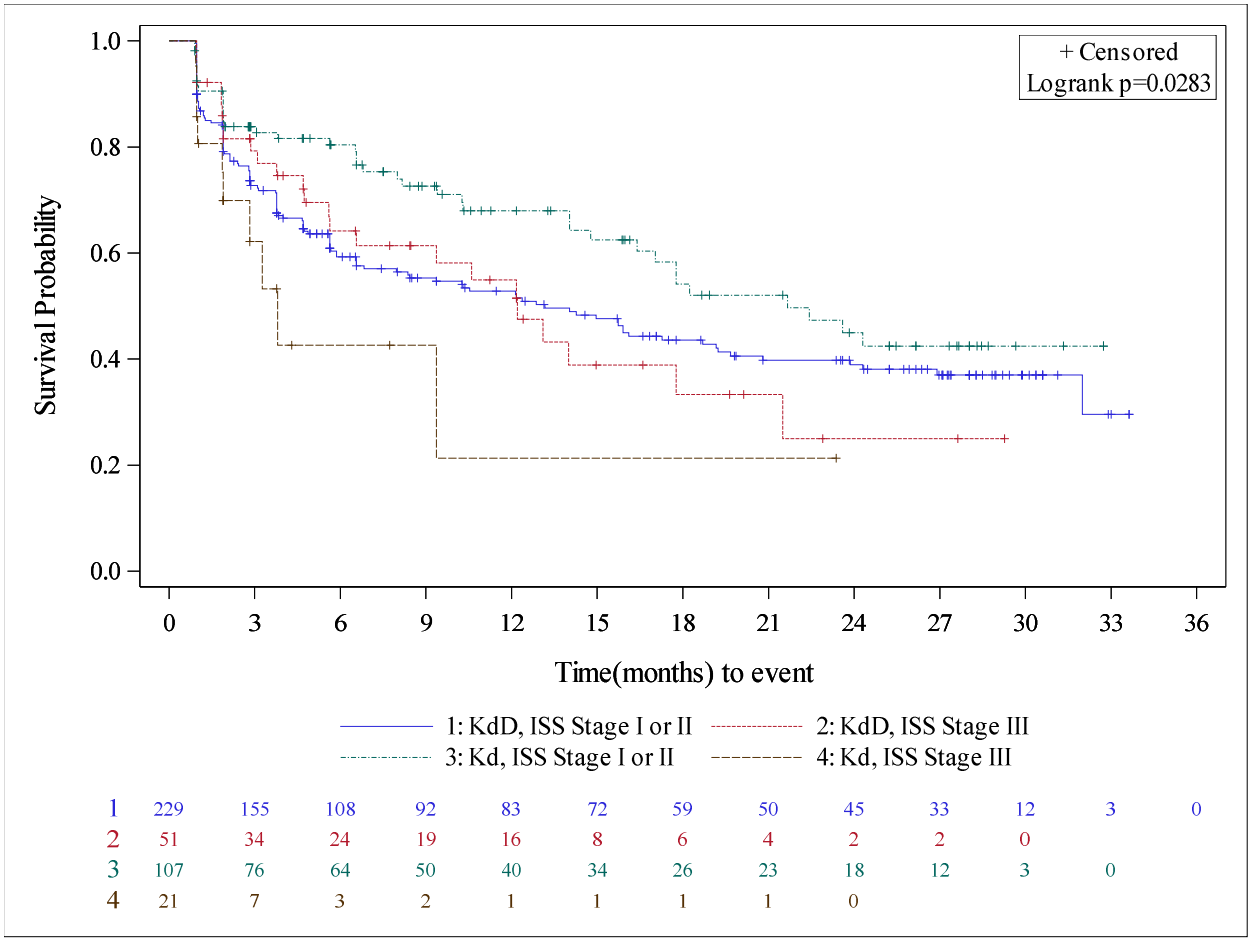


Figure 4.10a. Time to First Deterioration in QLQ-C30 Dyspnoea by Treatment and Age Group With Number of Subjects at Risk

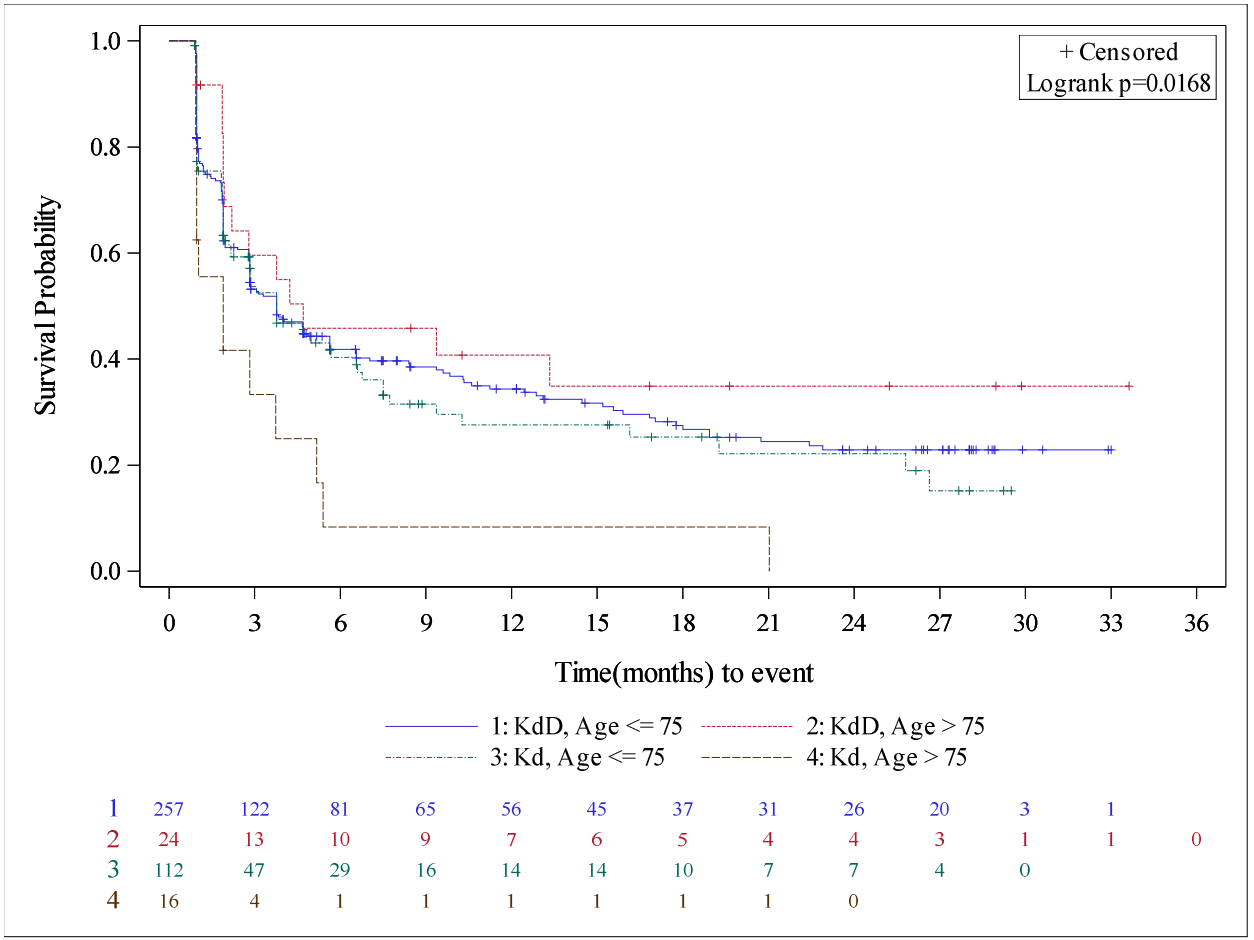


Figure 4.10b. Time to First Deterioration in QLQ-C30 Dyspnoea by treatment and Geographic Region With Number of Subjects at Risk

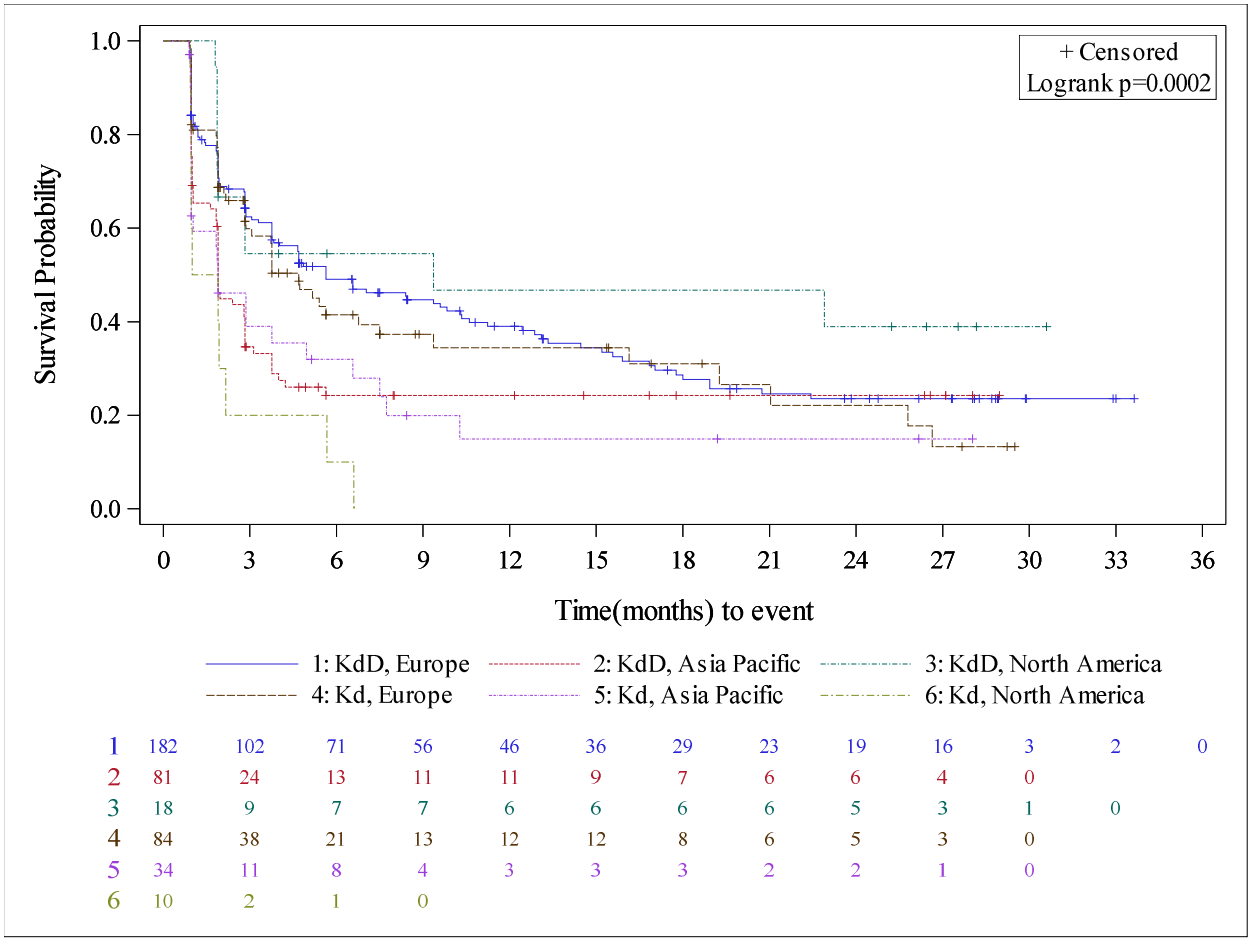


Table 14-6.1.501. Cox Regression of Adverse Events
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	148 (96.7)	0.5 [0.3, 0.5)	308	307 (99.7)	0.3 [0.2, 0.3)		1.420 (1.165, 1.729)	0.0007
Age - at baseline (years)	<= 75	135	130 (96.3)	0.5 [0.3, 0.5)	283	283 (100.0)	0.3 [0.2, 0.3)	0.1871	1.475 (1.197, 1.819)	0.0004
	> 75	18	18 (100.0)	0.4 [0.1, 0.9)	25	24 (96.0)	0.3 [0.1, 1.0)		0.897 (0.480, 1.678)	0.7035

Includes subjects with at least one adverse event. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-sub.sas
Output: t14-06-001-501-ae-cox.rtf (Date Generated: 27AUG2020:00:35) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.501. Cox Regression of Adverse Events
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Sex	Male	91	88 (96.7)	0.5 [0.4, 1.0)	174	174 (100.0)	0.3 [0.2, 0.4)	0.2038	1.596 (1.232, 2.068)	0.0004
	Female	62	60 (96.8)	0.3 [0.2, 0.5)	134	133 (99.3)	0.2 [0.1, 0.3)		1.230 (0.905, 1.673)	0.2580
Race	White	122	117 (95.9)	0.5 [0.4, 0.7)	240	239 (99.6)	0.3 [0.3, 0.4)	0.4597	1.385 (1.108, 1.730)	0.0051
	Asian	20	20 (100.0)	0.2 [0.1, 0.4)	46	46 (100.0)	0.0 [0.0, 0.1)		2.387 (1.351, 4.219)	0.0023
	Other or Unknown	11	11 (100.0)	0.3 [0.0, 1.2)	22	22 (100.0)	0.1 [0.0, 0.4)		1.653 (0.747, 3.660)	0.2206

Includes subjects with at least one adverse event. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-sub.sas
Output: t14-06-001-501-ae-cox.rtf (Date Generated: 27AUG2020:00:35) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.501. Cox Regression of Adverse Events
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Region	North America	12	12 (100.0)	0.2 [0.1, 0.4)	21	21 (100.0)	0.0 [0.0, 0.1)	0.2998	2.323 (1.102, 4.899)	0.0325
	Europe	102	97 (95.1)	0.5 [0.4, 0.8)	203	202 (99.5)	0.4 [0.3, 0.5)		1.361 (1.066, 1.738)	0.0142
	Asia Pacific	39	39 (100.0)	0.3 [0.1, 0.5)	84	84 (100.0)	0.1 [0.0, 0.1)		1.823 (1.235, 2.691)	0.0031
Baseline ECOG PS	0-1	146	142 (97.3)	0.5 [0.3, 0.5)	294	293 (99.7)	0.3 [0.2, 0.3)	0.8030	1.425 (1.164, 1.743)	0.0008
	2	7	6 (85.7)	0.2 [0.0, 0.5)	13	13 (100.0)	0.1 [0.0, 0.7)		1.111 (0.414, 2.978)	0.8758

Includes subjects with at least one adverse event. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-sub.sas
Output: t14-06-001-501-ae-cox.rtf (Date Generated: 27AUG2020:00:35) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.501. Cox Regression of Adverse Events
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	133 (97.8)	0.4 [0.3, 0.5)	285	284 (99.6)	0.3 [0.2, 0.3)	0.2756	1.363 (1.108, 1.677)	0.0046
	No	17	15 (88.2)	0.5 [0.2, 1.4)	23	23 (100.0)	0.1 [0.0, 0.7)		1.532 (0.796, 2.948)	0.2423
Refractory to Bortezomib or Ixazomib	Yes	55	53 (96.4)	0.5 [0.3, 1.3)	99	99 (100.0)	0.3 [0.2, 0.4)	0.5168	1.518 (1.083, 2.129)	0.0159
	No	98	95 (96.9)	0.4 [0.3, 0.5)	209	208 (99.5)	0.2 [0.1, 0.3)		1.327 (1.039, 1.694)	0.0317

Includes subjects with at least one adverse event. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-sub.sas
Output: t14-06-001-501-ae-cox.rtf (Date Generated: 27AUG2020:00:35) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.501. Cox Regression of Adverse Events
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	70 (94.6)	0.3 [0.2, 0.5)	122	122 (100.0)	0.2 [0.1, 0.3)	0.2170	1.608 (1.195, 2.164)	0.0022
	No	79	78 (98.7)	0.5 [0.4, 0.7)	186	185 (99.5)	0.3 [0.2, 0.4)		1.323 (1.014, 1.727)	0.0494
Refractory to Lenalidomide	Yes	55	53 (96.4)	0.3 [0.2, 0.5)	98	98 (100.0)	0.2 [0.1, 0.3)	0.9250	1.379 (0.983, 1.934)	0.0760
	No	98	95 (96.9)	0.5 [0.3, 0.6)	210	209 (99.5)	0.3 [0.2, 0.3)		1.430 (1.120, 1.827)	0.0053

Includes subjects with at least one adverse event. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-sub.sas
Output: t14-06-001-501-ae-cox.rtf (Date Generated: 27AUG2020:00:35) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.501. Cox Regression of Adverse Events
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	106 (96.4)	0.3 [0.3, 0.5)	205	205 (100.0)	0.2 [0.1, 0.3)	0.7496	1.457 (1.150, 1.846)	0.0026
	No	43	42 (97.7)	0.7 [0.5, 1.3)	103	102 (99.0)	0.3 [0.2, 0.5)		1.388 (0.966, 1.993)	0.0827
Refractory to IMiD	Yes	65	63 (96.9)	0.3 [0.2, 0.5)	129	129 (100.0)	0.2 [0.1, 0.3)	0.9148	1.399 (1.031, 1.898)	0.0371
	No	88	85 (96.6)	0.5 [0.4, 0.7)	179	178 (99.4)	0.3 [0.1, 0.4)		1.422 (1.097, 1.843)	0.0098

Includes subjects with at least one adverse event. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-sub.sas
Output: t14-06-001-501-ae-cox.rtf (Date Generated: 27AUG2020:00:35) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.501. Cox Regression of Adverse Events
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	121 (96.0)	0.5 [0.3, 0.6)	250	249 (99.6)	0.3 [0.1, 0.3)	0.2631	1.480 (1.189, 1.842)	0.0007
	3	27	27 (100.0)	0.3 [0.0, 0.5)	58	58 (100.0)	0.3 [0.1, 0.3)		1.140 (0.719, 1.808)	0.5492
Prior proteasome inhibitor exposure per IXRS	Yes	138	134 (97.1)	0.5 [0.3, 0.5)	276	276 (100.0)	0.3 [0.2, 0.3)	0.8878	1.431 (1.162, 1.761)	0.0010
	No	15	14 (93.3)	0.5 [0.1, 1.0)	32	31 (96.9)	0.2 [0.0, 0.8)		1.175 (0.623, 2.214)	0.6789

Includes subjects with at least one adverse event. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-sub.sas
Output: t14-06-001-501-ae-cox.rtf (Date Generated: 27AUG2020:00:35) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.501. Cox Regression of Adverse Events
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	64 (97.0)	0.5 [0.4, 0.7)	131	130 (99.2)	0.3 [0.1, 0.3)	0.8723	1.426 (1.054, 1.929)	0.0267
	>= 2	87	84 (96.6)	0.3 [0.3, 0.5)	177	177 (100.0)	0.3 [0.1, 0.3)		1.401 (1.078, 1.820)	0.0137

Includes subjects with at least one adverse event. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-sub.sas
Output: t14-06-001-501-ae-cox.rtf (Date Generated: 27AUG2020:00:35) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.502. Cox Regression of Grade ≥3 Adverse Events
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	116 (75.8)	2.6 [1.9, 3.5)	308	268 (87.0)	1.7 [1.1, 2.4)		1.221 (0.982, 1.519)	0.0726
Age - at baseline (years)	<= 75	135	100 (74.1)	2.8 [1.9, 4.1)	283	247 (87.3)	1.6 [1.0, 2.3)	0.2207	1.284 (1.017, 1.619)	0.0353
	> 75	18	16 (88.9)	1.7 [0.5, 3.9)	25	21 (84.0)	3.1 [0.7, 4.2)		0.820 (0.427, 1.574)	0.5382

Includes subjects with at least one CTCAE Grade ≥3 adverse event. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-sub.sas
Output: t14-06-001-502-ae-cox-grd345.rtf (Date Generated: 27AUG2020:00:35) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.502. Cox Regression of Grade ≥3 Adverse Events
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Sex	Male	91	70 (76.9)	2.8 [1.9, 4.1)	174	153 (87.9)	1.5 [1.0, 2.8)	0.9958	1.218 (0.917, 1.618)	0.1748
	Female	62	46 (74.2)	2.3 [0.5, 4.4)	134	115 (85.8)	2.1 [0.8, 3.0)		1.223 (0.869, 1.723)	0.2448
Race	White	122	91 (74.6)	2.9 [2.1, 5.0)	240	202 (84.2)	2.4 [1.4, 4.0)	0.5242	1.155 (0.902, 1.480)	0.2548
	Asian	20	18 (90.0)	0.5 [0.2, 2.6)	46	45 (97.8)	0.5 [0.2, 0.6)		1.400 (0.807, 2.430)	0.2287
	Other or Unknown	11	7 (63.6)	4.1 [0.7, NE)	22	21 (95.5)	2.5 [0.7, 7.0)		1.823 (0.770, 4.315)	0.1668

Includes subjects with at least one CTCAE Grade ≥3 adverse event. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-sub.sas
Output: t14-06-001-502-ae-cox-grd345.rtf (Date Generated: 27AUG2020:00:35) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.502. Cox Regression of Grade ≥3 Adverse Events
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Region	North America	12	10 (83.3)	3.6 [0.4, 11.5)	21	19 (90.5)	0.7 [0.5, 6.3)	0.9373	1.253 (0.567, 2.766)	0.5875
	Europe	102	72 (70.6)	3.2 [2.2, 7.0)	203	170 (83.7)	2.8 [1.6, 4.2)		1.245 (0.945, 1.641)	0.1173
	Asia Pacific	39	34 (87.2)	1.4 [0.7, 2.1)	84	79 (94.0)	0.7 [0.5, 1.4)		1.149 (0.767, 1.721)	0.5094
Baseline ECOG PS	0-1	146	111 (76.0)	2.6 [1.9, 3.7)	294	255 (86.7)	1.7 [1.2, 2.5)	0.3760	1.241 (0.993, 1.551)	0.0580
	2	7	5 (71.4)	0.5 [0.2, NE)	13	12 (92.3)	0.7 [0.3, 4.0)		0.853 (0.289, 2.521)	0.7890

Includes subjects with at least one CTCAE Grade ≥3 adverse event. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-sub.sas
Output: t14-06-001-502-ae-cox-grd345.rtf (Date Generated: 27AUG2020:00:35) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.502. Cox Regression of Grade ≥3 Adverse Events
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	102 (75.0)	2.6 [1.9, 4.1)	285	246 (86.3)	1.7 [1.0, 2.5)	0.9148	1.223 (0.971, 1.541)	0.0874
	No	17	14 (82.4)	2.2 [1.0, 3.9)	23	22 (95.7)	1.7 [0.5, 6.5)		1.211 (0.616, 2.381)	0.5768
Refractory to Bortezomib or Ixazomib	Yes	55	42 (76.4)	2.6 [1.2, 4.0)	99	82 (82.8)	2.2 [0.6, 3.8)	0.3019	1.055 (0.726, 1.533)	0.7951
	No	98	74 (75.5)	2.4 [1.5, 4.4)	209	186 (89.0)	1.6 [1.0, 2.4)		1.322 (1.010, 1.731)	0.0413

Includes subjects with at least one CTCAE Grade ≥3 adverse event. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-sub.sas
Output: t14-06-001-502-ae-cox-grd345.rtf (Date Generated: 27AUG2020:00:35) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.502. Cox Regression of Grade ≥3 Adverse Events
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	56 (75.7)	2.4 [1.5, 4.4)	122	108 (88.5)	0.9 [0.5, 1.5)	0.2947	1.422 (1.029, 1.966)	0.0335
	No	79	60 (75.9)	2.6 [1.2, 4.1)	186	160 (86.0)	2.7 [1.6, 4.0)		1.109 (0.824, 1.493)	0.4944
Refractory to Lenalidomide	Yes	55	42 (76.4)	2.4 [1.4, 4.4)	98	84 (85.7)	1.1 [0.6, 2.3)	0.6833	1.165 (0.803, 1.691)	0.4295
	No	98	74 (75.5)	2.6 [1.4, 4.1)	210	184 (87.6)	2.1 [1.2, 3.1)		1.261 (0.962, 1.651)	0.0909

Includes subjects with at least one CTCAE Grade ≥3 adverse event. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-sub.sas
Output: t14-06-001-502-ae-cox-grd345.rtf (Date Generated: 27AUG2020:00:35) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.502. Cox Regression of Grade ≥3 Adverse Events
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	84 (76.4)	2.1 [1.4, 3.2)	205	181 (88.3)	1.2 [0.7, 1.7)	0.5858	1.305 (1.007, 1.691)	0.0452
	No	43	32 (74.4)	3.9 [1.9, 12.0)	103	87 (84.5)	4.0 [2.1, 5.1)		1.101 (0.732, 1.654)	0.6427
Refractory to IMiD	Yes	65	50 (76.9)	2.1 [1.4, 3.5)	129	110 (85.3)	1.3 [0.6, 2.3)	0.5291	1.143 (0.817, 1.598)	0.4432
	No	88	66 (75.0)	2.9 [1.9, 5.1)	179	158 (88.3)	2.1 [1.1, 3.2)		1.289 (0.967, 1.718)	0.0823

Includes subjects with at least one CTCAE Grade ≥3 adverse event. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-sub.sas
Output: t14-06-001-502-ae-cox-grd345.rtf (Date Generated: 27AUG2020:00:35) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.502. Cox Regression of Grade ≥3 Adverse Events
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	93 (73.8)	2.9 [2.1, 4.0)	250	216 (86.4)	2.3 [1.4, 3.2)	0.7619	1.233 (0.967, 1.573)	0.0910
	3	27	23 (85.2)	0.5 [0.3, 5.0)	58	52 (89.7)	0.5 [0.4, 0.7)		1.124 (0.688, 1.838)	0.6372
Prior proteasome inhibitor exposure per IXRS	Yes	138	103 (74.6)	2.4 [1.6, 4.0)	276	239 (86.6)	1.5 [1.0, 2.3)	0.5739	1.251 (0.993, 1.577)	0.0570
	No	15	13 (86.7)	2.6 [1.3, 3.9)	32	29 (90.6)	3.8 [0.7, 8.7)		0.909 (0.468, 1.765)	0.7647

Includes subjects with at least one CTCAE Grade ≥3 adverse event. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-sub.sas
Output: t14-06-001-502-ae-cox-grd345.rtf (Date Generated: 27AUG2020:00:35) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.502. Cox Regression of Grade ≥3 Adverse Events
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	49 (74.2)	2.9 [1.8, 5.8)	131	116 (88.5)	2.5 [1.1, 4.1)	0.8175	1.266 (0.907, 1.769)	0.1640
	>= 2	87	67 (77.0)	2.3 [1.4, 3.5)	177	152 (85.9)	1.3 [0.8, 2.3)		1.206 (0.904, 1.608)	0.2087

Includes subjects with at least one CTCAE Grade ≥3 adverse event. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-sub.sas
Output: t14-06-001-502-ae-cox-grd345.rtf (Date Generated: 27AUG2020:00:35) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.503. Cox Regression of Serious Adverse Events
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	76 (49.7)	13.2 [7.6, 28.7)	308	194 (63.0)	10.3 [8.2, 13.5)		1.158 (0.888, 1.511)	0.2770
Age - at baseline (years)	<= 75	135	65 (48.1)	13.2 [8.3, 32.9)	283	177 (62.5)	10.3 [8.5, 13.7)	0.6565	1.191 (0.896, 1.584)	0.2264
	> 75	18	11 (61.1)	7.0 [2.1, NE)	25	17 (68.0)	7.6 [3.0, 28.5)		0.977 (0.455, 2.095)	0.9546

Includes subjects with at least one serious adverse event. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-sub.sas
Output: t14-06-001-503-sae-cox.rtf (Date Generated: 27AUG2020:00:35) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.503. Cox Regression of Serious Adverse Events
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Sex	Male	91	45 (49.5)	13.2 [5.8, 32.9)	174	112 (64.4)	11.2 [7.0, 14.7)	0.8078	1.186 (0.838, 1.678)	0.3332
	Female	62	31 (50.0)	16.2 [2.7, NE)	134	82 (61.2)	9.8 [6.4, 17.8)		1.117 (0.738, 1.689)	0.5979
Race	White	122	63 (51.6)	12.0 [7.0, 27.5)	240	146 (60.8)	10.5 [7.6, 14.7)	0.4024	1.070 (0.795, 1.439)	0.6529
	Asian	20	8 (40.0)	NE [2.4, NE)	46	34 (73.9)	9.5 [3.8, 15.8)		1.905 (0.880, 4.123)	0.0963
	Other or Unknown	11	5 (45.5)	NE [0.9, NE)	22	14 (63.6)	17.4 [1.2, 24.0)		1.263 (0.453, 3.526)	0.6554

Includes subjects with at least one serious adverse event. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-sub.sas
Output: t14-06-001-503-sae-cox.rtf (Date Generated: 27AUG2020:00:35) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.503. Cox Regression of Serious Adverse Events
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Region	North America	12	4 (33.3)	16.2 [2.5, NE)	21	14 (66.7)	14.7 [4.1, NE)	0.7888	1.464 (0.470, 4.558)	0.5081
	Europe	102	51 (50.0)	19.4 [7.0, 28.7)	203	121 (59.6)	11.4 [8.7, 17.3)		1.108 (0.799, 1.538)	0.5350
	Asia Pacific	39	21 (53.8)	8.3 [3.0, NE)	84	59 (70.2)	7.9 [3.2, 12.7)		1.186 (0.720, 1.954)	0.5040
Baseline ECOG PS	0-1	146	73 (50.0)	13.2 [7.6, 28.7)	294	186 (63.3)	10.3 [8.2, 13.5)	0.4483	1.181 (0.900, 1.548)	0.2283
	2	7	3 (42.9)	NE [0.0, NE)	13	8 (61.5)	6.2 [0.3, NE)		0.932 (0.235, 3.699)	0.9138

Includes subjects with at least one serious adverse event. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Output: t14-06-001-503-sae-cox.rtf (Date Generated: 27AUG2020:00:35) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.503. Cox Regression of Serious Adverse Events
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	66 (48.5)	13.2 [7.6, 28.7)	285	179 (62.8)	10.4 [7.9, 13.7)	0.7286	1.179 (0.888, 1.564)	0.2519
	No	17	10 (58.8)	9.0 [2.1, NE)	23	15 (65.2)	9.7 [2.3, NE)		1.018 (0.455, 2.277)	0.9691
Refractory to Bortezomib or Ixazomib	Yes	55	27 (49.1)	11.6 [5.1, 28.7)	99	62 (62.6)	10.4 [4.6, 16.7)	0.9657	1.163 (0.738, 1.833)	0.5155
	No	98	49 (50.0)	16.2 [5.8, NE)	209	132 (63.2)	10.3 [8.2, 16.7)		1.164 (0.838, 1.616)	0.3607

Includes subjects with at least one serious adverse event. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Output: t14-06-001-503-sae-cox.rtf (Date Generated: 27AUG2020:00:35) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.503. Cox Regression of Serious Adverse Events
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	36 (48.6)	11.6 [3.5, NE)	122	82 (67.2)	9.5 [6.2, 15.8)	0.7845	1.232 (0.831, 1.826)	0.2957
	No	79	40 (50.6)	13.2 [7.3, 27.5)	186	112 (60.2)	10.9 [8.7, 16.7)		1.136 (0.792, 1.631)	0.4873
Refractory to Lenalidomide	Yes	55	27 (49.1)	11.6 [3.5, NE)	98	63 (64.3)	11.2 [6.8, 19.3)	0.5484	1.020 (0.647, 1.608)	0.9282
	No	98	49 (50.0)	19.4 [7.3, 32.9)	210	131 (62.4)	9.7 [7.0, 13.5)		1.230 (0.886, 1.708)	0.2152

Includes subjects with at least one serious adverse event. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Output: t14-06-001-503-sae-cox.rtf (Date Generated: 27AUG2020:00:35) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.503. Cox Regression of Serious Adverse Events
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	54 (49.1)	13.2 [5.8, NE)	205	134 (65.4)	9.5 [6.3, 11.4)	0.5975	1.235 (0.900, 1.694)	0.1896
	No	43	22 (51.2)	21.5 [5.1, NE)	103	60 (58.3)	16.7 [9.5, 18.8)		1.048 (0.643, 1.710)	0.8497
Refractory to IMiD	Yes	65	33 (50.8)	11.4 [3.5, NE)	129	85 (65.9)	9.8 [6.4, 14.7)	0.6548	1.058 (0.706, 1.586)	0.7817
	No	88	43 (48.9)	21.5 [5.8, 32.9)	179	109 (60.9)	10.3 [7.0, 17.2)		1.224 (0.860, 1.743)	0.2602

Includes subjects with at least one serious adverse event. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.503. Cox Regression of Serious Adverse Events
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	58 (46.0)	19.4 [11.4, 32.9)	250	148 (59.2)	12.7 [9.5, 17.6)	0.5816	1.171 (0.863, 1.587)	0.3083
	3	27	18 (66.7)	1.6 [0.5, 7.0)	58	46 (79.3)	3.5 [1.0, 9.5)		1.048 (0.606, 1.811)	0.8631
Prior proteasome inhibitor exposure per IXRS	Yes	138	66 (47.8)	16.2 [8.3, 28.7)	276	174 (63.0)	10.4 [7.9, 13.7)	0.3971	1.202 (0.905, 1.597)	0.2015
	No	15	10 (66.7)	5.3 [2.0, NE)	32	20 (62.5)	9.7 [2.9, NE)		0.843 (0.393, 1.806)	0.6593

Includes subjects with at least one serious adverse event. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.503. Cox Regression of Serious Adverse Events
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	34 (51.5)	12.5 [5.1, NE)	131	78 (59.5)	9.8 [7.4, 17.2)	0.6089	1.089 (0.728, 1.630)	0.6764
	>= 2	87	42 (48.3)	13.2 [7.0, 32.9)	177	116 (65.5)	10.9 [6.3, 15.8)		1.220 (0.856, 1.739)	0.2696

Includes subjects with at least one serious adverse event. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-sub.sas
Output: t14-06-001-503-sae-cox.rtf (Date Generated: 27AUG2020:00:35) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.504. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Blood and lymphatic system disorders										
Total subjects		153	90 (58.8)	2.8 [2.1, 11.6)	308	175 (56.8)	4.6 [1.7, 13.8)		0.958 (0.743, 1.237)	0.7306
Cardiac disorders										
Total subjects		153	33 (21.6)	NE [NE, NE)	308	82 (26.6)	NE [NE, NE)		1.090 (0.727, 1.634)	0.6771

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-soc.sas
Output: t14-06-001-504-ae-cox-soc-ge10.rtf (Date Generated: 27AUG2020:00:36) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.504. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Ear and labyrinth disorders										
Total subjects		153	8 (5.2)	NE [NE, NE)	308	19 (6.2)	NE [NE, NE)		0.938 (0.409, 2.151)	0.8798
Endocrine disorders										
Total subjects		153	10 (6.5)	NE [NE, NE)	308	11 (3.6)	NE [NE, NE)		0.424 (0.179, 1.003)	0.0444

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	8 (5.9)	NE [NE, NE)	283	8 (2.8)	NE [NE, NE)	0.4337	0.354 (0.132, 0.948)	0.0311
	> 75	18	2 (11.1)	NE [8.1, NE)	25	3 (12.0)	NE [NE, NE)		0.966 (0.161, 5.788)	0.9698
Sex	Male	91	3 (3.3)	NE [NE, NE)	174	7 (4.0)	NE [NE, NE)	0.1030	0.992 (0.255, 3.854)	0.9911
	Female	62	7 (11.3)	NE [NE, NE)	134	4 (3.0)	NE [NE, NE)		0.198 (0.058, 0.681)	0.0044

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	6 (4.9)	NE [NE, NE)	240	8 (3.3)	NE [NE, NE)	0.9153	0.550 (0.190, 1.593)	0.2637
	Asian	20	3 (15.0)	NE [12.3, NE)	46	3 (6.5)	NE [NE, NE)		0.298 (0.059, 1.501)	0.1201
	Other or Unknown	11	1 (9.1)	NE [8.1, NE)	22	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0833
Region	North America	12	1 (8.3)	NE [5.6, NE)	21	1 (4.8)	NE [NE, NE)	0.8212	0.515 (0.032, 8.228)	0.6323

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	6 (5.9)	NE [NE, NE)	203	5 (2.5)	NE [NE, NE)		0.337 (0.103, 1.107)	0.0599
	Asia Pacific	39	3 (7.7)	NE [20.8, NE)	84	5 (6.0)	NE [NE, NE)		0.535 (0.125, 2.287)	0.3911
Baseline ECOG PS	0-1	146	10 (6.8)	NE [NE, NE)	294	11 (3.7)	NE [NE, NE)	0.9999	0.439 (0.186, 1.036)	0.0537
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	7 (5.1)	NE [NE, NE)	285	11 (3.9)	NE [NE, NE)	0.9915	0.601 (0.232, 1.555)	0.2891
	No	17	3 (17.6)	NE [12.3, NE)	23	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0120
Refractory to Bortezomib or Ixazomib	Yes	55	1 (1.8)	NE [NE, NE)	99	3 (3.0)	NE [NE, NE)	0.2420	1.477 (0.153, 14.229)	0.7339
	No	98	9 (9.2)	NE [NE, NE)	209	8 (3.8)	NE [NE, NE)		0.316 (0.121, 0.822)	0.0128

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	4 (5.4)	NE [NE, NE)	122	6 (4.9)	NE [NE, NE)	0.3363	0.707 (0.198, 2.518)	0.5904
	No	79	6 (7.6)	NE [NE, NE)	186	5 (2.7)	NE [NE, NE)		0.287 (0.087, 0.943)	0.0284
Refractory to Lenalidomide	Yes	55	2 (3.6)	NE [NE, NE)	98	4 (4.1)	NE [NE, NE)	0.3887	0.826 (0.150, 4.567)	0.8267
	No	98	8 (8.2)	NE [NE, NE)	210	7 (3.3)	NE [NE, NE)		0.334 (0.121, 0.923)	0.0264

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	7 (6.4)	NE [NE, NE)	205	8 (3.9)	NE [NE, NE)	0.6936	0.463 (0.167, 1.288)	0.1317
	No	43	3 (7.0)	NE [NE, NE)	103	3 (2.9)	NE [NE, NE)		0.330 (0.066, 1.642)	0.1544
Refractory to IMiD	Yes	65	2 (3.1)	NE [NE, NE)	129	6 (4.7)	NE [NE, NE)	0.1360	1.070 (0.212, 5.401)	0.9348
	No	88	8 (9.1)	NE [NE, NE)	179	5 (2.8)	NE [NE, NE)		0.251 (0.082, 0.768)	0.0088

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	9 (7.1)	NE [NE, NE)	250	8 (3.2)	NE [NE, NE)	0.5172	0.365 (0.140, 0.952)	0.0319
	3	27	1 (3.7)	NE [6.9, NE)	58	3 (5.2)	NE [NE, NE)		0.761 (0.078, 7.459)	0.8141
Prior proteasome inhibitor exposure per IXRS	Yes	138	8 (5.8)	NE [NE, NE)	276	11 (4.0)	NE [NE, NE)	0.9876	0.555 (0.222, 1.384)	0.2002
	No	15	2 (13.3)	NE [12.3, NE)	32	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0094

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.504. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	5 (7.6)	NE [NE, NE)	131	3 (2.3)	NE [NE, NE)	0.3112	0.233 (0.055, 0.979)	0.0304
	>= 2	87	5 (5.7)	NE [NE, NE)	177	8 (4.5)	NE [NE, NE)		0.636 (0.207, 1.948)	0.4260
Eye disorders										
Total subjects		153	20 (13.1)	NE [NE, NE)	308	59 (19.2)	NE [NE, NE)		1.194 (0.718, 1.986)	0.4960

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Gastrointestinal disorders										
Total subjects		153	56 (36.6)	23.7 [15.6, NE)	308	182 (59.1)	9.4 [6.0, 11.2)		1.782 (1.321, 2.405)	0.0001
Age - at baseline (years)	<= 75	135	49 (36.3)	24.4 [15.2, NE)	283	168 (59.4)	9.2 [5.7, 11.2)	0.7211	1.816 (1.321, 2.496)	0.0002
	> 75	18	7 (38.9)	17.7 [1.8, NE)	25	14 (56.0)	9.9 [3.7, 28.7)		1.400 (0.557, 3.520)	0.4740

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.504. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Sex	Male	91	27 (29.7)	NE [16.9, NE)	174	102 (58.6)	10.2 [6.4, 15.7)	0.0913	2.223 (1.454, 3.399)	0.0002
	Female	62	29 (46.8)	21.9 [6.9, NE)	134	80 (59.7)	6.3 [4.1, 11.2)		1.328 (0.868, 2.033)	0.1940
Race	White	122	38 (31.1)	26.6 [17.7, NE)	240	127 (52.9)	11.2 [8.3, 16.1)	0.5370	1.884 (1.311, 2.707)	0.0005
	Asian	20	14 (70.0)	1.3 [0.3, 6.8)	46	42 (91.3)	1.4 [0.6, 6.2)		1.220 (0.664, 2.241)	0.5207

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.504. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Other or Unknown	11	4 (36.4)	16.9 [1.7, NE)	22	13 (59.1)	5.6 [0.3, NE)		1.851 (0.603, 5.684)	0.2828
Region	North America	12	7 (58.3)	7.3 [1.5, 15.6)	21	19 (90.5)	1.0 [0.1, 4.3)	0.3994	3.149 (1.303, 7.611)	0.0079
	Europe	102	25 (24.5)	NE [21.9, NE)	203	94 (46.3)	16.1 [10.9, 29.5)		2.018 (1.298, 3.137)	0.0015
	Asia Pacific	39	24 (61.5)	5.0 [1.0, 15.2)	84	69 (82.1)	1.9 [0.7, 6.2)		1.488 (0.934, 2.371)	0.0940

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Baseline ECOG PS	0-1	146	55 (37.7)	23.7 [15.6, NE)	294	174 (59.2)	9.2 [6.0, 11.1)	0.8146	1.770 (1.306, 2.397)	0.0002
	2	7	1 (14.3)	NE [1.3, NE)	13	7 (53.8)	15.6 [0.6, NE)		2.165 (0.241, 19.472)	0.4851
Prior Bortezomib or Ixazomib exposure	Yes	136	50 (36.8)	23.7 [15.6, NE)	285	167 (58.6)	9.9 [6.2, 12.1)	0.4956	1.739 (1.267, 2.386)	0.0005
	No	17	6 (35.3)	NE [1.5, NE)	23	15 (65.2)	6.0 [0.3, 9.7)		2.359 (0.913, 6.096)	0.0707

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Refractory to Bortezomib or Ixazomib	Yes	55	17 (30.9)	NE [23.7, NE)	99	49 (49.5)	15.7 [6.8, NE)	0.6155	1.609 (0.926, 2.795)	0.0883
	No	98	39 (39.8)	17.7 [14.3, NE)	209	133 (63.6)	7.3 [4.1, 10.2)		1.869 (1.308, 2.671)	0.0005
Prior Lenalidomide exposure	Yes	74	25 (33.8)	21.9 [15.6, NE)	122	73 (59.8)	6.8 [4.0, 15.6)	0.4828	2.006 (1.273, 3.161)	0.0022
	No	79	31 (39.2)	26.6 [14.3, NE)	186	109 (58.6)	10.2 [6.2, 13.3)		1.599 (1.072, 2.384)	0.0206

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.504. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Refractory to Lenalidomide	Yes	55	17 (30.9)	NE [14.1, NE)	98	59 (60.2)	7.2 [4.0, 15.7)	0.4024	2.147 (1.251, 3.685)	0.0046
	No	98	39 (39.8)	23.7 [14.4, NE)	210	123 (58.6)	10.2 [6.0, 13.3)		1.620 (1.129, 2.323)	0.0083
Prior IMiD exposure	Yes	110	43 (39.1)	18.7 [14.1, NE)	205	127 (62.0)	6.8 [3.7, 9.9)	0.7036	1.758 (1.244, 2.485)	0.0012
	No	43	13 (30.2)	NE [17.7, NE)	103	55 (53.4)	11.6 [7.0, 28.7)		1.999 (1.091, 3.664)	0.0227

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Refractory to IMiD	Yes	65	21 (32.3)	16.9 [14.1, NE)	129	75 (58.1)	7.2 [4.1, 11.8)	0.6291	1.960 (1.208, 3.182)	0.0056
	No	88	35 (39.8)	23.7 [14.4, NE)	179	107 (59.8)	10.4 [6.0, 13.4)		1.671 (1.140, 2.448)	0.0080
ISS stage per IXRS	1 or 2	126	50 (39.7)	21.9 [14.4, NE)	250	158 (63.2)	7.0 [4.1, 10.4)	0.8127	1.840 (1.338, 2.529)	0.0001
	3	27	6 (22.2)	NE [NE, NE)	58	24 (41.4)	15.7 [9.4, NE)		1.632 (0.665, 4.004)	0.2817

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.504. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior proteasome inhibitor exposure per IXRS	Yes	138	50 (36.2)	24.4 [15.6, NE)	276	162 (58.7)	9.9 [6.2, 12.1)	0.7803	1.758 (1.280, 2.415)	0.0004
	No	15	6 (40.0)	18.7 [1.0, NE)	32	20 (62.5)	3.5 [0.3, 11.8)		2.014 (0.806, 5.031)	0.1294
Number of prior lines of therapy per IXRS	1	66	24 (36.4)	26.6 [17.7, NE)	131	82 (62.6)	8.7 [5.6, 11.1)	0.5256	1.995 (1.265, 3.146)	0.0024
	>= 2	87	32 (36.8)	21.9 [14.1, NE)	177	100 (56.5)	9.4 [4.1, 15.7)		1.628 (1.093, 2.426)	0.0161

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
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<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
General disorders and administration site conditions										
Total subjects		153	78 (51.0)	8.4 [4.8, 18.7)	308	187 (60.7)	4.2 [2.9, 7.4)		1.285 (0.986, 1.674)	0.0638
Hepatobiliary disorders										
Total subjects		153	9 (5.9)	NE [NE, NE)	308	32 (10.4)	NE [NE, NE)		1.539 (0.734, 3.230)	0.2498

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Immune system disorders										
Total subjects		153	3 (2.0)	NE [NE, NE)	308	20 (6.5)	NE [NE, NE)		2.718 (0.806, 9.172)	0.0932
Infections and infestations										
Total subjects		153	106 (69.3)	3.3 [2.6, 6.3)	308	260 (84.4)	3.5 [2.4, 4.4)		1.266 (1.008, 1.589)	0.0425

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.504. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	93 (68.9)	3.1 [2.2, 5.8)	283	240 (84.8)	3.7 [2.3, 4.4)	0.7003	1.278 (1.004, 1.627)	0.0457
	> 75	18	13 (72.2)	6.3 [1.0, 11.9)	25	20 (80.0)	2.9 [1.9, 12.1)		1.062 (0.527, 2.138)	0.8694
Sex	Male	91	59 (64.8)	4.3 [2.8, 8.1)	174	148 (85.1)	3.8 [2.3, 5.1)	0.4498	1.337 (0.986, 1.815)	0.0620
	Female	62	47 (75.8)	2.6 [1.6, 7.4)	134	112 (83.6)	2.9 [1.8, 4.3)		1.148 (0.815, 1.616)	0.4338

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	84 (68.9)	3.3 [2.2, 7.4)	240	196 (81.7)	3.8 [2.5, 4.6)	0.6718	1.206 (0.932, 1.561)	0.1551
	Asian	20	14 (70.0)	4.1 [1.3, 15.0)	46	44 (95.7)	2.9 [1.8, 4.4)		1.651 (0.899, 3.031)	0.1023
	Other or Unknown	11	8 (72.7)	2.5 [1.3, 13.6)	22	20 (90.9)	2.2 [1.2, 6.6)		1.089 (0.469, 2.529)	0.8502
Region	North America	12	9 (75.0)	2.4 [0.2, 7.6)	21	19 (90.5)	4.1 [1.4, 5.6)	0.7111	0.939 (0.420, 2.096)	0.8698

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.504. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	68 (66.7)	4.9 [2.8, 9.5)	203	164 (80.8)	3.7 [2.3, 5.1)		1.329 (0.998, 1.768)	0.0512
	Asia Pacific	39	29 (74.4)	3.3 [1.3, 4.1)	84	77 (91.7)	3.2 [2.1, 4.4)		1.101 (0.716, 1.691)	0.6593
Baseline ECOG PS	0-1	146	104 (71.2)	3.3 [2.5, 6.3)	294	248 (84.4)	3.5 [2.4, 4.3)	0.9360	1.265 (1.004, 1.593)	0.0459
	2	7	2 (28.6)	2.8 [0.2, NE)	13	11 (84.6)	5.8 [0.7, 11.5)		1.087 (0.216, 5.470)	0.9196

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-soc.sas
Output: t14-06-001-504-ae-cox-soc-ge10.rtf (Date Generated: 27AUG2020:00:36) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.504. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	96 (70.6)	3.3 [2.2, 6.3)	285	238 (83.5)	3.3 [2.3, 4.3)	0.2987	1.214 (0.957, 1.541)	0.1115
	No	17	10 (58.8)	4.1 [0.5, NE)	23	22 (95.7)	4.6 [1.6, 8.8)		1.553 (0.727, 3.321)	0.2528
Refractory to Bortezomib or Ixazomib	Yes	55	36 (65.5)	4.3 [2.5, 10.3)	99	81 (81.8)	3.7 [2.0, 5.5)	0.9885	1.289 (0.866, 1.918)	0.2105
	No	98	70 (71.4)	3.1 [2.2, 6.3)	209	179 (85.6)	3.3 [2.3, 4.4)		1.254 (0.950, 1.657)	0.1098

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	47 (63.5)	3.5 [2.8, 7.4)	122	97 (79.5)	4.1 [2.2, 6.3)	0.5819	1.177 (0.827, 1.674)	0.3651
	No	79	59 (74.7)	2.9 [1.9, 7.3)	186	163 (87.6)	3.3 [2.3, 4.2)		1.357 (1.002, 1.837)	0.0482
Refractory to Lenalidomide	Yes	55	36 (65.5)	3.5 [2.7, 8.6)	98	78 (79.6)	3.7 [1.9, 6.3)	0.1433	1.034 (0.693, 1.544)	0.8699
	No	98	70 (71.4)	3.3 [2.1, 7.3)	210	182 (86.7)	3.5 [2.5, 4.3)		1.446 (1.089, 1.919)	0.0105

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
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Table 14-6.1.504. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	73 (66.4)	3.3 [2.6, 6.3)	205	174 (84.9)	3.2 [2.1, 4.1)	0.6256	1.306 (0.992, 1.720)	0.0571
	No	43	33 (76.7)	3.4 [1.8, 9.8)	103	86 (83.5)	4.5 [2.6, 6.5)		1.196 (0.797, 1.795)	0.3896
Refractory to IMiD	Yes	65	45 (69.2)	3.1 [2.1, 6.3)	129	104 (80.6)	3.7 [2.1, 5.5)	0.0377	0.964 (0.677, 1.372)	0.8353
	No	88	61 (69.3)	4.1 [2.2, 8.1)	179	156 (87.2)	3.4 [2.3, 4.3)		1.555 (1.148, 2.108)	0.0042

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	87 (69.0)	4.5 [2.9, 8.1)	250	214 (85.6)	3.4 [2.3, 4.4)	0.0004	1.460 (1.135, 1.878)	0.0031
	3	27	19 (70.4)	2.1 [1.2, 2.8)	58	46 (79.3)	4.1 [1.9, 8.0)		0.492 (0.275, 0.881)	0.0157
Prior proteasome inhibitor exposure per IXRS	Yes	138	97 (70.3)	3.4 [2.5, 6.5)	276	232 (84.1)	3.3 [2.3, 4.3)	0.7298	1.251 (0.986, 1.588)	0.0659
	No	15	9 (60.0)	3.3 [0.5, NE)	32	28 (87.5)	4.0 [1.6, 10.3)		1.368 (0.637, 2.936)	0.4185

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
SOC Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	48 (72.7)	3.8 [2.0, 8.1)	131	112 (85.5)	3.8 [2.4, 4.6)	0.5540	1.346 (0.956, 1.894)	0.0874
	>= 2	87	58 (66.7)	3.3 [2.6, 6.3)	177	148 (83.6)	3.3 [2.1, 4.6)		1.191 (0.877, 1.619)	0.2664
Injury, poisoning and procedural complications										

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	28 (18.3)	NE [NE, NE)	308	67 (21.8)	NE [NE, NE)		1.069 (0.686, 1.664)	0.7942
Investigations										
Total subjects		153	37 (24.2)	NE [NE, NE)	308	70 (22.7)	NE [NE, NE)		0.818 (0.548, 1.219)	0.3230

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Metabolism and nutrition disorders										
Total subjects		153	38 (24.8)	NE [NE, NE)	308	119 (38.6)	NE [22.6, NE)		1.443 (1.001, 2.081)	0.0480
Age - at baseline (years)	<= 75	135	33 (24.4)	NE [NE, NE)	283	111 (39.2)	NE [22.2, NE)	0.5725	1.498 (1.015, 2.212)	0.0403

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.504. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
SOC Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
	> 75	18	5 (27.8)	NE [9.5, NE)	25	8 (32.0)	NE [7.4, NE)		1.043 (0.341, 3.189)	0.9368
Sex	Male	91	18 (19.8)	NE [NE, NE)	174	70 (40.2)	NE [22.1, NE)	0.0758	1.938 (1.153, 3.257)	0.0110
	Female	62	20 (32.3)	NE [9.8, NE)	134	49 (36.6)	NE [19.4, NE)		0.997 (0.591, 1.680)	0.9904

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
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Table 14-6.1.504. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
SOC Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	27 (22.1)	NE [NE, NE)	240	87 (36.3)	NE [25.7, NE)	0.5656	1.510 (0.979, 2.327)	0.0599
	Asian	20	6 (30.0)	NE [3.5, NE)	46	22 (47.8)	12.7 [4.4, NE)		1.610 (0.652, 3.974)	0.2965
	Other or Unknown	11	5 (45.5)	9.5 [0.5, NE)	22	10 (45.5)	17.2 [2.7, NE)		0.821 (0.278, 2.429)	0.7240

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
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Table 14-6.1.504. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Region	North America	12	4 (33.3)	NE [2.8, NE)	21	15 (71.4)	4.4 [0.2, 11.4)	0.3074	2.530 (0.838, 7.645)	0.0878
	Europe	102	20 (19.6)	NE [NE, NE)	203	68 (33.5)	NE [26.1, NE)		1.591 (0.966, 2.620)	0.0655
	Asia Pacific	39	14 (35.9)	NE [4.8, NE)	84	36 (42.9)	NE [9.8, NE)		1.089 (0.585, 2.025)	0.7872

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.504. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Baseline ECOG PS	0-1	146	37 (25.3)	NE [NE, NE)	294	113 (38.4)	NE [22.2, NE)	0.8245	1.423 (0.981, 2.064)	0.0616
	2	7	1 (14.3)	NE [2.8, NE)	13	5 (38.5)	NE [0.7, NE)		2.478 (0.289, 21.232)	0.3963
Prior Bortezomib or Ixazomib exposure	Yes	136	34 (25.0)	NE [NE, NE)	285	109 (38.2)	NE [22.6, NE)	0.8375	1.434 (0.975, 2.109)	0.0654

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	No	17	4 (23.5)	NE [3.5, NE)	23	10 (43.5)	25.7 [7.7, NE)		1.530 (0.478, 4.899)	0.4702
Refractory to Bortezomib or Ixazomib	Yes	55	11 (20.0)	NE [NE, NE)	99	30 (30.3)	NE [19.4, NE)	0.9904	1.422 (0.712, 2.840)	0.3141
	No	98	27 (27.6)	NE [17.3, NE)	209	89 (42.6)	NE [19.6, NE)		1.434 (0.931, 2.208)	0.0997

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-soc.sas
Output: t14-06-001-504-ae-cox-soc-ge10.rtf (Date Generated: 27AUG2020:00:36) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.504. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
SOC Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	16 (21.6)	NE [14.0, NE)	122	59 (48.4)	13.2 [10.1, NE)	0.0428	2.242 (1.290, 3.899)	0.0033
	No	79	22 (27.8)	NE [19.4, NE)	186	60 (32.3)	NE [26.3, NE)		1.034 (0.634, 1.688)	0.8910
Refractory to Lenalidomide	Yes	55	11 (20.0)	NE [14.0, NE)	98	47 (48.0)	13.5 [10.1, NE)	0.0863	2.307 (1.195, 4.452)	0.0103

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Output: t14-06-001-504-ae-cox-soc-ge10.rtf (Date Generated: 27AUG2020:00:36) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.504. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	No	98	27 (27.6)	NE [19.4, NE)	210	72 (34.3)	NE [26.2, NE)		1.139 (0.731, 1.775)	0.5629
Prior IMiD exposure	Yes	110	27 (24.5)	NE [NE, NE)	205	84 (41.0)	NE [13.6, NE)	0.6159	1.583 (1.025, 2.444)	0.0365
	No	43	11 (25.6)	NE [15.9, NE)	103	35 (34.0)	NE [26.1, NE)		1.231 (0.624, 2.427)	0.5471

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
SOC Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Refractory to IMiD	Yes	65	14 (21.5)	NE [14.0, NE)	129	58 (45.0)	17.2 [10.9, NE)	0.1864	1.984 (1.106, 3.561)	0.0191
	No	88	24 (27.3)	NE [19.4, NE)	179	61 (34.1)	NE [26.1, NE)		1.141 (0.711, 1.832)	0.5843
ISS stage per IXRS	1 or 2	126	30 (23.8)	NE [NE, NE)	250	94 (37.6)	NE [26.1, NE)	0.5292	1.484 (0.983, 2.241)	0.0584

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Output: t14-06-001-504-ae-cox-soc-ge10.rtf (Date Generated: 27AUG2020:00:36) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.504. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	3	27	8 (29.6)	NE [2.8, NE)	58	25 (43.1)	19.6 [4.4, NE)		1.154 (0.518, 2.571)	0.7245
Prior proteasome inhibitor exposure per IXRS	Yes	138	33 (23.9)	NE [NE, NE)	276	107 (38.8)	NE [22.2, NE)	0.3171	1.545 (1.045, 2.284)	0.0279
	No	15	5 (33.3)	17.3 [3.5, NE)	32	12 (37.5)	NE [9.8, NE)		0.794 (0.278, 2.267)	0.6661

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
SOC Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	18 (27.3)	NE [19.4, NE)	131	52 (39.7)	NE [22.2, NE)	0.7261	1.331 (0.777, 2.278)	0.2939
	>= 2	87	20 (23.0)	NE [15.9, NE)	177	67 (37.9)	NE [18.7, NE)		1.546 (0.938, 2.550)	0.0849
Musculoskeletal and connective tissue disorders										

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	59 (38.6)	21.7 [14.2, NE)	308	147 (47.7)	17.0 [13.2, 22.2)		1.067 (0.788, 1.444)	0.6733
Neoplasms benign, malignant and unspecified (incl cysts and polyps)										
Total subjects		153	11 (7.2)	NE [NE, NE)	308	24 (7.8)	NE [NE, NE)		0.820 (0.400, 1.682)	0.5874

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Nervous system disorders										
Total subjects		153	48 (31.4)	NE [14.5, NE)	308	135 (43.8)	22.8 [15.5, NE)		1.324 (0.952, 1.842)	0.0950
Psychiatric disorders										

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	33 (21.6)	NE [NE, NE)	308	83 (26.9)	NE [NE, NE)		1.136 (0.759, 1.702)	0.5340
Renal and urinary disorders										
Total subjects		153	20 (13.1)	NE [NE, NE)	308	44 (14.3)	NE [NE, NE)		0.946 (0.556, 1.607)	0.8354

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Reproductive system and breast disorders										
Total subjects		153	7 (4.6)	NE [NE, NE)	308	15 (4.9)	NE [NE, NE)		0.849 (0.345, 2.092)	0.7227
Respiratory, thoracic and mediastinal disorders										

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	74 (48.4)	12.9 [6.1, 24.5)	308	159 (51.6)	12.5 [7.1, 21.2)		1.034 (0.784, 1.363)	0.8217
Skin and subcutaneous tissue disorders										
Total subjects		153	28 (18.3)	NE [NE, NE)	308	74 (24.0)	NE [NE, NE)		1.163 (0.752, 1.798)	0.5022

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.504. Cox Regression of Most Frequent Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Vascular disorders										
Total subjects		153	61 (39.9)	17.3 [10.0, NE)	308	139 (45.1)	18.7 [14.8, 28.8)		0.956 (0.706, 1.293)	0.7695

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-soc.sas
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Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Blood and lymphatic system disorders										
Thrombocytopenia										
Total subjects		153	45 (29.4)	NE [NE, NE)	308	117 (38.0)	NE [NE, NE)		1.370 (0.971, 1.932)	0.0735

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-soc-pt.sas
Output: t14-06-001-505-ae-cox-soc-pt-ge10.rtf (Date Generated: 27AUG2020:00:36) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Anaemia										
Total subjects		153	49 (32.0)	NE [NE, NE)	308	109 (35.4)	NE [NE, NE)		1.085 (0.774, 1.520)	0.6410
Neutropenia										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-soc-pt.sas
Output: t14-06-001-505-ae-cox-soc-pt-ge10.rtf (Date Generated: 27AUG2020:00:36) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	15 (9.8)	NE [NE, NE)	308	47 (15.3)	NE [NE, NE)		1.415 (0.790, 2.534)	0.2406
Lymphopenia										
Total subjects		153	13 (8.5)	NE [NE, NE)	308	29 (9.4)	NE [NE, NE)		1.059 (0.550, 2.041)	0.8648

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	 No. of Events (%)	 Median (months) (95%CI)	KdD (N = 308) N	 No. of Events (%)	 Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	 p-value (2-sided)[b]
Leukopenia										
Total subjects		153	6 (3.9)	NE [NE, NE)	308	21 (6.8)	NE [NE, NE)		1.688 (0.681, 4.188)	0.2533
Cardiac disorders										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Cardiac failure										
Total subjects		153	7 (4.6)	NE [NE, NE)	308	14 (4.5)	NE [NE, NE)		0.721 (0.289, 1.797)	0.4805
Tachycardia										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
SOC PT Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	7 (4.6)	NE [NE, NE)	308	13 (4.2)	NE [NE, NE)		0.822 (0.327, 2.063)	0.6753
Eye disorders										
Cataract										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
SOC PT Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	9 (5.9)	NE [NE, NE)	308	28 (9.1)	NE [NE, NE)		1.071 (0.504, 2.277)	0.8573
Gastrointestinal disorders										
Diarrhoea										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	 No. of Events (%)	 Median (months) (95%CI)	KdD (N = 308) N	 No. of Events (%)	 Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	 p-value (2-sided)[b]
Total subjects		153	26 (17.0)	NE [NE, NE)	308	110 (35.7)	NE [22.5, NE)		2.017 (1.315, 3.093)	0.0010
Age - at baseline (years)	<= 75	135	22 (16.3)	NE [NE, NE)	283	101 (35.7)	NE [24.1, NE)	0.7375	2.099 (1.323, 3.330)	0.0013
	> 75	18	4 (22.2)	NE [15.3, NE)	25	9 (36.0)	22.5 [9.3, NE)		1.699 (0.521, 5.540)	0.3735

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
SOC PT Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Sex	Male	91	12 (13.2)	NE [NE, NE)	174	60 (34.5)	NE [20.5, NE)	0.3355	2.433 (1.308, 4.525)	0.0037
	Female	62	14 (22.6)	NE [16.8, NE)	134	50 (37.3)	NE [15.7, NE)		1.631 (0.901, 2.950)	0.1024
Race	White	122	15 (12.3)	NE [NE, NE)	240	81 (33.8)	NE [24.1, NE)	0.0971	2.690 (1.550, 4.669)	0.0002

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Asian	20	8 (40.0)	NE [1.6, NE)	46	23 (50.0)	17.9 [10.2, NE)		1.104 (0.493, 2.470)	0.8147
	Other or Unknown	11	3 (27.3)	16.9 [4.6, NE)	22	6 (27.3)	NE [7.2, NE)		0.835 (0.207, 3.361)	0.7995
Region	North America	12	5 (41.7)	15.6 [3.9, 15.6)	21	12 (57.1)	9.3 [5.7, NE)	0.1994	1.016 (0.343, 3.004)	0.9774

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	10 (9.8)	NE [NE, NE)	203	58 (28.6)	NE [NE, NE)		2.913 (1.489, 5.701)	0.0011
	Asia Pacific	39	11 (28.2)	NE [13.8, NE)	84	40 (47.6)	19.3 [11.1, NE)		1.547 (0.793, 3.020)	0.1973
Baseline ECOG PS	0-1	146	26 (17.8)	NE [NE, NE)	294	106 (36.1)	NE [20.5, NE)	0.9792	1.998 (1.301, 3.069)	0.0013

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	2	7	0 (0.0)	NE [NE, NE)	13	4 (30.8)	25.1 [2.2, NE)		>999.999 (<.001, NE)	0.3723
Prior Bortezomib or Ixazomib exposure	Yes	136	24 (17.6)	NE [NE, NE)	285	103 (36.1)	NE [22.5, NE)	0.8270	1.964 (1.259, 3.064)	0.0024
	No	17	2 (11.8)	NE [NE, NE)	23	7 (30.4)	NE [8.6, NE)		2.438 (0.505, 11.765)	0.2516

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Refractory to Bortezomib or Ixazomib	Yes	55	9 (16.4)	NE [NE, NE)	99	29 (29.3)	NE [22.5, NE)	0.6553	1.776 (0.841, 3.754)	0.1271
	No	98	17 (17.3)	NE [NE, NE)	209	81 (38.8)	29.5 [19.6, NE)		2.125 (1.259, 3.587)	0.0038
Prior Lenalidomide exposure	Yes	74	14 (18.9)	NE [21.9, NE)	122	52 (42.6)	19.6 [15.6, NE)	0.8915	2.086 (1.154, 3.771)	0.0128

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	No	79	12 (15.2)	NE [NE, NE)	186	58 (31.2)	NE [29.5, NE)		2.020 (1.084, 3.762)	0.0237
Refractory to Lenalidomide	Yes	55	10 (18.2)	NE [16.8, NE)	98	43 (43.9)	19.8 [10.4, NE)	0.7529	2.140 (1.071, 4.272)	0.0273
	No	98	16 (16.3)	NE [NE, NE)	210	67 (31.9)	NE [29.5, NE)		1.928 (1.118, 3.328)	0.0163

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	22 (20.0)	NE [NE, NE)	205	83 (40.5)	22.5 [17.1, NE)	0.5544	1.941 (1.212, 3.106)	0.0049
	No	43	4 (9.3)	NE [NE, NE)	103	27 (26.2)	NE [NE, NE)		2.764 (0.966, 7.910)	0.0481
Refractory to IMiD	Yes	65	12 (18.5)	NE [16.9, NE)	129	51 (39.5)	25.1 [16.2, NE)	0.9212	1.925 (1.024, 3.619)	0.0384

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	No	88	14 (15.9)	NE [NE, NE)	179	59 (33.0)	NE [24.1, NE)		2.040 (1.139, 3.655)	0.0144
ISS stage per IXRS	1 or 2	126	23 (18.3)	NE [NE, NE)	250	94 (37.6)	NE [20.5, NE)	0.9628	2.029 (1.286, 3.203)	0.0019
	3	27	3 (11.1)	NE [NE, NE)	58	16 (27.6)	NE [15.6, NE)		1.938 (0.562, 6.683)	0.2860

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior proteasome inhibitor exposure per IXRS	Yes	138	24 (17.4)	NE [NE, NE)	276	100 (36.2)	NE [20.5, NE)	0.8810	1.991 (1.274, 3.109)	0.0020
	No	15	2 (13.3)	NE [NE, NE)	32	10 (31.3)	NE [16.2, NE)		2.360 (0.516, 10.783)	0.2536
Number of prior lines of therapy per IXRS	1	66	12 (18.2)	NE [NE, NE)	131	48 (36.6)	29.5 [19.3, NE)	0.9033	1.962 (1.042, 3.695)	0.0333

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	No. of Events (%)	Median (months) (95%CI)	KdD (N = 308) N	No. of Events (%)	Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	>= 2	87	14 (16.1)	NE [21.9, NE)	177	62 (35.0)	NE [19.6, NE)		2.071 (1.159, 3.701)	0.0120
Nausea										
Total subjects		153	22 (14.4)	NE [NE, NE)	308	59 (19.2)	NE [NE, NE)		1.230 (0.753, 2.010)	0.4105

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Vomiting										
Total subjects		153	13 (8.5)	NE [NE, NE)	308	47 (15.3)	NE [NE, NE)		1.521 (0.821, 2.818)	0.1813
Constipation										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	7 (4.6)	NE [NE, NE)	308	23 (7.5)	NE [NE, NE)		1.450 (0.621, 3.385)	0.3871
Abdominal pain										
Total subjects		153	7 (4.6)	NE [NE, NE)	308	13 (4.2)	NE [NE, NE)		0.786 (0.312, 1.976)	0.6074

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Abdominal pain upper										
Total subjects		153	5 (3.3)	NE [NE, NE)	308	10 (3.2)	NE [NE, NE)		0.782 (0.266, 2.302)	0.6549
General disorders and administration site conditions										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Fatigue										
Total subjects		153	29 (19.0)	NE [NE, NE)	308	78 (25.3)	NE [NE, NE)		1.287 (0.840, 1.973)	0.2449
Pyrexia										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	 No. of Events (%)	 Median (months) (95%CI)	KdD (N = 308) N	 No. of Events (%)	 Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	 p-value (2-sided)[b]
Total subjects		153	25 (16.3)	NE [NE, NE)	308	65 (21.1)	NE [NE, NE)		1.203 (0.757, 1.910)	0.4348
Oedema peripheral										
Total subjects		153	14 (9.2)	NE [NE, NE)	308	36 (11.7)	NE [NE, NE)		1.121 (0.604, 2.080)	0.7185

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Asthenia										
Total subjects		153	18 (11.8)	NE [NE, NE)	308	34 (11.0)	NE [NE, NE)		0.813 (0.458, 1.442)	0.4777
Chills										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
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Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	 No. of Events (%)	 Median (months) (95%CI)	KdD (N = 308) N	 No. of Events (%)	 Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	 p-value (2-sided)[b]
Total subjects		153	7 (4.6)	NE [NE, NE)	308	17 (5.5)	NE [NE, NE)		1.087 (0.450, 2.625)	0.8582
Chest pain										
Total subjects		153	7 (4.6)	NE [NE, NE)	308	14 (4.5)	NE [NE, NE)		0.873 (0.352, 2.167)	0.7689

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	No. of Events (%)	Median (months) (95%CI)	KdD (N = 308) N	No. of Events (%)	Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Oedema										
Total subjects		153	8 (5.2)	NE [NE, NE)	308	13 (4.2)	NE [NE, NE)		0.688 (0.284, 1.664)	0.4038
Pain										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	 No. of Events (%)	 Median (months) (95%CI)	KdD (N = 308) N	 No. of Events (%)	 Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	 p-value (2-sided)[b]
Total subjects		153	2 (1.3)	NE [NE, NE)	308	13 (4.2)	NE [NE, NE)		3.051 (0.688, 13.535)	0.1224
Malaise										
Total subjects		153	5 (3.3)	NE [NE, NE)	308	11 (3.6)	NE [NE, NE)		0.949 (0.328, 2.743)	0.9228

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Influenza like illness										
Total subjects		153	3 (2.0)	NE [NE, NE)	308	11 (3.6)	NE [NE, NE)		1.654 (0.461, 5.935)	0.4351
Chest discomfort										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-soc-pt.sas
Output: t14-06-001-505-ae-cox-soc-pt-ge10.rtf (Date Generated: 27AUG2020:00:36) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	 No. of Events (%)	 Median (months) (95%CI)	KdD (N = 308) N	 No. of Events (%)	 Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	 p-value (2-sided)[b]
Total subjects		153	3 (2.0)	NE [NE, NE)	308	10 (3.2)	NE [NE, NE)		1.361 (0.373, 4.961)	0.6388
Immune system disorders										
Hypogammaglobulinaemia										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	 No. of Events (%)	 Median (months) (95%CI)	KdD (N = 308) N	 No. of Events (%)	 Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	 p-value (2-sided)[b]
Total subjects		153	3 (2.0)	NE [NE, NE)	308	11 (3.6)	NE [NE, NE)		1.342 (0.372, 4.837)	0.6520
Infections and infestations										
Upper respiratory tract infection										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	 No. of Events (%)	 Median (months) (95%CI)	KdD (N = 308) N	 No. of Events (%)	 Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	 p-value (2-sided)[b]
Total subjects		153	36 (23.5)	NE [NE, NE)	308	100 (32.5)	NE [22.6, NE)		1.180 (0.806, 1.728)	0.3945
Pneumonia										
Total subjects		153	23 (15.0)	NE [NE, NE)	308	75 (24.4)	NE [NE, NE)		1.321 (0.827, 2.110)	0.2424

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Bronchitis										
Total subjects		153	19 (12.4)	NE [NE, NE)	308	57 (18.5)	NE [NE, NE)		1.311 (0.779, 2.206)	0.3062
Influenza										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	No. of Events (%)	Median (months) (95%CI)	KdD (N = 308) N	No. of Events (%)	Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	12 (7.8)	NE [NE, NE)	308	39 (12.7)	NE [NE, NE)		1.352 (0.706, 2.589)	0.3605
Respiratory tract infection										
Total subjects		153	9 (5.9)	NE [NE, NE)	308	33 (10.7)	NE [NE, NE)		1.512 (0.723, 3.162)	0.2685

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Nasopharyngitis										
Total subjects		153	15 (9.8)	NE [NE, NE)	308	29 (9.4)	NE [NE, NE)		0.800 (0.428, 1.496)	0.4833
Urinary tract infection										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	 No. of Events (%)	 Median (months) (95%CI)	KdD (N = 308) N	 No. of Events (%)	 Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	 p-value (2-sided)[b]
Total subjects		153	4 (2.6)	NE [NE, NE)	308	24 (7.8)	NE [NE, NE)		2.356 (0.815, 6.810)	0.1028
Lower respiratory tract infection										
Total subjects		153	4 (2.6)	NE [NE, NE)	308	22 (7.1)	NE [NE, NE)		2.158 (0.742, 6.277)	0.1482

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Conjunctivitis										
Total subjects		153	4 (2.6)	NE [NE, NE)	308	16 (5.2)	NE [NE, NE)		1.723 (0.575, 5.164)	0.3250
Sinusitis										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	 No. of Events (%)	 Median (months) (95%CI)	KdD (N = 308) N	 No. of Events (%)	 Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	 p-value (2-sided)[b]
Total subjects		153	5 (3.3)	NE [NE, NE)	308	15 (4.9)	NE [NE, NE)		1.258 (0.456, 3.464)	0.6575
Pharyngitis										
Total subjects		153	4 (2.6)	NE [NE, NE)	308	15 (4.9)	NE [NE, NE)		1.486 (0.492, 4.487)	0.4794

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	 No. of Events (%)	 Median (months) (95%CI)	KdD (N = 308) N	 No. of Events (%)	 Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	 p-value (2-sided)[b]
Viral infection										
Total subjects		153	6 (3.9)	NE [NE, NE)	308	14 (4.5)	NE [NE, NE)		0.970 (0.371, 2.532)	0.9501
Sepsis										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	 No. of Events (%)	 Median (months) (95%CI)	KdD (N = 308) N	 No. of Events (%)	 Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	 p-value (2-sided)[b]
Total subjects		153	2 (1.3)	NE [NE, NE)	308	12 (3.9)	NE [NE, NE)		2.775 (0.621, 12.409)	0.1632
Gastroenteritis										
Total subjects		153	5 (3.3)	NE [NE, NE)	308	10 (3.2)	NE [NE, NE)		0.753 (0.256, 2.213)	0.6051

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Infection										
Total subjects		153	4 (2.6)	NE [NE, NE)	308	10 (3.2)	NE [NE, NE)		1.023 (0.320, 3.274)	0.9692
Injury, poisoning and procedural complications										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Infusion related reaction										
Total subjects		153	3 (2.0)	NE [NE, NE)	308	25 (8.1)	NE [NE, NE)		4.176 (1.260, 13.838)	0.0113
Age - at baseline (years)	<= 75	135	3 (2.2)	NE [NE, NE)	283	24 (8.5)	NE [NE, NE)	0.9911	3.844 (1.157, 12.775)	0.0186

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	> 75	18	0 (0.0)	NE [NE, NE)	25	1 (4.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.3961
Sex	Male	91	2 (2.2)	NE [NE, NE)	174	15 (8.6)	NE [NE, NE)	0.8926	3.830 (0.875, 16.772)	0.0565
	Female	62	1 (1.6)	NE [NE, NE)	134	10 (7.5)	NE [NE, NE)		4.820 (0.617, 37.652)	0.0972

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	2 (1.6)	NE [NE, NE)	240	15 (6.3)	NE [NE, NE)	0.9911	3.789 (0.866, 16.577)	0.0576
	Asian	20	1 (5.0)	NE [10.4, NE)	46	7 (15.2)	NE [NE, NE)		3.163 (0.389, 25.731)	0.2640
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	3 (13.6)	NE [NE, NE)		>999.999 (<.001, NE)	0.2059

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Region	North America	12	2 (16.7)	NE [8.5, NE)	21	2 (9.5)	NE [NE, NE)	0.3610	0.519 (0.072, 3.725)	0.5062
	Europe	102	0 (0.0)	NE [NE, NE)	203	14 (6.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.0074
	Asia Pacific	39	1 (2.6)	NE [NE, NE)	84	9 (10.7)	NE [NE, NE)		4.290 (0.543, 33.880)	0.1344

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Baseline ECOG PS	0-1	146	3 (2.1)	NE [NE, NE)	294	23 (7.8)	NE [NE, NE)	0.9917	3.836 (1.151, 12.779)	0.0188
	2	7	0 (0.0)	NE [NE, NE)	13	1 (7.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.4631
Prior Bortezomib or Ixazomib exposure	Yes	136	3 (2.2)	NE [NE, NE)	285	22 (7.7)	NE [NE, NE)	0.9905	3.502 (1.048, 11.708)	0.0307

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	No	17	0 (0.0)	NE [NE, NE)	23	3 (13.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.1263
Refractory to Bortezomib or Ixazomib	Yes	55	1 (1.8)	NE [NE, NE)	99	7 (7.1)	NE [NE, NE)	0.9437	3.858 (0.474, 31.380)	0.1748
	No	98	2 (2.0)	NE [NE, NE)	209	18 (8.6)	NE [NE, NE)		4.288 (0.994, 18.491)	0.0339

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	3 (4.1)	NE [NE, NE)	122	8 (6.6)	NE [NE, NE)	0.9864	1.477 (0.389, 5.612)	0.5732
	No	79	0 (0.0)	NE [NE, NE)	186	17 (9.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.0057
Refractory to Lenalidomide	Yes	55	3 (5.5)	NE [NE, NE)	98	6 (6.1)	NE [NE, NE)	0.9846	0.956 (0.235, 3.891)	0.9420

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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SOC PT Characteristics	Subgroup	Kd (N = 153) N	 No. of Events (%)	 Median (months) (95%CI)	KdD (N = 308) N	 No. of Events (%)	 Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	 p-value (2-sided)[b]
	No	98	0 (0.0)	NE [NE, NE)	210	19 (9.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.0022
Prior IMiD exposure	Yes	110	3 (2.7)	NE [NE, NE)	205	19 (9.3)	NE [NE, NE)	0.9907	3.411 (1.008, 11.539)	0.0375
	No	43	0 (0.0)	NE [NE, NE)	103	6 (5.8)	NE [NE, NE)		>999.999 (<.001, NE)	0.1080

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Refractory to IMiD	Yes	65	3 (4.6)	NE [NE, NE)	129	8 (6.2)	NE [NE, NE)	0.9855	1.200 (0.315, 4.576)	0.8000
	No	88	0 (0.0)	NE [NE, NE)	179	17 (9.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.0029
ISS stage per IXRS	1 or 2	126	3 (2.4)	NE [NE, NE)	250	23 (9.2)	NE [NE, NE)	0.9898	3.940 (1.182, 13.128)	0.0165

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
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	3	27	0 (0.0)	NE [NE, NE)	58	2 (3.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.3617
Prior proteasome inhibitor exposure per IXRS	Yes	138	3 (2.2)	NE [NE, NE)	276	21 (7.6)	NE [NE, NE)	0.9911	3.496 (1.042, 11.728)	0.0315
	No	15	0 (0.0)	NE [NE, NE)	32	4 (12.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.1567

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
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Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	13 (9.9)	NE [NE, NE)	0.9877	>999.999 (<.001, NE)	0.0093
	>= 2	87	3 (3.4)	NE [NE, NE)	177	12 (6.8)	NE [NE, NE)		1.960 (0.553, 6.949)	0.2942
Fall										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
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Total subjects		153	6 (3.9)	NE [NE, NE)	308	17 (5.5)	NE [NE, NE)		1.115 (0.438, 2.839)	0.8189
Contusion										
Total subjects		153	2 (1.3)	NE [NE, NE)	308	13 (4.2)	NE [NE, NE)		2.619 (0.590, 11.628)	0.1885

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Investigations										
Alanine aminotransferase increased										
Total subjects		153	3 (2.0)	NE [NE, NE)	308	12 (3.9)	NE [NE, NE)		1.975 (0.557, 6.999)	0.2825

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Weight decreased										
Total subjects		153	4 (2.6)	NE [NE, NE)	308	11 (3.6)	NE [NE, NE)		1.196 (0.380, 3.764)	0.7587
Metabolism and nutrition disorders										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-soc-pt.sas
Output: t14-06-001-505-ae-cox-soc-pt-ge10.rtf (Date Generated: 27AUG2020:00:36) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	 No. of Events (%)	 Median (months) (95%CI)	KdD (N = 308) N	 No. of Events (%)	 Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	 p-value (2-sided)[b]
Hyperglycaemia										
Total subjects		153	12 (7.8)	NE [NE, NE)	308	28 (9.1)	NE [NE, NE)		1.045 (0.531, 2.058)	0.8962
Decreased appetite										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	 No. of Events (%)	 Median (months) (95%CI)	KdD (N = 308) N	 No. of Events (%)	 Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	 p-value (2-sided)[b]
Total subjects		153	9 (5.9)	NE [NE, NE)	308	27 (8.8)	NE [NE, NE)		1.305 (0.613, 2.781)	0.4881
Hypokalaemia										
Total subjects		153	10 (6.5)	NE [NE, NE)	308	23 (7.5)	NE [NE, NE)		0.938 (0.445, 1.979)	0.8679

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Hypocalcaemia										
Total subjects		153	4 (2.6)	NE [NE, NE)	308	19 (6.2)	NE [NE, NE)		1.934 (0.656, 5.699)	0.2233
Hypomagnesaemia										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	 No. of Events (%)	 Median (months) (95%CI)	KdD (N = 308) N	 No. of Events (%)	 Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	 p-value (2-sided)[b]
Total subjects		153	3 (2.0)	NE [NE, NE)	308	13 (4.2)	NE [NE, NE)		1.893 (0.538, 6.661)	0.3125
Musculoskeletal and connective tissue disorders										
Back pain										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	16 (10.5)	NE [NE, NE)	308	56 (18.2)	NE [NE, NE)		1.459 (0.836, 2.546)	0.1801
Muscle spasms										
Total subjects		153	18 (11.8)	NE [NE, NE)	308	38 (12.3)	NE [NE, NE)		0.922 (0.526, 1.617)	0.7772

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Arthralgia										
Total subjects		153	10 (6.5)	NE [NE, NE)	308	28 (9.1)	NE [NE, NE)		1.129 (0.547, 2.331)	0.7425
Pain in extremity										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	11 (7.2)	NE [NE, NE)	308	21 (6.8)	NE [NE, NE)		0.805 (0.387, 1.673)	0.5605
Muscular weakness										
Total subjects		153	6 (3.9)	NE [NE, NE)	308	17 (5.5)	NE [NE, NE)		1.037 (0.407, 2.640)	0.9396

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Myalgia										
Total subjects		153	4 (2.6)	NE [NE, NE)	308	17 (5.5)	NE [NE, NE)		1.681 (0.563, 5.015)	0.3464
Musculoskeletal chest pain										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	6 (3.9)	NE [NE, NE)	308	15 (4.9)	NE [NE, NE)		1.027 (0.397, 2.657)	0.9562
Bone pain										
Total subjects		153	6 (3.9)	NE [NE, NE)	308	11 (3.6)	NE [NE, NE)		0.696 (0.256, 1.887)	0.4740

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Nervous system disorders										
Headache										
Total subjects		153	19 (12.4)	NE [NE, NE)	308	45 (14.6)	NE [NE, NE)		1.066 (0.623, 1.825)	0.8177

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Neuropathy peripheral										
Total subjects		153	6 (3.9)	NE [NE, NE)	308	32 (10.4)	NE [NE, NE)		2.202 (0.919, 5.278)	0.0694
Dizziness										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	 No. of Events (%)	 Median (months) (95%CI)	KdD (N = 308) N	 No. of Events (%)	 Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	 p-value (2-sided)[b]
Total subjects		153	4 (2.6)	NE [NE, NE)	308	23 (7.5)	NE [NE, NE)		2.561 (0.885, 7.411)	0.0720
Peripheral sensory neuropathy										
Total subjects		153	2 (1.3)	NE [NE, NE)	308	22 (7.1)	NE [NE, NE)		4.929 (1.158, 20.983)	0.0167

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
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[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
SOC PT Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	2 (1.5)	NE [NE, NE)	283	20 (7.1)	NE [NE, NE)	0.9917	4.285 (1.000, 18.358)	0.0326
	> 75	18	0 (0.0)	NE [NE, NE)	25	2 (8.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.2563
Sex	Male	91	2 (2.2)	NE [NE, NE)	174	11 (6.3)	NE [NE, NE)	0.9896	2.631 (0.582, 11.898)	0.1916

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Female	62	0 (0.0)	NE [NE, NE)	134	11 (8.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.0338
Race	White	122	1 (0.8)	NE [NE, NE)	240	13 (5.4)	NE [NE, NE)	0.8760	5.870 (0.766, 44.951)	0.0531
	Asian	20	1 (5.0)	NE [NE, NE)	46	7 (15.2)	NE [NE, NE)		3.015 (0.371, 24.507)	0.2777

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Output: t14-06-001-505-ae-cox-soc-pt-ge10.rtf (Date Generated: 27AUG2020:00:36) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	2 (9.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.4259
Region	North America	12	0 (0.0)	NE [NE, NE)	21	5 (23.8)	NE [9.3, NE)	0.9999	>999.999 (<.001, NE)	0.0928
	Europe	102	1 (1.0)	NE [NE, NE)	203	8 (3.9)	NE [NE, NE)		3.607 (0.451, 28.854)	0.1957

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
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	Asia Pacific	39	1 (2.6)	NE [NE, NE)	84	9 (10.7)	NE [NE, NE)		3.791 (0.478, 30.080)	0.1753
Baseline ECOG PS	0-1	146	2 (1.4)	NE [NE, NE)	294	20 (6.8)	NE [NE, NE)	0.9916	4.529 (1.057, 19.397)	0.0255
	2	7	0 (0.0)	NE [NE, NE)	13	2 (15.4)	NE [2.5, NE)		>999.999 (<.001, NE)	0.3977

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	1 (0.7)	NE [NE, NE)	285	20 (7.0)	NE [NE, NE)	0.2381	8.538 (1.145, 63.652)	0.0119
	No	17	1 (5.9)	NE [NE, NE)	23	2 (8.7)	NE [NE, NE)		1.411 (0.128, 15.598)	0.7780
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	4 (4.0)	NE [NE, NE)	0.9911	>999.999 (<.001, NE)	0.1803

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	No	98	2 (2.0)	NE [NE, NE)	209	18 (8.6)	NE [NE, NE)		3.827 (0.887, 16.512)	0.0527
Prior Lenalidomide exposure	Yes	74	1 (1.4)	NE [NE, NE)	122	7 (5.7)	NE [NE, NE)	0.7398	3.673 (0.449, 30.013)	0.1931
	No	79	1 (1.3)	NE [NE, NE)	186	15 (8.1)	NE [NE, NE)		6.009 (0.793, 45.504)	0.0480

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Refractory to Lenalidomide	Yes	55	1 (1.8)	NE [NE, NE)	98	6 (6.1)	NE [NE, NE)	0.5491	2.856 (0.340, 23.975)	0.3114
	No	98	1 (1.0)	NE [NE, NE)	210	16 (7.6)	NE [NE, NE)		6.964 (0.923, 52.529)	0.0284
Prior IMiD exposure	Yes	110	2 (1.8)	NE [NE, NE)	205	14 (6.8)	NE [NE, NE)	0.9911	3.300 (0.748, 14.555)	0.0944

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	No	43	0 (0.0)	NE [NE, NE)	103	8 (7.8)	NE [NE, NE)		>999.999 (<.001, NE)	0.0743
Refractory to IMiD	Yes	65	1 (1.5)	NE [NE, NE)	129	7 (5.4)	NE [NE, NE)	0.5719	3.036 (0.371, 24.879)	0.2759
	No	88	1 (1.1)	NE [NE, NE)	179	15 (8.4)	NE [NE, NE)		6.911 (0.913, 52.327)	0.0295

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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ISS stage per IXRS	1 or 2	126	2 (1.6)	NE [NE, NE)	250	20 (8.0)	NE [NE, NE)	0.9917	4.742 (1.107, 20.307)	0.0206
	3	27	0 (0.0)	NE [NE, NE)	58	2 (3.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.4705
Prior proteasome inhibitor exposure per IXRS	Yes	138	1 (0.7)	NE [NE, NE)	276	20 (7.2)	NE [NE, NE)	0.1274	8.989 (1.206, 67.006)	0.0094

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
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	No	15	1 (6.7)	NE [4.9, NE)	32	2 (6.3)	NE [NE, NE)		0.870 (0.079, 9.641)	0.9098
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	10 (7.6)	NE [NE, NE)	0.9890	>999.999 (<.001, NE)	0.0282
	>= 2	87	2 (2.3)	NE [NE, NE)	177	12 (6.8)	NE [NE, NE)		2.496 (0.557, 11.191)	0.2161

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
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Psychiatric disorders										
Insomnia										
Total subjects		153	17 (11.1)	NE [NE, NE)	308	62 (20.1)	NE [NE, NE)		1.676 (0.979, 2.868)	0.0566

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Agitation										
Total subjects		153	5 (3.3)	NE [NE, NE)	308	10 (3.2)	NE [NE, NE)		0.913 (0.312, 2.676)	0.8684
Renal and urinary disorders										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
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Acute kidney injury										
Total subjects		153	9 (5.9)	NE [NE, NE)	308	16 (5.2)	NE [NE, NE)		0.719 (0.317, 1.634)	0.4290
Respiratory, thoracic and mediastinal disorders										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Dyspnoea										
Total subjects		153	36 (23.5)	NE [NE, NE)	308	67 (21.8)	NE [NE, NE)		0.821 (0.547, 1.232)	0.3394
Cough										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-soc-pt.sas
Output: t14-06-001-505-ae-cox-soc-pt-ge10.rtf (Date Generated: 27AUG2020:00:36) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	 No. of Events (%)	 Median (months) (95%CI)	KdD (N = 308) N	 No. of Events (%)	 Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	 p-value (2-sided)[b]
Total subjects		153	30 (19.6)	NE [NE, NE)	308	54 (17.5)	NE [NE, NE)		0.773 (0.494, 1.209)	0.2586
Productive cough										
Total subjects		153	6 (3.9)	NE [NE, NE)	308	21 (6.8)	NE [NE, NE)		1.566 (0.632, 3.885)	0.3285

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-soc-pt.sas
Output: t14-06-001-505-ae-cox-soc-pt-ge10.rtf (Date Generated: 27AUG2020:00:36) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Oropharyngeal pain										
Total subjects		153	3 (2.0)	NE [NE, NE)	308	15 (4.9)	NE [NE, NE)		2.101 (0.606, 7.278)	0.2310
Dysphonia										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-soc-pt.sas
Output: t14-06-001-505-ae-cox-soc-pt-ge10.rtf (Date Generated: 27AUG2020:00:36) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	3 (2.0)	NE [NE, NE)	308	13 (4.2)	NE [NE, NE)		2.080 (0.592, 7.304)	0.2428
Rhinorrhoea										
Total subjects		153	1 (0.7)	NE [NE, NE)	308	13 (4.2)	NE [NE, NE)		5.705 (0.745, 43.687)	0.0581

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-soc-pt.sas
Output: t14-06-001-505-ae-cox-soc-pt-ge10.rtf (Date Generated: 27AUG2020:00:36) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	No. of Events (%)	Median (months) (95%CI)	KdD (N = 308) N	No. of Events (%)	Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Dyspnoea exertional										
Total subjects		153	2 (1.3)	NE [NE, NE)	308	11 (3.6)	NE [NE, NE)		2.491 (0.552, 11.250)	0.2194
Skin and subcutaneous tissue disorders										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-soc-pt.sas
Output: t14-06-001-505-ae-cox-soc-pt-ge10.rtf (Date Generated: 27AUG2020:00:36) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Rash										
Total subjects		153	10 (6.5)	NE [NE, NE)	308	21 (6.8)	NE [NE, NE)		0.855 (0.401, 1.820)	0.6832
Pruritus										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-soc-pt.sas
Output: t14-06-001-505-ae-cox-soc-pt-ge10.rtf (Date Generated: 27AUG2020:00:36) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
SOC PT Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	5 (3.3)	NE [NE, NE)	308	16 (5.2)	NE [NE, NE)		1.317 (0.481, 3.605)	0.5913
Vascular disorders										
Hypertension										

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-soc-pt.sas
Output: t14-06-001-505-ae-cox-soc-pt-ge10.rtf (Date Generated: 27AUG2020:00:36) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	46 (30.1)	NE [17.3, NE)	308	109 (35.4)	NE [22.3, NE)		1.013 (0.717, 1.432)	0.9411
Hypotension										
Total subjects		153	4 (2.6)	NE [NE, NE)	308	14 (4.5)	NE [NE, NE)		1.539 (0.506, 4.682)	0.4443

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-soc-pt.sas
Output: t14-06-001-505-ae-cox-soc-pt-ge10.rtf (Date Generated: 27AUG2020:00:36) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.505. Cox Regression of Most Frequent Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Phlebitis										
Total subjects		153	6 (3.9)	NE [NE, NE)	308	11 (3.6)	NE [NE, NE)		0.796 (0.293, 2.160)	0.6529

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-soc-pt.sas
Output: t14-06-001-505-ae-cox-soc-pt-ge10.rtf (Date Generated: 27AUG2020:00:36) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.506. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
SOC Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Blood and lymphatic system disorders										
Total subjects		153	54 (35.3)	NE [17.3, NE)	308	117 (38.0)	NE [NE, NE)		1.103 (0.799, 1.524)	0.5598
Cardiac disorders										

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-soc-sub.sas
Output: t14-06-001-506-ae-cox-soc-grd345-ge5pct.rtf (Date Generated: 27AUG2020:00:37) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.506. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	17 (11.1)	NE [NE, NE)	308	34 (11.0)	NE [NE, NE)		0.793 (0.442, 1.422)	0.4351
Gastrointestinal disorders										
Total subjects		153	6 (3.9)	NE [NE, NE)	308	21 (6.8)	NE [NE, NE)		1.399 (0.563, 3.477)	0.4677

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-soc-sub.sas
Output: t14-06-001-506-ae-cox-soc-grd345-ge5pct.rtf (Date Generated: 27AUG2020:00:37) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.506. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
General disorders and administration site conditions										
Total subjects		153	21 (13.7)	NE [NE, NE)	308	48 (15.6)	NE [NE, NE)		1.002 (0.599, 1.674)	0.9942
Infections and infestations										

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-soc-sub.sas
Output: t14-06-001-506-ae-cox-soc-grd345-ge5pct.rtf (Date Generated: 27AUG2020:00:37) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.506. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC <Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	47 (30.7)	32.9 [27.7, NE)	308	129 (41.9)	23.7 [17.5, NE)		1.201 (0.860, 1.678)	0.2815
Injury, poisoning and procedural complications										
Total subjects		153	7 (4.6)	NE [NE, NE)	308	16 (5.2)	NE [NE, NE)		0.888 (0.363, 2.172)	0.7935

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-soc-sub.sas
Output: t14-06-001-506-ae-cox-soc-grd345-ge5pct.rtf (Date Generated: 27AUG2020:00:37) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.506. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
SOC Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Investigations										
Total subjects		153	9 (5.9)	NE [NE, NE)	308	24 (7.8)	NE [NE, NE)		1.213 (0.563, 2.613)	0.6205
Metabolism and nutrition disorders										

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-soc-sub.sas
Output: t14-06-001-506-ae-cox-soc-grd345-ge5pct.rtf (Date Generated: 27AUG2020:00:37) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.506. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC <Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	10 (6.5)	NE [NE, NE)	308	43 (14.0)	NE [NE, NE)		1.835 (0.920, 3.657)	0.0800
Musculoskeletal and connective tissue disorders										
Total subjects		153	8 (5.2)	NE [NE, NE)	308	29 (9.4)	NE [NE, NE)		1.462 (0.667, 3.206)	0.3400

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-soc-sub.sas
Output: t14-06-001-506-ae-cox-soc-grd345-ge5pct.rtf (Date Generated: 27AUG2020:00:37) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.506. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)										
Total subjects		153	9 (5.9)	NE [NE, NE)	308	16 (5.2)	NE [NE, NE)		0.703 (0.310, 1.598)	0.3986
Nervous system disorders										

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC <Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	4 (2.6)	NE [NE, NE)	308	21 (6.8)	NE [NE, NE)		2.064 (0.706, 6.029)	0.1759
Psychiatric disorders										
Total subjects		153	5 (3.3)	NE [NE, NE)	308	22 (7.1)	NE [NE, NE)		1.917 (0.724, 5.072)	0.1825

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-soc-sub.sas
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Table 14-6.1.506. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Renal and urinary disorders										
Total subjects		153	14 (9.2)	NE [NE, NE)	308	15 (4.9)	NE [NE, NE)		0.474 (0.228, 0.983)	0.0403
Age - at baseline (years)	<= 75	135	14 (10.4)	NE [NE, NE)	283	12 (4.2)	NE [NE, NE)	0.9894	0.362 (0.167, 0.785)	0.0073

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
SOC Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
	> 75	18	0 (0.0)	NE [NE, NE)	25	3 (12.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.1839
Sex	Male	91	11 (12.1)	NE [NE, NE)	174	10 (5.7)	NE [NE, NE)	0.5714	0.431 (0.183, 1.015)	0.0474
	Female	62	3 (4.8)	NE [NE, NE)	134	5 (3.7)	NE [NE, NE)		0.688 (0.164, 2.887)	0.6076

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
SOC Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	9 (7.4)	NE [NE, NE)	240	15 (6.3)	NE [NE, NE)	0.9999	0.777 (0.340, 1.779)	0.5500
	Asian	20	3 (15.0)	NE [11.5, NE)	46	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0036
	Other or Unknown	11	2 (18.2)	NE [1.1, NE)	22	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0219

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Region	North America	12	0 (0.0)	NE [NE, NE)	21	1 (4.8)	NE [NE, NE)	0.1157	>999.999 (<.001, NE)	0.4795
	Europe	102	8 (7.8)	NE [NE, NE)	203	13 (6.4)	NE [NE, NE)		0.755 (0.313, 1.823)	0.5312
	Asia Pacific	39	6 (15.4)	NE [NE, NE)	84	1 (1.2)	NE [NE, NE)		0.066 (0.008, 0.548)	0.0008

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC <Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Baseline ECOG PS	0-1	146	14 (9.6)	NE [NE, NE)	294	13 (4.4)	NE [NE, NE)	0.9888	0.418 (0.196, 0.890)	0.0195
	2	7	0 (0.0)	NE [NE, NE)	13	2 (15.4)	NE [3.3, NE)		>999.999 (<.001, NE)	0.4070
Prior Bortezomib or Ixazomib exposure	Yes	136	12 (8.8)	NE [NE, NE)	285	14 (4.9)	NE [NE, NE)	0.7022	0.501 (0.231, 1.085)	0.0738

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC <Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	No	17	2 (11.8)	NE [9.5, NE)	23	1 (4.3)	NE [NE, NE)		0.272 (0.024, 3.031)	0.2572
Refractory to Bortezomib or Ixazomib	Yes	55	4 (7.3)	NE [NE, NE)	99	5 (5.1)	NE [NE, NE)	0.6049	0.652 (0.175, 2.432)	0.5214
	No	98	10 (10.2)	NE [NE, NE)	209	10 (4.8)	NE [NE, NE)		0.408 (0.169, 0.981)	0.0385

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC <Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	7 (9.5)	NE [NE, NE)	122	6 (4.9)	NE [NE, NE)	0.8784	0.459 (0.154, 1.369)	0.1522
	No	79	7 (8.9)	NE [NE, NE)	186	9 (4.8)	NE [NE, NE)		0.499 (0.186, 1.343)	0.1611
Refractory to Lenalidomide	Yes	55	6 (10.9)	NE [NE, NE)	98	5 (5.1)	NE [NE, NE)	0.6918	0.402 (0.122, 1.321)	0.1203

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC <Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	No	98	8 (8.2)	NE [NE, NE)	210	10 (4.8)	NE [NE, NE)		0.534 (0.211, 1.354)	0.1797
Prior IMiD exposure	Yes	110	11 (10.0)	NE [NE, NE)	205	9 (4.4)	NE [NE, NE)	0.4006	0.393 (0.163, 0.950)	0.0316
	No	43	3 (7.0)	NE [NE, NE)	103	6 (5.8)	NE [NE, NE)		0.756 (0.189, 3.028)	0.6914

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.506. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
SOC Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Refractory to IMiD	Yes	65	8 (12.3)	NE [NE, NE)	129	6 (4.7)	NE [NE, NE)	0.3252	0.324 (0.112, 0.937)	0.0284
	No	88	6 (6.8)	NE [NE, NE)	179	9 (5.0)	NE [NE, NE)		0.679 (0.241, 1.908)	0.4604
ISS stage per IXRS	1 or 2	126	11 (8.7)	NE [NE, NE)	250	6 (2.4)	NE [NE, NE)	0.0816	0.242 (0.089, 0.656)	0.0025

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.506. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC <Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	3	27	3 (11.1)	NE [NE, NE)	58	9 (15.5)	NE [NE, NE)		1.168 (0.315, 4.327)	0.8158
Prior proteasome inhibitor exposure per IXRS	Yes	138	12 (8.7)	NE [NE, NE)	276	14 (5.1)	NE [NE, NE)	0.4332	0.527 (0.244, 1.142)	0.0988
	No	15	2 (13.3)	NE [9.5, NE)	32	1 (3.1)	NE [NE, NE)		0.191 (0.017, 2.117)	0.1320

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-soc-sub.sas
Output: t14-06-001-506-ae-cox-soc-grd345-ge5pct.rtf (Date Generated: 27AUG2020:00:37) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.506. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
SOC Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	5 (7.6)	NE [NE, NE)	131	5 (3.8)	NE [NE, NE)	0.9213	0.430 (0.124, 1.491)	0.1708
	>= 2	87	9 (10.3)	NE [NE, NE)	177	10 (5.6)	NE [NE, NE)		0.500 (0.203, 1.233)	0.1247
Respiratory, thoracic and mediastinal disorders										

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.506. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC <Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	14 (9.2)	NE [NE, NE)	308	43 (14.0)	NE [NE, NE)		1.389 (0.759, 2.542)	0.2834
Vascular disorders										
Total subjects		153	28 (18.3)	NE [NE, NE)	308	70 (22.7)	NE [30.9, NE)		1.029 (0.663, 1.598)	0.8956

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC and PT
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
SOC PT Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Blood and lymphatic system disorders										
Thrombocytopenia										
Total subjects		153	25 (16.3)	NE [NE, NE)	308	76 (24.7)	NE [NE, NE)		1.570 (0.999, 2.468)	0.0494

Includes PT where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.507. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	 No. of Events (%)	 Median (months) (95%CI)	KdD (N = 308) N	 No. of Events (%)	 Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	 p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	22 (16.3)	NE [NE, NE)	283	71 (25.1)	NE [NE, NE)	0.7282	1.611 (0.998, 2.599)	0.0493
	> 75	18	3 (16.7)	NE [10.9, NE)	25	5 (20.0)	NE [NE, NE)		1.178 (0.281, 4.930)	0.8227
Sex	Male	91	15 (16.5)	NE [NE, NE)	174	42 (24.1)	NE [NE, NE)	0.8947	1.538 (0.852, 2.775)	0.1532

Includes PT where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	 No. of Events (%)	 Median (months) (95%CI)	KdD (N = 308) N	 No. of Events (%)	 Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	 p-value (2-sided)[b]
	Female	62	10 (16.1)	NE [NE, NE)	134	34 (25.4)	NE [NE, NE)		1.612 (0.796, 3.264)	0.1790
Race	White	122	16 (13.1)	NE [NE, NE)	240	48 (20.0)	NE [NE, NE)	0.3962	1.618 (0.919, 2.850)	0.0934
	Asian	20	6 (30.0)	NE [2.1, NE)	46	24 (52.2)	13.8 [0.6, NE)		1.974 (0.806, 4.834)	0.1290

Includes PT where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.507. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	 No. of Events (%)	 Median (months) (95%CI)	KdD (N = 308) N	 No. of Events (%)	 Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	 p-value (2-sided)[b]
	Other or Unknown	11	3 (27.3)	NE [0.8, NE)	22	4 (18.2)	NE [NE, NE)		0.558 (0.124, 2.503)	0.4400
Region	North America	12	3 (25.0)	NE [1.2, NE)	21	6 (28.6)	NE [0.7, NE)	0.7337	1.221 (0.305, 4.889)	0.7891
	Europe	102	14 (13.7)	NE [NE, NE)	203	39 (19.2)	NE [NE, NE)		1.434 (0.778, 2.641)	0.2479

Includes PT where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.507. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	 No. of Events (%)	 Median (months) (95%CI)	KdD (N = 308) N	 No. of Events (%)	 Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	 p-value (2-sided)[b]
	Asia Pacific	39	8 (20.5)	NE [NE, NE)	84	31 (36.9)	NE [24.4, NE)		1.944 (0.893, 4.234)	0.0889
Baseline ECOG PS	0-1	146	23 (15.8)	NE [NE, NE)	294	72 (24.5)	NE [NE, NE)	0.5071	1.629 (1.018, 2.606)	0.0402
	2	7	2 (28.6)	NE [0.4, NE)	13	4 (30.8)	NE [0.4, NE)		1.149 (0.210, 6.290)	0.8597

Includes PT where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.507. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	 No. of Events (%)	 Median (months) (95%CI)	KdD (N = 308) N	 No. of Events (%)	 Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	 p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	24 (17.6)	NE [NE, NE)	285	74 (26.0)	NE [NE, NE)	0.9521	1.537 (0.970, 2.436)	0.0665
	No	17	1 (5.9)	NE [9.5, NE)	23	2 (8.7)	NE [NE, NE)		1.304 (0.118, 14.456)	0.8285
Refractory to Bortezomib or Ixazomib	Yes	55	13 (23.6)	NE [NE, NE)	99	28 (28.3)	NE [NE, NE)	0.3686	1.275 (0.660, 2.462)	0.4789

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CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.507. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	 No. of Events (%)	 Median (months) (95%CI)	KdD (N = 308) N	 No. of Events (%)	 Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	 p-value (2-sided)[b]
	No	98	12 (12.2)	NE [NE, NE)	209	48 (23.0)	NE [NE, NE)		1.927 (1.023, 3.630)	0.0387
Prior Lenalidomide exposure	Yes	74	16 (21.6)	NE [NE, NE)	122	39 (32.0)	NE [NE, NE)	0.8331	1.606 (0.897, 2.876)	0.1117
	No	79	9 (11.4)	NE [NE, NE)	186	37 (19.9)	NE [NE, NE)		1.777 (0.857, 3.683)	0.1168

Includes PT where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
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Table 14-6.1.507. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	 No. of Events (%)	 Median (months) (95%CI)	KdD (N = 308) N	 No. of Events (%)	 Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	 p-value (2-sided)[b]
Refractory to Lenalidomide	Yes	55	11 (20.0)	NE [NE, NE)	98	33 (33.7)	NE [NE, NE)	0.5793	1.869 (0.944, 3.701)	0.0698
	No	98	14 (14.3)	NE [NE, NE)	210	43 (20.5)	NE [NE, NE)		1.446 (0.791, 2.644)	0.2288
Prior IMiD exposure	Yes	110	18 (16.4)	NE [NE, NE)	205	55 (26.8)	NE [NE, NE)	0.5336	1.754 (1.030, 2.987)	0.0371

Includes PT where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
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<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	 No. of Events (%)	 Median (months) (95%CI)	KdD (N = 308) N	 No. of Events (%)	 Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	 p-value (2-sided)[b]
	No	43	7 (16.3)	NE [NE, NE)	103	21 (20.4)	NE [NE, NE)		1.237 (0.525, 2.913)	0.6265
Refractory to IMiD	Yes	65	13 (20.0)	NE [NE, NE)	129	40 (31.0)	NE [NE, NE)	0.7846	1.695 (0.906, 3.171)	0.0965
	No	88	12 (13.6)	NE [NE, NE)	179	36 (20.1)	NE [NE, NE)		1.480 (0.770, 2.846)	0.2365

Includes PT where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
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<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	 No. of Events (%)	 Median (months) (95%CI)	KdD (N = 308) N	 No. of Events (%)	 Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	 p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	17 (13.5)	NE [NE, NE)	250	56 (22.4)	NE [NE, NE)	0.3594	1.736 (1.009, 2.989)	0.0440
	3	27	8 (29.6)	NE [1.2, NE)	58	20 (34.5)	NE [NE, NE)		1.163 (0.512, 2.642)	0.7317
Prior proteasome inhibitor exposure per IXRS	Yes	138	23 (16.7)	NE [NE, NE)	276	71 (25.7)	NE [NE, NE)	0.7316	1.615 (1.009, 2.586)	0.0444

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Table 14-6.1.507. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	 No. of Events (%)	 Median (months) (95%CI)	KdD (N = 308) N	 No. of Events (%)	 Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	 p-value (2-sided)[b]
	No	15	2 (13.3)	NE [9.5, NE)	32	5 (15.6)	NE [NE, NE)		1.128 (0.218, 5.828)	0.8854
Number of prior lines of therapy per IXRS	1	66	8 (12.1)	NE [NE, NE)	131	28 (21.4)	NE [NE, NE)	0.6720	1.793 (0.817, 3.936)	0.1395
	>= 2	87	17 (19.5)	NE [NE, NE)	177	48 (27.1)	NE [NE, NE)		1.478 (0.849, 2.571)	0.1679

Includes PT where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-soc-pt-sub.sas
Output: t14-06-001-507-ae-cox-soc-pt-grd345-ge5pct.rtf (Date Generated: 27AUG2020:00:38) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.507. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	No. of Events (%)	Median (months) (95%CI)	KdD (N = 308) N	No. of Events (%)	Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Anaemia										
Total subjects		153	23 (15.0)	NE [NE, NE)	308	53 (17.2)	NE [NE, NE)		1.100 (0.674, 1.796)	0.7028
Neutropenia										

Includes PT where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	 No. of Events (%)	 Median (months) (95%CI)	KdD (N = 308) N	 No. of Events (%)	 Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	 p-value (2-sided)[b]
Total subjects		153	10 (6.5)	NE [NE, NE)	308	29 (9.4)	NE [NE, NE)		1.271 (0.618, 2.615)	0.5128
Lymphopenia										
Total subjects		153	11 (7.2)	NE [NE, NE)	308	22 (7.1)	NE [NE, NE)		0.960 (0.465, 1.983)	0.9105

Includes PT where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
General disorders and administration site conditions										
Fatigue										
Total subjects		153	7 (4.6)	NE [NE, NE)	308	24 (7.8)	NE [NE, NE)		1.496 (0.644, 3.475)	0.3453

Includes PT where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	No. of Events (%)	Median (months) (95%CI)	KdD (N = 308) N	No. of Events (%)	Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Infections and infestations										
Pneumonia										
Total subjects		153	14 (9.2)	NE [NE, NE)	308	54 (17.5)	NE [NE, NE)		1.549 (0.859, 2.791)	0.1420

Includes PT where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.507. Cox Regression of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC and PT
<Safety Population>

SOC PT Characteristics	Subgroup	Kd (N = 153) N	No. of Events (%)	Median (months) (95%CI)	KdD (N = 308) N	No. of Events (%)	Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Vascular disorders										
Hypertension										
Total subjects		153	23 (15.0)	NE [NE, NE)	308	65 (21.1)	NE [30.9, NE)		1.181 (0.733, 1.902)	0.4940

Includes PT where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant (p <0.05) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Most Frequent Serious Adverse Events by MedDRA SOC
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
SOC Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Blood and lymphatic system disorders										
Total subjects		153	6 (3.9)	NE [NE, NE)	308	17 (5.5)	NE [NE, NE)		1.292 (0.509, 3.281)	0.5895
Cardiac disorders										

Includes SOC where at least 5% subjects with at least one serious adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Most Frequent Serious Adverse Events by MedDRA SOC <Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	12 (7.8)	NE [NE, NE)	308	34 (11.0)	NE [NE, NE)		1.118 (0.578, 2.164)	0.7393
General disorders and administration site conditions										
Total subjects		153	6 (3.9)	NE [NE, NE)	308	27 (8.8)	NE [NE, NE)		1.946 (0.802, 4.724)	0.1338

Includes SOC where at least 5% subjects with at least one serious adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Most Frequent Serious Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Infections and infestations										
Total subjects		153	41 (26.8)	32.9 [32.9, NE)	308	106 (34.4)	NE [28.5, NE)		1.072 (0.746, 1.539)	0.7071
Injury, poisoning and procedural complications										

Includes SOC where at least 5% subjects with at least one serious adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Most Frequent Serious Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	7 (4.6)	NE [NE, NE)	308	17 (5.5)	NE [NE, NE)		0.961 (0.396, 2.332)	0.9306
Renal and urinary disorders										
Total subjects		153	10 (6.5)	NE [NE, NE)	308	10 (3.2)	NE [NE, NE)		0.416 (0.173, 1.004)	0.0443

Includes SOC where at least 5% subjects with at least one serious adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Most Frequent Serious Adverse Events by MedDRA SOC
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
SOC Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	10 (7.4)	NE [NE, NE)	283	9 (3.2)	NE [NE, NE)	0.9918	0.357 (0.144, 0.883)	0.0200
	> 75	18	0 (0.0)	NE [NE, NE)	25	1 (4.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.4096
Sex	Male	91	8 (8.8)	NE [NE, NE)	174	5 (2.9)	NE [NE, NE)	0.1945	0.285 (0.093, 0.875)	0.0194

Includes SOC where at least 5% subjects with at least one serious adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Most Frequent Serious Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Female	62	2 (3.2)	NE [NE, NE)	134	5 (3.7)	NE [NE, NE)		0.947 (0.183, 4.911)	0.9485
Race	White	122	6 (4.9)	NE [NE, NE)	240	9 (3.8)	NE [NE, NE)	0.9333	0.676 (0.240, 1.906)	0.4568
	Asian	20	3 (15.0)	NE [12.0, NE)	46	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0038

Includes SOC where at least 5% subjects with at least one serious adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Most Frequent Serious Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Other or Unknown	11	1 (9.1)	NE [1.1, NE)	22	1 (4.5)	NE [27.2, NE)		0.337 (0.020, 5.559)	0.4259
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE
	Europe	102	6 (5.9)	NE [NE, NE)	203	10 (4.9)	NE [NE, NE)		0.740 (0.269, 2.040)	0.5595

Includes SOC where at least 5% subjects with at least one serious adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Most Frequent Serious Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Asia Pacific	39	4 (10.3)	NE [NE, NE)	84	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0016
Baseline ECOG PS	0-1	146	10 (6.8)	NE [NE, NE)	294	9 (3.1)	NE [NE, NE)	0.9911	0.380 (0.154, 0.939)	0.0296
	2	7	0 (0.0)	NE [NE, NE)	13	1 (7.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.5186

Includes SOC where at least 5% subjects with at least one serious adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-soc-sub.sas
Output: t14-06-001-508-sae-cox-soc-ge5pct.rtf (Date Generated: 27AUG2020:00:37) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.508. Cox Regression of Most Frequent Serious Adverse Events by MedDRA SOC <Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	9 (6.6)	NE [NE, NE)	285	9 (3.2)	NE [NE, NE)	0.8111	0.400 (0.158, 1.011)	0.0452
	No	17	1 (5.9)	NE [9.5, NE)	23	1 (4.3)	NE [NE, NE)		0.608 (0.038, 9.849)	0.7235
Refractory to Bortezomib or Ixazomib	Yes	55	3 (5.5)	NE [NE, NE)	99	3 (3.0)	NE [NE, NE)	0.8248	0.513 (0.103, 2.545)	0.4052

Includes SOC where at least 5% subjects with at least one serious adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Most Frequent Serious Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	No	98	7 (7.1)	NE [NE, NE)	209	7 (3.3)	NE [NE, NE)		0.375 (0.131, 1.076)	0.0581
Prior Lenalidomide exposure	Yes	74	4 (5.4)	NE [NE, NE)	122	4 (3.3)	NE [NE, NE)	0.7623	0.443 (0.108, 1.805)	0.2435
	No	79	6 (7.6)	NE [NE, NE)	186	6 (3.2)	NE [NE, NE)		0.384 (0.123, 1.192)	0.0856

Includes SOC where at least 5% subjects with at least one serious adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Most Frequent Serious Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Refractory to Lenalidomide	Yes	55	4 (7.3)	NE [NE, NE)	98	3 (3.1)	NE [NE, NE)	0.6868	0.316 (0.069, 1.449)	0.1186
	No	98	6 (6.1)	NE [NE, NE)	210	7 (3.3)	NE [NE, NE)		0.476 (0.159, 1.420)	0.1738
Prior IMiD exposure	Yes	110	7 (6.4)	NE [NE, NE)	205	7 (3.4)	NE [NE, NE)	0.8461	0.428 (0.149, 1.231)	0.1053

Includes SOC where at least 5% subjects with at least one serious adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.508. Cox Regression of Most Frequent Serious Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	No	43	3 (7.0)	NE [NE, NE)	103	3 (2.9)	NE [NE, NE)		0.386 (0.078, 1.917)	0.2269
Refractory to IMiD	Yes	65	6 (9.2)	NE [NE, NE)	129	3 (2.3)	NE [NE, NE)	0.1576	0.188 (0.046, 0.770)	0.0097
	No	88	4 (4.5)	NE [NE, NE)	179	7 (3.9)	NE [NE, NE)		0.756 (0.221, 2.593)	0.6570

Includes SOC where at least 5% subjects with at least one serious adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-soc-sub.sas
Output: t14-06-001-508-sae-cox-soc-ge5pct.rtf (Date Generated: 27AUG2020:00:37) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.508. Cox Regression of Most Frequent Serious Adverse Events by MedDRA SOC <Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	7 (5.6)	NE [NE, NE)	250	6 (2.4)	NE [NE, NE)	0.8815	0.371 (0.124, 1.110)	0.0653
	3	27	3 (11.1)	NE [NE, NE)	58	4 (6.9)	NE [NE, NE)		0.445 (0.098, 2.011)	0.2800
Prior proteasome inhibitor exposure per IXRS	Yes	138	9 (6.5)	NE [NE, NE)	276	9 (3.3)	NE [NE, NE)	0.9358	0.419 (0.165, 1.060)	0.0584

Includes SOC where at least 5% subjects with at least one serious adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Output: t14-06-001-508-sae-cox-soc-ge5pct.rtf (Date Generated: 27AUG2020:00:37) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.508. Cox Regression of Most Frequent Serious Adverse Events by MedDRA SOC
<Safety Population>

SOC Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	No	15	1 (6.7)	NE [9.5, NE)	32	1 (3.1)	NE [NE, NE)		0.411 (0.026, 6.609)	0.5167
Number of prior lines of therapy per IXRS	1	66	4 (6.1)	NE [NE, NE)	131	4 (3.1)	NE [NE, NE)	0.9797	0.393 (0.097, 1.583)	0.1732
	>= 2	87	6 (6.9)	NE [NE, NE)	177	6 (3.4)	NE [NE, NE)		0.429 (0.137, 1.336)	0.1325

Includes SOC where at least 5% subjects with at least one serious adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Output: t14-06-001-508-sae-cox-soc-ge5pct.rtf (Date Generated: 27AUG2020:00:37) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.508. Cox Regression of Most Frequent Serious Adverse Events by MedDRA SOC
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
SOC Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Respiratory, thoracic and mediastinal disorders										
Total subjects		153	16 (10.5)	NE [NE, NE)	308	36 (11.7)	NE [NE, NE)		0.992 (0.549, 1.790)	0.9780

Includes SOC where at least 5% subjects with at least one serious adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-soc-sub.sas
Output: t14-06-001-508-sae-cox-soc-ge5pct.rtf (Date Generated: 27AUG2020:00:37) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.509. Cox Regression of Most Frequent Serious Adverse Events by MedDRA SOC and PT
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
SOC PT Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Infections and infestations										
Pneumonia										
Total subjects		153	15 (9.8)	NE [NE, NE)	308	49 (15.9)	NE [NE, NE)		1.331 (0.746, 2.378)	0.3313

Includes PT where at least 5% subjects with at least one serious adverse event in one treatment arm. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
Subgroup analyses are provided only if the respective SOC or SOC/PT event is statistically significant ($p < 0.05$) for the total population.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-soc-pt-sub.sas
Output: t14-06-001-509-sae-cox-soc-pt-ge5pct.rtf (Date Generated: 27AUG2020:00:38) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Acute renal failure (SMQ) - Narrow										
Total subjects		153	13 (8.5)	NE [NE, NE)	308	23 (7.5)	NE [NE, NE)		0.744 (0.376, 1.474)	0.3951

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-510-ae-cox-eoi-cfz.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	13 (9.6)	NE [NE, NE)	283	19 (6.7)	NE [NE, NE)	0.9880	0.583 (0.287, 1.185)	0.1317
	> 75	18	0 (0.0)	NE [NE, NE)	25	4 (16.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.0990
Sex	Male	91	11 (12.1)	NE [NE, NE)	174	12 (6.9)	NE [NE, NE)	0.0719	0.470 (0.206, 1.071)	0.0662
	Female	62	2 (3.2)	NE [NE, NE)	134	11 (8.2)	NE [NE, NE)		2.275 (0.503, 10.287)	0.2724

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	7 (5.7)	NE [NE, NE)	240	19 (7.9)	NE [NE, NE)	0.1087	1.208 (0.506, 2.882)	0.6707
	Asian	20	4 (20.0)	NE [11.5, NE)	46	2 (4.3)	NE [NE, NE)		0.182 (0.033, 1.000)	0.0278
	Other or Unknown	11	2 (18.2)	NE [0.5, NE)	22	2 (9.1)	NE [27.2, NE)		0.353 (0.049, 2.538)	0.2799
Region	North America	12	0 (0.0)	NE [NE, NE)	21	1 (4.8)	NE [NE, NE)	0.1268	>999.999 (<.001, NE)	0.4497

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	7 (6.9)	NE [NE, NE)	203	18 (8.9)	NE [NE, NE)		1.156 (0.482, 2.771)	0.7443
	Asia Pacific	39	6 (15.4)	NE [NE, NE)	84	4 (4.8)	NE [NE, NE)		0.237 (0.065, 0.861)	0.0179
Baseline ECOG PS	0-1	146	13 (8.9)	NE [NE, NE)	294	21 (7.1)	NE [NE, NE)	0.9870	0.686 (0.342, 1.374)	0.2844
	2	7	0 (0.0)	NE [NE, NE)	13	2 (15.4)	NE [1.6, NE)		>999.999 (<.001, NE)	0.3507

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-510-ae-cox-eoi-cfz.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	10 (7.4)	NE [NE, NE)	285	20 (7.0)	NE [NE, NE)	0.6958	0.821 (0.383, 1.760)	0.6120
	No	17	3 (17.6)	NE [9.5, NE)	23	3 (13.0)	NE [NE, NE)		0.548 (0.109, 2.749)	0.4582
Refractory to Bortezomib or Ixazomib	Yes	55	4 (7.3)	NE [NE, NE)	99	6 (6.1)	NE [NE, NE)	0.9838	0.780 (0.220, 2.766)	0.6998
	No	98	9 (9.2)	NE [NE, NE)	209	17 (8.1)	NE [NE, NE)		0.713 (0.316, 1.606)	0.4114

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	6 (8.1)	NE [NE, NE)	122	11 (9.0)	NE [NE, NE)	0.6316	0.943 (0.346, 2.571)	0.9083
	No	79	7 (8.9)	NE [NE, NE)	186	12 (6.5)	NE [NE, NE)		0.639 (0.251, 1.625)	0.3433
Refractory to Lenalidomide	Yes	55	5 (9.1)	NE [NE, NE)	98	8 (8.2)	NE [NE, NE)	0.8784	0.729 (0.236, 2.257)	0.5824
	No	98	8 (8.2)	NE [NE, NE)	210	15 (7.1)	NE [NE, NE)		0.768 (0.325, 1.816)	0.5470

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	11 (10.0)	NE [NE, NE)	205	17 (8.3)	NE [NE, NE)	0.5845	0.697 (0.325, 1.497)	0.3525
	No	43	2 (4.7)	NE [NE, NE)	103	6 (5.8)	NE [NE, NE)		1.122 (0.226, 5.574)	0.8877
Refractory to IMiD	Yes	65	8 (12.3)	NE [NE, NE)	129	10 (7.8)	NE [NE, NE)	0.2371	0.529 (0.207, 1.353)	0.1767
	No	88	5 (5.7)	NE [NE, NE)	179	13 (7.3)	NE [NE, NE)		1.110 (0.395, 3.119)	0.8432

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	10 (7.9)	NE [NE, NE)	250	15 (6.0)	NE [NE, NE)	0.6626	0.634 (0.283, 1.417)	0.2628
	3	27	3 (11.1)	NE [NE, NE)	58	8 (13.8)	NE [NE, NE)		1.004 (0.265, 3.808)	0.9950
Prior proteasome inhibitor exposure per IXRS	Yes	138	10 (7.2)	NE [NE, NE)	276	20 (7.2)	NE [NE, NE)	0.3446	0.864 (0.403, 1.852)	0.7065
	No	15	3 (20.0)	NE [9.5, NE)	32	3 (9.4)	NE [NE, NE)		0.358 (0.072, 1.787)	0.1915

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	4 (6.1)	NE [NE, NE)	131	7 (5.3)	NE [NE, NE)	0.9827	0.689 (0.201, 2.368)	0.5525
	>= 2	87	9 (10.3)	NE [NE, NE)	177	16 (9.0)	NE [NE, NE)		0.766 (0.337, 1.742)	0.5246

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Cardiac arrhythmias (SMQ) - Narrow										
Total subjects		153	9 (5.9)	NE [NE, NE)	308	22 (7.1)	NE [NE, NE)		1.079 (0.496, 2.347)	0.8479

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	7 (5.2)	NE [NE, NE)	283	18 (6.4)	NE [NE, NE)	0.8179	1.077 (0.449, 2.585)	0.8676
	> 75	18	2 (11.1)	NE [NE, NE)	25	4 (16.0)	NE [NE, NE)		1.327 (0.243, 7.257)	0.7430
Sex	Male	91	6 (6.6)	NE [NE, NE)	174	14 (8.0)	NE [NE, NE)	0.9992	1.091 (0.418, 2.846)	0.8586
	Female	62	3 (4.8)	NE [NE, NE)	134	8 (6.0)	NE [NE, NE)		1.097 (0.290, 4.146)	0.8911

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	8 (6.6)	NE [NE, NE)	240	18 (7.5)	NE [NE, NE)	0.9953	1.010 (0.438, 2.326)	0.9822
	Asian	20	1 (5.0)	NE [NE, NE)	46	3 (6.5)	NE [NE, NE)		1.264 (0.131, 12.171)	0.8392
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	1 (4.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.4795
Region	North America	12	1 (8.3)	NE [NE, NE)	21	4 (19.0)	NE [NE, NE)	0.8659	1.933 (0.212, 17.584)	0.5464

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	6 (5.9)	NE [NE, NE)	203	13 (6.4)	NE [NE, NE)		0.971 (0.369, 2.558)	0.9533
	Asia Pacific	39	2 (5.1)	NE [NE, NE)	84	5 (6.0)	NE [NE, NE)		1.102 (0.213, 5.684)	0.9080
Baseline ECOG PS	0-1	146	9 (6.2)	NE [NE, NE)	294	20 (6.8)	NE [NE, NE)	0.9881	1.011 (0.460, 2.223)	0.9777
	2	7	0 (0.0)	NE [NE, NE)	13	2 (15.4)	NE [18.9, NE)		>999.999 (<.001, NE)	0.6015

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	8 (5.9)	NE [NE, NE)	285	22 (7.7)	NE [NE, NE)	0.9866	1.168 (0.519, 2.628)	0.7063
	No	17	1 (5.9)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.2207
Refractory to Bortezomib or Ixazomib	Yes	55	6 (10.9)	NE [NE, NE)	99	6 (6.1)	NE [NE, NE)	0.0808	0.528 (0.170, 1.639)	0.2611
	No	98	3 (3.1)	NE [NE, NE)	209	16 (7.7)	NE [NE, NE)		2.132 (0.620, 7.333)	0.2187

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	5 (6.8)	NE [NE, NE)	122	9 (7.4)	NE [NE, NE)	0.7101	0.945 (0.315, 2.836)	0.9201
	No	79	4 (5.1)	NE [NE, NE)	186	13 (7.0)	NE [NE, NE)		1.257 (0.410, 3.858)	0.6883
Refractory to Lenalidomide	Yes	55	4 (7.3)	NE [NE, NE)	98	6 (6.1)	NE [NE, NE)	0.4265	0.719 (0.202, 2.562)	0.6096
	No	98	5 (5.1)	NE [NE, NE)	210	16 (7.6)	NE [NE, NE)		1.355 (0.496, 3.702)	0.5508

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	6 (5.5)	NE [NE, NE)	205	13 (6.3)	NE [NE, NE)	0.8859	1.045 (0.396, 2.755)	0.9279
	No	43	3 (7.0)	NE [NE, NE)	103	9 (8.7)	NE [NE, NE)		1.133 (0.306, 4.188)	0.8518
Refractory to IMiD	Yes	65	5 (7.7)	NE [NE, NE)	129	8 (6.2)	NE [NE, NE)	0.2941	0.707 (0.231, 2.170)	0.5430
	No	88	4 (4.5)	NE [NE, NE)	179	14 (7.8)	NE [NE, NE)		1.561 (0.514, 4.745)	0.4276

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Output: t14-06-001-510-ae-cox-eoi-cfz.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	7 (5.6)	NE [NE, NE)	250	16 (6.4)	NE [NE, NE)	0.9626	1.059 (0.435, 2.579)	0.8997
	3	27	2 (7.4)	NE [NE, NE)	58	6 (10.3)	NE [NE, NE)		0.971 (0.195, 4.837)	0.9717
Prior proteasome inhibitor exposure per IXRS	Yes	138	8 (5.8)	NE [NE, NE)	276	22 (8.0)	NE [NE, NE)	0.9897	1.226 (0.545, 2.759)	0.6212
	No	15	1 (6.7)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0986

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	2 (3.0)	NE [NE, NE)	131	12 (9.2)	NE [NE, NE)	0.1018	2.634 (0.588, 11.790)	0.1877
	>= 2	87	7 (8.0)	NE [NE, NE)	177	10 (5.6)	NE [NE, NE)		0.608 (0.230, 1.606)	0.3107

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Cardiac failure (SMQ) - Narrow										
Total subjects		153	17 (11.1)	NE [NE, NE)	308	27 (8.8)	NE [NE, NE)		0.632 (0.343, 1.163)	0.1371

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	10 (7.4)	NE [NE, NE)	283	22 (7.8)	NE [NE, NE)	0.3253	0.797 (0.376, 1.689)	0.5532
	> 75	18	7 (38.9)	NE [3.2, NE)	25	5 (20.0)	NE [NE, NE)		0.479 (0.152, 1.512)	0.1964
Sex	Male	91	11 (12.1)	NE [NE, NE)	174	14 (8.0)	NE [NE, NE)	0.4498	0.544 (0.246, 1.204)	0.1272
	Female	62	6 (9.7)	NE [NE, NE)	134	13 (9.7)	NE [NE, NE)		0.800 (0.303, 2.113)	0.6513

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	14 (11.5)	NE [NE, NE)	240	23 (9.6)	NE [NE, NE)	0.7555	0.681 (0.350, 1.327)	0.2567
	Asian	20	3 (15.0)	NE [NE, NE)	46	3 (6.5)	NE [NE, NE)		0.388 (0.078, 1.942)	0.2325
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	1 (4.5)	NE [29.0, NE)		NE (NE, NE)	NE
Region	North America	12	1 (8.3)	NE [11.5, NE)	21	2 (9.5)	NE [NE, NE)	0.5616	0.926 (0.083, 10.274)	0.9497

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	11 (10.8)	NE [NE, NE)	203	20 (9.9)	NE [NE, NE)		0.762 (0.364, 1.591)	0.4680
	Asia Pacific	39	5 (12.8)	NE [NE, NE)	84	5 (6.0)	NE [NE, NE)		0.383 (0.110, 1.336)	0.1185
Baseline ECOG PS	0-1	146	17 (11.6)	NE [NE, NE)	294	25 (8.5)	NE [NE, NE)	0.9881	0.596 (0.321, 1.107)	0.0981
	2	7	0 (0.0)	NE [NE, NE)	13	2 (15.4)	NE [7.0, NE)		>999.999 (<.001, NE)	0.5186

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	14 (10.3)	NE [NE, NE)	285	23 (8.1)	NE [NE, NE)	0.8091	0.620 (0.318, 1.209)	0.1569
	No	17	3 (17.6)	NE [7.3, NE)	23	4 (17.4)	NE [NE, NE)		0.851 (0.189, 3.829)	0.8332
Refractory to Bortezomib or Ixazomib	Yes	55	6 (10.9)	NE [27.4, NE)	99	7 (7.1)	NE [NE, NE)	0.7268	0.513 (0.171, 1.545)	0.2274
	No	98	11 (11.2)	NE [NE, NE)	209	20 (9.6)	NE [NE, NE)		0.682 (0.326, 1.429)	0.3085

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	8 (10.8)	NE [NE, NE)	122	8 (6.6)	NE [NE, NE)	0.4362	0.514 (0.192, 1.377)	0.1782
	No	79	9 (11.4)	NE [NE, NE)	186	19 (10.2)	NE [NE, NE)		0.744 (0.336, 1.647)	0.4642
Refractory to Lenalidomide	Yes	55	5 (9.1)	NE [NE, NE)	98	5 (5.1)	NE [NE, NE)	0.4073	0.500 (0.144, 1.730)	0.2642
	No	98	12 (12.2)	NE [NE, NE)	210	22 (10.5)	NE [NE, NE)		0.712 (0.352, 1.442)	0.3433

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	10 (9.1)	NE [NE, NE)	205	15 (7.3)	NE [NE, NE)	0.9087	0.660 (0.295, 1.477)	0.3096
	No	43	7 (16.3)	NE [27.4, NE)	103	12 (11.7)	NE [NE, NE)		0.579 (0.227, 1.475)	0.2460
Refractory to IMiD	Yes	65	5 (7.7)	NE [NE, NE)	129	8 (6.2)	NE [NE, NE)	0.8685	0.663 (0.215, 2.045)	0.4721
	No	88	12 (13.6)	NE [NE, NE)	179	19 (10.6)	NE [NE, NE)		0.649 (0.314, 1.341)	0.2395

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	13 (10.3)	NE [NE, NE)	250	24 (9.6)	NE [NE, NE)	0.1489	0.760 (0.385, 1.497)	0.4258
	3	27	4 (14.8)	NE [NE, NE)	58	3 (5.2)	NE [NE, NE)		0.252 (0.056, 1.139)	0.0536
Prior proteasome inhibitor exposure per IXRS	Yes	138	14 (10.1)	NE [NE, NE)	276	22 (8.0)	NE [NE, NE)	0.9692	0.618 (0.315, 1.212)	0.1576
	No	15	3 (20.0)	NE [3.5, NE)	32	5 (15.6)	NE [NE, NE)		0.680 (0.162, 2.855)	0.5963

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	10 (15.2)	NE [NE, NE)	131	10 (7.6)	NE [NE, NE)	0.1740	0.382 (0.158, 0.926)	0.0271
	>= 2	87	7 (8.0)	NE [NE, NE)	177	17 (9.6)	NE [NE, NE)		0.981 (0.405, 2.375)	0.9681

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Cardiomyopathy (SMQ) - Narrow										
Total subjects		153	4 (2.6)	NE [NE, NE)	308	4 (1.3)	NE [NE, NE)		0.391 (0.097, 1.571)	0.1701

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	2 (1.5)	NE [NE, NE)	283	4 (1.4)	NE [NE, NE)	0.9922	0.732 (0.133, 4.022)	0.7185
	> 75	18	2 (11.1)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0550
Sex	Male	91	3 (3.3)	NE [NE, NE)	174	4 (2.3)	NE [NE, NE)	0.9944	0.532 (0.118, 2.400)	0.4045
	Female	62	1 (1.6)	NE [NE, NE)	134	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.1080

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-510-ae-cox-eoi-cfz.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	4 (3.3)	NE [NE, NE)	240	3 (1.3)	NE [NE, NE)	1.0000	0.300 (0.067, 1.345)	0.0952
	Asian	20	0 (0.0)	NE [NE, NE)	46	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	1 (4.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.5465
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	0.6856	NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	2 (2.0)	NE [NE, NE)	203	3 (1.5)	NE [NE, NE)		0.646 (0.108, 3.869)	0.6298
	Asia Pacific	39	2 (5.1)	NE [NE, NE)	84	1 (1.2)	NE [NE, NE)		0.167 (0.015, 1.853)	0.0975
Baseline ECOG PS	0-1	146	4 (2.7)	NE [NE, NE)	294	4 (1.4)	NE [NE, NE)	0.9999	0.404 (0.101, 1.620)	0.1855
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	3 (2.2)	NE [NE, NE)	285	3 (1.1)	NE [NE, NE)	0.8621	0.377 (0.076, 1.879)	0.2157
	No	17	1 (5.9)	NE [NE, NE)	23	1 (4.3)	NE [NE, NE)		0.504 (0.031, 8.101)	0.6220
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	1 (1.0)	NE [NE, NE)	0.9925	>999.999 (<.001, NE)	0.4715
	No	98	4 (4.1)	NE [NE, NE)	209	3 (1.4)	NE [NE, NE)		0.268 (0.060, 1.202)	0.0650

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	2 (2.7)	NE [NE, NE)	122	1 (0.8)	NE [NE, NE)	0.5551	0.252 (0.023, 2.785)	0.2245
	No	79	2 (2.5)	NE [NE, NE)	186	3 (1.6)	NE [NE, NE)		0.526 (0.088, 3.153)	0.4741
Refractory to Lenalidomide	Yes	55	2 (3.6)	NE [NE, NE)	98	1 (1.0)	NE [NE, NE)	0.4694	0.238 (0.022, 2.628)	0.2027
	No	98	2 (2.0)	NE [NE, NE)	210	3 (1.4)	NE [NE, NE)		0.575 (0.096, 3.446)	0.5396

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	2 (1.8)	NE [NE, NE)	205	4 (2.0)	NE [NE, NE)	0.9918	0.813 (0.148, 4.470)	0.8111
	No	43	2 (4.7)	NE [NE, NE)	103	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0182
Refractory to IMiD	Yes	65	2 (3.1)	NE [NE, NE)	129	1 (0.8)	NE [NE, NE)	0.4069	0.210 (0.019, 2.316)	0.1592
	No	88	2 (2.3)	NE [NE, NE)	179	3 (1.7)	NE [NE, NE)		0.613 (0.102, 3.672)	0.5883

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	4 (3.2)	NE [NE, NE)	250	3 (1.2)	NE [NE, NE)	0.9949	0.304 (0.068, 1.368)	0.1004
	3	27	0 (0.0)	NE [NE, NE)	58	1 (1.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.5590
Prior proteasome inhibitor exposure per IXRS	Yes	138	3 (2.2)	NE [NE, NE)	276	2 (0.7)	NE [NE, NE)	0.5472	0.254 (0.042, 1.535)	0.1077
	No	15	1 (6.7)	NE [3.5, NE)	32	2 (6.3)	NE [NE, NE)		0.684 (0.062, 7.541)	0.7550

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	1 (1.5)	NE [NE, NE)	131	2 (1.5)	NE [NE, NE)	0.4551	0.815 (0.073, 9.042)	0.8675
	>= 2	87	3 (3.4)	NE [NE, NE)	177	2 (1.1)	NE [NE, NE)		0.264 (0.044, 1.580)	0.1167

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Dyspnoeas (HLT)										
Total subjects		153	39 (25.5)	NE [NE, NE)	308	73 (23.7)	NE [NE, NE)		0.837 (0.567, 1.236)	0.3692

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	30 (22.2)	NE [NE, NE)	283	69 (24.4)	NE [NE, NE)	0.0323	1.006 (0.655, 1.545)	0.9797
	> 75	18	9 (50.0)	24.5 [2.3, NE)	25	4 (16.0)	NE [NE, NE)		0.243 (0.075, 0.795)	0.0112
Sex	Male	91	25 (27.5)	NE [24.5, NE)	174	38 (21.8)	NE [NE, NE)	0.3442	0.724 (0.436, 1.201)	0.2081
	Female	62	14 (22.6)	NE [NE, NE)	134	35 (26.1)	NE [NE, NE)		1.054 (0.567, 1.960)	0.8652

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	30 (24.6)	NE [NE, NE)	240	56 (23.3)	NE [NE, NE)	0.9414	0.851 (0.546, 1.327)	0.4741
	Asian	20	5 (25.0)	NE [11.0, NE)	46	9 (19.6)	NE [NE, NE)		0.699 (0.234, 2.092)	0.5241
	Other or Unknown	11	4 (36.4)	14.3 [0.9, NE)	22	8 (36.4)	NE [1.8, NE)		0.926 (0.278, 3.082)	0.9005
Region	North America	12	6 (50.0)	10.8 [0.5, NE)	21	12 (57.1)	7.9 [1.8, NE)	0.5409	1.032 (0.387, 2.757)	0.9601

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	17 (16.7)	NE [NE, NE)	203	36 (17.7)	NE [NE, NE)		0.972 (0.545, 1.732)	0.9209
	Asia Pacific	39	16 (41.0)	24.5 [6.4, NE)	84	25 (29.8)	NE [NE, NE)		0.629 (0.335, 1.181)	0.1455
Baseline ECOG PS	0-1	146	37 (25.3)	NE [NE, NE)	294	69 (23.5)	NE [NE, NE)	0.4018	0.852 (0.571, 1.271)	0.4303
	2	7	2 (28.6)	NE [0.0, NE)	13	3 (23.1)	NE [1.3, NE)		0.442 (0.062, 3.153)	0.4205

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	36 (26.5)	NE [NE, NE)	285	68 (23.9)	NE [NE, NE)	0.6952	0.815 (0.544, 1.222)	0.3208
	No	17	3 (17.6)	NE [5.1, NE)	23	5 (21.7)	NE [13.8, NE)		0.941 (0.224, 3.958)	0.9343
Refractory to Bortezomib or Ixazomib	Yes	55	6 (10.9)	NE [NE, NE)	99	19 (19.2)	NE [NE, NE)	0.0781	1.619 (0.646, 4.058)	0.2986
	No	98	33 (33.7)	NE [15.8, NE)	209	54 (25.8)	NE [NE, NE)		0.673 (0.436, 1.039)	0.0709

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-510-ae-cox-eoi-cfz.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	17 (23.0)	NE [NE, NE)	122	29 (23.8)	NE [NE, NE)	0.6433	0.951 (0.522, 1.732)	0.8701
	No	79	22 (27.8)	NE [24.5, NE)	186	44 (23.7)	NE [NE, NE)		0.767 (0.459, 1.281)	0.3081
Refractory to Lenalidomide	Yes	55	12 (21.8)	NE [14.3, NE)	98	23 (23.5)	NE [NE, NE)	0.7348	0.934 (0.464, 1.882)	0.8478
	No	98	27 (27.6)	NE [24.5, NE)	210	50 (23.8)	NE [NE, NE)		0.796 (0.498, 1.273)	0.3389

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	27 (24.5)	NE [NE, NE)	205	55 (26.8)	NE [NE, NE)	0.2306	0.991 (0.625, 1.571)	0.9679
	No	43	12 (27.9)	NE [24.5, NE)	103	18 (17.5)	NE [NE, NE)		0.572 (0.275, 1.191)	0.1298
Refractory to IMiD	Yes	65	14 (21.5)	NE [14.3, NE)	129	35 (27.1)	NE [NE, NE)	0.2278	1.129 (0.606, 2.101)	0.7016
	No	88	25 (28.4)	NE [24.5, NE)	179	38 (21.2)	NE [NE, NE)		0.680 (0.410, 1.127)	0.1310

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	35 (27.8)	NE [NE, NE)	250	63 (25.2)	NE [NE, NE)	0.9155	0.837 (0.553, 1.266)	0.3966
	3	27	4 (14.8)	NE [NE, NE)	58	10 (17.2)	NE [NE, NE)		0.910 (0.283, 2.920)	0.8774
Prior proteasome inhibitor exposure per IXRS	Yes	138	36 (26.1)	NE [NE, NE)	276	64 (23.2)	NE [NE, NE)	0.4395	0.797 (0.529, 1.200)	0.2754
	No	15	3 (20.0)	NE [3.3, NE)	32	9 (28.1)	NE [13.8, NE)		1.315 (0.355, 4.866)	0.6859

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	17 (25.8)	NE [NE, NE)	131	36 (27.5)	NE [NE, NE)	0.4903	0.972 (0.545, 1.732)	0.9216
	>= 2	87	22 (25.3)	NE [24.5, NE)	177	37 (20.9)	NE [NE, NE)		0.739 (0.435, 1.254)	0.2601

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Embolic and thrombotic events, venous (SMQ) - Narrow										
Total subjects		153	17 (11.1)	NE [NE, NE)	308	22 (7.1)	NE [NE, NE)		0.500 (0.265, 0.944)	0.0293

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	16 (11.9)	NE [NE, NE)	283	19 (6.7)	NE [NE, NE)	0.2521	0.439 (0.225, 0.857)	0.0132
	> 75	18	1 (5.6)	NE [NE, NE)	25	3 (12.0)	NE [NE, NE)		1.830 (0.190, 17.630)	0.5956
Sex	Male	91	10 (11.0)	NE [NE, NE)	174	14 (8.0)	NE [NE, NE)	0.5741	0.600 (0.266, 1.355)	0.2149
	Female	62	7 (11.3)	NE [NE, NE)	134	8 (6.0)	NE [NE, NE)		0.390 (0.141, 1.082)	0.0609

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CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	16 (13.1)	NE [NE, NE)	240	19 (7.9)	NE [NE, NE)	0.9769	0.472 (0.242, 0.921)	0.0244
	Asian	20	1 (5.0)	NE [NE, NE)	46	1 (2.2)	NE [NE, NE)		0.222 (0.012, 3.990)	0.2704
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	2 (9.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.4038
Region	North America	12	2 (16.7)	NE [3.8, NE)	21	2 (9.5)	NE [NE, NE)	0.8352	0.220 (0.026, 1.876)	0.1403

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CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
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[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	10 (9.8)	NE [NE, NE)	203	14 (6.9)	NE [NE, NE)		0.568 (0.252, 1.280)	0.1672
	Asia Pacific	39	5 (12.8)	NE [NE, NE)	84	6 (7.1)	NE [NE, NE)		0.404 (0.121, 1.352)	0.1290
Baseline ECOG PS	0-1	146	17 (11.6)	NE [NE, NE)	294	21 (7.1)	NE [NE, NE)	0.9901	0.491 (0.258, 0.933)	0.0267
	2	7	0 (0.0)	NE [NE, NE)	13	1 (7.7)	NE [6.2, NE)		>999.999 (<.001, NE)	0.7389

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	15 (11.0)	NE [NE, NE)	285	21 (7.4)	NE [NE, NE)	0.5336	0.526 (0.271, 1.023)	0.0545
	No	17	2 (11.8)	NE [NE, NE)	23	1 (4.3)	NE [NE, NE)		0.235 (0.020, 2.721)	0.2113
Refractory to Bortezomib or Ixazomib	Yes	55	5 (9.1)	NE [NE, NE)	99	3 (3.0)	NE [NE, NE)	0.3495	0.249 (0.059, 1.049)	0.0407
	No	98	12 (12.2)	NE [NE, NE)	209	19 (9.1)	NE [NE, NE)		0.586 (0.284, 1.211)	0.1449

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	6 (8.1)	NE [NE, NE)	122	8 (6.6)	NE [NE, NE)	0.6188	0.579 (0.199, 1.681)	0.3089
	No	79	11 (13.9)	NE [NE, NE)	186	14 (7.5)	NE [NE, NE)		0.443 (0.201, 0.978)	0.0384
Refractory to Lenalidomide	Yes	55	4 (7.3)	NE [NE, NE)	98	6 (6.1)	NE [NE, NE)	0.7406	0.567 (0.157, 2.048)	0.3809
	No	98	13 (13.3)	NE [NE, NE)	210	16 (7.6)	NE [NE, NE)		0.473 (0.227, 0.985)	0.0408

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	11 (10.0)	NE [NE, NE)	205	13 (6.3)	NE [NE, NE)	0.9534	0.489 (0.218, 1.093)	0.0753
	No	43	6 (14.0)	NE [NE, NE)	103	9 (8.7)	NE [NE, NE)		0.502 (0.178, 1.418)	0.1848
Refractory to IMiD	Yes	65	5 (7.7)	NE [NE, NE)	129	8 (6.2)	NE [NE, NE)	0.7392	0.543 (0.175, 1.683)	0.2831
	No	88	12 (13.6)	NE [NE, NE)	179	14 (7.8)	NE [NE, NE)		0.475 (0.219, 1.029)	0.0536

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	15 (11.9)	NE [NE, NE)	250	20 (8.0)	NE [NE, NE)	0.5316	0.550 (0.281, 1.077)	0.0770
	3	27	2 (7.4)	NE [NE, NE)	58	2 (3.4)	NE [NE, NE)		0.231 (0.032, 1.674)	0.1148
Prior proteasome inhibitor exposure per IXRS	Yes	138	15 (10.9)	NE [NE, NE)	276	21 (7.6)	NE [NE, NE)	0.3141	0.547 (0.281, 1.064)	0.0717
	No	15	2 (13.3)	NE [3.9, NE)	32	1 (3.1)	NE [NE, NE)		0.177 (0.016, 1.970)	0.1127

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-510-ae-cox-eoi-cfz.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	10 (15.2)	NE [NE, NE)	131	10 (7.6)	NE [NE, NE)	0.4218	0.403 (0.167, 0.971)	0.0361
	>= 2	87	7 (8.0)	NE [NE, NE)	177	12 (6.8)	NE [NE, NE)		0.643 (0.252, 1.639)	0.3509

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Haematopoietic erythropenia (SMQ) - Broad										
Total subjects		153	51 (33.3)	NE [NE, NE)	308	110 (35.7)	NE [NE, NE)		1.045 (0.749, 1.457)	0.8012

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	43 (31.9)	NE [NE, NE)	283	100 (35.3)	NE [NE, NE)	0.5757	1.094 (0.765, 1.565)	0.6284
	> 75	18	8 (44.4)	11.9 [1.2, NE)	25	10 (40.0)	NE [2.8, NE)		0.798 (0.314, 2.024)	0.6379
Sex	Male	91	31 (34.1)	NE [17.5, NE)	174	54 (31.0)	NE [NE, NE)	0.1884	0.844 (0.542, 1.314)	0.4475
	Female	62	20 (32.3)	NE [10.2, NE)	134	56 (41.8)	NE [6.5, NE)		1.354 (0.812, 2.257)	0.2453

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	40 (32.8)	NE [17.5, NE)	240	80 (33.3)	NE [NE, NE)	0.3419	0.997 (0.682, 1.458)	0.9804
	Asian	20	7 (35.0)	NE [2.3, NE)	46	24 (52.2)	15.3 [1.7, NE)		1.658 (0.714, 3.852)	0.2339
	Other or Unknown	11	4 (36.4)	NE [0.8, NE)	22	6 (27.3)	NE [18.5, NE)		0.498 (0.139, 1.788)	0.2759
Region	North America	12	6 (50.0)	8.3 [1.4, NE)	21	8 (38.1)	NE [3.7, NE)	0.6328	0.610 (0.210, 1.772)	0.3593

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	31 (30.4)	NE [NE, NE)	203	67 (33.0)	NE [NE, NE)		1.067 (0.697, 1.634)	0.7740
	Asia Pacific	39	14 (35.9)	NE [11.9, NE)	84	35 (41.7)	NE [9.3, NE)		1.187 (0.638, 2.209)	0.5879
Baseline ECOG PS	0-1	146	48 (32.9)	NE [NE, NE)	294	105 (35.7)	NE [NE, NE)	0.2787	1.079 (0.766, 1.518)	0.6685
	2	7	3 (42.9)	NE [0.3, NE)	13	5 (38.5)	NE [0.5, NE)		0.617 (0.136, 2.793)	0.5274

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	43 (31.6)	NE [NE, NE)	285	105 (36.8)	NE [NE, NE)	0.0681	1.153 (0.808, 1.645)	0.4353
	No	17	8 (47.1)	17.3 [1.4, NE)	23	5 (21.7)	NE [NE, NE)		0.375 (0.122, 1.160)	0.0770
Refractory to Bortezomib or Ixazomib	Yes	55	18 (32.7)	NE [11.6, NE)	99	41 (41.4)	NE [16.6, NE)	0.3021	1.317 (0.756, 2.293)	0.3329
	No	98	33 (33.7)	NE [17.3, NE)	209	69 (33.0)	NE [NE, NE)		0.924 (0.610, 1.400)	0.7056

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	31 (41.9)	NE [4.6, NE)	122	56 (45.9)	22.9 [6.7, NE)	0.9386	1.102 (0.710, 1.711)	0.6704
	No	79	20 (25.3)	NE [NE, NE)	186	54 (29.0)	NE [NE, NE)		1.118 (0.669, 1.869)	0.6717
Refractory to Lenalidomide	Yes	55	22 (40.0)	NE [3.7, NE)	98	45 (45.9)	22.9 [3.9, NE)	0.7137	1.150 (0.689, 1.918)	0.5977
	No	98	29 (29.6)	NE [NE, NE)	210	65 (31.0)	NE [NE, NE)		1.015 (0.655, 1.572)	0.9482

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	39 (35.5)	NE [17.3, NE)	205	77 (37.6)	NE [NE, NE)	0.9056	1.063 (0.723, 1.563)	0.7619
	No	43	12 (27.9)	NE [17.5, NE)	103	33 (32.0)	NE [25.3, NE)		1.085 (0.560, 2.103)	0.8128
Refractory to IMiD	Yes	65	24 (36.9)	NE [4.7, NE)	129	55 (42.6)	NE [11.5, NE)	0.5750	1.174 (0.725, 1.900)	0.5183
	No	88	27 (30.7)	NE [NE, NE)	179	55 (30.7)	NE [NE, NE)		0.956 (0.603, 1.516)	0.8499

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	38 (30.2)	NE [NE, NE)	250	86 (34.4)	NE [NE, NE)	0.1083	1.154 (0.788, 1.692)	0.4631
	3	27	13 (48.1)	2.1 [0.7, NE)	58	24 (41.4)	NE [4.2, NE)		0.666 (0.338, 1.313)	0.2321
Prior proteasome inhibitor exposure per IXRS	Yes	138	44 (31.9)	NE [NE, NE)	276	105 (38.0)	NE [25.3, NE)	0.0177	1.185 (0.833, 1.686)	0.3468
	No	15	7 (46.7)	17.3 [1.4, NE)	32	5 (15.6)	NE [NE, NE)		0.285 (0.090, 0.902)	0.0229

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	19 (28.8)	NE [NE, NE)	131	46 (35.1)	NE [25.3, NE)	0.4489	1.218 (0.713, 2.081)	0.4709
	>= 2	87	32 (36.8)	NE [10.2, NE)	177	64 (36.2)	NE [NE, NE)		0.950 (0.621, 1.453)	0.8102

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Haematopoietic leukopenia (SMQ) - Narrow										
Total subjects		153	27 (17.6)	NE [NE, NE)	308	75 (24.4)	NE [NE, NE)		1.305 (0.840, 2.028)	0.2355

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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<Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	20 (14.8)	NE [NE, NE)	283	69 (24.4)	NE [NE, NE)	0.0680	1.583 (0.961, 2.606)	0.0687
	> 75	18	7 (38.9)	12.1 [6.5, NE)	25	6 (24.0)	NE [NE, NE)		0.525 (0.176, 1.571)	0.2408
Sex	Male	91	16 (17.6)	NE [NE, NE)	174	39 (22.4)	NE [NE, NE)	0.5652	1.148 (0.640, 2.059)	0.6433
	Female	62	11 (17.7)	NE [NE, NE)	134	36 (26.9)	NE [NE, NE)		1.527 (0.777, 3.003)	0.2172

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-510-ae-cox-eoi-cfz.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	16 (13.1)	NE [NE, NE)	240	45 (18.8)	NE [NE, NE)	0.9109	1.339 (0.756, 2.373)	0.3145
	Asian	20	10 (50.0)	6.9 [0.3, NE)	46	26 (56.5)	6.4 [0.5, NE)		1.136 (0.547, 2.358)	0.7429
	Other or Unknown	11	1 (9.1)	NE [12.1, NE)	22	4 (18.2)	NE [19.8, NE)		1.449 (0.158, 13.266)	0.7414
Region	North America	12	0 (0.0)	NE [NE, NE)	21	2 (9.5)	NE [NE, NE)	0.9524	>999.999 (<.001, NE)	0.4271

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	15 (14.7)	NE [NE, NE)	203	42 (20.7)	NE [NE, NE)		1.312 (0.727, 2.367)	0.3652
	Asia Pacific	39	12 (30.8)	NE [6.9, NE)	84	31 (36.9)	NE [24.0, NE)		1.187 (0.609, 2.316)	0.6183
Baseline ECOG PS	0-1	146	26 (17.8)	NE [NE, NE)	294	70 (23.8)	NE [NE, NE)	0.6921	1.273 (0.810, 1.999)	0.2942
	2	7	1 (14.3)	NE [0.3, NE)	13	5 (38.5)	NE [1.0, NE)		2.199 (0.256, 18.876)	0.4648

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	24 (17.6)	NE [NE, NE)	285	71 (24.9)	NE [NE, NE)	0.5893	1.336 (0.840, 2.125)	0.2194
	No	17	3 (17.6)	NE [NE, NE)	23	4 (17.4)	NE [NE, NE)		0.844 (0.187, 3.813)	0.8257
Refractory to Bortezomib or Ixazomib	Yes	55	10 (18.2)	NE [NE, NE)	99	27 (27.3)	NE [NE, NE)	0.7651	1.413 (0.683, 2.923)	0.3494
	No	98	17 (17.3)	NE [NE, NE)	209	48 (23.0)	NE [NE, NE)		1.272 (0.730, 2.215)	0.3951

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	12 (16.2)	NE [NE, NE)	122	38 (31.1)	NE [NE, NE)	0.1364	1.898 (0.990, 3.641)	0.0497
	No	79	15 (19.0)	NE [NE, NE)	186	37 (19.9)	NE [NE, NE)		0.955 (0.524, 1.743)	0.8846
Refractory to Lenalidomide	Yes	55	10 (18.2)	NE [NE, NE)	98	30 (30.6)	NE [NE, NE)	0.5202	1.576 (0.766, 3.241)	0.2119
	No	98	17 (17.3)	NE [NE, NE)	210	45 (21.4)	NE [NE, NE)		1.176 (0.672, 2.056)	0.5693

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	18 (16.4)	NE [NE, NE)	205	53 (25.9)	NE [NE, NE)	0.3490	1.506 (0.881, 2.575)	0.1318
	No	43	9 (20.9)	NE [NE, NE)	103	22 (21.4)	NE [NE, NE)		0.939 (0.431, 2.045)	0.8717
Refractory to IMiD	Yes	65	12 (18.5)	NE [NE, NE)	129	36 (27.9)	NE [NE, NE)	0.7652	1.411 (0.731, 2.722)	0.3020
	No	88	15 (17.0)	NE [NE, NE)	179	39 (21.8)	NE [NE, NE)		1.219 (0.671, 2.213)	0.5149

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	24 (19.0)	NE [NE, NE)	250	61 (24.4)	NE [NE, NE)	0.5277	1.224 (0.762, 1.965)	0.4038
	3	27	3 (11.1)	NE [NE, NE)	58	14 (24.1)	NE [NE, NE)		1.905 (0.546, 6.644)	0.3028
Prior proteasome inhibitor exposure per IXRS	Yes	138	25 (18.1)	NE [NE, NE)	276	70 (25.4)	NE [NE, NE)	0.8330	1.320 (0.835, 2.087)	0.2334
	No	15	2 (13.3)	NE [NE, NE)	32	5 (15.6)	NE [NE, NE)		1.083 (0.208, 5.629)	0.9285

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	12 (18.2)	NE [NE, NE)	131	29 (22.1)	NE [NE, NE)	0.5981	1.156 (0.590, 2.268)	0.6735
	>= 2	87	15 (17.2)	NE [NE, NE)	177	46 (26.0)	NE [NE, NE)		1.401 (0.780, 2.517)	0.2579

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Haematopoietic thrombocytopenia (SMQ) - Narrow										
Total subjects		153	46 (30.1)	NE [NE, NE)	308	117 (38.0)	NE [NE, NE)		1.343 (0.954, 1.889)	0.0916

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	41 (30.4)	NE [NE, NE)	283	111 (39.2)	NE [NE, NE)	0.5027	1.375 (0.961, 1.969)	0.0820
	> 75	18	5 (27.8)	NE [6.2, NE)	25	6 (24.0)	NE [NE, NE)		0.870 (0.265, 2.855)	0.8189
Sex	Male	91	28 (30.8)	NE [NE, NE)	174	65 (37.4)	NE [NE, NE)	0.8725	1.316 (0.845, 2.051)	0.2311
	Female	62	18 (29.0)	NE [NE, NE)	134	52 (38.8)	NE [24.4, NE)		1.371 (0.801, 2.345)	0.2475

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	29 (23.8)	NE [NE, NE)	240	82 (34.2)	NE [NE, NE)	0.2942	1.573 (1.029, 2.403)	0.0350
	Asian	20	12 (60.0)	9.5 [0.4, NE)	46	28 (60.9)	1.9 [0.5, NE)		1.087 (0.553, 2.140)	0.8193
	Other or Unknown	11	5 (45.5)	15.2 [0.5, NE)	22	7 (31.8)	NE [1.4, NE)		0.621 (0.196, 1.962)	0.4025
Region	North America	12	4 (33.3)	NE [1.2, NE)	21	11 (52.4)	0.7 [0.5, NE)	0.6570	2.071 (0.657, 6.533)	0.2205

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	26 (25.5)	NE [NE, NE)	203	69 (34.0)	NE [NE, NE)		1.393 (0.887, 2.188)	0.1484
	Asia Pacific	39	16 (41.0)	NE [1.5, NE)	84	37 (44.0)	NE [3.0, NE)		1.131 (0.629, 2.036)	0.6940
Baseline ECOG PS	0-1	146	44 (30.1)	NE [NE, NE)	294	109 (37.1)	NE [NE, NE)	0.5250	1.318 (0.928, 1.871)	0.1237
	2	7	2 (28.6)	NE [0.2, NE)	13	8 (61.5)	11.3 [0.4, NE)		1.901 (0.383, 9.450)	0.4270

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
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[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	42 (30.9)	NE [NE, NE)	285	115 (40.4)	NE [NE, NE)	0.1163	1.399 (0.982, 1.992)	0.0626
	No	17	4 (23.5)	NE [9.5, NE)	23	2 (8.7)	NE [NE, NE)		0.296 (0.053, 1.640)	0.1397
Refractory to Bortezomib or Ixazomib	Yes	55	20 (36.4)	NE [10.9, NE)	99	37 (37.4)	NE [22.2, NE)	0.3157	1.076 (0.624, 1.855)	0.8018
	No	98	26 (26.5)	NE [NE, NE)	209	80 (38.3)	NE [NE, NE)		1.557 (1.000, 2.425)	0.0484

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	26 (35.1)	NE [15.2, NE)	122	59 (48.4)	19.5 [0.8, NE)	0.6248	1.525 (0.961, 2.420)	0.0749
	No	79	20 (25.3)	NE [NE, NE)	186	58 (31.2)	NE [NE, NE)		1.294 (0.778, 2.153)	0.3209
Refractory to Lenalidomide	Yes	55	19 (34.5)	NE [9.5, NE)	98	45 (45.9)	NE [0.8, NE)	0.7246	1.467 (0.858, 2.511)	0.1628
	No	98	27 (27.6)	NE [NE, NE)	210	72 (34.3)	NE [NE, NE)		1.307 (0.840, 2.035)	0.2354

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	35 (31.8)	NE [NE, NE)	205	81 (39.5)	NE [NE, NE)	0.8193	1.329 (0.894, 1.977)	0.1634
	No	43	11 (25.6)	NE [NE, NE)	103	36 (35.0)	NE [NE, NE)		1.459 (0.742, 2.868)	0.2731
Refractory to IMiD	Yes	65	23 (35.4)	NE [9.5, NE)	129	55 (42.6)	NE [2.2, NE)	0.8355	1.303 (0.800, 2.121)	0.2917
	No	88	23 (26.1)	NE [NE, NE)	179	62 (34.6)	NE [NE, NE)		1.400 (0.867, 2.260)	0.1678

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	33 (26.2)	NE [NE, NE)	250	86 (34.4)	NE [NE, NE)	0.5522	1.402 (0.938, 2.095)	0.0993
	3	27	13 (48.1)	1.4 [0.5, NE)	58	31 (53.4)	2.2 [0.5, NE)		1.127 (0.589, 2.155)	0.7278
Prior proteasome inhibitor exposure per IXRS	Yes	138	42 (30.4)	NE [NE, NE)	276	112 (40.6)	NE [NE, NE)	0.2045	1.433 (1.005, 2.044)	0.0464
	No	15	4 (26.7)	NE [9.5, NE)	32	5 (15.6)	NE [NE, NE)		0.523 (0.139, 1.964)	0.3289

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	15 (22.7)	NE [NE, NE)	131	47 (35.9)	NE [NE, NE)	0.2738	1.719 (0.961, 3.077)	0.0653
	>= 2	87	31 (35.6)	NE [13.3, NE)	177	70 (39.5)	NE [24.4, NE)		1.157 (0.758, 1.768)	0.5065

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Haemorrhage terms (excl laboratory terms) (SMQ) - Narrow										
Total subjects		153	19 (12.4)	NE [NE, NE)	308	46 (14.9)	NE [NE, NE)		1.039 (0.608, 1.776)	0.8871

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	15 (11.1)	NE [NE, NE)	283	40 (14.1)	NE [NE, NE)	0.8366	1.112 (0.613, 2.015)	0.7272
	> 75	18	4 (22.2)	NE [7.8, NE)	25	6 (24.0)	NE [11.7, NE)		0.933 (0.263, 3.315)	0.9151
Sex	Male	91	6 (6.6)	NE [NE, NE)	174	24 (13.8)	NE [NE, NE)	0.0817	1.810 (0.738, 4.438)	0.1884
	Female	62	13 (21.0)	NE [NE, NE)	134	22 (16.4)	NE [NE, NE)		0.669 (0.336, 1.330)	0.2483

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	13 (10.7)	NE [NE, NE)	240	36 (15.0)	NE [NE, NE)	0.1411	1.246 (0.660, 2.351)	0.4975
	Asian	20	3 (15.0)	NE [NE, NE)	46	9 (19.6)	NE [NE, NE)		1.148 (0.310, 4.260)	0.8361
	Other or Unknown	11	3 (27.3)	NE [7.2, NE)	22	1 (4.5)	NE [NE, NE)		0.113 (0.012, 1.100)	0.0240
Region	North America	12	4 (33.3)	14.7 [6.9, 14.7)	21	7 (33.3)	NE [11.7, NE)	0.7658	0.658 (0.187, 2.320)	0.5127

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	8 (7.8)	NE [NE, NE)	203	22 (10.8)	NE [NE, NE)		1.224 (0.544, 2.751)	0.6246
	Asia Pacific	39	7 (17.9)	NE [19.8, NE)	84	17 (20.2)	NE [NE, NE)		0.964 (0.398, 2.337)	0.9356
Baseline ECOG PS	0-1	146	19 (13.0)	NE [NE, NE)	294	43 (14.6)	NE [NE, NE)	0.9844	0.991 (0.577, 1.703)	0.9750
	2	7	0 (0.0)	NE [NE, NE)	13	3 (23.1)	NE [8.2, NE)		>999.999 (<.001, NE)	0.4631

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	16 (11.8)	NE [NE, NE)	285	41 (14.4)	NE [NE, NE)	0.9247	1.049 (0.588, 1.871)	0.8716
	No	17	3 (17.6)	NE [19.8, NE)	23	5 (21.7)	NE [15.1, NE)		1.164 (0.276, 4.908)	0.8362
Refractory to Bortezomib or Ixazomib	Yes	55	3 (5.5)	NE [NE, NE)	99	18 (18.2)	NE [NE, NE)	0.0296	3.238 (0.953, 11.002)	0.0464
	No	98	16 (16.3)	NE [NE, NE)	209	28 (13.4)	NE [NE, NE)		0.670 (0.362, 1.240)	0.1995

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	13 (17.6)	NE [19.8, NE)	122	16 (13.1)	NE [NE, NE)	0.0416	0.612 (0.293, 1.279)	0.1874
	No	79	6 (7.6)	NE [NE, NE)	186	30 (16.1)	NE [NE, NE)		1.944 (0.809, 4.673)	0.1302
Refractory to Lenalidomide	Yes	55	9 (16.4)	NE [19.8, NE)	98	15 (15.3)	NE [NE, NE)	0.2558	0.727 (0.315, 1.678)	0.4530
	No	98	10 (10.2)	NE [NE, NE)	210	31 (14.8)	NE [NE, NE)		1.331 (0.652, 2.716)	0.4301

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	16 (14.5)	NE [NE, NE)	205	29 (14.1)	NE [NE, NE)	0.1735	0.840 (0.455, 1.550)	0.5757
	No	43	3 (7.0)	NE [NE, NE)	103	17 (16.5)	NE [NE, NE)		2.095 (0.613, 7.154)	0.2275
Refractory to IMiD	Yes	65	9 (13.8)	NE [19.8, NE)	129	18 (14.0)	NE [NE, NE)	0.4057	0.804 (0.359, 1.804)	0.5964
	No	88	10 (11.4)	NE [NE, NE)	179	28 (15.6)	NE [NE, NE)		1.256 (0.610, 2.588)	0.5345

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-510-ae-cox-eoi-cfz.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	18 (14.3)	NE [NE, NE)	250	36 (14.4)	NE [NE, NE)	0.2048	0.882 (0.500, 1.555)	0.6628
	3	27	1 (3.7)	NE [NE, NE)	58	10 (17.2)	NE [NE, NE)		3.450 (0.439, 27.081)	0.2100
Prior proteasome inhibitor exposure per IXRS	Yes	138	16 (11.6)	NE [NE, NE)	276	41 (14.9)	NE [NE, NE)	0.5686	1.103 (0.618, 1.969)	0.7402
	No	15	3 (20.0)	NE [19.8, NE)	32	5 (15.6)	NE [NE, NE)		0.732 (0.175, 3.070)	0.6686

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	8 (12.1)	NE [NE, NE)	131	20 (15.3)	NE [NE, NE)	0.8842	1.081 (0.475, 2.459)	0.8522
	>= 2	87	11 (12.6)	NE [NE, NE)	177	26 (14.7)	NE [NE, NE)		1.019 (0.502, 2.067)	0.9591

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Hepatic failure, fibrosis and cirrhosis and other liver damage-related conditions (SMQ) - Narrow										
Total subjects		153	6 (3.9)	NE [NE, NE)	308	8 (2.6)	NE [NE, NE)		0.566 (0.195, 1.639)	0.2876

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	5 (3.7)	NE [NE, NE)	283	7 (2.5)	NE [NE, NE)	0.9340	0.553 (0.174, 1.754)	0.3077
	> 75	18	1 (5.6)	NE [NE, NE)	25	1 (4.0)	NE [NE, NE)		0.735 (0.046, 11.750)	0.8269
Sex	Male	91	6 (6.6)	NE [NE, NE)	174	4 (2.3)	NE [NE, NE)	0.9920	0.281 (0.078, 1.011)	0.0385
	Female	62	0 (0.0)	NE [NE, NE)	134	4 (3.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.1928

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	3 (2.5)	NE [NE, NE)	240	6 (2.5)	NE [NE, NE)	0.7711	0.817 (0.203, 3.289)	0.7755
	Asian	20	2 (10.0)	NE [NE, NE)	46	2 (4.3)	NE [NE, NE)		0.421 (0.059, 2.991)	0.3728
	Other or Unknown	11	1 (9.1)	NE [2.1, NE)	22	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0973
Region	North America	12	1 (8.3)	NE [6.0, NE)	21	0 (0.0)	NE [NE, NE)	0.7708	<.001 (<.001, NE)	0.1573

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	3 (2.9)	NE [NE, NE)	203	6 (3.0)	NE [NE, NE)		0.856 (0.214, 3.431)	0.8265
	Asia Pacific	39	2 (5.1)	NE [NE, NE)	84	2 (2.4)	NE [NE, NE)		0.460 (0.065, 3.266)	0.4260
Baseline ECOG PS	0-1	146	6 (4.1)	NE [NE, NE)	294	7 (2.4)	NE [NE, NE)	0.9915	0.502 (0.168, 1.502)	0.2091
	2	7	0 (0.0)	NE [NE, NE)	13	1 (7.7)	NE [5.5, NE)		>999.999 (<.001, NE)	0.7518

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	5 (3.7)	NE [NE, NE)	285	8 (2.8)	NE [NE, NE)	0.9910	0.653 (0.212, 2.006)	0.4533
	No	17	1 (5.9)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.2448
Refractory to Bortezomib or Ixazomib	Yes	55	3 (5.5)	NE [NE, NE)	99	5 (5.1)	NE [NE, NE)	0.4892	0.803 (0.190, 3.393)	0.7651
	No	98	3 (3.1)	NE [NE, NE)	209	3 (1.4)	NE [NE, NE)		0.428 (0.086, 2.123)	0.2844

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	4 (5.4)	NE [NE, NE)	122	5 (4.1)	NE [NE, NE)	0.9183	0.587 (0.154, 2.229)	0.4285
	No	79	2 (2.5)	NE [NE, NE)	186	3 (1.6)	NE [NE, NE)		0.588 (0.098, 3.523)	0.5566
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	4 (4.1)	NE [NE, NE)	0.9923	>999.999 (<.001, NE)	0.2539
	No	98	6 (6.1)	NE [NE, NE)	210	4 (1.9)	NE [NE, NE)		0.290 (0.082, 1.028)	0.0411

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	5 (4.5)	NE [NE, NE)	205	7 (3.4)	NE [NE, NE)	0.7331	0.624 (0.196, 1.986)	0.4205
	No	43	1 (2.3)	NE [NE, NE)	103	1 (1.0)	NE [NE, NE)		0.399 (0.025, 6.385)	0.5012
Refractory to IMiD	Yes	65	1 (1.5)	NE [NE, NE)	129	6 (4.7)	NE [NE, NE)	0.0487	2.268 (0.267, 19.245)	0.4407
	No	88	5 (5.7)	NE [NE, NE)	179	2 (1.1)	NE [NE, NE)		0.180 (0.035, 0.929)	0.0210

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	3 (2.4)	NE [NE, NE)	250	8 (3.2)	NE [NE, NE)	0.9920	1.156 (0.305, 4.382)	0.8304
	3	27	3 (11.1)	NE [NE, NE)	58	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0088
Prior proteasome inhibitor exposure per IXRS	Yes	138	5 (3.6)	NE [NE, NE)	276	8 (2.9)	NE [NE, NE)	0.9895	0.686 (0.223, 2.108)	0.5077
	No	15	1 (6.7)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.1441

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
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[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	2 (3.0)	NE [NE, NE)	131	1 (0.8)	NE [NE, NE)	0.3913	0.238 (0.022, 2.627)	0.2025
	>= 2	87	4 (4.6)	NE [NE, NE)	177	7 (4.0)	NE [NE, NE)		0.694 (0.201, 2.399)	0.5623

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Hepatitis B virus reactivation (AMQ) - Broad										
Total subjects		153	1 (0.7)	NE [NE, NE)	308	1 (0.3)	NE [NE, NE)		0.319 (0.019, 5.246)	0.3997

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	1 (0.7)	NE [NE, NE)	283	1 (0.4)	NE [NE, NE)	0.9999	0.308 (0.019, 5.073)	0.3841
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	0 (0.0)	NE [NE, NE)	0.9999	NE (NE, NE)	NE
	Female	62	1 (1.6)	NE [NE, NE)	134	1 (0.7)	NE [NE, NE)		0.321 (0.020, 5.190)	0.3990

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-510-ae-cox-eoi-cfz.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	1 (0.8)	NE [NE, NE)	240	1 (0.4)	NE [NE, NE)	1.0000	0.334 (0.020, 5.497)	0.4212
	Asian	20	0 (0.0)	NE [NE, NE)	46	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	1 (1.0)	NE [NE, NE)	203	1 (0.5)	NE [NE, NE)		0.376 (0.023, 6.054)	0.4729
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Baseline ECOG PS	0-1	146	1 (0.7)	NE [NE, NE)	294	0 (0.0)	NE [NE, NE)	0.9966	<.001 (<.001, NE)	0.0445
	2	7	0 (0.0)	NE [NE, NE)	13	1 (7.7)	NE [5.8, NE)		>999.999 (<.001, NE)	0.7518

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	1 (0.7)	NE [NE, NE)	285	1 (0.4)	NE [NE, NE)	0.9999	0.312 (0.019, 5.134)	0.3902
	No	17	0 (0.0)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to Bortezomib or Ixazomib	Yes	55	1 (1.8)	NE [27.4, NE)	99	1 (1.0)	NE [NE, NE)	0.9999	0.379 (0.023, 6.266)	0.4817
	No	98	0 (0.0)	NE [NE, NE)	209	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	0 (0.0)	NE [NE, NE)	0.9999	NE (NE, NE)	NE
	No	79	1 (1.3)	NE [NE, NE)	186	1 (0.5)	NE [NE, NE)		0.300 (0.018, 4.875)	0.3699
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	0 (0.0)	NE [NE, NE)	0.9999	NE (NE, NE)	NE
	No	98	1 (1.0)	NE [NE, NE)	210	1 (0.5)	NE [NE, NE)		0.338 (0.021, 5.479)	0.4239

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	0 (0.0)	NE [NE, NE)	205	0 (0.0)	NE [NE, NE)	0.9999	NE (NE, NE)	NE
	No	43	1 (2.3)	NE [27.4, NE)	103	1 (1.0)	NE [NE, NE)		0.301 (0.019, 4.882)	0.3706
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	0 (0.0)	NE [NE, NE)	0.9999	NE (NE, NE)	NE
	No	88	1 (1.1)	NE [NE, NE)	179	1 (0.6)	NE [NE, NE)		0.354 (0.022, 5.731)	0.4449

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	1 (0.8)	NE [NE, NE)	250	1 (0.4)	NE [NE, NE)	0.9999	0.336 (0.020, 5.522)	0.4235
	3	27	0 (0.0)	NE [NE, NE)	58	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Prior proteasome inhibitor exposure per IXRS	Yes	138	1 (0.7)	NE [NE, NE)	276	1 (0.4)	NE [NE, NE)	0.9999	0.325 (0.020, 5.358)	0.4091
	No	15	0 (0.0)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	1 (1.5)	NE [NE, NE)	131	1 (0.8)	NE [NE, NE)	0.9999	0.349 (0.021, 5.682)	0.4396
	>= 2	87	0 (0.0)	NE [NE, NE)	177	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Hypertension (SMQ) - Narrow										
Total subjects		153	48 (31.4)	27.4 [16.8, NE)	308	112 (36.4)	NE [21.4, NE)		1.000 (0.712, 1.404)	0.9988

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	42 (31.1)	NE [16.8, NE)	283	101 (35.7)	NE [21.4, NE)	0.8483	0.992 (0.691, 1.423)	0.9620
	> 75	18	6 (33.3)	27.4 [1.9, NE)	25	11 (44.0)	8.6 [4.2, NE)		1.064 (0.393, 2.884)	0.9023
Sex	Male	91	27 (29.7)	NE [16.7, NE)	174	65 (37.4)	NE [20.8, NE)	0.4902	1.117 (0.712, 1.753)	0.6306
	Female	62	21 (33.9)	22.7 [14.2, NE)	134	47 (35.1)	NE [18.4, NE)		0.868 (0.518, 1.454)	0.5881

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	37 (30.3)	22.7 [16.8, NE)	240	76 (31.7)	NE [28.8, NE)	0.5813	0.885 (0.597, 1.313)	0.5450
	Asian	20	7 (35.0)	NE [5.0, NE)	46	24 (52.2)	15.3 [5.1, NE)		1.480 (0.637, 3.441)	0.3589
	Other or Unknown	11	4 (36.4)	27.4 [1.2, NE)	22	12 (54.5)	15.9 [9.0, NE)		1.352 (0.431, 4.238)	0.6113
Region	North America	12	5 (41.7)	11.5 [0.3, NE)	21	10 (47.6)	23.5 [8.1, NE)	0.3672	0.673 (0.213, 2.125)	0.4969

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	31 (30.4)	27.4 [16.7, NE)	203	61 (30.0)	NE [28.8, NE)		0.836 (0.542, 1.290)	0.4185
	Asia Pacific	39	12 (30.8)	NE [9.8, NE)	84	41 (48.8)	15.9 [8.6, NE)		1.509 (0.792, 2.875)	0.2064
Baseline ECOG PS	0-1	146	47 (32.2)	27.4 [16.8, NE)	294	110 (37.4)	NE [20.8, NE)	0.4062	1.035 (0.735, 1.458)	0.8429
	2	7	1 (14.3)	NE [3.1, NE)	13	2 (15.4)	NE [8.9, NE)		0.402 (0.024, 6.621)	0.5101

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	40 (29.4)	NE [18.9, NE)	285	103 (36.1)	NE [21.4, NE)	0.3221	1.072 (0.743, 1.546)	0.7122
	No	17	8 (47.1)	9.8 [1.3, NE)	23	9 (39.1)	NE [10.6, NE)		0.622 (0.238, 1.626)	0.3317
Refractory to Bortezomib or Ixazomib	Yes	55	13 (23.6)	NE [18.9, NE)	99	30 (30.3)	NE [20.9, NE)	0.7083	1.063 (0.552, 2.047)	0.8549
	No	98	35 (35.7)	27.4 [14.2, NE)	209	82 (39.2)	NE [16.3, NE)		0.968 (0.651, 1.439)	0.8732

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-510-ae-cox-eoi-cfz.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	20 (27.0)	27.4 [17.3, NE)	122	42 (34.4)	NE [20.8, NE)	0.5227	1.105 (0.647, 1.888)	0.7150
	No	79	28 (35.4)	NE [11.5, NE)	186	70 (37.6)	NE [18.7, NE)		0.902 (0.581, 1.400)	0.6476
Refractory to Lenalidomide	Yes	55	18 (32.7)	18.9 [11.1, NE)	98	33 (33.7)	NE [19.8, NE)	0.4725	0.799 (0.446, 1.431)	0.4478
	No	98	30 (30.6)	NE [16.7, NE)	210	79 (37.6)	NE [18.7, NE)		1.096 (0.720, 1.670)	0.6675

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	33 (30.0)	27.4 [16.8, NE)	205	74 (36.1)	NE [19.8, NE)	0.5012	1.088 (0.721, 1.641)	0.6889
	No	43	15 (34.9)	19.4 [7.6, NE)	103	38 (36.9)	NE [18.7, NE)		0.827 (0.453, 1.509)	0.5397
Refractory to IMiD	Yes	65	19 (29.2)	18.9 [16.8, NE)	129	43 (33.3)	NE [20.9, NE)	0.8083	0.915 (0.530, 1.580)	0.7486
	No	88	29 (33.0)	NE [12.3, NE)	179	69 (38.5)	NE [18.4, NE)		1.034 (0.670, 1.596)	0.8783

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	41 (32.5)	NE [17.3, NE)	250	97 (38.8)	NE [19.8, NE)	0.3213	1.067 (0.740, 1.538)	0.7308
	3	27	7 (25.9)	NE [7.6, NE)	58	15 (25.9)	NE [18.7, NE)		0.729 (0.293, 1.813)	0.4943
Prior proteasome inhibitor exposure per IXRS	Yes	138	40 (29.0)	NE [18.9, NE)	276	102 (37.0)	NE [20.9, NE)	0.0535	1.122 (0.778, 1.620)	0.5383
	No	15	8 (53.3)	9.8 [0.5, NE)	32	10 (31.3)	NE [11.0, NE)		0.415 (0.163, 1.056)	0.0578

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	22 (33.3)	NE [12.3, NE)	131	57 (43.5)	21.4 [14.8, NE)	0.3647	1.178 (0.720, 1.927)	0.5158
	>= 2	87	26 (29.9)	27.4 [17.3, NE)	177	55 (31.1)	NE [28.8, NE)		0.863 (0.540, 1.380)	0.5369

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Infusion reaction (AMQ) - Narrow (event on same date of any carfilzomib dosing)										
Total subjects		153	48 (31.4)	NE [17.3, NE)	308	139 (45.1)	20.9 [13.4, NE)		1.473 (1.060, 2.046)	0.0243

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	43 (31.9)	NE [16.8, NE)	283	127 (44.9)	21.4 [13.4, NE)	0.6549	1.438 (1.017, 2.034)	0.0467
	> 75	18	5 (27.8)	NE [5.6, NE)	25	12 (48.0)	14.3 [3.8, NE)		1.794 (0.630, 5.109)	0.2677
Sex	Male	91	25 (27.5)	NE [16.8, NE)	174	74 (42.5)	27.7 [15.0, NE)	0.6520	1.565 (0.993, 2.465)	0.0562
	Female	62	23 (37.1)	18.9 [8.3, NE)	134	65 (48.5)	15.2 [8.4, NE)		1.354 (0.841, 2.180)	0.2385

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CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	35 (28.7)	NE [17.5, NE)	240	90 (37.5)	NE [20.9, NE)	0.3044	1.275 (0.862, 1.886)	0.2390
	Asian	20	10 (50.0)	10.4 [3.0, NE)	46	33 (71.7)	3.1 [0.4, 9.1)		1.862 (0.917, 3.784)	0.0919
	Other or Unknown	11	3 (27.3)	NE [0.5, NE)	22	16 (72.7)	7.4 [0.0, 21.7)		3.244 (0.941, 11.185)	0.0511
Region	North America	12	7 (58.3)	7.6 [0.3, NE)	21	14 (66.7)	11.1 [0.5, 27.7)	0.5413	0.852 (0.332, 2.183)	0.7101

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	24 (23.5)	NE [24.6, NE)	203	70 (34.5)	NE [25.2, NE)		1.476 (0.928, 2.348)	0.1066
	Asia Pacific	39	17 (43.6)	14.1 [6.4, NE)	84	55 (65.5)	6.1 [2.8, 10.4)		1.711 (0.992, 2.952)	0.0569
Baseline ECOG PS	0-1	146	46 (31.5)	NE [17.3, NE)	294	135 (45.9)	18.4 [13.2, NE)	0.2001	1.516 (1.084, 2.119)	0.0169
	2	7	2 (28.6)	NE [0.3, NE)	13	3 (23.1)	NE [0.1, NE)		0.836 (0.138, 5.052)	0.8296

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CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	42 (30.9)	NE [17.3, NE)	285	127 (44.6)	21.4 [14.3, NE)	0.8558	1.470 (1.037, 2.085)	0.0344
	No	17	6 (35.3)	NE [1.2, NE)	23	12 (52.2)	11.0 [1.4, NE)		1.593 (0.597, 4.254)	0.3817
Refractory to Bortezomib or Ixazomib	Yes	55	14 (25.5)	NE [12.3, NE)	99	37 (37.4)	27.7 [16.6, NE)	0.8501	1.479 (0.797, 2.743)	0.2255
	No	98	34 (34.7)	NE [14.1, NE)	209	102 (48.8)	15.3 [10.4, NE)		1.441 (0.977, 2.126)	0.0731

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	23 (31.1)	18.9 [16.8, NE)	122	52 (42.6)	27.7 [12.0, NE)	0.6645	1.365 (0.834, 2.235)	0.2288
	No	79	25 (31.6)	NE [12.3, NE)	186	87 (46.8)	18.4 [10.4, NE)		1.555 (0.996, 2.427)	0.0570
Refractory to Lenalidomide	Yes	55	21 (38.2)	17.3 [10.4, NE)	98	37 (37.8)	NE [15.9, NE)	0.0193	0.844 (0.491, 1.452)	0.5322
	No	98	27 (27.6)	NE [24.6, NE)	210	102 (48.6)	15.3 [10.2, 28.8)		1.948 (1.274, 2.979)	0.0021

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	36 (32.7)	NE [16.8, NE)	205	95 (46.3)	16.3 [11.0, NE)	0.8100	1.454 (0.989, 2.135)	0.0656
	No	43	12 (27.9)	NE [12.3, NE)	103	44 (42.7)	28.8 [10.6, NE)		1.598 (0.843, 3.028)	0.1514
Refractory to IMiD	Yes	65	23 (35.4)	17.3 [10.4, NE)	129	52 (40.3)	27.7 [15.2, NE)	0.0627	0.996 (0.606, 1.636)	0.9668
	No	88	25 (28.4)	NE [17.5, NE)	179	87 (48.6)	15.3 [10.1, NE)		1.915 (1.227, 2.988)	0.0044

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-510-ae-cox-eoi-cfz.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	41 (32.5)	NE [17.3, NE)	250	121 (48.4)	16.3 [10.7, 28.8)	0.3676	1.563 (1.096, 2.228)	0.0156
	3	27	7 (25.9)	NE [3.1, NE)	58	18 (31.0)	NE [17.1, NE)		1.143 (0.476, 2.748)	0.7751
Prior proteasome inhibitor exposure per IXRS	Yes	138	42 (30.4)	NE [17.3, NE)	276	124 (44.9)	21.4 [13.4, NE)	0.5903	1.520 (1.070, 2.158)	0.0220
	No	15	6 (40.0)	17.3 [1.0, NE)	32	15 (46.9)	15.0 [5.8, NE)		1.169 (0.452, 3.021)	0.7701

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	19 (28.8)	NE [14.1, NE)	131	65 (49.6)	15.3 [9.1, NE)	0.2199	1.862 (1.116, 3.105)	0.0180
	>= 2	87	29 (33.3)	18.9 [11.1, NE)	177	74 (41.8)	27.7 [14.3, NE)		1.239 (0.805, 1.907)	0.3489

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Infusion reaction (AMQ) - Narrow (event on same date of first carfilzomib dosing)										
Total subjects		153	1 (0.7)	NE [NE, NE)	308	43 (14.0)	NE [NE, NE)		22.885 (3.152, 166.149)	<.0001

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	0 (0.0)	NE [NE, NE)	283	40 (14.1)	NE [NE, NE)	0.9862	>999.999 (<.001, NE)	<.0001
	> 75	18	1 (5.6)	NE [NE, NE)	25	3 (12.0)	NE [NE, NE)		2.216 (0.230, 21.305)	0.4781
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	20 (11.5)	NE [NE, NE)	0.9850	>999.999 (<.001, NE)	0.0008
	Female	62	1 (1.6)	NE [NE, NE)	134	23 (17.2)	NE [NE, NE)		11.535 (1.558, 85.425)	0.0021

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	1 (0.8)	NE [NE, NE)	240	25 (10.4)	NE [NE, NE)	0.9999	13.337 (1.807, 98.434)	0.0008
	Asian	20	0 (0.0)	NE [NE, NE)	46	12 (26.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.0122
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	6 (27.3)	NE [0.0, NE)		>999.999 (<.001, NE)	0.0593
Region	North America	12	0 (0.0)	NE [NE, NE)	21	4 (19.0)	NE [NE, NE)	0.9998	>999.999 (<.001, NE)	0.1123

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	22 (10.8)	NE [NE, NE)		>999.999 (<.001, NE)	0.0006
	Asia Pacific	39	1 (2.6)	NE [NE, NE)	84	17 (20.2)	NE [NE, NE)		8.649 (1.151, 64.982)	0.0102
Baseline ECOG PS	0-1	146	1 (0.7)	NE [NE, NE)	294	40 (13.6)	NE [NE, NE)	0.9905	21.236 (2.920, 154.455)	<.0001
	2	7	0 (0.0)	NE [NE, NE)	13	2 (15.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.2863

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	1 (0.7)	NE [NE, NE)	285	37 (13.0)	NE [NE, NE)	0.9902	18.806 (2.580, 137.059)	<.0001
	No	17	0 (0.0)	NE [NE, NE)	23	6 (26.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.0241
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	12 (12.1)	NE [NE, NE)	0.9883	>999.999 (<.001, NE)	0.0074
	No	98	1 (1.0)	NE [NE, NE)	209	31 (14.8)	NE [NE, NE)		15.614 (2.131, 114.377)	0.0002

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	15 (12.3)	NE [NE, NE)	0.9862	>999.999 (<.001, NE)	0.0017
	No	79	1 (1.3)	NE [NE, NE)	186	28 (15.1)	NE [NE, NE)		12.771 (1.738, 93.869)	0.0010
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	7 (7.1)	NE [NE, NE)	0.9894	>999.999 (<.001, NE)	0.0431
	No	98	1 (1.0)	NE [NE, NE)	210	36 (17.1)	NE [NE, NE)		18.285 (2.507, 133.367)	<.0001

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	0 (0.0)	NE [NE, NE)	205	32 (15.6)	NE [NE, NE)	0.9882	>999.999 (<.001, NE)	<.0001
	No	43	1 (2.3)	NE [NE, NE)	103	11 (10.7)	NE [NE, NE)		4.781 (0.617, 37.031)	0.0950
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	12 (9.3)	NE [NE, NE)	0.9880	>999.999 (<.001, NE)	0.0113
	No	88	1 (1.1)	NE [NE, NE)	179	31 (17.3)	NE [NE, NE)		16.589 (2.264, 121.524)	0.0001

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	1 (0.8)	NE [NE, NE)	250	38 (15.2)	NE [NE, NE)	0.9883	20.644 (2.835, 150.348)	<.0001
	3	27	0 (0.0)	NE [NE, NE)	58	5 (8.6)	NE [NE, NE)		>999.999 (<.001, NE)	0.1180
Prior proteasome inhibitor exposure per IXRS	Yes	138	1 (0.7)	NE [NE, NE)	276	38 (13.8)	NE [NE, NE)	0.9907	20.326 (2.791, 148.029)	<.0001
	No	15	0 (0.0)	NE [NE, NE)	32	5 (15.6)	NE [NE, NE)		>999.999 (<.001, NE)	0.1091

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	1 (1.5)	NE [NE, NE)	131	23 (17.6)	NE [NE, NE)	0.9855	12.594 (1.701, 93.268)	0.0012
	>= 2	87	0 (0.0)	NE [NE, NE)	177	20 (11.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.0011

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Interstitial lung disease (SMQ) - Narrow										
Total subjects		153	2 (1.3)	NE [NE, NE)	308	8 (2.6)	NE [NE, NE)		1.693 (0.358, 8.016)	0.5019

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	1 (0.7)	NE [NE, NE)	283	7 (2.5)	NE [NE, NE)	0.4000	2.744 (0.335, 22.445)	0.3265
	> 75	18	1 (5.6)	NE [NE, NE)	25	1 (4.0)	NE [NE, NE)		0.685 (0.043, 10.965)	0.7881
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	6 (3.4)	NE [NE, NE)	0.9912	>999.999 (<.001, NE)	0.1225
	Female	62	2 (3.2)	NE [NE, NE)	134	2 (1.5)	NE [NE, NE)		0.447 (0.063, 3.177)	0.4085

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	2 (1.6)	NE [NE, NE)	240	6 (2.5)	NE [NE, NE)	1.0000	1.336 (0.268, 6.663)	0.7229
	Asian	20	0 (0.0)	NE [NE, NE)	46	2 (4.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.4148
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	0.7132	NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	1 (1.0)	NE [NE, NE)	203	6 (3.0)	NE [NE, NE)		2.745 (0.330, 22.839)	0.3299
	Asia Pacific	39	1 (2.6)	NE [NE, NE)	84	2 (2.4)	NE [NE, NE)		0.751 (0.067, 8.384)	0.8158
Baseline ECOG PS	0-1	146	2 (1.4)	NE [NE, NE)	294	8 (2.7)	NE [NE, NE)	0.9999	1.722 (0.364, 8.149)	0.4877
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	2 (1.5)	NE [NE, NE)	285	6 (2.1)	NE [NE, NE)	0.9920	1.221 (0.245, 6.099)	0.8070
	No	17	0 (0.0)	NE [NE, NE)	23	2 (8.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.2908
Refractory to Bortezomib or Ixazomib	Yes	55	1 (1.8)	NE [NE, NE)	99	4 (4.0)	NE [NE, NE)	0.8844	1.799 (0.199, 16.266)	0.5960
	No	98	1 (1.0)	NE [NE, NE)	209	4 (1.9)	NE [NE, NE)		1.687 (0.188, 15.140)	0.6369

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	1 (1.4)	NE [NE, NE)	122	3 (2.5)	NE [NE, NE)	0.8539	1.525 (0.157, 14.774)	0.7135
	No	79	1 (1.3)	NE [NE, NE)	186	5 (2.7)	NE [NE, NE)		1.914 (0.223, 16.429)	0.5471
Refractory to Lenalidomide	Yes	55	1 (1.8)	NE [NE, NE)	98	1 (1.0)	NE [NE, NE)	0.2742	0.401 (0.024, 6.662)	0.5100
	No	98	1 (1.0)	NE [NE, NE)	210	7 (3.3)	NE [NE, NE)		2.966 (0.364, 24.150)	0.2861

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	2 (1.8)	NE [NE, NE)	205	3 (1.5)	NE [NE, NE)	0.9939	0.705 (0.117, 4.236)	0.7009
	No	43	0 (0.0)	NE [NE, NE)	103	5 (4.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.1629
Refractory to IMiD	Yes	65	2 (3.1)	NE [NE, NE)	129	1 (0.8)	NE [NE, NE)	0.9910	0.198 (0.018, 2.246)	0.1487
	No	88	0 (0.0)	NE [NE, NE)	179	7 (3.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.0763

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	1 (0.8)	NE [NE, NE)	250	7 (2.8)	NE [NE, NE)	0.2315	2.958 (0.362, 24.175)	0.2884
	3	27	1 (3.7)	NE [NE, NE)	58	1 (1.7)	NE [NE, NE)		0.427 (0.027, 6.825)	0.5347
Prior proteasome inhibitor exposure per IXRS	Yes	138	2 (1.4)	NE [NE, NE)	276	7 (2.5)	NE [NE, NE)	0.9944	1.467 (0.303, 7.111)	0.6319
	No	15	0 (0.0)	NE [NE, NE)	32	1 (3.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.5271

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	4 (3.1)	NE [NE, NE)	0.9924	>999.999 (<.001, NE)	0.2005
	>= 2	87	2 (2.3)	NE [NE, NE)	177	4 (2.3)	NE [NE, NE)		0.849 (0.154, 4.689)	0.8507

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Ischaemic heart disease (SMQ) - Narrow										
Total subjects		153	6 (3.9)	NE [NE, NE)	308	17 (5.5)	NE [NE, NE)		1.101 (0.432, 2.804)	0.8402

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	5 (3.7)	NE [NE, NE)	283	16 (5.7)	NE [NE, NE)	0.6427	1.187 (0.433, 3.258)	0.7389
	> 75	18	1 (5.6)	NE [NE, NE)	25	1 (4.0)	NE [NE, NE)		0.546 (0.033, 8.909)	0.6665
Sex	Male	91	4 (4.4)	NE [NE, NE)	174	13 (7.5)	NE [NE, NE)	0.6324	1.257 (0.406, 3.890)	0.6906
	Female	62	2 (3.2)	NE [NE, NE)	134	4 (3.0)	NE [NE, NE)		0.812 (0.148, 4.443)	0.8096

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	3 (2.5)	NE [NE, NE)	240	15 (6.3)	NE [NE, NE)	0.1197	2.014 (0.581, 6.981)	0.2600
	Asian	20	2 (10.0)	NE [11.3, NE)	46	1 (2.2)	NE [NE, NE)		0.133 (0.012, 1.501)	0.0570
	Other or Unknown	11	1 (9.1)	NE [2.4, NE)	22	1 (4.5)	NE [NE, NE)		0.437 (0.027, 7.023)	0.5474
Region	North America	12	0 (0.0)	NE [NE, NE)	21	2 (9.5)	NE [NE, NE)	0.1436	>999.999 (<.001, NE)	0.2791

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	3 (2.9)	NE [NE, NE)	203	13 (6.4)	NE [NE, NE)		1.854 (0.528, 6.515)	0.3282
	Asia Pacific	39	3 (7.7)	NE [19.7, NE)	84	2 (2.4)	NE [NE, NE)		0.142 (0.023, 0.886)	0.0169
Baseline ECOG PS	0-1	146	6 (4.1)	NE [NE, NE)	294	17 (5.8)	NE [NE, NE)	1.0000	1.132 (0.445, 2.882)	0.7944
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	5 (3.7)	NE [NE, NE)	285	15 (5.3)	NE [NE, NE)	0.9782	1.152 (0.417, 3.182)	0.7854
	No	17	1 (5.9)	NE [19.7, NE)	23	2 (8.7)	NE [NE, NE)		0.902 (0.081, 10.006)	0.9329
Refractory to Bortezomib or Ixazomib	Yes	55	2 (3.6)	NE [NE, NE)	99	0 (0.0)	NE [NE, NE)	0.9862	<.001 (<.001, NE)	0.0352
	No	98	4 (4.1)	NE [NE, NE)	209	17 (8.1)	NE [NE, NE)		1.560 (0.522, 4.655)	0.4220

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	2 (2.7)	NE [NE, NE)	122	8 (6.6)	NE [NE, NE)	0.4207	1.960 (0.411, 9.344)	0.3897
	No	79	4 (5.1)	NE [NE, NE)	186	9 (4.8)	NE [NE, NE)		0.780 (0.240, 2.536)	0.6786
Refractory to Lenalidomide	Yes	55	2 (3.6)	NE [19.7, NE)	98	6 (6.1)	NE [NE, NE)	0.9553	1.174 (0.231, 5.980)	0.8464
	No	98	4 (4.1)	NE [NE, NE)	210	11 (5.2)	NE [NE, NE)		1.077 (0.342, 3.388)	0.8996

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	5 (4.5)	NE [NE, NE)	205	10 (4.9)	NE [NE, NE)	0.3412	0.830 (0.281, 2.454)	0.7356
	No	43	1 (2.3)	NE [NE, NE)	103	7 (6.8)	NE [NE, NE)		2.419 (0.297, 19.690)	0.3937
Refractory to IMiD	Yes	65	3 (4.6)	NE [19.7, NE)	129	8 (6.2)	NE [NE, NE)	0.7432	0.915 (0.237, 3.542)	0.8980
	No	88	3 (3.4)	NE [NE, NE)	179	9 (5.0)	NE [NE, NE)		1.252 (0.338, 4.631)	0.7359

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	5 (4.0)	NE [NE, NE)	250	13 (5.2)	NE [NE, NE)	0.8974	1.009 (0.358, 2.845)	0.9866
	3	27	1 (3.7)	NE [NE, NE)	58	4 (6.9)	NE [NE, NE)		1.365 (0.148, 12.608)	0.7829
Prior proteasome inhibitor exposure per IXRS	Yes	138	5 (3.6)	NE [NE, NE)	276	12 (4.3)	NE [NE, NE)	0.5163	0.908 (0.318, 2.591)	0.8568
	No	15	1 (6.7)	NE [19.7, NE)	32	5 (15.6)	NE [NE, NE)		2.067 (0.240, 17.774)	0.4991

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	3 (4.5)	NE [NE, NE)	131	8 (6.1)	NE [NE, NE)	0.9390	1.049 (0.277, 3.969)	0.9437
	>= 2	87	3 (3.4)	NE [NE, NE)	177	9 (5.1)	NE [NE, NE)		1.147 (0.307, 4.278)	0.8383

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Liver related investigations, signs and symptoms (SMQ) - Narrow										
Total subjects		153	13 (8.5)	NE [NE, NE)	308	38 (12.3)	NE [NE, NE)		1.356 (0.722, 2.548)	0.3416

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	12 (8.9)	NE [NE, NE)	283	34 (12.0)	NE [NE, NE)	0.5230	1.268 (0.656, 2.452)	0.4787
	> 75	18	1 (5.6)	NE [NE, NE)	25	4 (16.0)	NE [19.3, NE)		2.599 (0.290, 23.274)	0.3752
Sex	Male	91	8 (8.8)	NE [NE, NE)	174	18 (10.3)	NE [NE, NE)	0.4481	1.056 (0.458, 2.433)	0.8970
	Female	62	5 (8.1)	NE [NE, NE)	134	20 (14.9)	NE [NE, NE)		1.806 (0.677, 4.815)	0.2314

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	10 (8.2)	NE [NE, NE)	240	25 (10.4)	NE [NE, NE)	0.9347	1.176 (0.564, 2.452)	0.6645
	Asian	20	3 (15.0)	NE [NE, NE)	46	11 (23.9)	NE [NE, NE)		1.601 (0.446, 5.745)	0.4688
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	2 (9.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.3807
Region	North America	12	2 (16.7)	NE [7.4, NE)	21	1 (4.8)	NE [NE, NE)	0.3312	0.270 (0.024, 2.977)	0.2511

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	6 (5.9)	NE [NE, NE)	203	21 (10.3)	NE [NE, NE)		1.668 (0.673, 4.134)	0.2636
	Asia Pacific	39	5 (12.8)	NE [NE, NE)	84	16 (19.0)	NE [NE, NE)		1.346 (0.491, 3.691)	0.5632
Baseline ECOG PS	0-1	146	12 (8.2)	NE [NE, NE)	294	36 (12.2)	NE [NE, NE)	0.4602	1.426 (0.741, 2.741)	0.2854
	2	7	1 (14.3)	NE [0.5, NE)	13	2 (15.4)	NE [19.3, NE)		0.408 (0.025, 6.622)	0.5151

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	11 (8.1)	NE [NE, NE)	285	33 (11.6)	NE [NE, NE)	0.7255	1.331 (0.672, 2.636)	0.4093
	No	17	2 (11.8)	NE [17.3, NE)	23	5 (21.7)	NE [NE, NE)		1.828 (0.353, 9.471)	0.4689
Refractory to Bortezomib or Ixazomib	Yes	55	6 (10.9)	NE [NE, NE)	99	8 (8.1)	NE [NE, NE)	0.1410	0.670 (0.232, 1.934)	0.4557
	No	98	7 (7.1)	NE [NE, NE)	209	30 (14.4)	NE [NE, NE)		1.902 (0.835, 4.334)	0.1199

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	6 (8.1)	NE [NE, NE)	122	15 (12.3)	NE [NE, NE)	0.9449	1.394 (0.540, 3.603)	0.4910
	No	79	7 (8.9)	NE [NE, NE)	186	23 (12.4)	NE [NE, NE)		1.336 (0.573, 3.114)	0.5009
Refractory to Lenalidomide	Yes	55	5 (9.1)	NE [NE, NE)	98	11 (11.2)	NE [NE, NE)	0.6365	1.111 (0.384, 3.215)	0.8461
	No	98	8 (8.2)	NE [NE, NE)	210	27 (12.9)	NE [NE, NE)		1.507 (0.685, 3.319)	0.3045

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	9 (8.2)	NE [NE, NE)	205	26 (12.7)	NE [NE, NE)	0.7909	1.417 (0.663, 3.029)	0.3664
	No	43	4 (9.3)	NE [NE, NE)	103	12 (11.7)	NE [NE, NE)		1.202 (0.387, 3.729)	0.7485
Refractory to IMiD	Yes	65	6 (9.2)	NE [NE, NE)	129	15 (11.6)	NE [NE, NE)	0.5919	1.074 (0.414, 2.784)	0.8838
	No	88	7 (8.0)	NE [NE, NE)	179	23 (12.8)	NE [NE, NE)		1.580 (0.678, 3.682)	0.2852

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	10 (7.9)	NE [NE, NE)	250	33 (13.2)	NE [NE, NE)	0.2316	1.606 (0.791, 3.260)	0.1858
	3	27	3 (11.1)	NE [NE, NE)	58	5 (8.6)	NE [NE, NE)		0.599 (0.142, 2.527)	0.4851
Prior proteasome inhibitor exposure per IXRS	Yes	138	11 (8.0)	NE [NE, NE)	276	33 (12.0)	NE [NE, NE)	0.7871	1.400 (0.707, 2.772)	0.3317
	No	15	2 (13.3)	NE [17.3, NE)	32	5 (15.6)	NE [NE, NE)		1.101 (0.213, 5.693)	0.9128

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	7 (10.6)	NE [NE, NE)	131	16 (12.2)	NE [NE, NE)	0.4884	1.073 (0.441, 2.613)	0.8759
	>= 2	87	6 (6.9)	NE [NE, NE)	177	22 (12.4)	NE [NE, NE)		1.654 (0.670, 4.086)	0.2702

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-510-ae-cox-eoi-cfz.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Myocardial infarction (SMQ) - Narrow										
Total subjects		153	2 (1.3)	NE [NE, NE)	308	6 (1.9)	NE [NE, NE)		0.964 (0.194, 4.795)	0.9647

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Output: t14-06-001-510-ae-cox-eoi-cfz.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	2 (1.5)	NE [NE, NE)	283	5 (1.8)	NE [NE, NE)	0.9946	0.746 (0.144, 3.869)	0.7261
	> 75	18	0 (0.0)	NE [NE, NE)	25	1 (4.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.4795
Sex	Male	91	1 (1.1)	NE [NE, NE)	174	5 (2.9)	NE [NE, NE)	0.3988	1.498 (0.174, 12.915)	0.7112
	Female	62	1 (1.6)	NE [NE, NE)	134	1 (0.7)	NE [NE, NE)		0.357 (0.022, 5.736)	0.4475

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	1 (0.8)	NE [NE, NE)	240	5 (2.1)	NE [NE, NE)	1.0000	1.682 (0.196, 14.446)	0.6320
	Asian	20	1 (5.0)	NE [11.3, NE)	46	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0593
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	1 (4.5)	NE [24.0, NE)		>999.999 (<.001, NE)	0.5839
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	6 (3.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.1293
	Asia Pacific	39	2 (5.1)	NE [19.7, NE)	84	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0047
Baseline ECOG PS	0-1	146	2 (1.4)	NE [NE, NE)	294	6 (2.0)	NE [NE, NE)	1.0000	1.004 (0.202, 4.993)	0.9961
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	1 (0.7)	NE [NE, NE)	285	6 (2.1)	NE [NE, NE)	0.9922	1.917 (0.230, 15.978)	0.5406
	No	17	1 (5.9)	NE [19.7, NE)	23	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.1138
Refractory to Bortezomib or Ixazomib	Yes	55	1 (1.8)	NE [NE, NE)	99	0 (0.0)	NE [NE, NE)	0.9918	<.001 (<.001, NE)	0.1103
	No	98	1 (1.0)	NE [NE, NE)	209	6 (2.9)	NE [NE, NE)		1.775 (0.213, 14.805)	0.5908

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	1 (1.4)	NE [NE, NE)	122	3 (2.5)	NE [NE, NE)	0.9985	0.997 (0.100, 9.920)	0.9982
	No	79	1 (1.3)	NE [NE, NE)	186	3 (1.6)	NE [NE, NE)		0.953 (0.099, 9.168)	0.9670
Refractory to Lenalidomide	Yes	55	1 (1.8)	NE [19.7, NE)	98	3 (3.1)	NE [NE, NE)	0.8580	0.806 (0.080, 8.124)	0.8545
	No	98	1 (1.0)	NE [NE, NE)	210	3 (1.4)	NE [NE, NE)		1.030 (0.107, 9.906)	0.9795

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	2 (1.8)	NE [NE, NE)	205	4 (2.0)	NE [NE, NE)	0.9946	0.651 (0.117, 3.607)	0.6204
	No	43	0 (0.0)	NE [NE, NE)	103	2 (1.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.4387
Refractory to IMiD	Yes	65	2 (3.1)	NE [19.7, NE)	129	4 (3.1)	NE [NE, NE)	0.9942	0.476 (0.084, 2.706)	0.3926
	No	88	0 (0.0)	NE [NE, NE)	179	2 (1.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.3922

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	2 (1.6)	NE [NE, NE)	250	5 (2.0)	NE [NE, NE)	0.9935	0.826 (0.159, 4.280)	0.8194
	3	27	0 (0.0)	NE [NE, NE)	58	1 (1.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.6698
Prior proteasome inhibitor exposure per IXRS	Yes	138	1 (0.7)	NE [NE, NE)	276	5 (1.8)	NE [NE, NE)	0.3586	1.709 (0.199, 14.683)	0.6213
	No	15	1 (6.7)	NE [19.7, NE)	32	1 (3.1)	NE [NE, NE)		0.289 (0.018, 4.618)	0.3493

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	3 (2.3)	NE [NE, NE)	0.9936	>999.999 (<.001, NE)	0.3131
	>= 2	87	2 (2.3)	NE [NE, NE)	177	3 (1.7)	NE [NE, NE)		0.415 (0.068, 2.524)	0.3245

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Peripheral neuropathy (SMQ) - Narrow										
Total subjects		153	14 (9.2)	NE [NE, NE)	308	60 (19.5)	NE [NE, NE)		1.908 (1.065, 3.416)	0.0272

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	13 (9.6)	NE [NE, NE)	283	55 (19.4)	NE [NE, NE)	0.5579	1.779 (0.971, 3.261)	0.0588
	> 75	18	1 (5.6)	NE [NE, NE)	25	5 (20.0)	NE [NE, NE)		3.465 (0.405, 29.673)	0.2279
Sex	Male	91	9 (9.9)	NE [NE, NE)	174	33 (19.0)	NE [NE, NE)	0.6026	1.679 (0.801, 3.519)	0.1650
	Female	62	5 (8.1)	NE [NE, NE)	134	27 (20.1)	NE [NE, NE)		2.301 (0.886, 5.977)	0.0783

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-510-ae-cox-eoi-cfz.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	12 (9.8)	NE [NE, NE)	240	39 (16.3)	NE [NE, NE)	0.3851	1.485 (0.777, 2.840)	0.2289
	Asian	20	1 (5.0)	NE [NE, NE)	46	11 (23.9)	NE [24.9, NE)		4.422 (0.569, 34.347)	0.1200
	Other or Unknown	11	1 (9.1)	NE [3.8, NE)	22	10 (45.5)	21.0 [4.6, NE)		4.278 (0.546, 33.487)	0.1316
Region	North America	12	2 (16.7)	NE [3.8, NE)	21	7 (33.3)	NE [4.6, NE)	0.3256	2.046 (0.424, 9.873)	0.3624

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	10 (9.8)	NE [NE, NE)	203	31 (15.3)	NE [NE, NE)		1.371 (0.671, 2.799)	0.3855
	Asia Pacific	39	2 (5.1)	NE [NE, NE)	84	22 (26.2)	NE [NE, NE)		4.788 (1.124, 20.397)	0.0193
Baseline ECOG PS	0-1	146	14 (9.6)	NE [NE, NE)	294	58 (19.7)	NE [NE, NE)	0.9851	1.884 (1.050, 3.381)	0.0308
	2	7	0 (0.0)	NE [NE, NE)	13	2 (15.4)	NE [2.5, NE)		>999.999 (<.001, NE)	0.3977

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	13 (9.6)	NE [NE, NE)	285	57 (20.0)	NE [NE, NE)	0.9944	1.881 (1.029, 3.439)	0.0370
	No	17	1 (5.9)	NE [NE, NE)	23	3 (13.0)	NE [NE, NE)		1.851 (0.190, 18.052)	0.5904
Refractory to Bortezomib or Ixazomib	Yes	55	4 (7.3)	NE [NE, NE)	99	14 (14.1)	NE [NE, NE)	0.8737	1.759 (0.578, 5.357)	0.3143
	No	98	10 (10.2)	NE [NE, NE)	209	46 (22.0)	NE [NE, NE)		1.934 (0.975, 3.835)	0.0547

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	5 (6.8)	NE [NE, NE)	122	23 (18.9)	NE [NE, NE)	0.5314	2.315 (0.877, 6.114)	0.0810
	No	79	9 (11.4)	NE [NE, NE)	186	37 (19.9)	NE [NE, NE)		1.634 (0.788, 3.388)	0.1831
Refractory to Lenalidomide	Yes	55	2 (3.6)	NE [NE, NE)	98	18 (18.4)	NE [NE, NE)	0.1868	4.407 (1.019, 19.052)	0.0299
	No	98	12 (12.2)	NE [NE, NE)	210	42 (20.0)	NE [NE, NE)		1.487 (0.782, 2.827)	0.2232

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	8 (7.3)	NE [NE, NE)	205	44 (21.5)	NE [NE, NE)	0.1113	2.630 (1.236, 5.594)	0.0091
	No	43	6 (14.0)	NE [NE, NE)	103	16 (15.5)	NE [NE, NE)		1.016 (0.397, 2.600)	0.9760
Refractory to IMiD	Yes	65	3 (4.6)	NE [NE, NE)	129	26 (20.2)	NE [NE, NE)	0.1543	3.839 (1.159, 12.712)	0.0178
	No	88	11 (12.5)	NE [NE, NE)	179	34 (19.0)	NE [NE, NE)		1.384 (0.701, 2.734)	0.3484

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	12 (9.5)	NE [NE, NE)	250	52 (20.8)	NE [NE, NE)	0.6146	2.041 (1.089, 3.828)	0.0232
	3	27	2 (7.4)	NE [6.3, NE)	58	8 (13.8)	NE [NE, NE)		1.161 (0.244, 5.526)	0.8508
Prior proteasome inhibitor exposure per IXRS	Yes	138	13 (9.4)	NE [NE, NE)	276	54 (19.6)	NE [NE, NE)	0.8171	1.879 (1.024, 3.446)	0.0384
	No	15	1 (6.7)	NE [4.9, NE)	32	6 (18.8)	NE [NE, NE)		2.357 (0.283, 19.620)	0.4139

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	6 (9.1)	NE [NE, NE)	131	22 (16.8)	NE [NE, NE)	0.6968	1.637 (0.663, 4.044)	0.2817
	>= 2	87	8 (9.2)	NE [NE, NE)	177	38 (21.5)	NE [NE, NE)		2.100 (0.978, 4.508)	0.0515

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Pulmonary hypertension (SMQ) - Narrow										
Total subjects		153	6 (3.9)	NE [NE, NE)	308	8 (2.6)	NE [NE, NE)		0.497 (0.171, 1.441)	0.1893

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	5 (3.7)	NE [NE, NE)	283	8 (2.8)	NE [NE, NE)	0.9910	0.570 (0.185, 1.755)	0.3212
	> 75	18	1 (5.6)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.1573
Sex	Male	91	5 (5.5)	NE [NE, NE)	174	6 (3.4)	NE [NE, NE)	0.7508	0.483 (0.146, 1.598)	0.2238
	Female	62	1 (1.6)	NE [NE, NE)	134	2 (1.5)	NE [NE, NE)		0.627 (0.057, 6.967)	0.7021

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	6 (4.9)	NE [NE, NE)	240	6 (2.5)	NE [NE, NE)	1.0000	0.388 (0.124, 1.213)	0.0915
	Asian	20	0 (0.0)	NE [NE, NE)	46	2 (4.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.4208
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	1 (4.8)	NE [NE, NE)	0.5304	>999.999 (<.001, NE)	0.4795

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	2 (2.0)	NE [NE, NE)	203	4 (2.0)	NE [NE, NE)		0.822 (0.150, 4.512)	0.8213
	Asia Pacific	39	4 (10.3)	NE [19.4, NE)	84	3 (3.6)	NE [NE, NE)		0.237 (0.053, 1.073)	0.0425
Baseline ECOG PS	0-1	146	6 (4.1)	NE [NE, NE)	294	8 (2.7)	NE [NE, NE)	0.9999	0.514 (0.177, 1.489)	0.2120
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	4 (2.9)	NE [NE, NE)	285	6 (2.1)	NE [NE, NE)	0.9460	0.536 (0.150, 1.916)	0.3296
	No	17	2 (11.8)	NE [19.4, NE)	23	2 (8.7)	NE [NE, NE)		0.539 (0.076, 3.836)	0.5306
Refractory to Bortezomib or Ixazomib	Yes	55	1 (1.8)	NE [NE, NE)	99	4 (4.0)	NE [NE, NE)	0.1459	1.474 (0.162, 13.384)	0.7287
	No	98	5 (5.1)	NE [NE, NE)	209	4 (1.9)	NE [NE, NE)		0.300 (0.080, 1.120)	0.0573

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-510-ae-cox-eoi-cfz.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	2 (2.7)	NE [NE, NE)	122	3 (2.5)	NE [NE, NE)	0.7354	0.703 (0.116, 4.283)	0.7013
	No	79	4 (5.1)	NE [NE, NE)	186	5 (2.7)	NE [NE, NE)		0.422 (0.113, 1.578)	0.1863
Refractory to Lenalidomide	Yes	55	2 (3.6)	NE [NE, NE)	98	2 (2.0)	NE [NE, NE)	0.7015	0.403 (0.055, 2.974)	0.3575
	No	98	4 (4.1)	NE [NE, NE)	210	6 (2.9)	NE [NE, NE)		0.560 (0.158, 1.991)	0.3643

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	3 (2.7)	NE [NE, NE)	205	5 (2.4)	NE [NE, NE)	0.5552	0.701 (0.167, 2.952)	0.6269
	No	43	3 (7.0)	NE [NE, NE)	103	3 (2.9)	NE [NE, NE)		0.335 (0.067, 1.669)	0.1611
Refractory to IMiD	Yes	65	2 (3.1)	NE [NE, NE)	129	2 (1.6)	NE [NE, NE)	0.6026	0.358 (0.048, 2.646)	0.2945
	No	88	4 (4.5)	NE [NE, NE)	179	6 (3.4)	NE [NE, NE)		0.601 (0.169, 2.136)	0.4266

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	6 (4.8)	NE [NE, NE)	250	7 (2.8)	NE [NE, NE)	0.9934	0.443 (0.148, 1.328)	0.1357
	3	27	0 (0.0)	NE [NE, NE)	58	1 (1.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.4951
Prior proteasome inhibitor exposure per IXRS	Yes	138	4 (2.9)	NE [NE, NE)	276	6 (2.2)	NE [NE, NE)	0.6490	0.560 (0.156, 2.004)	0.3667
	No	15	2 (13.3)	NE [5.3, NE)	32	2 (6.3)	NE [NE, NE)		0.336 (0.047, 2.384)	0.2516

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	3 (4.5)	NE [NE, NE)	131	3 (2.3)	NE [NE, NE)	0.7046	0.411 (0.083, 2.038)	0.2605
	>= 2	87	3 (3.4)	NE [NE, NE)	177	5 (2.8)	NE [NE, NE)		0.560 (0.131, 2.389)	0.4271

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Respiratory failure (SMQ) - Narrow										
Total subjects		153	1 (0.7)	NE [NE, NE)	308	3 (1.0)	NE [NE, NE)		1.273 (0.132, 12.271)	0.8345

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	1 (0.7)	NE [NE, NE)	283	3 (1.1)	NE [NE, NE)	1.0000	1.227 (0.127, 11.835)	0.8593
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	1 (0.6)	NE [NE, NE)	0.9952	>999.999 (<.001, NE)	0.5132
	Female	62	1 (1.6)	NE [NE, NE)	134	2 (1.5)	NE [NE, NE)		0.820 (0.074, 9.069)	0.8716

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	0 (0.0)	NE [NE, NE)	240	3 (1.3)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.2358
	Asian	20	1 (5.0)	NE [12.0, NE)	46	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0635
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	3 (1.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.2437
	Asia Pacific	39	1 (2.6)	NE [NE, NE)	84	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0752
Baseline ECOG PS	0-1	146	1 (0.7)	NE [NE, NE)	294	3 (1.0)	NE [NE, NE)	1.0000	1.304 (0.135, 12.565)	0.8179
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	1 (0.7)	NE [NE, NE)	285	3 (1.1)	NE [NE, NE)	1.0000	1.234 (0.128, 11.896)	0.8555
	No	17	0 (0.0)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to Bortezomib or Ixazomib	Yes	55	1 (1.8)	NE [NE, NE)	99	0 (0.0)	NE [NE, NE)	0.9953	<.001 (<.001, NE)	0.1213
	No	98	0 (0.0)	NE [NE, NE)	209	3 (1.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.2618

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	1 (0.8)	NE [NE, NE)	0.9953	>999.999 (<.001, NE)	0.4723
	No	79	1 (1.3)	NE [NE, NE)	186	2 (1.1)	NE [NE, NE)		0.752 (0.068, 8.318)	0.8153
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	1 (1.0)	NE [NE, NE)	0.9958	>999.999 (<.001, NE)	0.5036
	No	98	1 (1.0)	NE [NE, NE)	210	2 (1.0)	NE [NE, NE)		0.822 (0.074, 9.088)	0.8727

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	1 (0.9)	NE [NE, NE)	205	1 (0.5)	NE [NE, NE)	0.9940	0.425 (0.027, 6.815)	0.5333
	No	43	0 (0.0)	NE [NE, NE)	103	2 (1.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.3632
Refractory to IMiD	Yes	65	1 (1.5)	NE [NE, NE)	129	1 (0.8)	NE [NE, NE)	0.9945	0.362 (0.023, 5.832)	0.4551
	No	88	0 (0.0)	NE [NE, NE)	179	2 (1.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.3354

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	1 (0.8)	NE [NE, NE)	250	1 (0.4)	NE [NE, NE)	0.9958	0.412 (0.026, 6.600)	0.5174
	3	27	0 (0.0)	NE [NE, NE)	58	2 (3.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.3876
Prior proteasome inhibitor exposure per IXRS	Yes	138	1 (0.7)	NE [NE, NE)	276	3 (1.1)	NE [NE, NE)	1.0000	1.294 (0.134, 12.479)	0.8231
	No	15	0 (0.0)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-510-ae-cox-eoi-cfz.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	1 (0.8)	NE [NE, NE)	0.9955	>999.999 (<.001, NE)	0.4829
	>= 2	87	1 (1.1)	NE [NE, NE)	177	2 (1.1)	NE [NE, NE)		0.802 (0.073, 8.854)	0.8569

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Respiratory tract infections (AMQ) - Broad										
Total subjects		153	88 (57.5)	7.6 [4.3, 11.6)	308	240 (77.9)	5.1 [3.9, 6.5)		1.378 (1.079, 1.760)	0.0099

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	80 (59.3)	7.6 [3.7, 11.6)	283	220 (77.7)	4.6 [3.9, 6.5)	0.3124	1.307 (1.012, 1.689)	0.0397
	> 75	18	8 (44.4)	10.2 [1.9, NE)	25	20 (80.0)	6.8 [2.1, 12.1)		1.901 (0.831, 4.348)	0.1218
Sex	Male	91	53 (58.2)	6.5 [3.4, 11.6)	174	138 (79.3)	5.3 [3.8, 8.1)	0.8960	1.344 (0.978, 1.847)	0.0688
	Female	62	35 (56.5)	8.6 [4.1, 13.2)	134	102 (76.1)	4.5 [3.5, 6.6)		1.399 (0.952, 2.055)	0.0854

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	69 (56.6)	8.6 [3.7, 11.6)	240	183 (76.3)	5.3 [3.9, 6.9)	0.3791	1.349 (1.022, 1.781)	0.0339
	Asian	20	12 (60.0)	7.3 [3.3, 17.3)	46	41 (89.1)	4.4 [2.0, 7.9)		1.850 (0.964, 3.551)	0.0596
	Other or Unknown	11	7 (63.6)	4.6 [1.3, 13.6)	22	16 (72.7)	4.0 [1.2, 14.9)		0.862 (0.342, 2.168)	0.7417
Region	North America	12	8 (66.7)	2.6 [0.5, NE)	21	18 (85.7)	5.4 [1.5, 11.1)	0.6686	0.951 (0.409, 2.212)	0.8939

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	58 (56.9)	9.7 [4.6, 12.1)	203	148 (72.9)	5.1 [3.8, 8.3)		1.358 (1.001, 1.841)	0.0488
	Asia Pacific	39	22 (56.4)	6.5 [2.7, 15.3)	84	74 (88.1)	5.1 [3.3, 6.1)		1.417 (0.876, 2.292)	0.1524
Baseline ECOG PS	0-1	146	87 (59.6)	7.6 [4.1, 11.6)	294	230 (78.2)	4.5 [3.8, 6.5)	0.7495	1.382 (1.079, 1.769)	0.0101
	2	7	1 (14.3)	NE [0.5, NE)	13	9 (69.2)	8.3 [0.7, 17.9)		1.348 (0.144, 12.643)	0.7930

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	79 (58.1)	7.6 [4.3, 11.6)	285	218 (76.5)	5.1 [3.9, 6.5)	0.2918	1.314 (1.015, 1.700)	0.0377
	No	17	9 (52.9)	7.3 [1.0, NE)	23	22 (95.7)	4.6 [1.6, 9.7)		1.977 (0.904, 4.324)	0.0817
Refractory to Bortezomib or Ixazomib	Yes	55	25 (45.5)	11.6 [4.3, 17.3)	99	72 (72.7)	5.7 [3.7, 8.2)	0.3916	1.651 (1.047, 2.604)	0.0291
	No	98	63 (64.3)	6.3 [2.9, 8.6)	209	168 (80.4)	4.4 [3.7, 6.6)		1.271 (0.951, 1.700)	0.1047

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	38 (51.4)	8.6 [4.3, 12.1)	122	91 (74.6)	5.9 [3.8, 9.2)	0.8548	1.329 (0.909, 1.943)	0.1409
	No	79	50 (63.3)	7.3 [2.8, 12.3)	186	149 (80.1)	4.6 [3.7, 6.4)		1.394 (1.010, 1.924)	0.0426
Refractory to Lenalidomide	Yes	55	30 (54.5)	7.4 [3.5, 11.6)	98	74 (75.5)	5.5 [2.2, 9.2)	0.1995	1.108 (0.719, 1.706)	0.6428
	No	98	58 (59.2)	8.1 [3.4, 12.5)	210	166 (79.0)	4.6 [3.8, 6.5)		1.545 (1.143, 2.089)	0.0044

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	60 (54.5)	7.6 [4.1, 12.1)	205	163 (79.5)	4.3 [3.4, 6.4)	0.3913	1.479 (1.100, 1.989)	0.0092
	No	43	28 (65.1)	8.1 [2.4, 12.3)	103	77 (74.8)	6.5 [4.2, 10.1)		1.190 (0.770, 1.837)	0.4377
Refractory to IMiD	Yes	65	36 (55.4)	7.4 [3.5, 11.6)	129	98 (76.0)	5.5 [3.3, 7.9)	0.2266	1.139 (0.774, 1.676)	0.5089
	No	88	52 (59.1)	8.1 [3.4, 12.5)	179	142 (79.3)	4.6 [3.8, 6.5)		1.554 (1.128, 2.141)	0.0067

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	73 (57.9)	8.6 [5.8, 12.3)	250	202 (80.8)	4.4 [3.7, 6.0)	0.0011	1.611 (1.232, 2.106)	0.0004
	3	27	15 (55.6)	2.8 [1.3, 12.1)	58	38 (65.5)	10.6 [5.3, 12.7)		0.501 (0.261, 0.959)	0.0342
Prior proteasome inhibitor exposure per IXRS	Yes	138	80 (58.0)	7.6 [4.3, 11.6)	276	212 (76.8)	5.1 [3.9, 6.5)	0.5887	1.343 (1.038, 1.737)	0.0245
	No	15	8 (53.3)	9.7 [0.7, NE)	32	28 (87.5)	5.5 [1.6, 11.5)		1.770 (0.802, 3.910)	0.1508

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	42 (63.6)	5.8 [2.4, 12.3)	131	104 (79.4)	4.6 [3.8, 7.9)	0.9795	1.358 (0.947, 1.948)	0.0950
	>= 2	87	46 (52.9)	9.7 [4.6, 12.1)	177	136 (76.8)	5.5 [3.5, 7.3)		1.381 (0.988, 1.930)	0.0583

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Reversible posterior leukoencephalopathy syndrome (AMQ) - Narrow										
Total subjects		153	8 (5.2)	NE [NE, NE)	308	41 (13.3)	NE [NE, NE)		2.347 (1.099, 5.010)	0.0232

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	5 (3.7)	NE [NE, NE)	283	35 (12.4)	NE [NE, NE)	0.3475	3.096 (1.212, 7.911)	0.0129
	> 75	18	3 (16.7)	NE [16.9, NE)	25	6 (24.0)	NE [11.7, NE)		1.336 (0.333, 5.356)	0.6816
Sex	Male	91	5 (5.5)	NE [NE, NE)	174	22 (12.6)	NE [NE, NE)	0.6913	1.962 (0.741, 5.190)	0.1668
	Female	62	3 (4.8)	NE [NE, NE)	134	19 (14.2)	NE [NE, NE)		2.909 (0.860, 9.840)	0.0724

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-510-ae-cox-eoi-cfz.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	5 (4.1)	NE [NE, NE)	240	33 (13.8)	NE [NE, NE)	0.2665	3.153 (1.230, 8.081)	0.0116
	Asian	20	1 (5.0)	NE [NE, NE)	46	5 (10.9)	NE [NE, NE)		1.991 (0.232, 17.089)	0.5219
	Other or Unknown	11	2 (18.2)	NE [1.2, NE)	22	3 (13.6)	NE [25.6, NE)		0.612 (0.101, 3.694)	0.5891
Region	North America	12	2 (16.7)	NE [3.8, NE)	21	10 (47.6)	15.0 [8.5, NE)	0.9729	2.486 (0.540, 11.451)	0.2267

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	3 (2.9)	NE [NE, NE)	203	14 (6.9)	NE [NE, NE)		2.119 (0.608, 7.386)	0.2280
	Asia Pacific	39	3 (7.7)	NE [NE, NE)	84	17 (20.2)	NE [NE, NE)		2.605 (0.763, 8.894)	0.1121
Baseline ECOG PS	0-1	146	8 (5.5)	NE [NE, NE)	294	40 (13.6)	NE [NE, NE)	0.9870	2.333 (1.091, 4.988)	0.0245
	2	7	0 (0.0)	NE [NE, NE)	13	1 (7.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.6015

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	7 (5.1)	NE [NE, NE)	285	39 (13.7)	NE [NE, NE)	0.5808	2.483 (1.110, 5.555)	0.0221
	No	17	1 (5.9)	NE [NE, NE)	23	2 (8.7)	NE [NE, NE)		1.145 (0.103, 12.751)	0.9121
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	10 (10.1)	NE [NE, NE)	0.9858	>999.999 (<.001, NE)	0.0196
	No	98	8 (8.2)	NE [NE, NE)	209	31 (14.8)	NE [NE, NE)		1.644 (0.755, 3.582)	0.2066

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	4 (5.4)	NE [NE, NE)	122	20 (16.4)	NE [NE, NE)	0.7297	2.561 (0.872, 7.515)	0.0761
	No	79	4 (5.1)	NE [NE, NE)	186	21 (11.3)	NE [NE, NE)		2.160 (0.741, 6.295)	0.1482
Refractory to Lenalidomide	Yes	55	3 (5.5)	NE [NE, NE)	98	19 (19.4)	NE [NE, NE)	0.5263	2.909 (0.856, 9.883)	0.0731
	No	98	5 (5.1)	NE [NE, NE)	210	22 (10.5)	NE [NE, NE)		1.967 (0.744, 5.196)	0.1644

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	7 (6.4)	NE [NE, NE)	205	32 (15.6)	NE [NE, NE)	0.7118	2.284 (1.007, 5.181)	0.0423
	No	43	1 (2.3)	NE [NE, NE)	103	9 (8.7)	NE [NE, NE)		3.460 (0.438, 27.349)	0.2099
Refractory to IMiD	Yes	65	3 (4.6)	NE [NE, NE)	129	24 (18.6)	NE [NE, NE)	0.2786	3.452 (1.036, 11.498)	0.0318
	No	88	5 (5.7)	NE [NE, NE)	179	17 (9.5)	NE [NE, NE)		1.590 (0.586, 4.313)	0.3573

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	6 (4.8)	NE [NE, NE)	250	33 (13.2)	NE [NE, NE)	0.4933	2.650 (1.110, 6.329)	0.0225
	3	27	2 (7.4)	NE [7.0, NE)	58	8 (13.8)	NE [25.3, NE)		1.288 (0.267, 6.220)	0.7520
Prior proteasome inhibitor exposure per IXRS	Yes	138	8 (5.8)	NE [NE, NE)	276	38 (13.8)	NE [NE, NE)	0.9884	2.208 (1.029, 4.738)	0.0370
	No	15	0 (0.0)	NE [NE, NE)	32	3 (9.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.2729

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	4 (6.1)	NE [NE, NE)	131	17 (13.0)	NE [NE, NE)	0.6667	1.964 (0.660, 5.846)	0.2160
	>= 2	87	4 (4.6)	NE [NE, NE)	177	24 (13.6)	NE [NE, NE)		2.747 (0.952, 7.926)	0.0514

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Thrombotic Microangiopathy (Carfilzomib) (AMQ) - Narrow										
Total subjects		153	2 (1.3)	NE [NE, NE)	308	2 (0.6)	NE [NE, NE)		0.472 (0.066, 3.349)	0.4416

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	1 (0.7)	NE [NE, NE)	283	2 (0.7)	NE [NE, NE)	0.9943	0.910 (0.082, 10.042)	0.9387
	> 75	18	1 (5.6)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.2305
Sex	Male	91	1 (1.1)	NE [NE, NE)	174	0 (0.0)	NE [NE, NE)	0.9954	<.001 (<.001, NE)	0.1635
	Female	62	1 (1.6)	NE [NE, NE)	134	2 (1.5)	NE [NE, NE)		0.850 (0.077, 9.390)	0.8945

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	2 (1.6)	NE [NE, NE)	240	1 (0.4)	NE [NE, NE)	1.0000	0.242 (0.022, 2.670)	0.2085
	Asian	20	0 (0.0)	NE [NE, NE)	46	1 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.5097
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	2 (2.0)	NE [NE, NE)	203	1 (0.5)	NE [NE, NE)		0.232 (0.021, 2.564)	0.1936
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	1 (1.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.4956
Baseline ECOG PS	0-1	146	2 (1.4)	NE [NE, NE)	294	2 (0.7)	NE [NE, NE)	0.9999	0.478 (0.067, 3.393)	0.4500
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	0 (0.0)	NE [NE, NE)	285	2 (0.7)	NE [NE, NE)	0.9965	>999.999 (<.001, NE)	0.3419
	No	17	2 (11.8)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.1024
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	1 (1.0)	NE [NE, NE)	0.9958	>999.999 (<.001, NE)	0.4744
	No	98	2 (2.0)	NE [NE, NE)	209	1 (0.5)	NE [NE, NE)		0.226 (0.020, 2.488)	0.1831

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	2 (2.7)	NE [NE, NE)	122	1 (0.8)	NE [NE, NE)	0.9941	0.274 (0.025, 3.022)	0.2575
	No	79	0 (0.0)	NE [NE, NE)	186	1 (0.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.5146
Refractory to Lenalidomide	Yes	55	1 (1.8)	NE [NE, NE)	98	1 (1.0)	NE [NE, NE)	0.9348	0.513 (0.032, 8.203)	0.6307
	No	98	1 (1.0)	NE [NE, NE)	210	1 (0.5)	NE [NE, NE)		0.461 (0.029, 7.364)	0.5741

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	2 (1.8)	NE [NE, NE)	205	2 (1.0)	NE [NE, NE)	0.9999	0.501 (0.071, 3.563)	0.4816
	No	43	0 (0.0)	NE [NE, NE)	103	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to IMiD	Yes	65	1 (1.5)	NE [NE, NE)	129	1 (0.8)	NE [NE, NE)	0.9954	0.454 (0.028, 7.256)	0.5663
	No	88	1 (1.1)	NE [NE, NE)	179	1 (0.6)	NE [NE, NE)		0.487 (0.030, 7.784)	0.6031

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	2 (1.6)	NE [NE, NE)	250	2 (0.8)	NE [NE, NE)	0.9999	0.488 (0.069, 3.465)	0.4636
	3	27	0 (0.0)	NE [NE, NE)	58	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Prior proteasome inhibitor exposure per IXRS	Yes	138	0 (0.0)	NE [NE, NE)	276	2 (0.7)	NE [NE, NE)	0.9948	>999.999 (<.001, NE)	0.3298
	No	15	2 (13.3)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0320

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	2 (3.0)	NE [NE, NE)	131	1 (0.8)	NE [NE, NE)	0.9946	0.245 (0.022, 2.705)	0.2134
	>= 2	87	0 (0.0)	NE [NE, NE)	177	1 (0.6)	NE [NE, NE)		>999.999 (<.001, NE)	0.5105

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Torsade de pointes/QT prolongation (SMQ) - Narrow										
Total subjects		153	0 (0.0)	NE [NE, NE)	308	1 (0.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.5604

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	0 (0.0)	NE [NE, NE)	283	1 (0.4)	NE [NE, NE)	0.9995	>999.999 (<.001, NE)	0.5685
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	1 (0.6)	NE [NE, NE)	0.9992	>999.999 (<.001, NE)	0.5618
	Female	62	0 (0.0)	NE [NE, NE)	134	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	0 (0.0)	NE [NE, NE)	240	1 (0.4)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.5550
	Asian	20	0 (0.0)	NE [NE, NE)	46	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	1 (4.8)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.6650

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Baseline ECOG PS	0-1	146	0 (0.0)	NE [NE, NE)	294	1 (0.3)	NE [NE, NE)	NE	>999.999 (<.001, NE)	0.5513
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	0 (0.0)	NE [NE, NE)	285	1 (0.4)	NE [NE, NE)	0.9995	>999.999 (<.001, NE)	0.5649
	No	17	0 (0.0)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	0 (0.0)	NE [NE, NE)	0.9992	NE (NE, NE)	NE
	No	98	0 (0.0)	NE [NE, NE)	209	1 (0.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.5756

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	1 (0.8)	NE [NE, NE)	0.9994	>999.999 (<.001, NE)	0.5525
	No	79	0 (0.0)	NE [NE, NE)	186	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	1 (1.0)	NE [NE, NE)	0.9993	>999.999 (<.001, NE)	0.5962
	No	98	0 (0.0)	NE [NE, NE)	210	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	0 (0.0)	NE [NE, NE)	205	1 (0.5)	NE [NE, NE)	0.9992	>999.999 (<.001, NE)	0.5519
	No	43	0 (0.0)	NE [NE, NE)	103	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	1 (0.8)	NE [NE, NE)	0.9994	>999.999 (<.001, NE)	0.6121
	No	88	0 (0.0)	NE [NE, NE)	179	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	0 (0.0)	NE [NE, NE)	250	1 (0.4)	NE [NE, NE)	0.9995	>999.999 (<.001, NE)	0.5511
	3	27	0 (0.0)	NE [NE, NE)	58	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Prior proteasome inhibitor exposure per IXRS	Yes	138	0 (0.0)	NE [NE, NE)	276	1 (0.4)	NE [NE, NE)	0.9994	>999.999 (<.001, NE)	0.5587
	No	15	0 (0.0)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-510-ae-cox-eoi-cfz.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	1 (0.8)	NE [NE, NE)	0.9993	>999.999 (<.001, NE)	0.5708
	>= 2	87	0 (0.0)	NE [NE, NE)	177	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-510-ae-cox-eoi-cfz.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Tumour lysis syndrome (SMQ) - Narrow										
Total subjects		153	1 (0.7)	NE [NE, NE)	308	4 (1.3)	NE [NE, NE)		1.775 (0.196, 16.059)	0.6046

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-510-ae-cox-eoi-cfz.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	1 (0.7)	NE [NE, NE)	283	4 (1.4)	NE [NE, NE)	0.9999	1.705 (0.189, 15.426)	0.6308
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	1 (1.1)	NE [NE, NE)	174	2 (1.1)	NE [NE, NE)	0.9948	0.815 (0.071, 9.323)	0.8690
	Female	62	0 (0.0)	NE [NE, NE)	134	2 (1.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.3342

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-510-ae-cox-eoi-cfz.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	0 (0.0)	NE [NE, NE)	240	3 (1.3)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.2146
	Asian	20	0 (0.0)	NE [NE, NE)	46	1 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.6949
	Other or Unknown	11	1 (9.1)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.1573
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-510-ae-cox-eoi-cfz.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	1 (1.0)	NE [NE, NE)	203	3 (1.5)	NE [NE, NE)		1.524 (0.159, 14.649)	0.7130
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	1 (1.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.7557
Baseline ECOG PS	0-1	146	1 (0.7)	NE [NE, NE)	294	4 (1.4)	NE [NE, NE)	0.9999	1.784 (0.197, 16.125)	0.6012
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-510-ae-cox-eoi-cfz.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	1 (0.7)	NE [NE, NE)	285	4 (1.4)	NE [NE, NE)	0.9999	1.713 (0.189, 15.480)	0.6279
	No	17	0 (0.0)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	2 (2.0)	NE [NE, NE)	0.9953	>999.999 (<.001, NE)	0.3653
	No	98	1 (1.0)	NE [NE, NE)	209	2 (1.0)	NE [NE, NE)		0.941 (0.085, 10.373)	0.9601

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-510-ae-cox-eoi-cfz.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	2 (1.6)	NE [NE, NE)	0.9945	>999.999 (<.001, NE)	0.2687
	No	79	1 (1.3)	NE [NE, NE)	186	2 (1.1)	NE [NE, NE)		0.707 (0.063, 7.950)	0.7782
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	2 (2.0)	NE [NE, NE)	0.9953	>999.999 (<.001, NE)	0.2869
	No	98	1 (1.0)	NE [NE, NE)	210	2 (1.0)	NE [NE, NE)		0.789 (0.070, 8.841)	0.8472

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-510-ae-cox-eoi-cfz.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	1 (0.9)	NE [NE, NE)	205	3 (1.5)	NE [NE, NE)	0.9959	1.377 (0.141, 13.486)	0.7828
	No	43	0 (0.0)	NE [NE, NE)	103	1 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.5162
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	2 (1.6)	NE [NE, NE)	0.9949	>999.999 (<.001, NE)	0.3135
	No	88	1 (1.1)	NE [NE, NE)	179	2 (1.1)	NE [NE, NE)		0.827 (0.074, 9.273)	0.8771

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-510-ae-cox-eoi-cfz.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	0 (0.0)	NE [NE, NE)	250	2 (0.8)	NE [NE, NE)	0.9940	>999.999 (<.001, NE)	0.3832
	3	27	1 (3.7)	NE [NE, NE)	58	2 (3.4)	NE [NE, NE)		0.941 (0.085, 10.381)	0.9605
Prior proteasome inhibitor exposure per IXRS	Yes	138	1 (0.7)	NE [NE, NE)	276	4 (1.4)	NE [NE, NE)	0.9999	1.791 (0.198, 16.195)	0.5989
	No	15	0 (0.0)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-510-ae-cox-eoi-cfz.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.510. Cox Regression of Adverse Events of Interest for Carfilzomib
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	1 (1.5)	NE [NE, NE)	131	2 (1.5)	NE [NE, NE)	0.9942	1.008 (0.091, 11.113)	0.9950
	>= 2	87	0 (0.0)	NE [NE, NE)	177	2 (1.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.4013

Includes subjects with at least one adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-510-ae-cox-eoi-cfz.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Acute renal failure (SMQ) - Narrow										
Total subjects		153	10 (6.5)	NE [NE, NE)	308	10 (3.2)	NE [NE, NE)		0.436 (0.181, 1.050)	0.0570

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-511-ae-cox-eoi-cfz-grd345.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	10 (7.4)	NE [NE, NE)	283	8 (2.8)	NE [NE, NE)	0.9912	0.331 (0.130, 0.842)	0.0147
	> 75	18	0 (0.0)	NE [NE, NE)	25	2 (8.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.2648
Sex	Male	91	8 (8.8)	NE [NE, NE)	174	5 (2.9)	NE [NE, NE)	0.1979	0.290 (0.094, 0.887)	0.0209
	Female	62	2 (3.2)	NE [NE, NE)	134	5 (3.7)	NE [NE, NE)		1.039 (0.201, 5.369)	0.9635

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-511-ae-cox-eoi-cfz-grd345.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	6 (4.9)	NE [NE, NE)	240	10 (4.2)	NE [NE, NE)	0.9999	0.767 (0.278, 2.116)	0.6073
	Asian	20	3 (15.0)	NE [11.5, NE)	46	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0036
	Other or Unknown	11	1 (9.1)	NE [1.1, NE)	22	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.1380
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	0.1570	NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	5 (4.9)	NE [NE, NE)	203	9 (4.4)	NE [NE, NE)		0.833 (0.279, 2.487)	0.7425
	Asia Pacific	39	5 (12.8)	NE [NE, NE)	84	1 (1.2)	NE [NE, NE)		0.079 (0.009, 0.679)	0.0029
Baseline ECOG PS	0-1	146	10 (6.8)	NE [NE, NE)	294	8 (2.7)	NE [NE, NE)	0.9916	0.353 (0.139, 0.896)	0.0220
	2	7	0 (0.0)	NE [NE, NE)	13	2 (15.4)	NE [3.3, NE)		>999.999 (<.001, NE)	0.4070

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	8 (5.9)	NE [NE, NE)	285	9 (3.2)	NE [NE, NE)	0.7281	0.477 (0.184, 1.239)	0.1204
	No	17	2 (11.8)	NE [9.5, NE)	23	1 (4.3)	NE [NE, NE)		0.272 (0.024, 3.031)	0.2572
Refractory to Bortezomib or Ixazomib	Yes	55	3 (5.5)	NE [NE, NE)	99	5 (5.1)	NE [NE, NE)	0.2561	0.869 (0.207, 3.640)	0.8473
	No	98	7 (7.1)	NE [NE, NE)	209	5 (2.4)	NE [NE, NE)		0.280 (0.089, 0.887)	0.0209

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	5 (6.8)	NE [NE, NE)	122	4 (3.3)	NE [NE, NE)	0.9022	0.434 (0.116, 1.618)	0.2005
	No	79	5 (6.3)	NE [NE, NE)	186	6 (3.2)	NE [NE, NE)		0.457 (0.139, 1.499)	0.1858
Refractory to Lenalidomide	Yes	55	5 (9.1)	NE [NE, NE)	98	4 (4.1)	NE [NE, NE)	0.7318	0.396 (0.106, 1.480)	0.1540
	No	98	5 (5.1)	NE [NE, NE)	210	6 (2.9)	NE [NE, NE)		0.501 (0.153, 1.644)	0.2457

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	8 (7.3)	NE [NE, NE)	205	7 (3.4)	NE [NE, NE)	0.7463	0.424 (0.154, 1.171)	0.0877
	No	43	2 (4.7)	NE [NE, NE)	103	3 (2.9)	NE [NE, NE)		0.542 (0.090, 3.259)	0.4971
Refractory to IMiD	Yes	65	7 (10.8)	NE [NE, NE)	129	5 (3.9)	NE [NE, NE)	0.3365	0.312 (0.099, 0.987)	0.0362
	No	88	3 (3.4)	NE [NE, NE)	179	5 (2.8)	NE [NE, NE)		0.734 (0.175, 3.079)	0.6732

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	8 (6.3)	NE [NE, NE)	250	5 (2.0)	NE [NE, NE)	0.2847	0.277 (0.090, 0.849)	0.0164
	3	27	2 (7.4)	NE [NE, NE)	58	5 (8.6)	NE [NE, NE)		0.930 (0.180, 4.818)	0.9312
Prior proteasome inhibitor exposure per IXRS	Yes	138	8 (5.8)	NE [NE, NE)	276	9 (3.3)	NE [NE, NE)	0.4656	0.502 (0.193, 1.303)	0.1490
	No	15	2 (13.3)	NE [9.5, NE)	32	1 (3.1)	NE [NE, NE)		0.191 (0.017, 2.117)	0.1320

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	3 (4.5)	NE [NE, NE)	131	2 (1.5)	NE [NE, NE)	0.6211	0.260 (0.043, 1.568)	0.1140
	>= 2	87	7 (8.0)	NE [NE, NE)	177	8 (4.5)	NE [NE, NE)		0.519 (0.188, 1.432)	0.1974

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Cardiac arrhythmias (SMQ) - Narrow										
Total subjects		153	4 (2.6)	NE [NE, NE)	308	10 (3.2)	NE [NE, NE)		1.058 (0.331, 3.381)	0.9244

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	3 (2.2)	NE [NE, NE)	283	7 (2.5)	NE [NE, NE)	0.6196	0.919 (0.237, 3.570)	0.9034
	> 75	18	1 (5.6)	NE [NE, NE)	25	3 (12.0)	NE [NE, NE)		1.838 (0.191, 17.709)	0.5930
Sex	Male	91	4 (4.4)	NE [NE, NE)	174	9 (5.2)	NE [NE, NE)	0.9931	1.009 (0.309, 3.290)	0.9881
	Female	62	0 (0.0)	NE [NE, NE)	134	1 (0.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.5344

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	4 (3.3)	NE [NE, NE)	240	9 (3.8)	NE [NE, NE)	1.0000	0.980 (0.301, 3.189)	0.9730
	Asian	20	0 (0.0)	NE [NE, NE)	46	1 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.5097
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	1 (4.8)	NE [NE, NE)	0.9834	>999.999 (<.001, NE)	0.6650

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	3 (2.9)	NE [NE, NE)	203	6 (3.0)	NE [NE, NE)		0.872 (0.218, 3.488)	0.8459
	Asia Pacific	39	1 (2.6)	NE [NE, NE)	84	3 (3.6)	NE [NE, NE)		1.283 (0.133, 12.344)	0.8286
Baseline ECOG PS	0-1	146	4 (2.7)	NE [NE, NE)	294	9 (3.1)	NE [NE, NE)	0.9936	0.973 (0.299, 3.166)	0.9634
	2	7	0 (0.0)	NE [NE, NE)	13	1 (7.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.6015

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	3 (2.2)	NE [NE, NE)	285	10 (3.5)	NE [NE, NE)	0.9905	1.360 (0.374, 4.954)	0.6394
	No	17	1 (5.9)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.2207
Refractory to Bortezomib or Ixazomib	Yes	55	2 (3.6)	NE [NE, NE)	99	3 (3.0)	NE [NE, NE)	0.6315	0.787 (0.132, 4.713)	0.7931
	No	98	2 (2.0)	NE [NE, NE)	209	7 (3.3)	NE [NE, NE)		1.330 (0.275, 6.428)	0.7214

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-511-ae-cox-eoi-cfz-grd345.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	2 (2.7)	NE [NE, NE)	122	4 (3.3)	NE [NE, NE)	0.9037	1.037 (0.189, 5.693)	0.9662
	No	79	2 (2.5)	NE [NE, NE)	186	6 (3.2)	NE [NE, NE)		1.106 (0.223, 5.487)	0.9016
Refractory to Lenalidomide	Yes	55	2 (3.6)	NE [NE, NE)	98	2 (2.0)	NE [NE, NE)	0.2912	0.421 (0.059, 3.032)	0.3764
	No	98	2 (2.0)	NE [NE, NE)	210	8 (3.8)	NE [NE, NE)		1.672 (0.355, 7.879)	0.5115

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	2 (1.8)	NE [NE, NE)	205	6 (2.9)	NE [NE, NE)	0.6333	1.399 (0.282, 6.942)	0.6800
	No	43	2 (4.7)	NE [NE, NE)	103	4 (3.9)	NE [NE, NE)		0.727 (0.133, 3.976)	0.7122
Refractory to IMiD	Yes	65	2 (3.1)	NE [NE, NE)	129	4 (3.1)	NE [NE, NE)	0.6675	0.789 (0.144, 4.330)	0.7841
	No	88	2 (2.3)	NE [NE, NE)	179	6 (3.4)	NE [NE, NE)		1.319 (0.266, 6.541)	0.7340

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	4 (3.2)	NE [NE, NE)	250	7 (2.8)	NE [NE, NE)	0.9925	0.763 (0.223, 2.617)	0.6666
	3	27	0 (0.0)	NE [NE, NE)	58	3 (5.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.3142
Prior proteasome inhibitor exposure per IXRS	Yes	138	3 (2.2)	NE [NE, NE)	276	10 (3.6)	NE [NE, NE)	0.9890	1.429 (0.392, 5.206)	0.5861
	No	15	1 (6.7)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0986

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	1 (1.5)	NE [NE, NE)	131	5 (3.8)	NE [NE, NE)	0.3834	2.065 (0.240, 17.728)	0.4995
	>= 2	87	3 (3.4)	NE [NE, NE)	177	5 (2.8)	NE [NE, NE)		0.682 (0.162, 2.876)	0.6005

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Cardiac failure (SMQ) - Narrow										
Total subjects		153	13 (8.5)	NE [NE, NE)	308	12 (3.9)	NE [NE, NE)		0.381 (0.174, 0.837)	0.0126

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	9 (6.7)	NE [NE, NE)	283	9 (3.2)	NE [NE, NE)	0.8407	0.381 (0.151, 0.963)	0.0343
	> 75	18	4 (22.2)	NE [12.9, NE)	25	3 (12.0)	NE [NE, NE)		0.509 (0.114, 2.276)	0.3675
Sex	Male	91	9 (9.9)	NE [NE, NE)	174	7 (4.0)	NE [NE, NE)	0.6450	0.345 (0.128, 0.929)	0.0276
	Female	62	4 (6.5)	NE [NE, NE)	134	5 (3.7)	NE [NE, NE)		0.479 (0.128, 1.789)	0.2634

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	10 (8.2)	NE [NE, NE)	240	12 (5.0)	NE [NE, NE)	0.9999	0.511 (0.220, 1.185)	0.1114
	Asian	20	3 (15.0)	NE [NE, NE)	46	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0077
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	1 (8.3)	NE [11.5, NE)	21	2 (9.5)	NE [NE, NE)	0.3869	0.926 (0.083, 10.274)	0.9497

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	7 (6.9)	NE [NE, NE)	203	8 (3.9)	NE [NE, NE)		0.492 (0.178, 1.360)	0.1634
	Asia Pacific	39	5 (12.8)	NE [NE, NE)	84	2 (2.4)	NE [NE, NE)		0.156 (0.030, 0.807)	0.0110
Baseline ECOG PS	0-1	146	13 (8.9)	NE [NE, NE)	294	10 (3.4)	NE [NE, NE)	0.9910	0.329 (0.144, 0.752)	0.0056
	2	7	0 (0.0)	NE [NE, NE)	13	2 (15.4)	NE [19.2, NE)		>999.999 (<.001, NE)	0.5186

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	11 (8.1)	NE [NE, NE)	285	9 (3.2)	NE [NE, NE)	0.3094	0.319 (0.132, 0.772)	0.0076
	No	17	2 (11.8)	NE [7.3, NE)	23	3 (13.0)	NE [NE, NE)		0.958 (0.159, 5.767)	0.9624
Refractory to Bortezomib or Ixazomib	Yes	55	5 (9.1)	NE [NE, NE)	99	2 (2.0)	NE [NE, NE)	0.3237	0.193 (0.037, 0.998)	0.0287
	No	98	8 (8.2)	NE [NE, NE)	209	10 (4.8)	NE [NE, NE)		0.483 (0.190, 1.227)	0.1182

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	7 (9.5)	NE [NE, NE)	122	4 (3.3)	NE [NE, NE)	0.4749	0.273 (0.079, 0.939)	0.0278
	No	79	6 (7.6)	NE [NE, NE)	186	8 (4.3)	NE [NE, NE)		0.491 (0.170, 1.416)	0.1789
Refractory to Lenalidomide	Yes	55	4 (7.3)	NE [NE, NE)	98	3 (3.1)	NE [NE, NE)	0.7877	0.352 (0.079, 1.577)	0.1536
	No	98	9 (9.2)	NE [NE, NE)	210	9 (4.3)	NE [NE, NE)		0.404 (0.160, 1.020)	0.0471

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	8 (7.3)	NE [NE, NE)	205	6 (2.9)	NE [NE, NE)	0.7516	0.335 (0.116, 0.970)	0.0343
	No	43	5 (11.6)	NE [NE, NE)	103	6 (5.8)	NE [NE, NE)		0.425 (0.129, 1.398)	0.1470
Refractory to IMiD	Yes	65	4 (6.2)	NE [NE, NE)	129	3 (2.3)	NE [NE, NE)	0.6642	0.320 (0.071, 1.430)	0.1154
	No	88	9 (10.2)	NE [NE, NE)	179	9 (5.0)	NE [NE, NE)		0.429 (0.170, 1.082)	0.0648

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
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[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	9 (7.1)	NE [NE, NE)	250	10 (4.0)	NE [NE, NE)	0.2383	0.487 (0.198, 1.201)	0.1105
	3	27	4 (14.8)	NE [NE, NE)	58	2 (3.4)	NE [NE, NE)		0.163 (0.029, 0.906)	0.0187
Prior proteasome inhibitor exposure per IXRS	Yes	138	11 (8.0)	NE [NE, NE)	276	9 (3.3)	NE [NE, NE)	0.5963	0.332 (0.137, 0.802)	0.0101
	No	15	2 (13.3)	NE [3.5, NE)	32	3 (9.4)	NE [NE, NE)		0.624 (0.104, 3.750)	0.6027

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-511-ae-cox-eoi-cfz-grd345.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	8 (12.1)	NE [NE, NE)	131	5 (3.8)	NE [NE, NE)	0.3350	0.254 (0.083, 0.780)	0.0098
	>= 2	87	5 (5.7)	NE [NE, NE)	177	7 (4.0)	NE [NE, NE)		0.572 (0.181, 1.808)	0.3361

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Cardiomyopathy (SMQ) - Narrow										
Total subjects		153	1 (0.7)	NE [NE, NE)	308	1 (0.3)	NE [NE, NE)		0.403 (0.025, 6.452)	0.5060

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	0 (0.0)	NE [NE, NE)	283	1 (0.4)	NE [NE, NE)	0.9975	>999.999 (<.001, NE)	0.5516
	> 75	18	1 (5.6)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.1835
Sex	Male	91	1 (1.1)	NE [NE, NE)	174	1 (0.6)	NE [NE, NE)	0.9999	0.417 (0.026, 6.710)	0.5242
	Female	62	0 (0.0)	NE [NE, NE)	134	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	1 (0.8)	NE [NE, NE)	240	1 (0.4)	NE [NE, NE)	1.0000	0.419 (0.026, 6.715)	0.5258
	Asian	20	0 (0.0)	NE [NE, NE)	46	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
	Asia Pacific	39	1 (2.6)	NE [NE, NE)	84	1 (1.2)	NE [NE, NE)		0.368 (0.023, 5.901)	0.4621
Baseline ECOG PS	0-1	146	1 (0.7)	NE [NE, NE)	294	1 (0.3)	NE [NE, NE)	0.9999	0.416 (0.026, 6.669)	0.5226
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	0 (0.0)	NE [NE, NE)	285	0 (0.0)	NE [NE, NE)	0.9999	NE (NE, NE)	NE
	No	17	1 (5.9)	NE [NE, NE)	23	1 (4.3)	NE [NE, NE)		0.504 (0.031, 8.101)	0.6220
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	0 (0.0)	NE [NE, NE)	0.9999	NE (NE, NE)	NE
	No	98	1 (1.0)	NE [NE, NE)	209	1 (0.5)	NE [NE, NE)		0.382 (0.024, 6.115)	0.4800

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	1 (1.4)	NE [NE, NE)	122	0 (0.0)	NE [NE, NE)	0.9972	<.001 (<.001, NE)	0.1573
	No	79	0 (0.0)	NE [NE, NE)	186	1 (0.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.5622
Refractory to Lenalidomide	Yes	55	1 (1.8)	NE [NE, NE)	98	0 (0.0)	NE [NE, NE)	0.9974	<.001 (<.001, NE)	0.1504
	No	98	0 (0.0)	NE [NE, NE)	210	1 (0.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.5412

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	1 (0.9)	NE [NE, NE)	205	1 (0.5)	NE [NE, NE)	0.9999	0.425 (0.027, 6.797)	0.5326
	No	43	0 (0.0)	NE [NE, NE)	103	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to IMiD	Yes	65	1 (1.5)	NE [NE, NE)	129	0 (0.0)	NE [NE, NE)	0.9963	<.001 (<.001, NE)	0.1250
	No	88	0 (0.0)	NE [NE, NE)	179	1 (0.6)	NE [NE, NE)		>999.999 (<.001, NE)	0.5271

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	1 (0.8)	NE [NE, NE)	250	1 (0.4)	NE [NE, NE)	0.9999	0.435 (0.027, 6.966)	0.5451
	3	27	0 (0.0)	NE [NE, NE)	58	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Prior proteasome inhibitor exposure per IXRS	Yes	138	0 (0.0)	NE [NE, NE)	276	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE
	No	15	1 (6.7)	NE [3.5, NE)	32	1 (3.1)	NE [NE, NE)		0.333 (0.021, 5.329)	0.4142

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	0 (0.0)	NE [NE, NE)	0.9999	NE (NE, NE)	NE
	>= 2	87	1 (1.1)	NE [NE, NE)	177	1 (0.6)	NE [NE, NE)		0.397 (0.025, 6.356)	0.4984

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Dyspnoeas (HLT)										
Total subjects		153	4 (2.6)	NE [NE, NE)	308	14 (4.5)	NE [NE, NE)		1.532 (0.503, 4.668)	0.4493

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	4 (3.0)	NE [NE, NE)	283	14 (4.9)	NE [NE, NE)	0.9999	1.477 (0.485, 4.501)	0.4898
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	2 (2.2)	NE [NE, NE)	174	9 (5.2)	NE [NE, NE)	0.5320	2.178 (0.469, 10.114)	0.3084
	Female	62	2 (3.2)	NE [NE, NE)	134	5 (3.7)	NE [NE, NE)		0.998 (0.193, 5.172)	0.9981

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	3 (2.5)	NE [NE, NE)	240	11 (4.6)	NE [NE, NE)	0.6108	1.685 (0.469, 6.055)	0.4189
	Asian	20	1 (5.0)	NE [NE, NE)	46	1 (2.2)	NE [NE, NE)		0.275 (0.016, 4.729)	0.3447
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	2 (9.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.3324
Region	North America	12	0 (0.0)	NE [NE, NE)	21	1 (4.8)	NE [NE, NE)	0.9602	>999.999 (<.001, NE)	0.4497

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	2 (2.0)	NE [NE, NE)	203	7 (3.4)	NE [NE, NE)		1.586 (0.329, 7.652)	0.5616
	Asia Pacific	39	2 (5.1)	NE [NE, NE)	84	6 (7.1)	NE [NE, NE)		1.152 (0.230, 5.766)	0.8632
Baseline ECOG PS	0-1	146	3 (2.1)	NE [NE, NE)	294	12 (4.1)	NE [NE, NE)	0.4674	1.733 (0.488, 6.161)	0.3895
	2	7	1 (14.3)	NE [0.3, NE)	13	2 (15.4)	NE [1.3, NE)		1.080 (0.098, 11.920)	0.9500

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	4 (2.9)	NE [NE, NE)	285	14 (4.9)	NE [NE, NE)	0.9999	1.475 (0.484, 4.494)	0.4913
	No	17	0 (0.0)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to Bortezomib or Ixazomib	Yes	55	1 (1.8)	NE [NE, NE)	99	4 (4.0)	NE [NE, NE)	0.7667	1.715 (0.189, 15.571)	0.6276
	No	98	3 (3.1)	NE [NE, NE)	209	10 (4.8)	NE [NE, NE)		1.438 (0.395, 5.232)	0.5789

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	1 (1.4)	NE [NE, NE)	122	7 (5.7)	NE [NE, NE)	0.2644	3.943 (0.484, 32.095)	0.1660
	No	79	3 (3.8)	NE [NE, NE)	186	7 (3.8)	NE [NE, NE)		0.866 (0.223, 3.360)	0.8351
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	5 (5.1)	NE [NE, NE)	0.9910	>999.999 (<.001, NE)	0.1127
	No	98	4 (4.1)	NE [NE, NE)	210	9 (4.3)	NE [NE, NE)		0.939 (0.288, 3.055)	0.9163

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	3 (2.7)	NE [NE, NE)	205	13 (6.3)	NE [NE, NE)	0.2824	2.092 (0.595, 7.358)	0.2397
	No	43	1 (2.3)	NE [NE, NE)	103	1 (1.0)	NE [NE, NE)		0.324 (0.020, 5.282)	0.4053
Refractory to IMiD	Yes	65	1 (1.5)	NE [NE, NE)	129	7 (5.4)	NE [NE, NE)	0.4078	3.198 (0.393, 26.059)	0.2509
	No	88	3 (3.4)	NE [NE, NE)	179	7 (3.9)	NE [NE, NE)		1.021 (0.263, 3.959)	0.9763

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	3 (2.4)	NE [NE, NE)	250	12 (4.8)	NE [NE, NE)	0.5079	1.795 (0.505, 6.382)	0.3595
	3	27	1 (3.7)	NE [NE, NE)	58	2 (3.4)	NE [NE, NE)		0.851 (0.076, 9.475)	0.8952
Prior proteasome inhibitor exposure per IXRS	Yes	138	4 (2.9)	NE [NE, NE)	276	13 (4.7)	NE [NE, NE)	0.9930	1.427 (0.464, 4.391)	0.5329
	No	15	0 (0.0)	NE [NE, NE)	32	1 (3.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.4867

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	2 (3.0)	NE [NE, NE)	131	6 (4.6)	NE [NE, NE)	0.8228	1.358 (0.274, 6.742)	0.7067
	>= 2	87	2 (2.3)	NE [NE, NE)	177	8 (4.5)	NE [NE, NE)		1.673 (0.352, 7.947)	0.5132

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Embolic and thrombotic events, venous (SMQ) - Narrow										
Total subjects		153	10 (6.5)	NE [NE, NE)	308	6 (1.9)	NE [NE, NE)		0.234 (0.085, 0.646)	0.0023

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	9 (6.7)	NE [NE, NE)	283	5 (1.8)	NE [NE, NE)	0.5251	0.211 (0.070, 0.631)	0.0022
	> 75	18	1 (5.6)	NE [NE, NE)	25	1 (4.0)	NE [NE, NE)		0.522 (0.033, 8.355)	0.6402
Sex	Male	91	5 (5.5)	NE [NE, NE)	174	5 (2.9)	NE [NE, NE)	0.1612	0.405 (0.117, 1.407)	0.1418
	Female	62	5 (8.1)	NE [NE, NE)	134	1 (0.7)	NE [NE, NE)		0.075 (0.009, 0.642)	0.0021

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	10 (8.2)	NE [NE, NE)	240	5 (2.1)	NE [NE, NE)	1.0000	0.199 (0.068, 0.584)	0.0011
	Asian	20	0 (0.0)	NE [NE, NE)	46	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	1 (4.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.5741
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	0.8120	NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	7 (6.9)	NE [NE, NE)	203	5 (2.5)	NE [NE, NE)		0.281 (0.089, 0.888)	0.0209
	Asia Pacific	39	3 (7.7)	NE [NE, NE)	84	1 (1.2)	NE [NE, NE)		0.111 (0.011, 1.090)	0.0233
Baseline ECOG PS	0-1	146	10 (6.8)	NE [NE, NE)	294	6 (2.0)	NE [NE, NE)	0.9997	0.242 (0.088, 0.668)	0.0030
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

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CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	8 (5.9)	NE [NE, NE)	285	5 (1.8)	NE [NE, NE)	0.9357	0.245 (0.080, 0.751)	0.0076
	No	17	2 (11.8)	NE [18.6, NE)	23	1 (4.3)	NE [NE, NE)		0.213 (0.019, 2.388)	0.1686
Refractory to Bortezomib or Ixazomib	Yes	55	2 (3.6)	NE [NE, NE)	99	1 (1.0)	NE [NE, NE)	0.9998	0.230 (0.021, 2.554)	0.1919
	No	98	8 (8.2)	NE [NE, NE)	209	5 (2.4)	NE [NE, NE)		0.228 (0.074, 0.700)	0.0048

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CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	2 (2.7)	NE [NE, NE)	122	1 (0.8)	NE [NE, NE)	0.9762	0.235 (0.021, 2.613)	0.1998
	No	79	8 (10.1)	NE [NE, NE)	186	5 (2.7)	NE [NE, NE)		0.217 (0.071, 0.666)	0.0033
Refractory to Lenalidomide	Yes	55	2 (3.6)	NE [NE, NE)	98	1 (1.0)	NE [NE, NE)	0.8754	0.207 (0.018, 2.330)	0.1602
	No	98	8 (8.2)	NE [NE, NE)	210	5 (2.4)	NE [NE, NE)		0.242 (0.079, 0.742)	0.0070

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	5 (4.5)	NE [NE, NE)	205	3 (1.5)	NE [NE, NE)	0.7982	0.251 (0.060, 1.054)	0.0415
	No	43	5 (11.6)	NE [NE, NE)	103	3 (2.9)	NE [NE, NE)		0.196 (0.047, 0.824)	0.0134
Refractory to IMiD	Yes	65	3 (4.6)	NE [NE, NE)	129	1 (0.8)	NE [NE, NE)	0.4887	0.125 (0.013, 1.221)	0.0345
	No	88	7 (8.0)	NE [NE, NE)	179	5 (2.8)	NE [NE, NE)		0.293 (0.093, 0.923)	0.0258

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	9 (7.1)	NE [NE, NE)	250	5 (2.0)	NE [NE, NE)	0.9206	0.233 (0.078, 0.696)	0.0045
	3	27	1 (3.7)	NE [NE, NE)	58	1 (1.7)	NE [NE, NE)		0.261 (0.016, 4.223)	0.3090
Prior proteasome inhibitor exposure per IXRS	Yes	138	8 (5.8)	NE [NE, NE)	276	5 (1.8)	NE [NE, NE)	0.7719	0.254 (0.083, 0.778)	0.0096
	No	15	2 (13.3)	NE [3.9, NE)	32	1 (3.1)	NE [NE, NE)		0.163 (0.015, 1.801)	0.0910

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	7 (10.6)	NE [NE, NE)	131	3 (2.3)	NE [NE, NE)	0.4560	0.175 (0.045, 0.680)	0.0045
	>= 2	87	3 (3.4)	NE [NE, NE)	177	3 (1.7)	NE [NE, NE)		0.391 (0.079, 1.943)	0.2341

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Haematopoietic erythropenia (SMQ) - Broad										
Total subjects		153	23 (15.0)	NE [NE, NE)	308	54 (17.5)	NE [NE, NE)		1.122 (0.689, 1.830)	0.6431

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	21 (15.6)	NE [NE, NE)	283	51 (18.0)	NE [NE, NE)	0.9397	1.113 (0.669, 1.852)	0.6792
	> 75	18	2 (11.1)	NE [NE, NE)	25	3 (12.0)	NE [NE, NE)		1.038 (0.173, 6.213)	0.9673
Sex	Male	91	16 (17.6)	NE [NE, NE)	174	23 (13.2)	NE [NE, NE)	0.0429	0.696 (0.367, 1.319)	0.2641
	Female	62	7 (11.3)	NE [NE, NE)	134	31 (23.1)	NE [NE, NE)		2.060 (0.907, 4.679)	0.0776

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	18 (14.8)	NE [NE, NE)	240	35 (14.6)	NE [NE, NE)	0.5821	0.962 (0.544, 1.699)	0.8928
	Asian	20	4 (20.0)	NE [11.8, NE)	46	16 (34.8)	NE [15.3, NE)		1.742 (0.582, 5.221)	0.3141
	Other or Unknown	11	1 (9.1)	NE [0.8, NE)	22	3 (13.6)	NE [NE, NE)		1.039 (0.107, 10.084)	0.9733
Region	North America	12	1 (8.3)	NE [NE, NE)	21	3 (14.3)	NE [NE, NE)	0.6580	1.189 (0.118, 11.981)	0.8832

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	12 (11.8)	NE [NE, NE)	203	32 (15.8)	NE [NE, NE)		1.320 (0.680, 2.563)	0.4107
	Asia Pacific	39	10 (25.6)	NE [17.3, NE)	84	19 (22.6)	NE [NE, NE)		0.814 (0.377, 1.757)	0.5997
Baseline ECOG PS	0-1	146	21 (14.4)	NE [NE, NE)	294	52 (17.7)	NE [NE, NE)	0.1595	1.206 (0.726, 2.003)	0.4685
	2	7	2 (28.6)	NE [0.3, NE)	13	2 (15.4)	NE [2.1, NE)		0.333 (0.045, 2.447)	0.2578

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	20 (14.7)	NE [NE, NE)	285	51 (17.9)	NE [NE, NE)	0.5369	1.184 (0.706, 1.987)	0.5211
	No	17	3 (17.6)	NE [11.8, NE)	23	3 (13.0)	NE [NE, NE)		0.542 (0.107, 2.749)	0.4529
Refractory to Bortezomib or Ixazomib	Yes	55	9 (16.4)	NE [NE, NE)	99	23 (23.2)	NE [NE, NE)	0.4588	1.430 (0.662, 3.092)	0.3591
	No	98	14 (14.3)	NE [NE, NE)	209	31 (14.8)	NE [NE, NE)		0.964 (0.512, 1.814)	0.9092

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	13 (17.6)	NE [NE, NE)	122	27 (22.1)	NE [NE, NE)	0.8676	1.233 (0.635, 2.392)	0.5359
	No	79	10 (12.7)	NE [NE, NE)	186	27 (14.5)	NE [NE, NE)		1.103 (0.534, 2.280)	0.7912
Refractory to Lenalidomide	Yes	55	10 (18.2)	NE [NE, NE)	98	24 (24.5)	NE [NE, NE)	0.6655	1.307 (0.623, 2.740)	0.4769
	No	98	13 (13.3)	NE [NE, NE)	210	30 (14.3)	NE [NE, NE)		1.036 (0.540, 1.987)	0.9141

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	18 (16.4)	NE [NE, NE)	205	39 (19.0)	NE [NE, NE)	0.9115	1.140 (0.651, 1.994)	0.6473
	No	43	5 (11.6)	NE [NE, NE)	103	15 (14.6)	NE [NE, NE)		1.194 (0.434, 3.287)	0.7319
Refractory to IMiD	Yes	65	12 (18.5)	NE [NE, NE)	129	28 (21.7)	NE [NE, NE)	0.9983	1.153 (0.585, 2.272)	0.6817
	No	88	11 (12.5)	NE [NE, NE)	179	26 (14.5)	NE [NE, NE)		1.119 (0.553, 2.265)	0.7555

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	13 (10.3)	NE [NE, NE)	250	40 (16.0)	NE [NE, NE)	0.0266	1.526 (0.815, 2.855)	0.1831
	3	27	10 (37.0)	NE [0.9, NE)	58	14 (24.1)	NE [NE, NE)		0.534 (0.237, 1.203)	0.1240
Prior proteasome inhibitor exposure per IXRS	Yes	138	20 (14.5)	NE [NE, NE)	276	50 (18.1)	NE [NE, NE)	0.3669	1.213 (0.722, 2.038)	0.4648
	No	15	3 (20.0)	NE [11.8, NE)	32	4 (12.5)	NE [NE, NE)		0.570 (0.127, 2.560)	0.4581

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-511-ae-cox-eoi-cfz-grd345.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	6 (9.1)	NE [NE, NE)	131	19 (14.5)	NE [NE, NE)	0.4054	1.520 (0.606, 3.809)	0.3683
	>= 2	87	17 (19.5)	NE [NE, NE)	177	35 (19.8)	NE [NE, NE)		0.980 (0.549, 1.751)	0.9455

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Haematopoietic leukopenia (SMQ) - Narrow										
Total subjects		153	19 (12.4)	NE [NE, NE)	308	49 (15.9)	NE [NE, NE)		1.204 (0.708, 2.048)	0.4939

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	15 (11.1)	NE [NE, NE)	283	47 (16.6)	NE [NE, NE)	0.1076	1.415 (0.790, 2.533)	0.2411
	> 75	18	4 (22.2)	NE [12.1, NE)	25	2 (8.0)	NE [NE, NE)		0.338 (0.062, 1.853)	0.1851
Sex	Male	91	10 (11.0)	NE [NE, NE)	174	27 (15.5)	NE [NE, NE)	0.7427	1.316 (0.636, 2.724)	0.4584
	Female	62	9 (14.5)	NE [NE, NE)	134	22 (16.4)	NE [NE, NE)		1.085 (0.499, 2.360)	0.8389

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	9 (7.4)	NE [NE, NE)	240	20 (8.3)	NE [NE, NE)	0.9058	1.012 (0.459, 2.230)	0.9777
	Asian	20	9 (45.0)	NE [0.4, NE)	46	26 (56.5)	6.4 [0.6, NE)		1.317 (0.616, 2.812)	0.4817
	Other or Unknown	11	1 (9.1)	NE [12.1, NE)	22	3 (13.6)	NE [NE, NE)		1.255 (0.129, 12.175)	0.8444
Region	North America	12	0 (0.0)	NE [NE, NE)	21	1 (4.8)	NE [NE, NE)	0.9974	>999.999 (<.001, NE)	0.4497

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	8 (7.8)	NE [NE, NE)	203	20 (9.9)	NE [NE, NE)		1.142 (0.502, 2.597)	0.7517
	Asia Pacific	39	11 (28.2)	NE [NE, NE)	84	28 (33.3)	NE [NE, NE)		1.171 (0.582, 2.357)	0.6622
Baseline ECOG PS	0-1	146	18 (12.3)	NE [NE, NE)	294	46 (15.6)	NE [NE, NE)	0.9333	1.202 (0.696, 2.075)	0.5107
	2	7	1 (14.3)	NE [0.3, NE)	13	3 (23.1)	NE [1.0, NE)		1.216 (0.126, 11.773)	0.8799

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	17 (12.5)	NE [NE, NE)	285	46 (16.1)	NE [NE, NE)	0.8256	1.213 (0.694, 2.119)	0.4985
	No	17	2 (11.8)	NE [NE, NE)	23	3 (13.0)	NE [NE, NE)		1.018 (0.169, 6.132)	0.9849
Refractory to Bortezomib or Ixazomib	Yes	55	8 (14.5)	NE [NE, NE)	99	17 (17.2)	NE [NE, NE)	0.7828	1.094 (0.471, 2.537)	0.8337
	No	98	11 (11.2)	NE [NE, NE)	209	32 (15.3)	NE [NE, NE)		1.315 (0.662, 2.614)	0.4339

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	7 (9.5)	NE [NE, NE)	122	28 (23.0)	NE [NE, NE)	0.0253	2.413 (1.052, 5.533)	0.0319
	No	79	12 (15.2)	NE [NE, NE)	186	21 (11.3)	NE [NE, NE)		0.671 (0.330, 1.367)	0.2690
Refractory to Lenalidomide	Yes	55	5 (9.1)	NE [NE, NE)	98	21 (21.4)	NE [NE, NE)	0.1219	2.214 (0.831, 5.895)	0.1025
	No	98	14 (14.3)	NE [NE, NE)	210	28 (13.3)	NE [NE, NE)		0.878 (0.462, 1.670)	0.6919

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	13 (11.8)	NE [NE, NE)	205	38 (18.5)	NE [NE, NE)	0.2301	1.489 (0.792, 2.799)	0.2146
	No	43	6 (14.0)	NE [NE, NE)	103	11 (10.7)	NE [NE, NE)		0.712 (0.263, 1.931)	0.5018
Refractory to IMiD	Yes	65	7 (10.8)	NE [NE, NE)	129	25 (19.4)	NE [NE, NE)	0.2862	1.703 (0.735, 3.950)	0.2096
	No	88	12 (13.6)	NE [NE, NE)	179	24 (13.4)	NE [NE, NE)		0.924 (0.462, 1.850)	0.8240

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	16 (12.7)	NE [NE, NE)	250	41 (16.4)	NE [NE, NE)	0.7953	1.244 (0.697, 2.220)	0.4613
	3	27	3 (11.1)	NE [NE, NE)	58	8 (13.8)	NE [NE, NE)		1.017 (0.268, 3.854)	0.9806
Prior proteasome inhibitor exposure per IXRS	Yes	138	18 (13.0)	NE [NE, NE)	276	45 (16.3)	NE [NE, NE)	0.7115	1.167 (0.675, 2.020)	0.5814
	No	15	1 (6.7)	NE [NE, NE)	32	4 (12.5)	NE [NE, NE)		1.876 (0.209, 16.829)	0.5703

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	9 (13.6)	NE [NE, NE)	131	17 (13.0)	NE [NE, NE)	0.3090	0.884 (0.394, 1.987)	0.7648
	>= 2	87	10 (11.5)	NE [NE, NE)	177	32 (18.1)	NE [NE, NE)		1.491 (0.731, 3.040)	0.2692

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Haematopoietic thrombocytopenia (SMQ) - Narrow										
Total subjects		153	25 (16.3)	NE [NE, NE)	308	77 (25.0)	NE [NE, NE)		1.595 (1.015, 2.505)	0.0415

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	22 (16.3)	NE [NE, NE)	283	72 (25.4)	NE [NE, NE)	0.7117	1.638 (1.016, 2.641)	0.0413
	> 75	18	3 (16.7)	NE [10.9, NE)	25	5 (20.0)	NE [NE, NE)		1.178 (0.281, 4.930)	0.8227
Sex	Male	91	15 (16.5)	NE [NE, NE)	174	42 (24.1)	NE [NE, NE)	0.8362	1.538 (0.852, 2.775)	0.1532
	Female	62	10 (16.1)	NE [NE, NE)	134	35 (26.1)	NE [NE, NE)		1.671 (0.827, 3.377)	0.1470

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	16 (13.1)	NE [NE, NE)	240	48 (20.0)	NE [NE, NE)	0.3651	1.618 (0.919, 2.850)	0.0934
	Asian	20	6 (30.0)	NE [2.1, NE)	46	25 (54.3)	9.4 [0.6, NE)		2.081 (0.853, 5.077)	0.0994
	Other or Unknown	11	3 (27.3)	NE [0.8, NE)	22	4 (18.2)	NE [NE, NE)		0.558 (0.124, 2.503)	0.4400
Region	North America	12	3 (25.0)	NE [1.2, NE)	21	6 (28.6)	NE [0.7, NE)	0.6865	1.221 (0.305, 4.889)	0.7891

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	14 (13.7)	NE [NE, NE)	203	39 (19.2)	NE [NE, NE)		1.434 (0.778, 2.641)	0.2479
	Asia Pacific	39	8 (20.5)	NE [NE, NE)	84	32 (38.1)	NE [24.4, NE)		2.026 (0.932, 4.401)	0.0693
Baseline ECOG PS	0-1	146	23 (15.8)	NE [NE, NE)	294	73 (24.8)	NE [NE, NE)	0.4981	1.656 (1.036, 2.646)	0.0335
	2	7	2 (28.6)	NE [0.4, NE)	13	4 (30.8)	NE [0.4, NE)		1.149 (0.210, 6.290)	0.8597

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	24 (17.6)	NE [NE, NE)	285	75 (26.3)	NE [NE, NE)	0.9420	1.562 (0.986, 2.474)	0.0563
	No	17	1 (5.9)	NE [9.5, NE)	23	2 (8.7)	NE [NE, NE)		1.304 (0.118, 14.456)	0.8285
Refractory to Bortezomib or Ixazomib	Yes	55	13 (23.6)	NE [NE, NE)	99	29 (29.3)	NE [NE, NE)	0.4184	1.331 (0.691, 2.561)	0.3998
	No	98	12 (12.2)	NE [NE, NE)	209	48 (23.0)	NE [NE, NE)		1.927 (1.023, 3.630)	0.0387

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	16 (21.6)	NE [NE, NE)	122	39 (32.0)	NE [NE, NE)	0.7834	1.606 (0.897, 2.876)	0.1117
	No	79	9 (11.4)	NE [NE, NE)	186	38 (20.4)	NE [NE, NE)		1.833 (0.886, 3.792)	0.0970
Refractory to Lenalidomide	Yes	55	11 (20.0)	NE [NE, NE)	98	33 (33.7)	NE [NE, NE)	0.6178	1.869 (0.944, 3.701)	0.0698
	No	98	14 (14.3)	NE [NE, NE)	210	44 (21.0)	NE [NE, NE)		1.485 (0.814, 2.711)	0.1952

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	18 (16.4)	NE [NE, NE)	205	56 (27.3)	NE [NE, NE)	0.5065	1.792 (1.054, 3.049)	0.0298
	No	43	7 (16.3)	NE [NE, NE)	103	21 (20.4)	NE [NE, NE)		1.237 (0.525, 2.913)	0.6265
Refractory to IMiD	Yes	65	13 (20.0)	NE [NE, NE)	129	41 (31.8)	NE [NE, NE)	0.7317	1.749 (0.937, 3.265)	0.0769
	No	88	12 (13.6)	NE [NE, NE)	179	36 (20.1)	NE [NE, NE)		1.480 (0.770, 2.846)	0.2365

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	17 (13.5)	NE [NE, NE)	250	57 (22.8)	NE [NE, NE)	0.3387	1.773 (1.031, 3.049)	0.0360
	3	27	8 (29.6)	NE [1.2, NE)	58	20 (34.5)	NE [NE, NE)		1.163 (0.512, 2.642)	0.7317
Prior proteasome inhibitor exposure per IXRS	Yes	138	23 (16.7)	NE [NE, NE)	276	72 (26.1)	NE [NE, NE)	0.7173	1.643 (1.027, 2.628)	0.0369
	No	15	2 (13.3)	NE [9.5, NE)	32	5 (15.6)	NE [NE, NE)		1.128 (0.218, 5.828)	0.8854

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	8 (12.1)	NE [NE, NE)	131	28 (21.4)	NE [NE, NE)	0.7096	1.793 (0.817, 3.936)	0.1395
	>= 2	87	17 (19.5)	NE [NE, NE)	177	49 (27.7)	NE [NE, NE)		1.516 (0.873, 2.634)	0.1400

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Haemorrhage terms (excl laboratory terms) (SMQ) - Narrow										
Total subjects		153	5 (3.3)	NE [NE, NE)	308	7 (2.3)	NE [NE, NE)		0.584 (0.184, 1.853)	0.3557

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	4 (3.0)	NE [NE, NE)	283	7 (2.5)	NE [NE, NE)	0.9917	0.697 (0.202, 2.402)	0.5660
	> 75	18	1 (5.6)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.2305
Sex	Male	91	2 (2.2)	NE [NE, NE)	174	4 (2.3)	NE [NE, NE)	0.4951	0.811 (0.146, 4.519)	0.8107
	Female	62	3 (4.8)	NE [NE, NE)	134	3 (2.2)	NE [NE, NE)		0.410 (0.083, 2.034)	0.2594

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	5 (4.1)	NE [NE, NE)	240	5 (2.1)	NE [NE, NE)	0.9999	0.415 (0.119, 1.446)	0.1543
	Asian	20	0 (0.0)	NE [NE, NE)	46	1 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.5097
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	1 (4.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.4795
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	0.9795	NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	4 (3.9)	NE [NE, NE)	203	5 (2.5)	NE [NE, NE)		0.549 (0.147, 2.048)	0.3648
	Asia Pacific	39	1 (2.6)	NE [19.8, NE)	84	2 (2.4)	NE [NE, NE)		0.713 (0.062, 8.209)	0.7851
Baseline ECOG PS	0-1	146	5 (3.4)	NE [NE, NE)	294	6 (2.0)	NE [NE, NE)	0.9927	0.501 (0.152, 1.654)	0.2476
	2	7	0 (0.0)	NE [NE, NE)	13	1 (7.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.4631

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	2 (1.5)	NE [NE, NE)	285	6 (2.1)	NE [NE, NE)	0.1939	1.272 (0.255, 6.337)	0.7687
	No	17	3 (17.6)	NE [19.8, NE)	23	1 (4.3)	NE [NE, NE)		0.180 (0.018, 1.761)	0.0989
Refractory to Bortezomib or Ixazomib	Yes	55	1 (1.8)	NE [NE, NE)	99	4 (4.0)	NE [NE, NE)	0.1595	2.136 (0.239, 19.116)	0.4872
	No	98	4 (4.1)	NE [NE, NE)	209	3 (1.4)	NE [NE, NE)		0.266 (0.059, 1.206)	0.0659

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-511-ae-cox-eoi-cfz-grd345.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	4 (5.4)	NE [NE, NE)	122	3 (2.5)	NE [NE, NE)	0.2953	0.361 (0.079, 1.647)	0.1708
	No	79	1 (1.3)	NE [NE, NE)	186	4 (2.2)	NE [NE, NE)		1.463 (0.162, 13.192)	0.7325
Refractory to Lenalidomide	Yes	55	2 (3.6)	NE [19.8, NE)	98	3 (3.1)	NE [NE, NE)	0.8867	0.632 (0.101, 3.934)	0.6197
	No	98	3 (3.1)	NE [NE, NE)	210	4 (1.9)	NE [NE, NE)		0.551 (0.123, 2.477)	0.4310

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	4 (3.6)	NE [NE, NE)	205	4 (2.0)	NE [NE, NE)	0.4996	0.459 (0.114, 1.851)	0.2619
	No	43	1 (2.3)	NE [NE, NE)	103	3 (2.9)	NE [NE, NE)		1.035 (0.107, 10.037)	0.9764
Refractory to IMiD	Yes	65	2 (3.1)	NE [19.8, NE)	129	3 (2.3)	NE [NE, NE)	0.9891	0.559 (0.090, 3.477)	0.5273
	No	88	3 (3.4)	NE [NE, NE)	179	4 (2.2)	NE [NE, NE)		0.582 (0.129, 2.613)	0.4745

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	4 (3.2)	NE [NE, NE)	250	5 (2.0)	NE [NE, NE)	0.8765	0.523 (0.139, 1.967)	0.3295
	3	27	1 (3.7)	NE [NE, NE)	58	2 (3.4)	NE [NE, NE)		0.742 (0.067, 8.231)	0.8070
Prior proteasome inhibitor exposure per IXRS	Yes	138	2 (1.4)	NE [NE, NE)	276	6 (2.2)	NE [NE, NE)	0.0998	1.335 (0.268, 6.652)	0.7237
	No	15	3 (20.0)	NE [19.8, NE)	32	1 (3.1)	NE [NE, NE)		0.121 (0.013, 1.174)	0.0299

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	2 (3.0)	NE [NE, NE)	131	4 (3.1)	NE [NE, NE)	0.5353	0.847 (0.154, 4.670)	0.8489
	>= 2	87	3 (3.4)	NE [NE, NE)	177	3 (1.7)	NE [NE, NE)		0.404 (0.080, 2.029)	0.2550

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Hepatic failure, fibrosis and cirrhosis and other liver damage-related conditions (SMQ) - Narrow										
Total subjects		153	1 (0.7)	NE [NE, NE)	308	3 (1.0)	NE [NE, NE)		1.373 (0.143, 13.213)	0.7827

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	1 (0.7)	NE [NE, NE)	283	3 (1.1)	NE [NE, NE)	1.0000	1.332 (0.138, 12.813)	0.8033
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	1 (1.1)	NE [NE, NE)	174	0 (0.0)	NE [NE, NE)	0.9959	<.001 (<.001, NE)	0.1377
	Female	62	0 (0.0)	NE [NE, NE)	134	3 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.2533

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	1 (0.8)	NE [NE, NE)	240	2 (0.8)	NE [NE, NE)	1.0000	0.929 (0.084, 10.252)	0.9521
	Asian	20	0 (0.0)	NE [NE, NE)	46	1 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.5097
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	1 (8.3)	NE [6.0, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	<.001 (<.001, NE)	0.1573

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	2 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.3384
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	1 (1.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.4930
Baseline ECOG PS	0-1	146	1 (0.7)	NE [NE, NE)	294	2 (0.7)	NE [NE, NE)	0.9949	0.947 (0.086, 10.446)	0.9643
	2	7	0 (0.0)	NE [NE, NE)	13	1 (7.7)	NE [5.5, NE)		>999.999 (<.001, NE)	0.7518

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	1 (0.7)	NE [NE, NE)	285	3 (1.1)	NE [NE, NE)	1.0000	1.326 (0.138, 12.751)	0.8066
	No	17	0 (0.0)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to Bortezomib or Ixazomib	Yes	55	1 (1.8)	NE [NE, NE)	99	2 (2.0)	NE [NE, NE)	0.9954	1.060 (0.096, 11.697)	0.9618
	No	98	0 (0.0)	NE [NE, NE)	209	1 (0.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.4938

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	1 (1.4)	NE [NE, NE)	122	1 (0.8)	NE [NE, NE)	0.9947	0.545 (0.034, 8.726)	0.6633
	No	79	0 (0.0)	NE [NE, NE)	186	2 (1.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.3724
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE
	No	98	1 (1.0)	NE [NE, NE)	210	3 (1.4)	NE [NE, NE)		1.308 (0.136, 12.581)	0.8155

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	1 (0.9)	NE [NE, NE)	205	2 (1.0)	NE [NE, NE)	0.9960	1.004 (0.091, 11.081)	0.9976
	No	43	0 (0.0)	NE [NE, NE)	103	1 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.5365
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	2 (1.6)	NE [NE, NE)	0.9953	>999.999 (<.001, NE)	0.3183
	No	88	1 (1.1)	NE [NE, NE)	179	1 (0.6)	NE [NE, NE)		0.436 (0.027, 6.973)	0.5459

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	1 (0.8)	NE [NE, NE)	250	3 (1.2)	NE [NE, NE)	0.9999	1.437 (0.149, 13.827)	0.7520
	3	27	0 (0.0)	NE [NE, NE)	58	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Prior proteasome inhibitor exposure per IXRS	Yes	138	1 (0.7)	NE [NE, NE)	276	3 (1.1)	NE [NE, NE)	1.0000	1.395 (0.145, 13.423)	0.7719
	No	15	0 (0.0)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-511-ae-cox-eoi-cfz-grd345.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	1 (0.8)	NE [NE, NE)	0.9953	>999.999 (<.001, NE)	0.5054
	>= 2	87	1 (1.1)	NE [NE, NE)	177	2 (1.1)	NE [NE, NE)		0.926 (0.084, 10.222)	0.9497

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Hypertension (SMQ) - Narrow										
Total subjects		153	24 (15.7)	NE [NE, NE)	308	66 (21.4)	NE [30.9, NE)		1.157 (0.724, 1.849)	0.5406

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	19 (14.1)	NE [NE, NE)	283	57 (20.1)	NE [30.9, NE)	0.7781	1.222 (0.726, 2.057)	0.4502
	> 75	18	5 (27.8)	NE [2.4, NE)	25	9 (36.0)	NE [5.6, NE)		0.982 (0.328, 2.938)	0.9743
Sex	Male	91	14 (15.4)	NE [NE, NE)	174	40 (23.0)	NE [30.9, NE)	0.7729	1.228 (0.667, 2.264)	0.5083
	Female	62	10 (16.1)	NE [27.4, NE)	134	26 (19.4)	NE [NE, NE)		1.077 (0.519, 2.236)	0.8400

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	16 (13.1)	NE [NE, NE)	240	43 (17.9)	NE [NE, NE)	0.8285	1.175 (0.660, 2.089)	0.5832
	Asian	20	5 (25.0)	NE [7.5, NE)	46	13 (28.3)	NE [20.8, NE)		0.900 (0.318, 2.542)	0.8419
	Other or Unknown	11	3 (27.3)	27.4 [1.9, NE)	22	10 (45.5)	22.3 [9.3, NE)		1.565 (0.430, 5.699)	0.4932
Region	North America	12	2 (16.7)	NE [11.5, NE)	21	7 (33.3)	NE [8.1, NE)	0.7859	1.937 (0.398, 9.437)	0.4047

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	12 (11.8)	NE [NE, NE)	203	33 (16.3)	NE [30.9, NE)		1.190 (0.614, 2.306)	0.6049
	Asia Pacific	39	10 (25.6)	NE [17.3, NE)	84	26 (31.0)	NE [27.3, NE)		0.967 (0.464, 2.015)	0.9285
Baseline ECOG PS	0-1	146	23 (15.8)	NE [NE, NE)	294	65 (22.1)	NE [30.9, NE)	0.1621	1.225 (0.761, 1.973)	0.4020
	2	7	1 (14.3)	NE [3.1, NE)	13	1 (7.7)	NE [NE, NE)		0.402 (0.024, 6.621)	0.5101

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	19 (14.0)	NE [NE, NE)	285	61 (21.4)	NE [30.9, NE)	0.2335	1.300 (0.775, 2.178)	0.3177
	No	17	5 (29.4)	NE [6.9, NE)	23	5 (21.7)	NE [15.9, NE)		0.599 (0.172, 2.088)	0.4160
Refractory to Bortezomib or Ixazomib	Yes	55	8 (14.5)	NE [22.7, NE)	99	16 (16.2)	NE [NE, NE)	0.5283	0.868 (0.369, 2.038)	0.7444
	No	98	16 (16.3)	NE [NE, NE)	209	50 (23.9)	NE [30.9, NE)		1.282 (0.729, 2.254)	0.3877

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	9 (12.2)	NE [27.4, NE)	122	27 (22.1)	NE [NE, NE)	0.2695	1.576 (0.739, 3.359)	0.2344
	No	79	15 (19.0)	NE [NE, NE)	186	39 (21.0)	NE [30.9, NE)		0.913 (0.502, 1.663)	0.7686
Refractory to Lenalidomide	Yes	55	9 (16.4)	NE [22.7, NE)	98	20 (20.4)	NE [NE, NE)	0.6651	1.015 (0.459, 2.243)	0.9709
	No	98	15 (15.3)	NE [NE, NE)	210	46 (21.9)	NE [30.9, NE)		1.241 (0.692, 2.224)	0.4667

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	18 (16.4)	NE [NE, NE)	205	43 (21.0)	NE [NE, NE)	0.6855	1.109 (0.639, 1.926)	0.7115
	No	43	6 (14.0)	NE [NE, NE)	103	23 (22.3)	NE [30.9, NE)		1.298 (0.525, 3.209)	0.5692
Refractory to IMiD	Yes	65	10 (15.4)	NE [22.7, NE)	129	26 (20.2)	NE [NE, NE)	0.7774	1.086 (0.521, 2.263)	0.8257
	No	88	14 (15.9)	NE [NE, NE)	179	40 (22.3)	NE [30.9, NE)		1.209 (0.657, 2.225)	0.5401

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	19 (15.1)	NE [NE, NE)	250	58 (23.2)	NE [30.9, NE)	0.1064	1.345 (0.800, 2.261)	0.2616
	3	27	5 (18.5)	NE [14.2, NE)	58	8 (13.8)	NE [NE, NE)		0.518 (0.168, 1.600)	0.2450
Prior proteasome inhibitor exposure per IXRS	Yes	138	19 (13.8)	NE [NE, NE)	276	61 (22.1)	NE [30.9, NE)	0.0447	1.379 (0.823, 2.311)	0.2202
	No	15	5 (33.3)	NE [6.9, NE)	32	5 (15.6)	NE [NE, NE)		0.359 (0.103, 1.246)	0.0922

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	11 (16.7)	NE [NE, NE)	131	32 (24.4)	NE [30.9, NE)	0.7921	1.238 (0.623, 2.462)	0.5420
	>= 2	87	13 (14.9)	NE [27.4, NE)	177	34 (19.2)	NE [NE, NE)		1.087 (0.572, 2.065)	0.7993

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Infusion reaction (AMQ) - Narrow (event on same date of any carfilzomib dosing)										
Total subjects		153	8 (5.2)	NE [NE, NE)	308	44 (14.3)	NE [NE, NE)		2.399 (1.128, 5.103)	0.0190

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	6 (4.4)	NE [NE, NE)	283	36 (12.7)	NE [NE, NE)	0.9678	2.487 (1.046, 5.915)	0.0330
	> 75	18	2 (11.1)	NE [NE, NE)	25	8 (32.0)	NE [8.6, NE)		2.600 (0.552, 12.254)	0.2082
Sex	Male	91	5 (5.5)	NE [NE, NE)	174	28 (16.1)	NE [NE, NE)	0.8589	2.502 (0.963, 6.502)	0.0514
	Female	62	3 (4.8)	NE [NE, NE)	134	16 (11.9)	NE [NE, NE)		2.268 (0.660, 7.790)	0.1809

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	7 (5.7)	NE [NE, NE)	240	30 (12.5)	NE [NE, NE)	0.9068	1.882 (0.825, 4.296)	0.1268
	Asian	20	1 (5.0)	NE [NE, NE)	46	8 (17.4)	NE [NE, NE)		3.178 (0.397, 25.459)	0.2502
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	6 (27.3)	NE [12.2, NE)		>999.999 (<.001, NE)	0.0895
Region	North America	12	0 (0.0)	NE [NE, NE)	21	6 (28.6)	NE [8.1, NE)	0.8382	>999.999 (<.001, NE)	0.0659

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	4 (3.9)	NE [NE, NE)	203	22 (10.8)	NE [NE, NE)		2.385 (0.821, 6.931)	0.0994
	Asia Pacific	39	4 (10.3)	NE [NE, NE)	84	16 (19.0)	NE [NE, NE)		1.650 (0.550, 4.950)	0.3663
Baseline ECOG PS	0-1	146	7 (4.8)	NE [NE, NE)	294	42 (14.3)	NE [NE, NE)	0.1655	2.670 (1.198, 5.950)	0.0125
	2	7	1 (14.3)	NE [3.1, NE)	13	2 (15.4)	NE [6.0, NE)		0.402 (0.024, 6.621)	0.5101

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	6 (4.4)	NE [NE, NE)	285	40 (14.0)	NE [NE, NE)	0.4184	2.785 (1.179, 6.580)	0.0148
	No	17	2 (11.8)	NE [17.3, NE)	23	4 (17.4)	NE [NE, NE)		1.271 (0.231, 6.985)	0.7823
Refractory to Bortezomib or Ixazomib	Yes	55	3 (5.5)	NE [NE, NE)	99	10 (10.1)	NE [NE, NE)	0.5225	1.545 (0.424, 5.634)	0.5065
	No	98	5 (5.1)	NE [NE, NE)	209	34 (16.3)	NE [NE, NE)		2.818 (1.100, 7.223)	0.0241

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	3 (4.1)	NE [NE, NE)	122	16 (13.1)	NE [NE, NE)	0.7239	2.809 (0.816, 9.662)	0.0874
	No	79	5 (6.3)	NE [NE, NE)	186	28 (15.1)	NE [NE, NE)		2.090 (0.804, 5.434)	0.1221
Refractory to Lenalidomide	Yes	55	3 (5.5)	NE [NE, NE)	98	11 (11.2)	NE [NE, NE)	0.5155	1.648 (0.457, 5.942)	0.4414
	No	98	5 (5.1)	NE [NE, NE)	210	33 (15.7)	NE [NE, NE)		2.818 (1.099, 7.227)	0.0242

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	6 (5.5)	NE [NE, NE)	205	25 (12.2)	NE [NE, NE)	0.4988	2.019 (0.827, 4.927)	0.1156
	No	43	2 (4.7)	NE [NE, NE)	103	19 (18.4)	NE [30.9, NE)		3.421 (0.793, 14.762)	0.0791
Refractory to IMiD	Yes	65	3 (4.6)	NE [NE, NE)	129	16 (12.4)	NE [NE, NE)	0.8882	2.258 (0.655, 7.781)	0.1851
	No	88	5 (5.7)	NE [NE, NE)	179	28 (15.6)	NE [NE, NE)		2.489 (0.960, 6.457)	0.0523

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	6 (4.8)	NE [NE, NE)	250	37 (14.8)	NE [NE, NE)	0.3532	2.807 (1.183, 6.663)	0.0145
	3	27	2 (7.4)	NE [NE, NE)	58	7 (12.1)	NE [NE, NE)		1.105 (0.227, 5.375)	0.9019
Prior proteasome inhibitor exposure per IXRS	Yes	138	6 (4.3)	NE [NE, NE)	276	41 (14.9)	NE [NE, NE)	0.1026	3.033 (1.286, 7.154)	0.0077
	No	15	2 (13.3)	NE [17.3, NE)	32	3 (9.4)	NE [NE, NE)		0.611 (0.102, 3.668)	0.5867

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	3 (4.5)	NE [NE, NE)	131	20 (15.3)	NE [NE, NE)	0.6946	2.842 (0.842, 9.597)	0.0783
	>= 2	87	5 (5.7)	NE [NE, NE)	177	24 (13.6)	NE [NE, NE)		2.146 (0.818, 5.635)	0.1124

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Infusion reaction (AMQ) - Narrow (event on same date of first carfilzomib dosing)										
Total subjects		153	1 (0.7)	NE [NE, NE)	308	5 (1.6)	NE [NE, NE)		2.494 (0.291, 21.346)	0.3875

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	0 (0.0)	NE [NE, NE)	283	4 (1.4)	NE [NE, NE)	0.9948	>999.999 (<.001, NE)	0.1656
	> 75	18	1 (5.6)	NE [NE, NE)	25	1 (4.0)	NE [NE, NE)		0.717 (0.045, 11.465)	0.8133
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	3 (1.7)	NE [NE, NE)	0.9930	>999.999 (<.001, NE)	0.2086
	Female	62	1 (1.6)	NE [NE, NE)	134	2 (1.5)	NE [NE, NE)		0.925 (0.084, 10.201)	0.9492

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	1 (0.8)	NE [NE, NE)	240	2 (0.8)	NE [NE, NE)	1.0000	1.017 (0.092, 11.212)	0.9892
	Asian	20	0 (0.0)	NE [NE, NE)	46	2 (4.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.3473
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	1 (4.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.4795
Region	North America	12	0 (0.0)	NE [NE, NE)	21	1 (4.8)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.4497

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	2 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.3153
	Asia Pacific	39	1 (2.6)	NE [NE, NE)	84	2 (2.4)	NE [NE, NE)		0.928 (0.084, 10.234)	0.9513
Baseline ECOG PS	0-1	146	1 (0.7)	NE [NE, NE)	294	5 (1.7)	NE [NE, NE)	0.9998	2.494 (0.291, 21.343)	0.3876
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	1 (0.7)	NE [NE, NE)	285	4 (1.4)	NE [NE, NE)	0.9936	1.914 (0.214, 17.124)	0.5544
	No	17	0 (0.0)	NE [NE, NE)	23	1 (4.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.3899
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	0 (0.0)	NE [NE, NE)	0.9999	NE (NE, NE)	NE
	No	98	1 (1.0)	NE [NE, NE)	209	5 (2.4)	NE [NE, NE)		2.358 (0.275, 20.183)	0.4190

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CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-511-ae-cox-eoi-cfz-grd345.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	3 (2.5)	NE [NE, NE)	0.9938	>999.999 (<.001, NE)	0.1751
	No	79	1 (1.3)	NE [NE, NE)	186	2 (1.1)	NE [NE, NE)		0.849 (0.077, 9.362)	0.8935
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	0 (0.0)	NE [NE, NE)	0.9999	NE (NE, NE)	NE
	No	98	1 (1.0)	NE [NE, NE)	210	5 (2.4)	NE [NE, NE)		2.347 (0.274, 20.086)	0.4218

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-511-ae-cox-eoi-cfz-grd345.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	0 (0.0)	NE [NE, NE)	205	4 (2.0)	NE [NE, NE)	0.9950	>999.999 (<.001, NE)	0.1410
	No	43	1 (2.3)	NE [NE, NE)	103	1 (1.0)	NE [NE, NE)		0.416 (0.026, 6.653)	0.5224
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	1 (0.8)	NE [NE, NE)	0.9949	>999.999 (<.001, NE)	0.4778
	No	88	1 (1.1)	NE [NE, NE)	179	4 (2.2)	NE [NE, NE)		1.975 (0.221, 17.672)	0.5345

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	1 (0.8)	NE [NE, NE)	250	4 (1.6)	NE [NE, NE)	0.9943	2.023 (0.226, 18.096)	0.5199
	3	27	0 (0.0)	NE [NE, NE)	58	1 (1.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.4951
Prior proteasome inhibitor exposure per IXRS	Yes	138	1 (0.7)	NE [NE, NE)	276	5 (1.8)	NE [NE, NE)	0.9999	2.511 (0.293, 21.496)	0.3836
	No	15	0 (0.0)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	1 (1.5)	NE [NE, NE)	131	3 (2.3)	NE [NE, NE)	0.9938	1.516 (0.158, 14.568)	0.7166
	>= 2	87	0 (0.0)	NE [NE, NE)	177	2 (1.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.3205

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Interstitial lung disease (SMQ) - Narrow										
Total subjects		153	0 (0.0)	NE [NE, NE)	308	6 (1.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.1027

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	0 (0.0)	NE [NE, NE)	283	5 (1.8)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.1476
	> 75	18	0 (0.0)	NE [NE, NE)	25	1 (4.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.4193
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	4 (2.3)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.1813
	Female	62	0 (0.0)	NE [NE, NE)	134	2 (1.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.3454

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	0 (0.0)	NE [NE, NE)	240	5 (2.1)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.1299
	Asian	20	0 (0.0)	NE [NE, NE)	46	1 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.5271
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	5 (2.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.1273
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	1 (1.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.5171
Baseline ECOG PS	0-1	146	0 (0.0)	NE [NE, NE)	294	6 (2.0)	NE [NE, NE)	0.9993	>999.999 (<.001, NE)	0.1001
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	0 (0.0)	NE [NE, NE)	285	5 (1.8)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.1474
	No	17	0 (0.0)	NE [NE, NE)	23	1 (4.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.3980
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	3 (3.0)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.2379
	No	98	0 (0.0)	NE [NE, NE)	209	3 (1.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.2482

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	2 (1.6)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.2971
	No	79	0 (0.0)	NE [NE, NE)	186	4 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.2111
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	0 (0.0)	NE [NE, NE)	0.9981	NE (NE, NE)	NE
	No	98	0 (0.0)	NE [NE, NE)	210	6 (2.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.1058

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	0 (0.0)	NE [NE, NE)	205	2 (1.0)	NE [NE, NE)	0.9997	>999.999 (<.001, NE)	0.3262
	No	43	0 (0.0)	NE [NE, NE)	103	4 (3.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.2070
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	0 (0.0)	NE [NE, NE)	0.9981	NE (NE, NE)	NE
	No	88	0 (0.0)	NE [NE, NE)	179	6 (3.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.0954

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	0 (0.0)	NE [NE, NE)	250	5 (2.0)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.1340
	3	27	0 (0.0)	NE [NE, NE)	58	1 (1.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.5040
Prior proteasome inhibitor exposure per IXRS	Yes	138	0 (0.0)	NE [NE, NE)	276	5 (1.8)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.1373
	No	15	0 (0.0)	NE [NE, NE)	32	1 (3.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.5271

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-511-ae-cox-eoi-cfz-grd345.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	3 (2.3)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.2524
	>= 2	87	0 (0.0)	NE [NE, NE)	177	3 (1.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.2364

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-511-ae-cox-eoi-cfz-grd345.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Ischaemic heart disease (SMQ) - Narrow										
Total subjects		153	5 (3.3)	NE [NE, NE)	308	14 (4.5)	NE [NE, NE)		1.022 (0.366, 2.850)	0.9671

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-511-ae-cox-eoi-cfz-grd345.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	4 (3.0)	NE [NE, NE)	283	13 (4.6)	NE [NE, NE)	0.6619	1.119 (0.363, 3.452)	0.8451
	> 75	18	1 (5.6)	NE [NE, NE)	25	1 (4.0)	NE [NE, NE)		0.546 (0.033, 8.909)	0.6665
Sex	Male	91	3 (3.3)	NE [NE, NE)	174	11 (6.3)	NE [NE, NE)	0.4335	1.311 (0.362, 4.744)	0.6789
	Female	62	2 (3.2)	NE [NE, NE)	134	3 (2.2)	NE [NE, NE)		0.590 (0.098, 3.544)	0.5601

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	3 (2.5)	NE [NE, NE)	240	12 (5.0)	NE [NE, NE)	0.3987	1.552 (0.436, 5.523)	0.4933
	Asian	20	1 (5.0)	NE [11.3, NE)	46	1 (2.2)	NE [NE, NE)		0.231 (0.014, 3.749)	0.2618
	Other or Unknown	11	1 (9.1)	NE [2.4, NE)	22	1 (4.5)	NE [24.0, NE)		0.330 (0.021, 5.297)	0.4106
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	0.1920	NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	3 (2.9)	NE [NE, NE)	203	13 (6.4)	NE [NE, NE)		1.807 (0.514, 6.351)	0.3490
	Asia Pacific	39	2 (5.1)	NE [19.7, NE)	84	1 (1.2)	NE [NE, NE)		0.102 (0.009, 1.157)	0.0252
Baseline ECOG PS	0-1	146	5 (3.4)	NE [NE, NE)	294	14 (4.8)	NE [NE, NE)	1.0000	1.056 (0.379, 2.944)	0.9172
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	4 (2.9)	NE [NE, NE)	285	13 (4.6)	NE [NE, NE)	0.5952	1.150 (0.373, 3.544)	0.8078
	No	17	1 (5.9)	NE [19.7, NE)	23	1 (4.3)	NE [NE, NE)		0.486 (0.030, 7.804)	0.6024
Refractory to Bortezomib or Ixazomib	Yes	55	2 (3.6)	NE [NE, NE)	99	0 (0.0)	NE [NE, NE)	0.9873	<.001 (<.001, NE)	0.0352
	No	98	3 (3.1)	NE [NE, NE)	209	14 (6.7)	NE [NE, NE)		1.601 (0.458, 5.597)	0.4571

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	2 (2.7)	NE [NE, NE)	122	6 (4.9)	NE [NE, NE)	0.8225	1.183 (0.233, 6.005)	0.8395
	No	79	3 (3.8)	NE [NE, NE)	186	8 (4.3)	NE [NE, NE)		0.927 (0.245, 3.499)	0.9106
Refractory to Lenalidomide	Yes	55	2 (3.6)	NE [19.7, NE)	98	5 (5.1)	NE [NE, NE)	0.7660	0.747 (0.139, 4.010)	0.7333
	No	98	3 (3.1)	NE [NE, NE)	210	9 (4.3)	NE [NE, NE)		1.156 (0.312, 4.281)	0.8276

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	4 (3.6)	NE [NE, NE)	205	7 (3.4)	NE [NE, NE)	0.2867	0.653 (0.189, 2.264)	0.4991
	No	43	1 (2.3)	NE [NE, NE)	103	7 (6.8)	NE [NE, NE)		2.396 (0.294, 19.509)	0.3992
Refractory to IMiD	Yes	65	3 (4.6)	NE [19.7, NE)	129	7 (5.4)	NE [NE, NE)	0.5073	0.661 (0.165, 2.647)	0.5567
	No	88	2 (2.3)	NE [NE, NE)	179	7 (3.9)	NE [NE, NE)		1.433 (0.297, 6.910)	0.6519

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	4 (3.2)	NE [NE, NE)	250	10 (4.0)	NE [NE, NE)	0.8995	0.881 (0.275, 2.823)	0.8310
	3	27	1 (3.7)	NE [NE, NE)	58	4 (6.9)	NE [NE, NE)		1.365 (0.148, 12.608)	0.7829
Prior proteasome inhibitor exposure per IXRS	Yes	138	4 (2.9)	NE [NE, NE)	276	11 (4.0)	NE [NE, NE)	0.9580	1.004 (0.318, 3.171)	0.9939
	No	15	1 (6.7)	NE [19.7, NE)	32	3 (9.4)	NE [NE, NE)		1.059 (0.109, 10.257)	0.9603

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	2 (3.0)	NE [NE, NE)	131	7 (5.3)	NE [NE, NE)	0.6158	1.396 (0.289, 6.743)	0.6762
	>= 2	87	3 (3.4)	NE [NE, NE)	177	7 (4.0)	NE [NE, NE)		0.741 (0.189, 2.908)	0.6665

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Liver related investigations, signs and symptoms (SMQ) - Narrow										
Total subjects		153	3 (2.0)	NE [NE, NE)	308	15 (4.9)	NE [NE, NE)		2.322 (0.671, 8.032)	0.1708

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	3 (2.2)	NE [NE, NE)	283	13 (4.6)	NE [NE, NE)	0.9920	1.982 (0.564, 6.962)	0.2766
	> 75	18	0 (0.0)	NE [NE, NE)	25	2 (8.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.2741
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	4 (2.3)	NE [NE, NE)	0.9903	>999.999 (<.001, NE)	0.1944
	Female	62	3 (4.8)	NE [NE, NE)	134	11 (8.2)	NE [NE, NE)		1.643 (0.458, 5.894)	0.4415

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	1 (0.8)	NE [NE, NE)	240	10 (4.2)	NE [NE, NE)	0.4238	4.754 (0.608, 37.202)	0.1011
	Asian	20	2 (10.0)	NE [NE, NE)	46	4 (8.7)	NE [NE, NE)		0.860 (0.157, 4.696)	0.8613
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	1 (4.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.5839
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-511-ae-cox-eoi-cfz-grd345.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	9 (4.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.0378
	Asia Pacific	39	3 (7.7)	NE [NE, NE)	84	6 (7.1)	NE [NE, NE)		0.856 (0.212, 3.449)	0.8263
Baseline ECOG PS	0-1	146	2 (1.4)	NE [NE, NE)	294	14 (4.8)	NE [NE, NE)	0.1446	3.365 (0.765, 14.812)	0.0882
	2	7	1 (14.3)	NE [0.5, NE)	13	1 (7.7)	NE [19.3, NE)		<.001 (<.001, NE)	0.1573

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	2 (1.5)	NE [NE, NE)	285	12 (4.2)	NE [NE, NE)	0.8765	2.620 (0.585, 11.726)	0.1907
	No	17	1 (5.9)	NE [NE, NE)	23	3 (13.0)	NE [NE, NE)		2.324 (0.242, 22.344)	0.4558
Refractory to Bortezomib or Ixazomib	Yes	55	1 (1.8)	NE [NE, NE)	99	3 (3.0)	NE [NE, NE)	0.7150	1.403 (0.145, 13.592)	0.7692
	No	98	2 (2.0)	NE [NE, NE)	209	12 (5.7)	NE [NE, NE)		2.716 (0.608, 12.139)	0.1731

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	1 (1.4)	NE [NE, NE)	122	4 (3.3)	NE [NE, NE)	0.9934	2.417 (0.270, 21.638)	0.4150
	No	79	2 (2.5)	NE [NE, NE)	186	11 (5.9)	NE [NE, NE)		2.216 (0.491, 10.006)	0.2883
Refractory to Lenalidomide	Yes	55	1 (1.8)	NE [NE, NE)	98	3 (3.1)	NE [NE, NE)	0.6788	1.650 (0.172, 15.876)	0.6610
	No	98	2 (2.0)	NE [NE, NE)	210	12 (5.7)	NE [NE, NE)		2.656 (0.594, 11.877)	0.1837

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	2 (1.8)	NE [NE, NE)	205	10 (4.9)	NE [NE, NE)	0.8746	2.495 (0.545, 11.414)	0.2229
	No	43	1 (2.3)	NE [NE, NE)	103	5 (4.9)	NE [NE, NE)		2.024 (0.236, 17.346)	0.5115
Refractory to IMiD	Yes	65	1 (1.5)	NE [NE, NE)	129	5 (3.9)	NE [NE, NE)	0.9741	2.084 (0.240, 18.085)	0.4960
	No	88	2 (2.3)	NE [NE, NE)	179	10 (5.6)	NE [NE, NE)		2.413 (0.529, 11.016)	0.2405

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	2 (1.6)	NE [NE, NE)	250	13 (5.2)	NE [NE, NE)	0.3304	3.202 (0.722, 14.195)	0.1054
	3	27	1 (3.7)	NE [NE, NE)	58	2 (3.4)	NE [NE, NE)		0.617 (0.055, 6.962)	0.6938
Prior proteasome inhibitor exposure per IXRS	Yes	138	2 (1.4)	NE [NE, NE)	276	12 (4.3)	NE [NE, NE)	0.5825	2.749 (0.614, 12.304)	0.1679
	No	15	1 (6.7)	NE [NE, NE)	32	3 (9.4)	NE [NE, NE)		1.393 (0.145, 13.406)	0.7776

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	2 (3.0)	NE [NE, NE)	131	5 (3.8)	NE [NE, NE)	0.3090	1.184 (0.229, 6.121)	0.8405
	>= 2	87	1 (1.1)	NE [NE, NE)	177	10 (5.6)	NE [NE, NE)		4.533 (0.579, 35.492)	0.1142

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Myocardial infarction (SMQ) - Narrow										
Total subjects		153	2 (1.3)	NE [NE, NE)	308	6 (1.9)	NE [NE, NE)		0.964 (0.194, 4.795)	0.9647

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	2 (1.5)	NE [NE, NE)	283	5 (1.8)	NE [NE, NE)	0.9946	0.746 (0.144, 3.869)	0.7261
	> 75	18	0 (0.0)	NE [NE, NE)	25	1 (4.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.4795
Sex	Male	91	1 (1.1)	NE [NE, NE)	174	5 (2.9)	NE [NE, NE)	0.3988	1.498 (0.174, 12.915)	0.7112
	Female	62	1 (1.6)	NE [NE, NE)	134	1 (0.7)	NE [NE, NE)		0.357 (0.022, 5.736)	0.4475

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	1 (0.8)	NE [NE, NE)	240	5 (2.1)	NE [NE, NE)	1.0000	1.682 (0.196, 14.446)	0.6320
	Asian	20	1 (5.0)	NE [11.3, NE)	46	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0593
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	1 (4.5)	NE [24.0, NE)		>999.999 (<.001, NE)	0.5839
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	6 (3.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.1293
	Asia Pacific	39	2 (5.1)	NE [19.7, NE)	84	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0047
Baseline ECOG PS	0-1	146	2 (1.4)	NE [NE, NE)	294	6 (2.0)	NE [NE, NE)	1.0000	1.004 (0.202, 4.993)	0.9961
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	1 (0.7)	NE [NE, NE)	285	6 (2.1)	NE [NE, NE)	0.9922	1.917 (0.230, 15.978)	0.5406
	No	17	1 (5.9)	NE [19.7, NE)	23	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.1138
Refractory to Bortezomib or Ixazomib	Yes	55	1 (1.8)	NE [NE, NE)	99	0 (0.0)	NE [NE, NE)	0.9918	<.001 (<.001, NE)	0.1103
	No	98	1 (1.0)	NE [NE, NE)	209	6 (2.9)	NE [NE, NE)		1.775 (0.213, 14.805)	0.5908

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	1 (1.4)	NE [NE, NE)	122	3 (2.5)	NE [NE, NE)	0.9985	0.997 (0.100, 9.920)	0.9982
	No	79	1 (1.3)	NE [NE, NE)	186	3 (1.6)	NE [NE, NE)		0.953 (0.099, 9.168)	0.9670
Refractory to Lenalidomide	Yes	55	1 (1.8)	NE [19.7, NE)	98	3 (3.1)	NE [NE, NE)	0.8580	0.806 (0.080, 8.124)	0.8545
	No	98	1 (1.0)	NE [NE, NE)	210	3 (1.4)	NE [NE, NE)		1.030 (0.107, 9.906)	0.9795

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-511-ae-cox-eoi-cfz-grd345.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	2 (1.8)	NE [NE, NE)	205	4 (2.0)	NE [NE, NE)	0.9946	0.651 (0.117, 3.607)	0.6204
	No	43	0 (0.0)	NE [NE, NE)	103	2 (1.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.4387
Refractory to IMiD	Yes	65	2 (3.1)	NE [19.7, NE)	129	4 (3.1)	NE [NE, NE)	0.9942	0.476 (0.084, 2.706)	0.3926
	No	88	0 (0.0)	NE [NE, NE)	179	2 (1.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.3922

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	2 (1.6)	NE [NE, NE)	250	5 (2.0)	NE [NE, NE)	0.9935	0.826 (0.159, 4.280)	0.8194
	3	27	0 (0.0)	NE [NE, NE)	58	1 (1.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.6698
Prior proteasome inhibitor exposure per IXRS	Yes	138	1 (0.7)	NE [NE, NE)	276	5 (1.8)	NE [NE, NE)	0.3586	1.709 (0.199, 14.683)	0.6213
	No	15	1 (6.7)	NE [19.7, NE)	32	1 (3.1)	NE [NE, NE)		0.289 (0.018, 4.618)	0.3493

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	3 (2.3)	NE [NE, NE)	0.9936	>999.999 (<.001, NE)	0.3131
	>= 2	87	2 (2.3)	NE [NE, NE)	177	3 (1.7)	NE [NE, NE)		0.415 (0.068, 2.524)	0.3245

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Peripheral neuropathy (SMQ) - Narrow										
Total subjects		153	0 (0.0)	NE [NE, NE)	308	6 (1.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.1452

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	0 (0.0)	NE [NE, NE)	283	6 (2.1)	NE [NE, NE)	0.9987	>999.999 (<.001, NE)	0.1544
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	3 (1.7)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.3069
	Female	62	0 (0.0)	NE [NE, NE)	134	3 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.3042

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	0 (0.0)	NE [NE, NE)	240	5 (2.1)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.1731
	Asian	20	0 (0.0)	NE [NE, NE)	46	1 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.6056
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	1 (4.8)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.7893

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	3 (1.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.2606
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	2 (2.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.4981
Baseline ECOG PS	0-1	146	0 (0.0)	NE [NE, NE)	294	6 (2.0)	NE [NE, NE)	0.9997	>999.999 (<.001, NE)	0.1374
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	0 (0.0)	NE [NE, NE)	285	6 (2.1)	NE [NE, NE)	0.9987	>999.999 (<.001, NE)	0.1516
	No	17	0 (0.0)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	1 (1.0)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.4821
	No	98	0 (0.0)	NE [NE, NE)	209	5 (2.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.2057

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	3 (2.5)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.3633
	No	79	0 (0.0)	NE [NE, NE)	186	3 (1.6)	NE [NE, NE)		>999.999 (<.001, NE)	0.2960
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	3 (3.1)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.4277
	No	98	0 (0.0)	NE [NE, NE)	210	3 (1.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.2738

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	0 (0.0)	NE [NE, NE)	205	4 (2.0)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.2556
	No	43	0 (0.0)	NE [NE, NE)	103	2 (1.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.4034
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	4 (3.1)	NE [NE, NE)	0.9998	>999.999 (<.001, NE)	0.3260
	No	88	0 (0.0)	NE [NE, NE)	179	2 (1.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.3620

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	0 (0.0)	NE [NE, NE)	250	6 (2.4)	NE [NE, NE)	0.9987	>999.999 (<.001, NE)	0.1343
	3	27	0 (0.0)	NE [NE, NE)	58	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Prior proteasome inhibitor exposure per IXRS	Yes	138	0 (0.0)	NE [NE, NE)	276	6 (2.2)	NE [NE, NE)	0.9987	>999.999 (<.001, NE)	0.1433
	No	15	0 (0.0)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	1 (0.8)	NE [NE, NE)	0.9998	>999.999 (<.001, NE)	0.5637
	>= 2	87	0 (0.0)	NE [NE, NE)	177	5 (2.8)	NE [NE, NE)		>999.999 (<.001, NE)	0.1798

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-511-ae-cox-eoi-cfz-grd345.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Pulmonary hypertension (SMQ) - Narrow										
Total subjects		153	0 (0.0)	NE [NE, NE)	308	3 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.2429

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-511-ae-cox-eoi-cfz-grd345.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	0 (0.0)	NE [NE, NE)	283	3 (1.1)	NE [NE, NE)	0.9991	>999.999 (<.001, NE)	0.2498
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	3 (1.7)	NE [NE, NE)	0.9987	>999.999 (<.001, NE)	0.2263
	Female	62	0 (0.0)	NE [NE, NE)	134	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	0 (0.0)	NE [NE, NE)	240	3 (1.3)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.2342
	Asian	20	0 (0.0)	NE [NE, NE)	46	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	2 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.3300
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	1 (1.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.5258
Baseline ECOG PS	0-1	146	0 (0.0)	NE [NE, NE)	294	3 (1.0)	NE [NE, NE)	0.9995	>999.999 (<.001, NE)	0.2381
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Output: t14-06-001-511-ae-cox-eoi-cfz-grd345.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	0 (0.0)	NE [NE, NE)	285	2 (0.7)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.3425
	No	17	0 (0.0)	NE [NE, NE)	23	1 (4.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.4386
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	1 (1.0)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.4561
	No	98	0 (0.0)	NE [NE, NE)	209	2 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.3740

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	1 (0.8)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.4716
	No	79	0 (0.0)	NE [NE, NE)	186	2 (1.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.3692
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	1 (1.0)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.4795
	No	98	0 (0.0)	NE [NE, NE)	210	2 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.3496

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	0 (0.0)	NE [NE, NE)	205	2 (1.0)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.3387
	No	43	0 (0.0)	NE [NE, NE)	103	1 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.5162
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	1 (0.8)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.5091
	No	88	0 (0.0)	NE [NE, NE)	179	2 (1.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.3354

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	0 (0.0)	NE [NE, NE)	250	2 (0.8)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.3397
	3	27	0 (0.0)	NE [NE, NE)	58	1 (1.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.4951
Prior proteasome inhibitor exposure per IXRS	Yes	138	0 (0.0)	NE [NE, NE)	276	2 (0.7)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.3304
	No	15	0 (0.0)	NE [NE, NE)	32	1 (3.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.5501

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	1 (0.8)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.5138
	>= 2	87	0 (0.0)	NE [NE, NE)	177	2 (1.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.3349

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Respiratory failure (SMQ) - Narrow										
Total subjects		153	1 (0.7)	NE [NE, NE)	308	3 (1.0)	NE [NE, NE)		1.273 (0.132, 12.271)	0.8345

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	1 (0.7)	NE [NE, NE)	283	3 (1.1)	NE [NE, NE)	1.0000	1.227 (0.127, 11.835)	0.8593
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	1 (0.6)	NE [NE, NE)	0.9952	>999.999 (<.001, NE)	0.5132
	Female	62	1 (1.6)	NE [NE, NE)	134	2 (1.5)	NE [NE, NE)		0.820 (0.074, 9.069)	0.8716

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	0 (0.0)	NE [NE, NE)	240	3 (1.3)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.2358
	Asian	20	1 (5.0)	NE [12.0, NE)	46	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0635
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-511-ae-cox-eoi-cfz-grd345.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	3 (1.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.2437
	Asia Pacific	39	1 (2.6)	NE [NE, NE)	84	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0752
Baseline ECOG PS	0-1	146	1 (0.7)	NE [NE, NE)	294	3 (1.0)	NE [NE, NE)	1.0000	1.304 (0.135, 12.565)	0.8179
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	1 (0.7)	NE [NE, NE)	285	3 (1.1)	NE [NE, NE)	1.0000	1.234 (0.128, 11.896)	0.8555
	No	17	0 (0.0)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to Bortezomib or Ixazomib	Yes	55	1 (1.8)	NE [NE, NE)	99	0 (0.0)	NE [NE, NE)	0.9953	<.001 (<.001, NE)	0.1213
	No	98	0 (0.0)	NE [NE, NE)	209	3 (1.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.2618

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	1 (0.8)	NE [NE, NE)	0.9953	>999.999 (<.001, NE)	0.4723
	No	79	1 (1.3)	NE [NE, NE)	186	2 (1.1)	NE [NE, NE)		0.752 (0.068, 8.318)	0.8153
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	1 (1.0)	NE [NE, NE)	0.9958	>999.999 (<.001, NE)	0.5036
	No	98	1 (1.0)	NE [NE, NE)	210	2 (1.0)	NE [NE, NE)		0.822 (0.074, 9.088)	0.8727

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	1 (0.9)	NE [NE, NE)	205	1 (0.5)	NE [NE, NE)	0.9940	0.425 (0.027, 6.815)	0.5333
	No	43	0 (0.0)	NE [NE, NE)	103	2 (1.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.3632
Refractory to IMiD	Yes	65	1 (1.5)	NE [NE, NE)	129	1 (0.8)	NE [NE, NE)	0.9945	0.362 (0.023, 5.832)	0.4551
	No	88	0 (0.0)	NE [NE, NE)	179	2 (1.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.3354

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	1 (0.8)	NE [NE, NE)	250	1 (0.4)	NE [NE, NE)	0.9958	0.412 (0.026, 6.600)	0.5174
	3	27	0 (0.0)	NE [NE, NE)	58	2 (3.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.3876
Prior proteasome inhibitor exposure per IXRS	Yes	138	1 (0.7)	NE [NE, NE)	276	3 (1.1)	NE [NE, NE)	1.0000	1.294 (0.134, 12.479)	0.8231
	No	15	0 (0.0)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	1 (0.8)	NE [NE, NE)	0.9955	>999.999 (<.001, NE)	0.4829
	>= 2	87	1 (1.1)	NE [NE, NE)	177	2 (1.1)	NE [NE, NE)		0.802 (0.073, 8.854)	0.8569

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Respiratory tract infections (AMQ) - Broad										
Total subjects		153	25 (16.3)	NE [NE, NE)	308	104 (33.8)	NE [25.9, NE)		1.823 (1.178, 2.823)	0.0063

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	23 (17.0)	NE [NE, NE)	283	96 (33.9)	NE [25.3, NE)	0.5896	1.737 (1.101, 2.740)	0.0161
	> 75	18	2 (11.1)	NE [NE, NE)	25	8 (32.0)	NE [11.7, NE)		2.812 (0.596, 13.265)	0.1723
Sex	Male	91	16 (17.6)	NE [NE, NE)	174	58 (33.3)	NE [25.3, NE)	0.4408	1.584 (0.910, 2.759)	0.1009
	Female	62	9 (14.5)	NE [NE, NE)	134	46 (34.3)	NE [18.7, NE)		2.243 (1.097, 4.583)	0.0229

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	21 (17.2)	NE [NE, NE)	240	82 (34.2)	NE [23.7, NE)	0.9735	1.779 (1.101, 2.875)	0.0171
	Asian	20	4 (20.0)	NE [12.0, NE)	46	16 (34.8)	NE [17.8, NE)		1.480 (0.493, 4.443)	0.4819
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	6 (27.3)	NE [14.9, NE)		>999.999 (<.001, NE)	0.1193
Region	North America	12	1 (8.3)	NE [16.2, NE)	21	10 (47.6)	18.1 [11.1, NE)	0.5594	3.359 (0.420, 26.886)	0.2263

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	16 (15.7)	NE [NE, NE)	203	65 (32.0)	NE [23.7, NE)		1.900 (1.099, 3.283)	0.0193
	Asia Pacific	39	8 (20.5)	NE [18.9, NE)	84	29 (34.5)	NE [22.4, NE)		1.359 (0.618, 2.989)	0.4440
Baseline ECOG PS	0-1	146	25 (17.1)	NE [NE, NE)	294	102 (34.7)	NE [23.7, NE)	0.9827	1.840 (1.188, 2.851)	0.0056
	2	7	0 (0.0)	NE [NE, NE)	13	2 (15.4)	NE [6.0, NE)		>999.999 (<.001, NE)	0.4700

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	21 (15.4)	NE [NE, NE)	285	97 (34.0)	NE [23.6, NE)	0.3146	1.954 (1.218, 3.133)	0.0046
	No	17	4 (23.5)	NE [7.3, NE)	23	7 (30.4)	NE [9.7, NE)		1.122 (0.327, 3.851)	0.8547
Refractory to Bortezomib or Ixazomib	Yes	55	7 (12.7)	NE [NE, NE)	99	33 (33.3)	NE [17.2, NE)	0.4699	2.281 (1.008, 5.165)	0.0420
	No	98	18 (18.4)	NE [NE, NE)	209	71 (34.0)	NE [23.7, NE)		1.634 (0.974, 2.742)	0.0604

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	12 (16.2)	NE [27.7, NE)	122	38 (31.1)	NE [21.2, NE)	0.5316	1.544 (0.804, 2.965)	0.1878
	No	79	13 (16.5)	NE [NE, NE)	186	66 (35.5)	NE [23.6, NE)		2.047 (1.129, 3.712)	0.0159
Refractory to Lenalidomide	Yes	55	11 (20.0)	27.7 [16.2, NE)	98	30 (30.6)	NE [21.2, NE)	0.1009	1.097 (0.545, 2.207)	0.7956
	No	98	14 (14.3)	NE [NE, NE)	210	74 (35.2)	NE [23.6, NE)		2.375 (1.341, 4.205)	0.0022

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-511-ae-cox-eoi-cfz-grd345.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	19 (17.3)	NE [27.7, NE)	205	69 (33.7)	NE [22.4, NE)	0.5168	1.658 (0.997, 2.759)	0.0492
	No	43	6 (14.0)	NE [NE, NE)	103	35 (34.0)	NE [23.7, NE)		2.302 (0.968, 5.475)	0.0522
Refractory to IMiD	Yes	65	12 (18.5)	NE [27.7, NE)	129	39 (30.2)	NE [22.4, NE)	0.1395	1.185 (0.616, 2.278)	0.6103
	No	88	13 (14.8)	NE [NE, NE)	179	65 (36.3)	NE [23.6, NE)		2.393 (1.319, 4.341)	0.0030

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	22 (17.5)	NE [NE, NE)	250	84 (33.6)	NE [27.5, NE)	0.6632	1.738 (1.086, 2.781)	0.0196
	3	27	3 (11.1)	NE [NE, NE)	58	20 (34.5)	23.7 [14.8, NE)		2.393 (0.708, 8.084)	0.1469
Prior proteasome inhibitor exposure per IXRS	Yes	138	22 (15.9)	NE [NE, NE)	276	94 (34.1)	NE [23.7, NE)	0.5842	1.895 (1.191, 3.016)	0.0061
	No	15	3 (20.0)	NE [18.9, NE)	32	10 (31.3)	NE [14.9, NE)		1.382 (0.380, 5.030)	0.6215

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	12 (18.2)	NE [NE, NE)	131	46 (35.1)	NE [23.7, NE)	0.8872	1.773 (0.939, 3.348)	0.0736
	>= 2	87	13 (14.9)	NE [27.7, NE)	177	58 (32.8)	NE [22.4, NE)		1.867 (1.022, 3.412)	0.0391

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Reversible posterior leukoencephalopathy syndrome (AMQ) - Narrow										
Total subjects		153	0 (0.0)	NE [NE, NE)	308	7 (2.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.1006

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	0 (0.0)	NE [NE, NE)	283	6 (2.1)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.1346
	> 75	18	0 (0.0)	NE [NE, NE)	25	1 (4.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.4795
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	4 (2.3)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.2385
	Female	62	0 (0.0)	NE [NE, NE)	134	3 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.2610

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	0 (0.0)	NE [NE, NE)	240	6 (2.5)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.1172
	Asian	20	0 (0.0)	NE [NE, NE)	46	1 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.6106
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	1 (4.8)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.5403

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	3 (1.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.2444
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	3 (3.6)	NE [NE, NE)		>999.999 (<.001, NE)	0.3371
Baseline ECOG PS	0-1	146	0 (0.0)	NE [NE, NE)	294	7 (2.4)	NE [NE, NE)	0.9994	>999.999 (<.001, NE)	0.0955
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	0 (0.0)	NE [NE, NE)	285	6 (2.1)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.1265
	No	17	0 (0.0)	NE [NE, NE)	23	1 (4.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.4945
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	2 (2.0)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.2926
	No	98	0 (0.0)	NE [NE, NE)	209	5 (2.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.2016

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	4 (3.3)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.2014
	No	79	0 (0.0)	NE [NE, NE)	186	3 (1.6)	NE [NE, NE)		>999.999 (<.001, NE)	0.2948
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	4 (4.1)	NE [NE, NE)	0.9998	>999.999 (<.001, NE)	0.2359
	No	98	0 (0.0)	NE [NE, NE)	210	3 (1.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.2740

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	0 (0.0)	NE [NE, NE)	205	5 (2.4)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.1557
	No	43	0 (0.0)	NE [NE, NE)	103	2 (1.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.3961
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	5 (3.9)	NE [NE, NE)	0.9997	>999.999 (<.001, NE)	0.1989
	No	88	0 (0.0)	NE [NE, NE)	179	2 (1.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.3516

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	0 (0.0)	NE [NE, NE)	250	6 (2.4)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.1259
	3	27	0 (0.0)	NE [NE, NE)	58	1 (1.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.5040
Prior proteasome inhibitor exposure per IXRS	Yes	138	0 (0.0)	NE [NE, NE)	276	6 (2.2)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.1195
	No	15	0 (0.0)	NE [NE, NE)	32	1 (3.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.5541

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	3 (2.3)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.2755
	>= 2	87	0 (0.0)	NE [NE, NE)	177	4 (2.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.2255

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-511-ae-cox-eoi-cfz-grd345.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Thrombotic Microangiopathy (Carfilzomib) (AMQ) - Narrow										
Total subjects		153	2 (1.3)	NE [NE, NE)	308	2 (0.6)	NE [NE, NE)		0.472 (0.066, 3.352)	0.4421

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	1 (0.7)	NE [NE, NE)	283	2 (0.7)	NE [NE, NE)	0.9943	0.911 (0.083, 10.054)	0.9395
	> 75	18	1 (5.6)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.2305
Sex	Male	91	1 (1.1)	NE [NE, NE)	174	0 (0.0)	NE [NE, NE)	0.9954	<.001 (<.001, NE)	0.1635
	Female	62	1 (1.6)	NE [NE, NE)	134	2 (1.5)	NE [NE, NE)		0.852 (0.077, 9.415)	0.8962

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	2 (1.6)	NE [NE, NE)	240	1 (0.4)	NE [NE, NE)	1.0000	0.242 (0.022, 2.670)	0.2085
	Asian	20	0 (0.0)	NE [NE, NE)	46	1 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.5097
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	2 (2.0)	NE [NE, NE)	203	1 (0.5)	NE [NE, NE)		0.232 (0.021, 2.564)	0.1936
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	1 (1.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.4956
Baseline ECOG PS	0-1	146	2 (1.4)	NE [NE, NE)	294	2 (0.7)	NE [NE, NE)	0.9999	0.478 (0.067, 3.396)	0.4505
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	0 (0.0)	NE [NE, NE)	285	2 (0.7)	NE [NE, NE)	0.9964	>999.999 (<.001, NE)	0.3415
	No	17	2 (11.8)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.1024
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	1 (1.0)	NE [NE, NE)	0.9958	>999.999 (<.001, NE)	0.4744
	No	98	2 (2.0)	NE [NE, NE)	209	1 (0.5)	NE [NE, NE)		0.226 (0.020, 2.492)	0.1836

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	2 (2.7)	NE [NE, NE)	122	1 (0.8)	NE [NE, NE)	0.9941	0.274 (0.025, 3.022)	0.2575
	No	79	0 (0.0)	NE [NE, NE)	186	1 (0.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.5135
Refractory to Lenalidomide	Yes	55	1 (1.8)	NE [NE, NE)	98	1 (1.0)	NE [NE, NE)	0.9353	0.513 (0.032, 8.203)	0.6307
	No	98	1 (1.0)	NE [NE, NE)	210	1 (0.5)	NE [NE, NE)		0.462 (0.029, 7.382)	0.5753

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	2 (1.8)	NE [NE, NE)	205	2 (1.0)	NE [NE, NE)	0.9999	0.501 (0.071, 3.563)	0.4816
	No	43	0 (0.0)	NE [NE, NE)	103	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to IMiD	Yes	65	1 (1.5)	NE [NE, NE)	129	1 (0.8)	NE [NE, NE)	0.9949	0.454 (0.028, 7.256)	0.5663
	No	88	1 (1.1)	NE [NE, NE)	179	1 (0.6)	NE [NE, NE)		0.488 (0.031, 7.806)	0.6045

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	2 (1.6)	NE [NE, NE)	250	2 (0.8)	NE [NE, NE)	0.9999	0.488 (0.069, 3.468)	0.4642
	3	27	0 (0.0)	NE [NE, NE)	58	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Prior proteasome inhibitor exposure per IXRS	Yes	138	0 (0.0)	NE [NE, NE)	276	2 (0.7)	NE [NE, NE)	0.9947	>999.999 (<.001, NE)	0.3294
	No	15	2 (13.3)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0320

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	2 (3.0)	NE [NE, NE)	131	1 (0.8)	NE [NE, NE)	0.9946	0.245 (0.022, 2.705)	0.2134
	>= 2	87	0 (0.0)	NE [NE, NE)	177	1 (0.6)	NE [NE, NE)		>999.999 (<.001, NE)	0.5105

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Tumour lysis syndrome (SMQ) - Narrow										
Total subjects		153	1 (0.7)	NE [NE, NE)	308	4 (1.3)	NE [NE, NE)		1.775 (0.196, 16.059)	0.6046

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	1 (0.7)	NE [NE, NE)	283	4 (1.4)	NE [NE, NE)	0.9999	1.705 (0.189, 15.426)	0.6308
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	1 (1.1)	NE [NE, NE)	174	2 (1.1)	NE [NE, NE)	0.9948	0.815 (0.071, 9.323)	0.8690
	Female	62	0 (0.0)	NE [NE, NE)	134	2 (1.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.3342

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	0 (0.0)	NE [NE, NE)	240	3 (1.3)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.2146
	Asian	20	0 (0.0)	NE [NE, NE)	46	1 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.6949
	Other or Unknown	11	1 (9.1)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.1573
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-511-ae-cox-eoi-cfz-grd345.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	1 (1.0)	NE [NE, NE)	203	3 (1.5)	NE [NE, NE)		1.524 (0.159, 14.649)	0.7130
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	1 (1.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.7557
Baseline ECOG PS	0-1	146	1 (0.7)	NE [NE, NE)	294	4 (1.4)	NE [NE, NE)	0.9999	1.784 (0.197, 16.125)	0.6012
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Output: t14-06-001-511-ae-cox-eoi-cfz-grd345.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	1 (0.7)	NE [NE, NE)	285	4 (1.4)	NE [NE, NE)	0.9999	1.713 (0.189, 15.480)	0.6279
	No	17	0 (0.0)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	2 (2.0)	NE [NE, NE)	0.9953	>999.999 (<.001, NE)	0.3653
	No	98	1 (1.0)	NE [NE, NE)	209	2 (1.0)	NE [NE, NE)		0.941 (0.085, 10.373)	0.9601

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Output: t14-06-001-511-ae-cox-eoi-cfz-grd345.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	2 (1.6)	NE [NE, NE)	0.9945	>999.999 (<.001, NE)	0.2687
	No	79	1 (1.3)	NE [NE, NE)	186	2 (1.1)	NE [NE, NE)		0.707 (0.063, 7.950)	0.7782
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	2 (2.0)	NE [NE, NE)	0.9953	>999.999 (<.001, NE)	0.2869
	No	98	1 (1.0)	NE [NE, NE)	210	2 (1.0)	NE [NE, NE)		0.789 (0.070, 8.841)	0.8472

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	1 (0.9)	NE [NE, NE)	205	3 (1.5)	NE [NE, NE)	0.9959	1.377 (0.141, 13.486)	0.7828
	No	43	0 (0.0)	NE [NE, NE)	103	1 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.5162
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	2 (1.6)	NE [NE, NE)	0.9949	>999.999 (<.001, NE)	0.3135
	No	88	1 (1.1)	NE [NE, NE)	179	2 (1.1)	NE [NE, NE)		0.827 (0.074, 9.273)	0.8771

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	0 (0.0)	NE [NE, NE)	250	2 (0.8)	NE [NE, NE)	0.9940	>999.999 (<.001, NE)	0.3832
	3	27	1 (3.7)	NE [NE, NE)	58	2 (3.4)	NE [NE, NE)		0.941 (0.085, 10.381)	0.9605
Prior proteasome inhibitor exposure per IXRS	Yes	138	1 (0.7)	NE [NE, NE)	276	4 (1.4)	NE [NE, NE)	0.9999	1.791 (0.198, 16.195)	0.5989
	No	15	0 (0.0)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.511. Cox Regression of Grade ≥3 Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	1 (1.5)	NE [NE, NE)	131	2 (1.5)	NE [NE, NE)	0.9942	1.008 (0.091, 11.113)	0.9950
	>= 2	87	0 (0.0)	NE [NE, NE)	177	2 (1.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.4013

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and for subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Output: t14-06-001-511-ae-cox-eoi-cfz-grd345.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Acute renal failure (SMQ) - Narrow										
Total subjects		153	9 (5.9)	NE [NE, NE)	308	9 (2.9)	NE [NE, NE)		0.410 (0.162, 1.037)	0.0519

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-512-sae-cox-eoi-cfz.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	9 (6.7)	NE [NE, NE)	283	8 (2.8)	NE [NE, NE)	0.9922	0.346 (0.133, 0.901)	0.0231
	> 75	18	0 (0.0)	NE [NE, NE)	25	1 (4.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.4096
Sex	Male	91	7 (7.7)	NE [NE, NE)	174	4 (2.3)	NE [NE, NE)	0.1751	0.255 (0.074, 0.875)	0.0192
	Female	62	2 (3.2)	NE [NE, NE)	134	5 (3.7)	NE [NE, NE)		0.947 (0.183, 4.911)	0.9485

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	5 (4.1)	NE [NE, NE)	240	8 (3.3)	NE [NE, NE)	0.9214	0.710 (0.232, 2.179)	0.5481
	Asian	20	3 (15.0)	NE [12.0, NE)	46	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0038
	Other or Unknown	11	1 (9.1)	NE [1.1, NE)	22	1 (4.5)	NE [27.2, NE)		0.337 (0.020, 5.559)	0.4259
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	0.9999	NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	5 (4.9)	NE [NE, NE)	203	9 (4.4)	NE [NE, NE)		0.787 (0.263, 2.354)	0.6681
	Asia Pacific	39	4 (10.3)	NE [NE, NE)	84	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0016
Baseline ECOG PS	0-1	146	9 (6.2)	NE [NE, NE)	294	8 (2.7)	NE [NE, NE)	0.9918	0.369 (0.142, 0.962)	0.0338
	2	7	0 (0.0)	NE [NE, NE)	13	1 (7.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.5186

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	8 (5.9)	NE [NE, NE)	285	8 (2.8)	NE [NE, NE)	0.8107	0.392 (0.146, 1.051)	0.0538
	No	17	1 (5.9)	NE [9.5, NE)	23	1 (4.3)	NE [NE, NE)		0.608 (0.038, 9.849)	0.7235
Refractory to Bortezomib or Ixazomib	Yes	55	3 (5.5)	NE [NE, NE)	99	3 (3.0)	NE [NE, NE)	0.8254	0.513 (0.103, 2.545)	0.4052
	No	98	6 (6.1)	NE [NE, NE)	209	6 (2.9)	NE [NE, NE)		0.365 (0.117, 1.137)	0.0703

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	4 (5.4)	NE [NE, NE)	122	4 (3.3)	NE [NE, NE)	0.7707	0.443 (0.108, 1.805)	0.2435
	No	79	5 (6.3)	NE [NE, NE)	186	5 (2.7)	NE [NE, NE)		0.377 (0.109, 1.304)	0.1096
Refractory to Lenalidomide	Yes	55	4 (7.3)	NE [NE, NE)	98	3 (3.1)	NE [NE, NE)	0.6667	0.316 (0.069, 1.449)	0.1186
	No	98	5 (5.1)	NE [NE, NE)	210	6 (2.9)	NE [NE, NE)		0.481 (0.146, 1.581)	0.2184

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-512-sae-cox-eoi-cfz.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	7 (6.4)	NE [NE, NE)	205	7 (3.4)	NE [NE, NE)	0.8619	0.428 (0.149, 1.231)	0.1053
	No	43	2 (4.7)	NE [NE, NE)	103	2 (1.9)	NE [NE, NE)		0.370 (0.052, 2.641)	0.3019
Refractory to IMiD	Yes	65	6 (9.2)	NE [NE, NE)	129	3 (2.3)	NE [NE, NE)	0.1403	0.188 (0.046, 0.770)	0.0097
	No	88	3 (3.4)	NE [NE, NE)	179	6 (3.4)	NE [NE, NE)		0.846 (0.211, 3.396)	0.8145

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	7 (5.6)	NE [NE, NE)	250	6 (2.4)	NE [NE, NE)	0.8331	0.371 (0.124, 1.110)	0.0653
	3	27	2 (7.4)	NE [NE, NE)	58	3 (5.2)	NE [NE, NE)		0.463 (0.076, 2.804)	0.3906
Prior proteasome inhibitor exposure per IXRS	Yes	138	8 (5.8)	NE [NE, NE)	276	8 (2.9)	NE [NE, NE)	0.9415	0.411 (0.153, 1.101)	0.0680
	No	15	1 (6.7)	NE [9.5, NE)	32	1 (3.1)	NE [NE, NE)		0.411 (0.026, 6.609)	0.5167

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	3 (4.5)	NE [NE, NE)	131	3 (2.3)	NE [NE, NE)	0.9867	0.366 (0.073, 1.830)	0.2024
	>= 2	87	6 (6.9)	NE [NE, NE)	177	6 (3.4)	NE [NE, NE)		0.429 (0.137, 1.336)	0.1325

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Cardiac arrhythmias (SMQ) - Narrow										
Total subjects		153	2 (1.3)	NE [NE, NE)	308	8 (2.6)	NE [NE, NE)		1.677 (0.355, 7.919)	0.5093

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	1 (0.7)	NE [NE, NE)	283	5 (1.8)	NE [NE, NE)	0.9546	1.889 (0.220, 16.252)	0.5560
	> 75	18	1 (5.6)	NE [NE, NE)	25	3 (12.0)	NE [NE, NE)		1.838 (0.191, 17.709)	0.5930
Sex	Male	91	2 (2.2)	NE [NE, NE)	174	7 (4.0)	NE [NE, NE)	0.9942	1.541 (0.319, 7.455)	0.5876
	Female	62	0 (0.0)	NE [NE, NE)	134	1 (0.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.5344

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	2 (1.6)	NE [NE, NE)	240	7 (2.9)	NE [NE, NE)	1.0000	1.490 (0.309, 7.195)	0.6168
	Asian	20	0 (0.0)	NE [NE, NE)	46	1 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.5097
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	1 (4.8)	NE [NE, NE)	0.8088	>999.999 (<.001, NE)	0.6650

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	1 (1.0)	NE [NE, NE)	203	5 (2.5)	NE [NE, NE)		2.147 (0.251, 18.397)	0.4750
	Asia Pacific	39	1 (2.6)	NE [NE, NE)	84	2 (2.4)	NE [NE, NE)		0.862 (0.078, 9.517)	0.9034
Baseline ECOG PS	0-1	146	2 (1.4)	NE [NE, NE)	294	7 (2.4)	NE [NE, NE)	0.9935	1.495 (0.310, 7.219)	0.6139
	2	7	0 (0.0)	NE [NE, NE)	13	1 (7.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.6015

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	1 (0.7)	NE [NE, NE)	285	8 (2.8)	NE [NE, NE)	0.9920	3.220 (0.402, 25.800)	0.2441
	No	17	1 (5.9)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.2207
Refractory to Bortezomib or Ixazomib	Yes	55	1 (1.8)	NE [NE, NE)	99	2 (2.0)	NE [NE, NE)	0.6024	1.047 (0.095, 11.544)	0.9701
	No	98	1 (1.0)	NE [NE, NE)	209	6 (2.9)	NE [NE, NE)		2.317 (0.278, 19.321)	0.4242

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	1 (1.4)	NE [NE, NE)	122	3 (2.5)	NE [NE, NE)	0.8753	1.563 (0.161, 15.154)	0.6975
	No	79	1 (1.3)	NE [NE, NE)	186	5 (2.7)	NE [NE, NE)		1.822 (0.213, 15.608)	0.5785
Refractory to Lenalidomide	Yes	55	1 (1.8)	NE [NE, NE)	98	1 (1.0)	NE [NE, NE)	0.2826	0.371 (0.023, 6.085)	0.4698
	No	98	1 (1.0)	NE [NE, NE)	210	7 (3.3)	NE [NE, NE)		2.904 (0.357, 23.622)	0.2962

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	1 (0.9)	NE [NE, NE)	205	5 (2.4)	NE [NE, NE)	0.6687	2.343 (0.273, 20.102)	0.4237
	No	43	1 (2.3)	NE [NE, NE)	103	3 (2.9)	NE [NE, NE)		1.052 (0.109, 10.125)	0.9650
Refractory to IMiD	Yes	65	1 (1.5)	NE [NE, NE)	129	3 (2.3)	NE [NE, NE)	0.7004	1.140 (0.118, 11.057)	0.9097
	No	88	1 (1.1)	NE [NE, NE)	179	5 (2.8)	NE [NE, NE)		2.165 (0.253, 18.556)	0.4702

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	2 (1.6)	NE [NE, NE)	250	5 (2.0)	NE [NE, NE)	0.9944	1.073 (0.207, 5.562)	0.9330
	3	27	0 (0.0)	NE [NE, NE)	58	3 (5.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.3142
Prior proteasome inhibitor exposure per IXRS	Yes	138	1 (0.7)	NE [NE, NE)	276	8 (2.9)	NE [NE, NE)	0.9910	3.374 (0.421, 27.040)	0.2236
	No	15	1 (6.7)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0986

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	1 (1.5)	NE [NE, NE)	131	4 (3.1)	NE [NE, NE)	0.9736	1.685 (0.188, 15.122)	0.6374
	>= 2	87	1 (1.1)	NE [NE, NE)	177	4 (2.3)	NE [NE, NE)		1.592 (0.176, 14.395)	0.6762

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-512-sae-cox-eoi-cfz.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Cardiac failure (SMQ) - Narrow										
Total subjects		153	8 (5.2)	NE [NE, NE)	308	11 (3.6)	NE [NE, NE)		0.580 (0.233, 1.445)	0.2371

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	7 (5.2)	NE [NE, NE)	283	8 (2.8)	NE [NE, NE)	0.2555	0.455 (0.165, 1.257)	0.1197
	> 75	18	1 (5.6)	NE [12.9, NE)	25	3 (12.0)	NE [NE, NE)		2.053 (0.213, 19.749)	0.5247
Sex	Male	91	4 (4.4)	NE [NE, NE)	174	6 (3.4)	NE [NE, NE)	0.7676	0.649 (0.182, 2.315)	0.5023
	Female	62	4 (6.5)	NE [NE, NE)	134	5 (3.7)	NE [NE, NE)		0.503 (0.135, 1.876)	0.2972

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	8 (6.6)	NE [NE, NE)	240	11 (4.6)	NE [NE, NE)	1.0000	0.600 (0.241, 1.495)	0.2686
	Asian	20	0 (0.0)	NE [NE, NE)	46	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	1 (8.3)	NE [11.5, NE)	21	1 (4.8)	NE [NE, NE)	0.9295	0.478 (0.030, 7.729)	0.5952

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	6 (5.9)	NE [NE, NE)	203	9 (4.4)	NE [NE, NE)		0.658 (0.234, 1.850)	0.4248
	Asia Pacific	39	1 (2.6)	NE [NE, NE)	84	1 (1.2)	NE [NE, NE)		0.321 (0.020, 5.134)	0.3967
Baseline ECOG PS	0-1	146	8 (5.5)	NE [NE, NE)	294	9 (3.1)	NE [NE, NE)	0.9912	0.482 (0.186, 1.253)	0.1263
	2	7	0 (0.0)	NE [NE, NE)	13	2 (15.4)	NE [7.0, NE)		>999.999 (<.001, NE)	0.5186

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	8 (5.9)	NE [NE, NE)	285	8 (2.8)	NE [NE, NE)	0.9875	0.400 (0.150, 1.068)	0.0584
	No	17	0 (0.0)	NE [NE, NE)	23	3 (13.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.1604
Refractory to Bortezomib or Ixazomib	Yes	55	3 (5.5)	NE [NE, NE)	99	1 (1.0)	NE [NE, NE)	0.2112	0.159 (0.016, 1.539)	0.0693
	No	98	5 (5.1)	NE [NE, NE)	209	10 (4.8)	NE [NE, NE)		0.798 (0.272, 2.339)	0.6802

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	4 (5.4)	NE [NE, NE)	122	2 (1.6)	NE [NE, NE)	0.2426	0.255 (0.047, 1.394)	0.0893
	No	79	4 (5.1)	NE [NE, NE)	186	9 (4.8)	NE [NE, NE)		0.838 (0.258, 2.727)	0.7692
Refractory to Lenalidomide	Yes	55	2 (3.6)	NE [NE, NE)	98	1 (1.0)	NE [NE, NE)	0.3863	0.256 (0.023, 2.824)	0.2299
	No	98	6 (6.1)	NE [NE, NE)	210	10 (4.8)	NE [NE, NE)		0.685 (0.249, 1.888)	0.4624

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	4 (3.6)	NE [NE, NE)	205	4 (2.0)	NE [NE, NE)	0.7087	0.463 (0.116, 1.856)	0.2663
	No	43	4 (9.3)	NE [NE, NE)	103	7 (6.8)	NE [NE, NE)		0.635 (0.185, 2.175)	0.4659
Refractory to IMiD	Yes	65	2 (3.1)	NE [NE, NE)	129	1 (0.8)	NE [NE, NE)	0.3286	0.228 (0.021, 2.523)	0.1879
	No	88	6 (6.8)	NE [NE, NE)	179	10 (5.6)	NE [NE, NE)		0.725 (0.263, 1.998)	0.5329

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	6 (4.8)	NE [NE, NE)	250	10 (4.0)	NE [NE, NE)	0.2452	0.731 (0.265, 2.016)	0.5438
	3	27	2 (7.4)	NE [NE, NE)	58	1 (1.7)	NE [NE, NE)		0.171 (0.015, 1.911)	0.1049
Prior proteasome inhibitor exposure per IXRS	Yes	138	7 (5.1)	NE [NE, NE)	276	7 (2.5)	NE [NE, NE)	0.2927	0.413 (0.144, 1.179)	0.0880
	No	15	1 (6.7)	NE [NE, NE)	32	4 (12.5)	NE [NE, NE)		1.670 (0.186, 15.001)	0.6433

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	5 (7.6)	NE [NE, NE)	131	5 (3.8)	NE [NE, NE)	0.4773	0.403 (0.116, 1.399)	0.1388
	>= 2	87	3 (3.4)	NE [NE, NE)	177	6 (3.4)	NE [NE, NE)		0.863 (0.216, 3.456)	0.8366

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Cardiomyopathy (SMQ) - Narrow										
Total subjects		153	0 (0.0)	NE [NE, NE)	308	2 (0.6)	NE [NE, NE)		>999.999 (<.001, NE)	0.3700

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	0 (0.0)	NE [NE, NE)	283	2 (0.7)	NE [NE, NE)	0.9993	>999.999 (<.001, NE)	0.3774
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	2 (1.1)	NE [NE, NE)	0.9989	>999.999 (<.001, NE)	0.3647
	Female	62	0 (0.0)	NE [NE, NE)	134	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	0 (0.0)	NE [NE, NE)	240	2 (0.8)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.3597
	Asian	20	0 (0.0)	NE [NE, NE)	46	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	1 (0.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.5066
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	1 (1.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.5604
Baseline ECOG PS	0-1	146	0 (0.0)	NE [NE, NE)	294	2 (0.7)	NE [NE, NE)	0.9998	>999.999 (<.001, NE)	0.3607
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-512-sae-cox-eoi-cfz.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	0 (0.0)	NE [NE, NE)	285	1 (0.4)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.5171
	No	17	0 (0.0)	NE [NE, NE)	23	1 (4.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.5050
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	1 (1.0)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.4715
	No	98	0 (0.0)	NE [NE, NE)	209	1 (0.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.5435

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	1 (0.8)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.4686
	No	79	0 (0.0)	NE [NE, NE)	186	1 (0.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.5622
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	1 (1.0)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.4904
	No	98	0 (0.0)	NE [NE, NE)	210	1 (0.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.5412

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	0 (0.0)	NE [NE, NE)	205	2 (1.0)	NE [NE, NE)	0.9989	>999.999 (<.001, NE)	0.3539
	No	43	0 (0.0)	NE [NE, NE)	103	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	1 (0.8)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.5167
	No	88	0 (0.0)	NE [NE, NE)	179	1 (0.6)	NE [NE, NE)		>999.999 (<.001, NE)	0.5271

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	0 (0.0)	NE [NE, NE)	250	1 (0.4)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.5211
	3	27	0 (0.0)	NE [NE, NE)	58	1 (1.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.5590
Prior proteasome inhibitor exposure per IXRS	Yes	138	0 (0.0)	NE [NE, NE)	276	1 (0.4)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.5068
	No	15	0 (0.0)	NE [NE, NE)	32	1 (3.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.5637

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	0 (0.0)	NE [NE, NE)	0.9989	NE (NE, NE)	NE
	>= 2	87	0 (0.0)	NE [NE, NE)	177	2 (1.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.3747

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Dyspnoeas (HLT)										
Total subjects		153	6 (3.9)	NE [NE, NE)	308	5 (1.6)	NE [NE, NE)		0.345 (0.104, 1.142)	0.0686

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	4 (3.0)	NE [NE, NE)	283	5 (1.8)	NE [NE, NE)	0.9917	0.537 (0.143, 2.016)	0.3505
	> 75	18	2 (11.1)	NE [12.6, NE)	25	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0646
Sex	Male	91	2 (2.2)	NE [NE, NE)	174	3 (1.7)	NE [NE, NE)	0.3546	0.750 (0.125, 4.489)	0.7516
	Female	62	4 (6.5)	NE [NE, NE)	134	2 (1.5)	NE [NE, NE)		0.187 (0.034, 1.032)	0.0317

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	5 (4.1)	NE [NE, NE)	240	4 (1.7)	NE [NE, NE)	1.0000	0.333 (0.088, 1.253)	0.0881
	Asian	20	1 (5.0)	NE [NE, NE)	46	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.1294
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	1 (4.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.5002
Region	North America	12	0 (0.0)	NE [NE, NE)	21	1 (4.8)	NE [NE, NE)	0.6270	>999.999 (<.001, NE)	0.4497

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	3 (2.9)	NE [NE, NE)	203	3 (1.5)	NE [NE, NE)		0.453 (0.091, 2.255)	0.3217
	Asia Pacific	39	3 (7.7)	NE [NE, NE)	84	1 (1.2)	NE [NE, NE)		0.125 (0.013, 1.206)	0.0328
Baseline ECOG PS	0-1	146	4 (2.7)	NE [NE, NE)	294	4 (1.4)	NE [NE, NE)	0.4376	0.397 (0.098, 1.605)	0.1796
	2	7	2 (28.6)	NE [0.0, NE)	13	1 (7.7)	NE [NE, NE)		0.249 (0.023, 2.753)	0.2200

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	5 (3.7)	NE [NE, NE)	285	5 (1.8)	NE [NE, NE)	0.9926	0.419 (0.120, 1.457)	0.1585
	No	17	1 (5.9)	NE [24.5, NE)	23	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.1069
Refractory to Bortezomib or Ixazomib	Yes	55	1 (1.8)	NE [NE, NE)	99	2 (2.0)	NE [NE, NE)	0.3201	0.856 (0.076, 9.684)	0.8998
	No	98	5 (5.1)	NE [NE, NE)	209	3 (1.4)	NE [NE, NE)		0.244 (0.058, 1.028)	0.0375

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	2 (2.7)	NE [NE, NE)	122	3 (2.5)	NE [NE, NE)	0.2749	0.883 (0.147, 5.290)	0.8917
	No	79	4 (5.1)	NE [NE, NE)	186	2 (1.1)	NE [NE, NE)		0.170 (0.031, 0.936)	0.0211
Refractory to Lenalidomide	Yes	55	1 (1.8)	NE [NE, NE)	98	2 (2.0)	NE [NE, NE)	0.3733	1.078 (0.098, 11.902)	0.9508
	No	98	5 (5.1)	NE [NE, NE)	210	3 (1.4)	NE [NE, NE)		0.238 (0.056, 1.001)	0.0335

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	4 (3.6)	NE [NE, NE)	205	4 (2.0)	NE [NE, NE)	0.5499	0.512 (0.128, 2.047)	0.3352
	No	43	2 (4.7)	NE [NE, NE)	103	1 (1.0)	NE [NE, NE)		0.148 (0.013, 1.643)	0.0719
Refractory to IMiD	Yes	65	1 (1.5)	NE [NE, NE)	129	2 (1.6)	NE [NE, NE)	0.4298	0.961 (0.087, 10.608)	0.9741
	No	88	5 (5.7)	NE [NE, NE)	179	3 (1.7)	NE [NE, NE)		0.252 (0.060, 1.061)	0.0427

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-512-sae-cox-eoi-cfz.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	4 (3.2)	NE [NE, NE)	250	4 (1.6)	NE [NE, NE)	0.5434	0.404 (0.100, 1.636)	0.1894
	3	27	2 (7.4)	NE [NE, NE)	58	1 (1.7)	NE [NE, NE)		0.234 (0.021, 2.578)	0.1956
Prior proteasome inhibitor exposure per IXRS	Yes	138	5 (3.6)	NE [NE, NE)	276	4 (1.4)	NE [NE, NE)	0.9469	0.345 (0.092, 1.295)	0.0990
	No	15	1 (6.7)	NE [24.5, NE)	32	1 (3.1)	NE [NE, NE)		0.361 (0.022, 5.908)	0.4565

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	4 (6.1)	NE [NE, NE)	131	2 (1.5)	NE [NE, NE)	0.3992	0.212 (0.039, 1.165)	0.0494
	>= 2	87	2 (2.3)	NE [NE, NE)	177	3 (1.7)	NE [NE, NE)		0.611 (0.100, 3.741)	0.5907

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Embolic and thrombotic events, venous (SMQ) - Narrow										
Total subjects		153	8 (5.2)	NE [NE, NE)	308	9 (2.9)	NE [NE, NE)		0.453 (0.175, 1.175)	0.0950

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	8 (5.9)	NE [NE, NE)	283	8 (2.8)	NE [NE, NE)	0.9923	0.392 (0.147, 1.045)	0.0523
	> 75	18	0 (0.0)	NE [NE, NE)	25	1 (4.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.4497
Sex	Male	91	4 (4.4)	NE [NE, NE)	174	7 (4.0)	NE [NE, NE)	0.1925	0.746 (0.218, 2.552)	0.6403
	Female	62	4 (6.5)	NE [NE, NE)	134	2 (1.5)	NE [NE, NE)		0.191 (0.035, 1.044)	0.0328

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	8 (6.6)	NE [NE, NE)	240	8 (3.3)	NE [NE, NE)	1.0000	0.414 (0.155, 1.105)	0.0693
	Asian	20	0 (0.0)	NE [NE, NE)	46	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	1 (4.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.5741
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	0.9511	NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	6 (5.9)	NE [NE, NE)	203	6 (3.0)	NE [NE, NE)		0.400 (0.129, 1.243)	0.1010
	Asia Pacific	39	2 (5.1)	NE [NE, NE)	84	3 (3.6)	NE [NE, NE)		0.578 (0.097, 3.464)	0.5440
Baseline ECOG PS	0-1	146	8 (5.5)	NE [NE, NE)	294	8 (2.7)	NE [NE, NE)	0.9916	0.416 (0.156, 1.109)	0.0703
	2	7	0 (0.0)	NE [NE, NE)	13	1 (7.7)	NE [6.2, NE)		>999.999 (<.001, NE)	0.7389

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	8 (5.9)	NE [NE, NE)	285	8 (2.8)	NE [NE, NE)	0.9924	0.392 (0.147, 1.046)	0.0525
	No	17	0 (0.0)	NE [NE, NE)	23	1 (4.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.5329
Refractory to Bortezomib or Ixazomib	Yes	55	3 (5.5)	NE [NE, NE)	99	1 (1.0)	NE [NE, NE)	0.2794	0.152 (0.016, 1.464)	0.0602
	No	98	5 (5.1)	NE [NE, NE)	209	8 (3.8)	NE [NE, NE)		0.612 (0.200, 1.874)	0.3864

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	3 (4.1)	NE [NE, NE)	122	3 (2.5)	NE [NE, NE)	0.9360	0.473 (0.095, 2.354)	0.3495
	No	79	5 (6.3)	NE [NE, NE)	186	6 (3.2)	NE [NE, NE)		0.435 (0.132, 1.425)	0.1572
Refractory to Lenalidomide	Yes	55	3 (5.5)	NE [NE, NE)	98	3 (3.1)	NE [NE, NE)	0.8650	0.415 (0.083, 2.077)	0.2696
	No	98	5 (5.1)	NE [NE, NE)	210	6 (2.9)	NE [NE, NE)		0.485 (0.148, 1.591)	0.2227

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	5 (4.5)	NE [NE, NE)	205	6 (2.9)	NE [NE, NE)	0.6909	0.523 (0.160, 1.715)	0.2772
	No	43	3 (7.0)	NE [NE, NE)	103	3 (2.9)	NE [NE, NE)		0.342 (0.069, 1.703)	0.1700
Refractory to IMiD	Yes	65	4 (6.2)	NE [NE, NE)	129	4 (3.1)	NE [NE, NE)	0.7183	0.378 (0.094, 1.521)	0.1547
	No	88	4 (4.5)	NE [NE, NE)	179	5 (2.8)	NE [NE, NE)		0.534 (0.143, 1.991)	0.3426

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	6 (4.8)	NE [NE, NE)	250	8 (3.2)	NE [NE, NE)	0.2536	0.585 (0.203, 1.687)	0.3156
	3	27	2 (7.4)	NE [NE, NE)	58	1 (1.7)	NE [NE, NE)		0.126 (0.011, 1.417)	0.0477
Prior proteasome inhibitor exposure per IXRS	Yes	138	8 (5.8)	NE [NE, NE)	276	8 (2.9)	NE [NE, NE)	0.9894	0.408 (0.153, 1.088)	0.0640
	No	15	0 (0.0)	NE [NE, NE)	32	1 (3.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.5485

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	4 (6.1)	NE [NE, NE)	131	3 (2.3)	NE [NE, NE)	0.5338	0.330 (0.074, 1.477)	0.1273
	>= 2	87	4 (4.6)	NE [NE, NE)	177	6 (3.4)	NE [NE, NE)		0.584 (0.165, 2.074)	0.4005

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Haematopoietic erythropenia (SMQ) - Broad										
Total subjects		153	1 (0.7)	NE [NE, NE)	308	9 (2.9)	NE [NE, NE)		3.902 (0.493, 30.861)	0.1640

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-512-sae-cox-eoi-cfz.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	1 (0.7)	NE [NE, NE)	283	9 (3.2)	NE [NE, NE)	0.9998	3.758 (0.475, 29.727)	0.1778
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	1 (1.1)	NE [NE, NE)	174	3 (1.7)	NE [NE, NE)	0.9934	1.324 (0.136, 12.921)	0.8087
	Female	62	0 (0.0)	NE [NE, NE)	134	6 (4.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.1175

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	1 (0.8)	NE [NE, NE)	240	8 (3.3)	NE [NE, NE)	1.0000	3.772 (0.472, 30.161)	0.1784
	Asian	20	0 (0.0)	NE [NE, NE)	46	1 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.6481
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	1 (1.0)	NE [NE, NE)	203	8 (3.9)	NE [NE, NE)		3.685 (0.461, 29.461)	0.1872
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	1 (1.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.6733
Baseline ECOG PS	0-1	146	1 (0.7)	NE [NE, NE)	294	9 (3.1)	NE [NE, NE)	0.9998	3.992 (0.505, 31.567)	0.1559
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	1 (0.7)	NE [NE, NE)	285	8 (2.8)	NE [NE, NE)	0.9946	3.482 (0.436, 27.847)	0.2098
	No	17	0 (0.0)	NE [NE, NE)	23	1 (4.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.5271
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	6 (6.1)	NE [NE, NE)	0.9918	>999.999 (<.001, NE)	0.0707
	No	98	1 (1.0)	NE [NE, NE)	209	3 (1.4)	NE [NE, NE)		1.089 (0.113, 10.536)	0.9414

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	4 (3.3)	NE [NE, NE)	0.9928	>999.999 (<.001, NE)	0.1828
	No	79	1 (1.3)	NE [NE, NE)	186	5 (2.7)	NE [NE, NE)		2.009 (0.235, 17.201)	0.5160
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	4 (4.1)	NE [NE, NE)	0.9939	>999.999 (<.001, NE)	0.2131
	No	98	1 (1.0)	NE [NE, NE)	210	5 (2.4)	NE [NE, NE)		2.169 (0.253, 18.577)	0.4688

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	1 (0.9)	NE [NE, NE)	205	5 (2.4)	NE [NE, NE)	0.9942	2.143 (0.249, 18.467)	0.4777
	No	43	0 (0.0)	NE [NE, NE)	103	4 (3.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.2050
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	4 (3.1)	NE [NE, NE)	0.9934	>999.999 (<.001, NE)	0.2381
	No	88	1 (1.1)	NE [NE, NE)	179	5 (2.8)	NE [NE, NE)		2.313 (0.270, 19.809)	0.4306

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	1 (0.8)	NE [NE, NE)	250	6 (2.4)	NE [NE, NE)	0.9945	2.579 (0.310, 21.486)	0.3634
	3	27	0 (0.0)	NE [NE, NE)	58	3 (5.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.2566
Prior proteasome inhibitor exposure per IXRS	Yes	138	1 (0.7)	NE [NE, NE)	276	9 (3.3)	NE [NE, NE)	0.9997	3.953 (0.500, 31.267)	0.1595
	No	15	0 (0.0)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	1 (1.5)	NE [NE, NE)	131	3 (2.3)	NE [NE, NE)	0.9920	1.297 (0.134, 12.535)	0.8214
	>= 2	87	0 (0.0)	NE [NE, NE)	177	6 (3.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.1031

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Haematopoietic leukopenia (SMQ) - Narrow										
Total subjects		153	1 (0.7)	NE [NE, NE)	308	2 (0.6)	NE [NE, NE)		0.926 (0.084, 10.232)	0.9501

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	1 (0.7)	NE [NE, NE)	283	2 (0.7)	NE [NE, NE)	1.0000	0.894 (0.081, 9.877)	0.9273
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	1 (0.6)	NE [NE, NE)	0.9956	>999.999 (<.001, NE)	0.4719
	Female	62	1 (1.6)	NE [NE, NE)	134	1 (0.7)	NE [NE, NE)		0.421 (0.026, 6.732)	0.5276

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	1 (0.8)	NE [NE, NE)	240	1 (0.4)	NE [NE, NE)	1.0000	0.506 (0.032, 8.096)	0.6238
	Asian	20	0 (0.0)	NE [NE, NE)	46	1 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.5351
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	1 (0.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.4806
	Asia Pacific	39	1 (2.6)	NE [NE, NE)	84	1 (1.2)	NE [NE, NE)		0.426 (0.027, 6.830)	0.5348
Baseline ECOG PS	0-1	146	1 (0.7)	NE [NE, NE)	294	2 (0.7)	NE [NE, NE)	1.0000	0.937 (0.085, 10.349)	0.9578
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-512-sae-cox-eoi-cfz.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	1 (0.7)	NE [NE, NE)	285	2 (0.7)	NE [NE, NE)	1.0000	0.890 (0.081, 9.827)	0.9240
	No	17	0 (0.0)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE
	No	98	1 (1.0)	NE [NE, NE)	209	2 (1.0)	NE [NE, NE)		0.878 (0.079, 9.707)	0.9157

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	1 (0.8)	NE [NE, NE)	0.9956	>999.999 (<.001, NE)	0.4748
	No	79	1 (1.3)	NE [NE, NE)	186	1 (0.5)	NE [NE, NE)		0.419 (0.026, 6.703)	0.5259
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	1 (1.0)	NE [NE, NE)	0.9961	>999.999 (<.001, NE)	0.5064
	No	98	1 (1.0)	NE [NE, NE)	210	1 (0.5)	NE [NE, NE)		0.459 (0.029, 7.334)	0.5720

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	0 (0.0)	NE [NE, NE)	205	1 (0.5)	NE [NE, NE)	0.9964	>999.999 (<.001, NE)	0.4967
	No	43	1 (2.3)	NE [NE, NE)	103	1 (1.0)	NE [NE, NE)		0.416 (0.026, 6.651)	0.5218
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	1 (0.8)	NE [NE, NE)	0.9959	>999.999 (<.001, NE)	0.5208
	No	88	1 (1.1)	NE [NE, NE)	179	1 (0.6)	NE [NE, NE)		0.483 (0.030, 7.722)	0.5988

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	1 (0.8)	NE [NE, NE)	250	1 (0.4)	NE [NE, NE)	0.9965	0.470 (0.029, 7.518)	0.5843
	3	27	0 (0.0)	NE [NE, NE)	58	1 (1.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.5127
Prior proteasome inhibitor exposure per IXRS	Yes	138	1 (0.7)	NE [NE, NE)	276	2 (0.7)	NE [NE, NE)	1.0000	0.935 (0.085, 10.328)	0.9564
	No	15	0 (0.0)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	1 (1.5)	NE [NE, NE)	131	1 (0.8)	NE [NE, NE)	0.9956	0.463 (0.029, 7.409)	0.5768
	>= 2	87	0 (0.0)	NE [NE, NE)	177	1 (0.6)	NE [NE, NE)		>999.999 (<.001, NE)	0.4808

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Haematopoietic thrombocytopenia (SMQ) - Narrow										
Total subjects		153	1 (0.7)	NE [NE, NE)	308	5 (1.6)	NE [NE, NE)		2.415 (0.282, 20.679)	0.4059

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	1 (0.7)	NE [NE, NE)	283	5 (1.8)	NE [NE, NE)	0.9999	2.331 (0.272, 19.953)	0.4263
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	1 (0.6)	NE [NE, NE)	0.9947	>999.999 (<.001, NE)	0.4719
	Female	62	1 (1.6)	NE [NE, NE)	134	4 (3.0)	NE [NE, NE)		1.765 (0.197, 15.808)	0.6067

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	0 (0.0)	NE [NE, NE)	240	5 (2.1)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.1123
	Asian	20	1 (5.0)	NE [NE, NE)	46	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.1099
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	5 (2.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.1161
	Asia Pacific	39	1 (2.6)	NE [NE, NE)	84	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.1259
Baseline ECOG PS	0-1	146	1 (0.7)	NE [NE, NE)	294	5 (1.7)	NE [NE, NE)	0.9999	2.436 (0.285, 20.857)	0.4009
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	1 (0.7)	NE [NE, NE)	285	5 (1.8)	NE [NE, NE)	0.9999	2.321 (0.271, 19.870)	0.4287
	No	17	0 (0.0)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to Bortezomib or Ixazomib	Yes	55	1 (1.8)	NE [NE, NE)	99	2 (2.0)	NE [NE, NE)	0.9931	1.070 (0.097, 11.802)	0.9561
	No	98	0 (0.0)	NE [NE, NE)	209	3 (1.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.2352

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	0 (0.0)	NE [NE, NE)	0.9999	NE (NE, NE)	NE
	No	79	1 (1.3)	NE [NE, NE)	186	5 (2.7)	NE [NE, NE)		2.099 (0.245, 17.968)	0.4887
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	0 (0.0)	NE [NE, NE)	0.9999	NE (NE, NE)	NE
	No	98	1 (1.0)	NE [NE, NE)	210	5 (2.4)	NE [NE, NE)		2.281 (0.266, 19.528)	0.4389

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	1 (0.9)	NE [NE, NE)	205	1 (0.5)	NE [NE, NE)	0.9940	0.469 (0.029, 7.509)	0.5841
	No	43	0 (0.0)	NE [NE, NE)	103	4 (3.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.1928
Refractory to IMiD	Yes	65	1 (1.5)	NE [NE, NE)	129	0 (0.0)	NE [NE, NE)	0.9942	<.001 (<.001, NE)	0.1352
	No	88	0 (0.0)	NE [NE, NE)	179	5 (2.8)	NE [NE, NE)		>999.999 (<.001, NE)	0.1208

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-512-sae-cox-eoi-cfz.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	0 (0.0)	NE [NE, NE)	250	1 (0.4)	NE [NE, NE)	0.9958	>999.999 (<.001, NE)	0.4998
	3	27	1 (3.7)	NE [NE, NE)	58	4 (6.9)	NE [NE, NE)		1.748 (0.195, 15.653)	0.6131
Prior proteasome inhibitor exposure per IXRS	Yes	138	1 (0.7)	NE [NE, NE)	276	5 (1.8)	NE [NE, NE)	0.9999	2.441 (0.285, 20.898)	0.3998
	No	15	0 (0.0)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	2 (1.5)	NE [NE, NE)	0.9943	>999.999 (<.001, NE)	0.3211
	>= 2	87	1 (1.1)	NE [NE, NE)	177	3 (1.7)	NE [NE, NE)		1.417 (0.147, 13.629)	0.7617

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Haemorrhage terms (excl laboratory terms) (SMQ) - Narrow										
Total subjects		153	5 (3.3)	NE [NE, NE)	308	7 (2.3)	NE [NE, NE)		0.586 (0.185, 1.860)	0.3590

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	4 (3.0)	NE [NE, NE)	283	7 (2.5)	NE [NE, NE)	0.9917	0.699 (0.203, 2.407)	0.5684
	> 75	18	1 (5.6)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.2305
Sex	Male	91	2 (2.2)	NE [NE, NE)	174	5 (2.9)	NE [NE, NE)	0.2484	0.991 (0.189, 5.193)	0.9919
	Female	62	3 (4.8)	NE [NE, NE)	134	2 (1.5)	NE [NE, NE)		0.281 (0.047, 1.682)	0.1374

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	5 (4.1)	NE [NE, NE)	240	5 (2.1)	NE [NE, NE)	0.9999	0.418 (0.120, 1.456)	0.1577
	Asian	20	0 (0.0)	NE [NE, NE)	46	1 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.5097
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	1 (4.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.4795
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	0.9791	NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	4 (3.9)	NE [NE, NE)	203	5 (2.5)	NE [NE, NE)		0.548 (0.147, 2.045)	0.3637
	Asia Pacific	39	1 (2.6)	NE [21.9, NE)	84	2 (2.4)	NE [NE, NE)		0.703 (0.061, 8.137)	0.7771
Baseline ECOG PS	0-1	146	5 (3.4)	NE [NE, NE)	294	6 (2.0)	NE [NE, NE)	0.9928	0.502 (0.152, 1.658)	0.2493
	2	7	0 (0.0)	NE [NE, NE)	13	1 (7.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.4631

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	2 (1.5)	NE [NE, NE)	285	7 (2.5)	NE [NE, NE)	0.9932	1.453 (0.300, 7.028)	0.6403
	No	17	3 (17.6)	NE [21.9, NE)	23	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0258
Refractory to Bortezomib or Ixazomib	Yes	55	1 (1.8)	NE [NE, NE)	99	4 (4.0)	NE [NE, NE)	0.1636	2.136 (0.239, 19.116)	0.4872
	No	98	4 (4.1)	NE [NE, NE)	209	3 (1.4)	NE [NE, NE)		0.271 (0.060, 1.224)	0.0695

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	4 (5.4)	NE [NE, NE)	122	3 (2.5)	NE [NE, NE)	0.2992	0.366 (0.080, 1.662)	0.1753
	No	79	1 (1.3)	NE [NE, NE)	186	4 (2.2)	NE [NE, NE)		1.463 (0.162, 13.182)	0.7329
Refractory to Lenalidomide	Yes	55	2 (3.6)	NE [21.9, NE)	98	3 (3.1)	NE [NE, NE)	0.8790	0.639 (0.103, 3.962)	0.6278
	No	98	3 (3.1)	NE [NE, NE)	210	4 (1.9)	NE [NE, NE)		0.551 (0.123, 2.474)	0.4298

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	4 (3.6)	NE [NE, NE)	205	4 (2.0)	NE [NE, NE)	0.4981	0.458 (0.114, 1.850)	0.2613
	No	43	1 (2.3)	NE [NE, NE)	103	3 (2.9)	NE [NE, NE)		1.031 (0.106, 9.999)	0.9790
Refractory to IMiD	Yes	65	2 (3.1)	NE [21.9, NE)	129	3 (2.3)	NE [NE, NE)	0.9780	0.565 (0.091, 3.502)	0.5347
	No	88	3 (3.4)	NE [NE, NE)	179	4 (2.2)	NE [NE, NE)		0.579 (0.129, 2.600)	0.4701

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	4 (3.2)	NE [NE, NE)	250	5 (2.0)	NE [NE, NE)	0.8797	0.526 (0.140, 1.979)	0.3344
	3	27	1 (3.7)	NE [NE, NE)	58	2 (3.4)	NE [NE, NE)		0.742 (0.067, 8.231)	0.8070
Prior proteasome inhibitor exposure per IXRS	Yes	138	2 (1.4)	NE [NE, NE)	276	7 (2.5)	NE [NE, NE)	0.9927	1.523 (0.315, 7.367)	0.5983
	No	15	3 (20.0)	NE [21.9, NE)	32	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0056

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	2 (3.0)	NE [NE, NE)	131	3 (2.3)	NE [NE, NE)	0.8945	0.665 (0.110, 4.018)	0.6542
	>= 2	87	3 (3.4)	NE [NE, NE)	177	4 (2.3)	NE [NE, NE)		0.536 (0.119, 2.420)	0.4104

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Hypertension (SMQ) - Narrow										
Total subjects		153	4 (2.6)	NE [NE, NE)	308	3 (1.0)	NE [NE, NE)		0.249 (0.055, 1.132)	0.0525

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	4 (3.0)	NE [NE, NE)	283	3 (1.1)	NE [NE, NE)	0.9997	0.241 (0.053, 1.093)	0.0461
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	2 (2.2)	NE [NE, NE)	174	1 (0.6)	NE [NE, NE)	0.6546	0.182 (0.016, 2.044)	0.1223
	Female	62	2 (3.2)	NE [28.7, NE)	134	2 (1.5)	NE [NE, NE)		0.317 (0.043, 2.316)	0.2335

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-512-sae-cox-eoi-cfz.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	3 (2.5)	NE [NE, NE)	240	1 (0.4)	NE [NE, NE)	0.8283	0.102 (0.010, 1.011)	0.0181
	Asian	20	0 (0.0)	NE [NE, NE)	46	1 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.5762
	Other or Unknown	11	1 (9.1)	NE [NE, NE)	22	1 (4.5)	NE [NE, NE)		0.354 (0.021, 5.893)	0.4504
Region	North America	12	1 (8.3)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	0.9733	<.001 (<.001, NE)	0.1859

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	2 (2.0)	NE [28.7, NE)	203	2 (1.0)	NE [NE, NE)		0.368 (0.051, 2.656)	0.3026
	Asia Pacific	39	1 (2.6)	NE [NE, NE)	84	1 (1.2)	NE [NE, NE)		0.275 (0.017, 4.481)	0.3330
Baseline ECOG PS	0-1	146	4 (2.7)	NE [NE, NE)	294	3 (1.0)	NE [NE, NE)	0.9998	0.257 (0.057, 1.168)	0.0589
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	2 (1.5)	NE [28.7, NE)	285	3 (1.1)	NE [NE, NE)	0.9940	0.463 (0.076, 2.841)	0.3946
	No	17	2 (11.8)	NE [17.3, NE)	23	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0626
Refractory to Bortezomib or Ixazomib	Yes	55	1 (1.8)	NE [28.7, NE)	99	2 (2.0)	NE [NE, NE)	0.2198	0.667 (0.060, 7.401)	0.7402
	No	98	3 (3.1)	NE [NE, NE)	209	1 (0.5)	NE [NE, NE)		0.126 (0.013, 1.228)	0.0351

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	3 (4.1)	NE [28.7, NE)	122	1 (0.8)	NE [NE, NE)	0.3433	0.114 (0.012, 1.118)	0.0261
	No	79	1 (1.3)	NE [NE, NE)	186	2 (1.1)	NE [NE, NE)		0.701 (0.063, 7.773)	0.7709
Refractory to Lenalidomide	Yes	55	3 (5.5)	NE [28.7, NE)	98	1 (1.0)	NE [NE, NE)	0.2587	0.090 (0.009, 0.889)	0.0113
	No	98	1 (1.0)	NE [NE, NE)	210	2 (1.0)	NE [NE, NE)		0.772 (0.070, 8.569)	0.8329

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	4 (3.6)	NE [28.7, NE)	205	2 (1.0)	NE [NE, NE)	0.9946	0.168 (0.030, 0.936)	0.0219
	No	43	0 (0.0)	NE [NE, NE)	103	1 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.5772
Refractory to IMiD	Yes	65	3 (4.6)	NE [28.7, NE)	129	2 (1.6)	NE [NE, NE)	0.6940	0.146 (0.023, 0.907)	0.0186
	No	88	1 (1.1)	NE [NE, NE)	179	1 (0.6)	NE [NE, NE)		0.439 (0.027, 7.057)	0.5504

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	3 (2.4)	NE [NE, NE)	250	2 (0.8)	NE [NE, NE)	0.9522	0.214 (0.035, 1.309)	0.0677
	3	27	1 (3.7)	NE [NE, NE)	58	1 (1.7)	NE [NE, NE)		0.340 (0.020, 5.673)	0.4324
Prior proteasome inhibitor exposure per IXRS	Yes	138	2 (1.4)	NE [28.7, NE)	276	3 (1.1)	NE [NE, NE)	0.9935	0.478 (0.078, 2.938)	0.4159
	No	15	2 (13.3)	NE [17.3, NE)	32	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0275

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	2 (3.0)	NE [NE, NE)	131	2 (1.5)	NE [NE, NE)	0.6286	0.421 (0.059, 3.010)	0.3738
	>= 2	87	2 (2.3)	NE [28.7, NE)	177	1 (0.6)	NE [NE, NE)		0.121 (0.011, 1.375)	0.0439

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Infusion reaction (AMQ) - Narrow (event on same date of any carfilzomib dosing)										
Total subjects		153	2 (1.3)	NE [NE, NE)	308	7 (2.3)	NE [NE, NE)		1.417 (0.292, 6.868)	0.6637

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	2 (1.5)	NE [NE, NE)	283	7 (2.5)	NE [NE, NE)	0.9999	1.361 (0.281, 6.601)	0.7008
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	2 (2.2)	NE [NE, NE)	174	4 (2.3)	NE [NE, NE)	0.9933	0.847 (0.154, 4.669)	0.8484
	Female	62	0 (0.0)	NE [NE, NE)	134	3 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.2891

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	1 (0.8)	NE [NE, NE)	240	4 (1.7)	NE [NE, NE)	0.6888	1.723 (0.191, 15.498)	0.6234
	Asian	20	1 (5.0)	NE [13.2, NE)	46	1 (2.2)	NE [NE, NE)		0.346 (0.021, 5.637)	0.4359
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	2 (9.1)	NE [27.2, NE)		>999.999 (<.001, NE)	0.4177
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	3 (1.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.2596
	Asia Pacific	39	2 (5.1)	NE [NE, NE)	84	4 (4.8)	NE [NE, NE)		0.764 (0.138, 4.223)	0.7566
Baseline ECOG PS	0-1	146	2 (1.4)	NE [NE, NE)	294	6 (2.0)	NE [NE, NE)	0.9928	1.216 (0.244, 6.068)	0.8117
	2	7	0 (0.0)	NE [NE, NE)	13	1 (7.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.5002

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	1 (0.7)	NE [NE, NE)	285	6 (2.1)	NE [NE, NE)	0.4338	2.391 (0.286, 19.969)	0.4064
	No	17	1 (5.9)	NE [17.3, NE)	23	1 (4.3)	NE [NE, NE)		0.601 (0.037, 9.815)	0.7177
Refractory to Bortezomib or Ixazomib	Yes	55	1 (1.8)	NE [NE, NE)	99	1 (1.0)	NE [NE, NE)	0.3703	0.461 (0.029, 7.430)	0.5758
	No	98	1 (1.0)	NE [NE, NE)	209	6 (2.9)	NE [NE, NE)		2.292 (0.274, 19.172)	0.4313

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-512-sae-cox-eoi-cfz.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	1 (1.4)	NE [NE, NE)	122	3 (2.5)	NE [NE, NE)	0.9833	1.228 (0.123, 12.237)	0.8606
	No	79	1 (1.3)	NE [NE, NE)	186	4 (2.2)	NE [NE, NE)		1.532 (0.171, 13.724)	0.7004
Refractory to Lenalidomide	Yes	55	1 (1.8)	NE [NE, NE)	98	1 (1.0)	NE [NE, NE)	0.3227	0.345 (0.020, 5.909)	0.4445
	No	98	1 (1.0)	NE [NE, NE)	210	6 (2.9)	NE [NE, NE)		2.440 (0.293, 20.331)	0.3944

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	2 (1.8)	NE [NE, NE)	205	6 (2.9)	NE [NE, NE)	0.9948	1.282 (0.256, 6.415)	0.7623
	No	43	0 (0.0)	NE [NE, NE)	103	1 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.5338
Refractory to IMiD	Yes	65	1 (1.5)	NE [NE, NE)	129	2 (1.6)	NE [NE, NE)	0.5302	0.673 (0.059, 7.690)	0.7484
	No	88	1 (1.1)	NE [NE, NE)	179	5 (2.8)	NE [NE, NE)		2.166 (0.252, 18.626)	0.4708

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	2 (1.6)	NE [NE, NE)	250	7 (2.8)	NE [NE, NE)	0.9999	1.489 (0.308, 7.212)	0.6185
	3	27	0 (0.0)	NE [NE, NE)	58	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Prior proteasome inhibitor exposure per IXRS	Yes	138	1 (0.7)	NE [NE, NE)	276	6 (2.2)	NE [NE, NE)	0.2989	2.501 (0.299, 20.891)	0.3813
	No	15	1 (6.7)	NE [17.3, NE)	32	1 (3.1)	NE [NE, NE)		0.408 (0.025, 6.547)	0.5128

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	4 (3.1)	NE [NE, NE)	0.9928	>999.999 (<.001, NE)	0.1909
	>= 2	87	2 (2.3)	NE [NE, NE)	177	3 (1.7)	NE [NE, NE)		0.576 (0.095, 3.486)	0.5436

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Infusion reaction (AMQ) - Narrow (event on same date of first carfilzomib dosing)										
Total subjects		153	0 (0.0)	NE [NE, NE)	308	2 (0.6)	NE [NE, NE)		>999.999 (<.001, NE)	0.3184

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	0 (0.0)	NE [NE, NE)	283	2 (0.7)	NE [NE, NE)	0.9992	>999.999 (<.001, NE)	0.3281
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	1 (0.6)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.4696
	Female	62	0 (0.0)	NE [NE, NE)	134	1 (0.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.4964

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	0 (0.0)	NE [NE, NE)	240	1 (0.4)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.4759
	Asian	20	0 (0.0)	NE [NE, NE)	46	1 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.5097
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	1 (0.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.4784
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	1 (1.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.4956
Baseline ECOG PS	0-1	146	0 (0.0)	NE [NE, NE)	294	2 (0.7)	NE [NE, NE)	0.9995	>999.999 (<.001, NE)	0.3184
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	0 (0.0)	NE [NE, NE)	285	2 (0.7)	NE [NE, NE)	0.9992	>999.999 (<.001, NE)	0.3280
	No	17	0 (0.0)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	0 (0.0)	NE [NE, NE)	0.9988	NE (NE, NE)	NE
	No	98	0 (0.0)	NE [NE, NE)	209	2 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.3321

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	1 (0.8)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.4361
	No	79	0 (0.0)	NE [NE, NE)	186	1 (0.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.5146
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	0 (0.0)	NE [NE, NE)	0.9988	NE (NE, NE)	NE
	No	98	0 (0.0)	NE [NE, NE)	210	2 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.3332

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	0 (0.0)	NE [NE, NE)	205	2 (1.0)	NE [NE, NE)	0.9989	>999.999 (<.001, NE)	0.2995
	No	43	0 (0.0)	NE [NE, NE)	103	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	0 (0.0)	NE [NE, NE)	0.9989	NE (NE, NE)	NE
	No	88	0 (0.0)	NE [NE, NE)	179	2 (1.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.3205

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	0 (0.0)	NE [NE, NE)	250	2 (0.8)	NE [NE, NE)	0.9990	>999.999 (<.001, NE)	0.3147
	3	27	0 (0.0)	NE [NE, NE)	58	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Prior proteasome inhibitor exposure per IXRS	Yes	138	0 (0.0)	NE [NE, NE)	276	2 (0.7)	NE [NE, NE)	0.9992	>999.999 (<.001, NE)	0.3167
	No	15	0 (0.0)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-512-sae-cox-eoi-cfz.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	1 (0.8)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.4778
	>= 2	87	0 (0.0)	NE [NE, NE)	177	1 (0.6)	NE [NE, NE)		>999.999 (<.001, NE)	0.4832

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Interstitial lung disease (SMQ) - Narrow										
Total subjects		153	1 (0.7)	NE [NE, NE)	308	6 (1.9)	NE [NE, NE)		2.687 (0.322, 22.398)	0.3417

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-512-sae-cox-eoi-cfz.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	1 (0.7)	NE [NE, NE)	283	5 (1.8)	NE [NE, NE)	0.9952	2.127 (0.247, 18.315)	0.4817
	> 75	18	0 (0.0)	NE [NE, NE)	25	1 (4.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.4193
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	4 (2.3)	NE [NE, NE)	0.9927	>999.999 (<.001, NE)	0.1813
	Female	62	1 (1.6)	NE [NE, NE)	134	2 (1.5)	NE [NE, NE)		0.887 (0.080, 9.793)	0.9221

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	1 (0.8)	NE [NE, NE)	240	5 (2.1)	NE [NE, NE)	1.0000	2.320 (0.270, 19.951)	0.4299
	Asian	20	0 (0.0)	NE [NE, NE)	46	1 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.5271
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	5 (2.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.1273
	Asia Pacific	39	1 (2.6)	NE [NE, NE)	84	1 (1.2)	NE [NE, NE)		0.432 (0.027, 6.914)	0.5412
Baseline ECOG PS	0-1	146	1 (0.7)	NE [NE, NE)	294	6 (2.0)	NE [NE, NE)	0.9999	2.725 (0.327, 22.712)	0.3341
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	1 (0.7)	NE [NE, NE)	285	5 (1.8)	NE [NE, NE)	0.9952	2.124 (0.247, 18.274)	0.4826
	No	17	0 (0.0)	NE [NE, NE)	23	1 (4.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.3980
Refractory to Bortezomib or Ixazomib	Yes	55	1 (1.8)	NE [NE, NE)	99	3 (3.0)	NE [NE, NE)	0.9933	1.431 (0.147, 13.908)	0.7563
	No	98	0 (0.0)	NE [NE, NE)	209	3 (1.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.2482

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	2 (1.6)	NE [NE, NE)	0.9939	>999.999 (<.001, NE)	0.2971
	No	79	1 (1.3)	NE [NE, NE)	186	4 (2.2)	NE [NE, NE)		1.585 (0.177, 14.222)	0.6780
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	0 (0.0)	NE [NE, NE)	0.9998	NE (NE, NE)	NE
	No	98	1 (1.0)	NE [NE, NE)	210	6 (2.9)	NE [NE, NE)		2.622 (0.315, 21.810)	0.3541

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	1 (0.9)	NE [NE, NE)	205	2 (1.0)	NE [NE, NE)	0.9928	0.982 (0.089, 10.832)	0.9881
	No	43	0 (0.0)	NE [NE, NE)	103	4 (3.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.2070
Refractory to IMiD	Yes	65	1 (1.5)	NE [NE, NE)	129	0 (0.0)	NE [NE, NE)	0.9938	<.001 (<.001, NE)	0.1556
	No	88	0 (0.0)	NE [NE, NE)	179	6 (3.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.0954

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	0 (0.0)	NE [NE, NE)	250	5 (2.0)	NE [NE, NE)	0.9922	>999.999 (<.001, NE)	0.1340
	3	27	1 (3.7)	NE [NE, NE)	58	1 (1.7)	NE [NE, NE)		0.427 (0.027, 6.825)	0.5347
Prior proteasome inhibitor exposure per IXRS	Yes	138	1 (0.7)	NE [NE, NE)	276	5 (1.8)	NE [NE, NE)	0.9955	2.233 (0.259, 19.219)	0.4526
	No	15	0 (0.0)	NE [NE, NE)	32	1 (3.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.5271

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	3 (2.3)	NE [NE, NE)	0.9937	>999.999 (<.001, NE)	0.2524
	>= 2	87	1 (1.1)	NE [NE, NE)	177	3 (1.7)	NE [NE, NE)		1.406 (0.146, 13.518)	0.7670

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Ischaemic heart disease (SMQ) - Narrow										
Total subjects		153	4 (2.6)	NE [NE, NE)	308	13 (4.2)	NE [NE, NE)		1.193 (0.387, 3.676)	0.7587

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	3 (2.2)	NE [NE, NE)	283	12 (4.2)	NE [NE, NE)	0.5732	1.385 (0.388, 4.937)	0.6139
	> 75	18	1 (5.6)	NE [NE, NE)	25	1 (4.0)	NE [NE, NE)		0.546 (0.033, 8.909)	0.6665
Sex	Male	91	2 (2.2)	NE [NE, NE)	174	10 (5.7)	NE [NE, NE)	0.3209	1.800 (0.390, 8.294)	0.4447
	Female	62	2 (3.2)	NE [NE, NE)	134	3 (2.2)	NE [NE, NE)		0.590 (0.098, 3.544)	0.5601

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-512-sae-cox-eoi-cfz.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	2 (1.6)	NE [NE, NE)	240	12 (5.0)	NE [NE, NE)	0.4638	2.311 (0.515, 10.368)	0.2603
	Asian	20	1 (5.0)	NE [11.3, NE)	46	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0593
	Other or Unknown	11	1 (9.1)	NE [2.4, NE)	22	1 (4.5)	NE [24.0, NE)		0.330 (0.021, 5.297)	0.4106
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	2 (2.0)	NE [NE, NE)	203	13 (6.4)	NE [NE, NE)		2.709 (0.611, 12.021)	0.1720
	Asia Pacific	39	2 (5.1)	NE [19.7, NE)	84	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0047
Baseline ECOG PS	0-1	146	4 (2.7)	NE [NE, NE)	294	13 (4.4)	NE [NE, NE)	1.0000	1.232 (0.400, 3.794)	0.7158
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	3 (2.2)	NE [NE, NE)	285	12 (4.2)	NE [NE, NE)	0.5144	1.424 (0.400, 5.071)	0.5834
	No	17	1 (5.9)	NE [19.7, NE)	23	1 (4.3)	NE [NE, NE)		0.486 (0.030, 7.804)	0.6024
Refractory to Bortezomib or Ixazomib	Yes	55	1 (1.8)	NE [NE, NE)	99	0 (0.0)	NE [NE, NE)	0.9886	<.001 (<.001, NE)	0.1103
	No	98	3 (3.1)	NE [NE, NE)	209	13 (6.2)	NE [NE, NE)		1.504 (0.427, 5.304)	0.5221

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	2 (2.7)	NE [NE, NE)	122	6 (4.9)	NE [NE, NE)	0.9820	1.183 (0.233, 6.005)	0.8395
	No	79	2 (2.5)	NE [NE, NE)	186	7 (3.8)	NE [NE, NE)		1.217 (0.252, 5.867)	0.8067
Refractory to Lenalidomide	Yes	55	2 (3.6)	NE [19.7, NE)	98	5 (5.1)	NE [NE, NE)	0.6028	0.747 (0.139, 4.010)	0.7333
	No	98	2 (2.0)	NE [NE, NE)	210	8 (3.8)	NE [NE, NE)		1.551 (0.329, 7.320)	0.5758

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	4 (3.6)	NE [NE, NE)	205	7 (3.4)	NE [NE, NE)	0.9918	0.653 (0.189, 2.264)	0.4991
	No	43	0 (0.0)	NE [NE, NE)	103	6 (5.8)	NE [NE, NE)		>999.999 (<.001, NE)	0.1593
Refractory to IMiD	Yes	65	3 (4.6)	NE [19.7, NE)	129	7 (5.4)	NE [NE, NE)	0.3355	0.661 (0.165, 2.647)	0.5567
	No	88	1 (1.1)	NE [NE, NE)	179	6 (3.4)	NE [NE, NE)		2.473 (0.297, 20.578)	0.3863

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	3 (2.4)	NE [NE, NE)	250	9 (3.6)	NE [NE, NE)	0.9786	1.054 (0.284, 3.914)	0.9372
	3	27	1 (3.7)	NE [NE, NE)	58	4 (6.9)	NE [NE, NE)		1.365 (0.148, 12.608)	0.7829
Prior proteasome inhibitor exposure per IXRS	Yes	138	3 (2.2)	NE [NE, NE)	276	10 (3.6)	NE [NE, NE)	0.9297	1.225 (0.335, 4.474)	0.7589
	No	15	1 (6.7)	NE [19.7, NE)	32	3 (9.4)	NE [NE, NE)		1.059 (0.109, 10.257)	0.9603

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	1 (1.5)	NE [NE, NE)	131	6 (4.6)	NE [NE, NE)	0.4076	2.403 (0.288, 20.031)	0.4029
	>= 2	87	3 (3.4)	NE [NE, NE)	177	7 (4.0)	NE [NE, NE)		0.741 (0.189, 2.908)	0.6665

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Liver related investigations, signs and symptoms (SMQ) - Narrow										
Total subjects		153	0 (0.0)	NE [NE, NE)	308	4 (1.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.1757

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	0 (0.0)	NE [NE, NE)	283	4 (1.4)	NE [NE, NE)	0.9989	>999.999 (<.001, NE)	0.1832
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	0 (0.0)	NE [NE, NE)	0.9987	NE (NE, NE)	NE
	Female	62	0 (0.0)	NE [NE, NE)	134	4 (3.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.1902

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	0 (0.0)	NE [NE, NE)	240	2 (0.8)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.3234
	Asian	20	0 (0.0)	NE [NE, NE)	46	2 (4.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.3591
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	2 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.3284
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	2 (2.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.3508
Baseline ECOG PS	0-1	146	0 (0.0)	NE [NE, NE)	294	4 (1.4)	NE [NE, NE)	0.9994	>999.999 (<.001, NE)	0.1722
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	0 (0.0)	NE [NE, NE)	285	2 (0.7)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.3695
	No	17	0 (0.0)	NE [NE, NE)	23	2 (8.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.2189
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	0 (0.0)	NE [NE, NE)	0.9984	NE (NE, NE)	NE
	No	98	0 (0.0)	NE [NE, NE)	209	4 (1.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.1876

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-512-sae-cox-eoi-cfz.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	1 (0.8)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.4323
	No	79	0 (0.0)	NE [NE, NE)	186	3 (1.6)	NE [NE, NE)		>999.999 (<.001, NE)	0.2797
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	0 (0.0)	NE [NE, NE)	0.9984	NE (NE, NE)	NE
	No	98	0 (0.0)	NE [NE, NE)	210	4 (1.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.1869

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	0 (0.0)	NE [NE, NE)	205	3 (1.5)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.2167
	No	43	0 (0.0)	NE [NE, NE)	103	1 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.5217
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	1 (0.8)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.5386
	No	88	0 (0.0)	NE [NE, NE)	179	3 (1.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.2303

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	0 (0.0)	NE [NE, NE)	250	3 (1.2)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.2285
	3	27	0 (0.0)	NE [NE, NE)	58	1 (1.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.5762
Prior proteasome inhibitor exposure per IXRS	Yes	138	0 (0.0)	NE [NE, NE)	276	2 (0.7)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.3587
	No	15	0 (0.0)	NE [NE, NE)	32	2 (6.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.3291

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	1 (0.8)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.4778
	>= 2	87	0 (0.0)	NE [NE, NE)	177	3 (1.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.2518

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Myocardial infarction (SMQ) - Narrow										
Total subjects		153	2 (1.3)	NE [NE, NE)	308	6 (1.9)	NE [NE, NE)		0.964 (0.194, 4.795)	0.9647

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	2 (1.5)	NE [NE, NE)	283	5 (1.8)	NE [NE, NE)	0.9946	0.746 (0.144, 3.869)	0.7261
	> 75	18	0 (0.0)	NE [NE, NE)	25	1 (4.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.4795
Sex	Male	91	1 (1.1)	NE [NE, NE)	174	5 (2.9)	NE [NE, NE)	0.3988	1.498 (0.174, 12.915)	0.7112
	Female	62	1 (1.6)	NE [NE, NE)	134	1 (0.7)	NE [NE, NE)		0.357 (0.022, 5.736)	0.4475

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	1 (0.8)	NE [NE, NE)	240	5 (2.1)	NE [NE, NE)	1.0000	1.682 (0.196, 14.446)	0.6320
	Asian	20	1 (5.0)	NE [11.3, NE)	46	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0593
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	1 (4.5)	NE [24.0, NE)		>999.999 (<.001, NE)	0.5839
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	6 (3.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.1293
	Asia Pacific	39	2 (5.1)	NE [19.7, NE)	84	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0047
Baseline ECOG PS	0-1	146	2 (1.4)	NE [NE, NE)	294	6 (2.0)	NE [NE, NE)	1.0000	1.004 (0.202, 4.993)	0.9961
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	1 (0.7)	NE [NE, NE)	285	6 (2.1)	NE [NE, NE)	0.9922	1.917 (0.230, 15.978)	0.5406
	No	17	1 (5.9)	NE [19.7, NE)	23	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.1138
Refractory to Bortezomib or Ixazomib	Yes	55	1 (1.8)	NE [NE, NE)	99	0 (0.0)	NE [NE, NE)	0.9918	<.001 (<.001, NE)	0.1103
	No	98	1 (1.0)	NE [NE, NE)	209	6 (2.9)	NE [NE, NE)		1.775 (0.213, 14.805)	0.5908

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	1 (1.4)	NE [NE, NE)	122	3 (2.5)	NE [NE, NE)	0.9985	0.997 (0.100, 9.920)	0.9982
	No	79	1 (1.3)	NE [NE, NE)	186	3 (1.6)	NE [NE, NE)		0.953 (0.099, 9.168)	0.9670
Refractory to Lenalidomide	Yes	55	1 (1.8)	NE [19.7, NE)	98	3 (3.1)	NE [NE, NE)	0.8580	0.806 (0.080, 8.124)	0.8545
	No	98	1 (1.0)	NE [NE, NE)	210	3 (1.4)	NE [NE, NE)		1.030 (0.107, 9.906)	0.9795

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	2 (1.8)	NE [NE, NE)	205	4 (2.0)	NE [NE, NE)	0.9946	0.651 (0.117, 3.607)	0.6204
	No	43	0 (0.0)	NE [NE, NE)	103	2 (1.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.4387
Refractory to IMiD	Yes	65	2 (3.1)	NE [19.7, NE)	129	4 (3.1)	NE [NE, NE)	0.9942	0.476 (0.084, 2.706)	0.3926
	No	88	0 (0.0)	NE [NE, NE)	179	2 (1.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.3922

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	2 (1.6)	NE [NE, NE)	250	5 (2.0)	NE [NE, NE)	0.9935	0.826 (0.159, 4.280)	0.8194
	3	27	0 (0.0)	NE [NE, NE)	58	1 (1.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.6698
Prior proteasome inhibitor exposure per IXRS	Yes	138	1 (0.7)	NE [NE, NE)	276	5 (1.8)	NE [NE, NE)	0.3586	1.709 (0.199, 14.683)	0.6213
	No	15	1 (6.7)	NE [19.7, NE)	32	1 (3.1)	NE [NE, NE)		0.289 (0.018, 4.618)	0.3493

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	3 (2.3)	NE [NE, NE)	0.9936	>999.999 (<.001, NE)	0.3131
	>= 2	87	2 (2.3)	NE [NE, NE)	177	3 (1.7)	NE [NE, NE)		0.415 (0.068, 2.524)	0.3245

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-512-sae-cox-eoi-cfz.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Pulmonary hypertension (SMQ) - Narrow										
Total subjects		153	1 (0.7)	NE [NE, NE)	308	3 (1.0)	NE [NE, NE)		1.342 (0.139, 12.911)	0.7983

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	1 (0.7)	NE [NE, NE)	283	3 (1.1)	NE [NE, NE)	1.0000	1.308 (0.136, 12.581)	0.8157
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	1 (1.1)	NE [NE, NE)	174	3 (1.7)	NE [NE, NE)	1.0000	1.441 (0.150, 13.859)	0.7504
	Female	62	0 (0.0)	NE [NE, NE)	134	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	1 (0.8)	NE [NE, NE)	240	3 (1.3)	NE [NE, NE)	1.0000	1.399 (0.145, 13.460)	0.7700
	Asian	20	0 (0.0)	NE [NE, NE)	46	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	2 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.3300
	Asia Pacific	39	1 (2.6)	NE [NE, NE)	84	1 (1.2)	NE [NE, NE)		0.390 (0.024, 6.242)	0.4902
Baseline ECOG PS	0-1	146	1 (0.7)	NE [NE, NE)	294	3 (1.0)	NE [NE, NE)	1.0000	1.376 (0.143, 13.233)	0.7814
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	0 (0.0)	NE [NE, NE)	285	2 (0.7)	NE [NE, NE)	0.9960	>999.999 (<.001, NE)	0.3425
	No	17	1 (5.9)	NE [NE, NE)	23	1 (4.3)	NE [NE, NE)		0.589 (0.037, 9.424)	0.7053
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	1 (1.0)	NE [NE, NE)	0.9956	>999.999 (<.001, NE)	0.4561
	No	98	1 (1.0)	NE [NE, NE)	209	2 (1.0)	NE [NE, NE)		0.790 (0.072, 8.712)	0.8470

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	1 (0.8)	NE [NE, NE)	0.9951	>999.999 (<.001, NE)	0.4716
	No	79	1 (1.3)	NE [NE, NE)	186	2 (1.1)	NE [NE, NE)		0.785 (0.071, 8.667)	0.8431
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	1 (1.0)	NE [NE, NE)	0.9957	>999.999 (<.001, NE)	0.4795
	No	98	1 (1.0)	NE [NE, NE)	210	2 (1.0)	NE [NE, NE)		0.856 (0.078, 9.448)	0.8987

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	1 (0.9)	NE [NE, NE)	205	2 (1.0)	NE [NE, NE)	0.9961	0.911 (0.083, 10.041)	0.9390
	No	43	0 (0.0)	NE [NE, NE)	103	1 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.5162
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	1 (0.8)	NE [NE, NE)	0.9955	>999.999 (<.001, NE)	0.5091
	No	88	1 (1.1)	NE [NE, NE)	179	2 (1.1)	NE [NE, NE)		0.910 (0.082, 10.042)	0.9384

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	1 (0.8)	NE [NE, NE)	250	2 (0.8)	NE [NE, NE)	0.9959	0.905 (0.082, 9.976)	0.9347
	3	27	0 (0.0)	NE [NE, NE)	58	1 (1.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.4951
Prior proteasome inhibitor exposure per IXRS	Yes	138	0 (0.0)	NE [NE, NE)	276	2 (0.7)	NE [NE, NE)	0.9960	>999.999 (<.001, NE)	0.3304
	No	15	1 (6.7)	NE [5.3, NE)	32	1 (3.1)	NE [NE, NE)		0.352 (0.022, 5.622)	0.4394

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	1 (1.5)	NE [NE, NE)	131	1 (0.8)	NE [NE, NE)	0.9946	0.433 (0.027, 6.923)	0.5422
	>= 2	87	0 (0.0)	NE [NE, NE)	177	2 (1.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.3349

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Respiratory failure (SMQ) - Narrow										
Total subjects		153	1 (0.7)	NE [NE, NE)	308	3 (1.0)	NE [NE, NE)		1.273 (0.132, 12.271)	0.8345

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	1 (0.7)	NE [NE, NE)	283	3 (1.1)	NE [NE, NE)	1.0000	1.227 (0.127, 11.835)	0.8593
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	1 (0.6)	NE [NE, NE)	0.9952	>999.999 (<.001, NE)	0.5132
	Female	62	1 (1.6)	NE [NE, NE)	134	2 (1.5)	NE [NE, NE)		0.820 (0.074, 9.069)	0.8716

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	0 (0.0)	NE [NE, NE)	240	3 (1.3)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.2358
	Asian	20	1 (5.0)	NE [12.0, NE)	46	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0635
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-512-sae-cox-eoi-cfz.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	3 (1.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.2437
	Asia Pacific	39	1 (2.6)	NE [NE, NE)	84	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0752
Baseline ECOG PS	0-1	146	1 (0.7)	NE [NE, NE)	294	3 (1.0)	NE [NE, NE)	1.0000	1.304 (0.135, 12.565)	0.8179
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	1 (0.7)	NE [NE, NE)	285	3 (1.1)	NE [NE, NE)	1.0000	1.234 (0.128, 11.896)	0.8555
	No	17	0 (0.0)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to Bortezomib or Ixazomib	Yes	55	1 (1.8)	NE [NE, NE)	99	0 (0.0)	NE [NE, NE)	0.9953	<.001 (<.001, NE)	0.1213
	No	98	0 (0.0)	NE [NE, NE)	209	3 (1.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.2618

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	1 (0.8)	NE [NE, NE)	0.9953	>999.999 (<.001, NE)	0.4723
	No	79	1 (1.3)	NE [NE, NE)	186	2 (1.1)	NE [NE, NE)		0.752 (0.068, 8.318)	0.8153
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	1 (1.0)	NE [NE, NE)	0.9958	>999.999 (<.001, NE)	0.5036
	No	98	1 (1.0)	NE [NE, NE)	210	2 (1.0)	NE [NE, NE)		0.822 (0.074, 9.088)	0.8727

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	1 (0.9)	NE [NE, NE)	205	1 (0.5)	NE [NE, NE)	0.9940	0.425 (0.027, 6.815)	0.5333
	No	43	0 (0.0)	NE [NE, NE)	103	2 (1.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.3632
Refractory to IMiD	Yes	65	1 (1.5)	NE [NE, NE)	129	1 (0.8)	NE [NE, NE)	0.9945	0.362 (0.023, 5.832)	0.4551
	No	88	0 (0.0)	NE [NE, NE)	179	2 (1.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.3354

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	1 (0.8)	NE [NE, NE)	250	1 (0.4)	NE [NE, NE)	0.9958	0.412 (0.026, 6.600)	0.5174
	3	27	0 (0.0)	NE [NE, NE)	58	2 (3.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.3876
Prior proteasome inhibitor exposure per IXRS	Yes	138	1 (0.7)	NE [NE, NE)	276	3 (1.1)	NE [NE, NE)	1.0000	1.294 (0.134, 12.479)	0.8231
	No	15	0 (0.0)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	1 (0.8)	NE [NE, NE)	0.9955	>999.999 (<.001, NE)	0.4829
	>= 2	87	1 (1.1)	NE [NE, NE)	177	2 (1.1)	NE [NE, NE)		0.802 (0.073, 8.854)	0.8569

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Respiratory tract infections (AMQ) - Broad										
Total subjects		153	23 (15.0)	NE [NE, NE)	308	88 (28.6)	NE [NE, NE)		1.614 (1.019, 2.557)	0.0394

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	20 (14.8)	NE [NE, NE)	283	79 (27.9)	NE [NE, NE)	0.7111	1.577 (0.964, 2.578)	0.0672
	> 75	18	3 (16.7)	NE [21.5, NE)	25	9 (36.0)	NE [4.2, NE)		2.094 (0.566, 7.741)	0.2572
Sex	Male	91	16 (17.6)	NE [NE, NE)	174	54 (31.0)	NE [NE, NE)	0.5103	1.445 (0.826, 2.530)	0.1946
	Female	62	7 (11.3)	NE [NE, NE)	134	34 (25.4)	NE [NE, NE)		2.008 (0.889, 4.535)	0.0868

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	20 (16.4)	NE [NE, NE)	240	69 (28.8)	NE [NE, NE)	0.7216	1.500 (0.911, 2.470)	0.1085
	Asian	20	2 (10.0)	NE [12.0, NE)	46	15 (32.6)	NE [18.7, NE)		2.760 (0.629, 12.100)	0.1605
	Other or Unknown	11	1 (9.1)	NE [2.1, NE)	22	4 (18.2)	NE [21.6, NE)		1.511 (0.168, 13.573)	0.7106
Region	North America	12	1 (8.3)	NE [16.2, NE)	21	9 (42.9)	NE [11.1, NE)	0.6693	3.066 (0.377, 24.929)	0.2710

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	15 (14.7)	NE [NE, NE)	203	49 (24.1)	NE [NE, NE)		1.454 (0.815, 2.595)	0.2012
	Asia Pacific	39	7 (17.9)	NE [NE, NE)	84	30 (35.7)	NE [22.4, NE)		1.589 (0.694, 3.637)	0.2692
Baseline ECOG PS	0-1	146	23 (15.8)	NE [NE, NE)	294	85 (28.9)	NE [NE, NE)	0.9825	1.606 (1.012, 2.548)	0.0421
	2	7	0 (0.0)	NE [NE, NE)	13	3 (23.1)	25.0 [14.2, NE)		>999.999 (<.001, NE)	0.5186

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	21 (15.4)	NE [NE, NE)	285	83 (29.1)	NE [NE, NE)	0.8528	1.606 (0.994, 2.595)	0.0507
	No	17	2 (11.8)	NE [NE, NE)	23	5 (21.7)	NE [27.4, NE)		1.536 (0.293, 8.050)	0.6087
Refractory to Bortezomib or Ixazomib	Yes	55	6 (10.9)	NE [NE, NE)	99	27 (27.3)	NE [NE, NE)	0.4190	2.171 (0.894, 5.272)	0.0794
	No	98	17 (17.3)	NE [NE, NE)	209	61 (29.2)	NE [NE, NE)		1.415 (0.826, 2.425)	0.2037

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	11 (14.9)	NE [NE, NE)	122	35 (28.7)	NE [NE, NE)	0.8138	1.534 (0.776, 3.033)	0.2149
	No	79	12 (15.2)	NE [NE, NE)	186	53 (28.5)	NE [NE, NE)		1.683 (0.899, 3.151)	0.0998
Refractory to Lenalidomide	Yes	55	9 (16.4)	NE [NE, NE)	98	28 (28.6)	NE [NE, NE)	0.4663	1.300 (0.609, 2.779)	0.4961
	No	98	14 (14.3)	NE [NE, NE)	210	60 (28.6)	NE [NE, NE)		1.813 (1.013, 3.245)	0.0420

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-512-sae-cox-eoi-cfz.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	16 (14.5)	NE [NE, NE)	205	63 (30.7)	NE [NE, NE)	0.5746	1.746 (1.007, 3.028)	0.0444
	No	43	7 (16.3)	NE [NE, NE)	103	25 (24.3)	NE [NE, NE)		1.342 (0.580, 3.105)	0.4905
Refractory to IMiD	Yes	65	12 (18.5)	NE [16.2, NE)	129	37 (28.7)	NE [NE, NE)	0.2121	1.143 (0.592, 2.208)	0.6891
	No	88	11 (12.5)	NE [NE, NE)	179	51 (28.5)	NE [NE, NE)		2.090 (1.089, 4.012)	0.0234

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	19 (15.1)	NE [NE, NE)	250	69 (27.6)	NE [NE, NE)	0.9711	1.587 (0.954, 2.640)	0.0725
	3	27	4 (14.8)	NE [7.0, NE)	58	19 (32.8)	NE [14.8, NE)		1.584 (0.535, 4.688)	0.4013
Prior proteasome inhibitor exposure per IXRS	Yes	138	21 (15.2)	NE [NE, NE)	276	81 (29.3)	NE [NE, NE)	0.7832	1.646 (1.017, 2.663)	0.0402
	No	15	2 (13.3)	NE [NE, NE)	32	7 (21.9)	NE [NE, NE)		1.343 (0.277, 6.503)	0.7133

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	10 (15.2)	NE [NE, NE)	131	37 (28.2)	NE [NE, NE)	0.9519	1.636 (0.813, 3.293)	0.1632
	>= 2	87	13 (14.9)	NE [NE, NE)	177	51 (28.8)	NE [NE, NE)		1.583 (0.859, 2.918)	0.1372

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Reversible posterior leukoencephalopathy syndrome (AMQ) - Narrow										
Total subjects		153	0 (0.0)	NE [NE, NE)	308	4 (1.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.2268

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	0 (0.0)	NE [NE, NE)	283	4 (1.4)	NE [NE, NE)	0.9989	>999.999 (<.001, NE)	0.2393
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	2 (1.1)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.4249
	Female	62	0 (0.0)	NE [NE, NE)	134	2 (1.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.3727

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	0 (0.0)	NE [NE, NE)	240	3 (1.3)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.2759
	Asian	20	0 (0.0)	NE [NE, NE)	46	1 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.6106
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	1 (4.8)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.5403

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CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	2 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.3549
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	1 (1.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.6136
Baseline ECOG PS	0-1	146	0 (0.0)	NE [NE, NE)	294	4 (1.4)	NE [NE, NE)	0.9996	>999.999 (<.001, NE)	0.2196
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

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CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	0 (0.0)	NE [NE, NE)	285	3 (1.1)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.2857
	No	17	0 (0.0)	NE [NE, NE)	23	1 (4.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.4945
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	1 (1.0)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.4579
	No	98	0 (0.0)	NE [NE, NE)	209	3 (1.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.3364

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CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	2 (1.6)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.4123
	No	79	0 (0.0)	NE [NE, NE)	186	2 (1.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.3876
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	2 (2.0)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.4591
	No	98	0 (0.0)	NE [NE, NE)	210	2 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.3681

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CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	0 (0.0)	NE [NE, NE)	205	2 (1.0)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.4089
	No	43	0 (0.0)	NE [NE, NE)	103	2 (1.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.3961
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	2 (1.6)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.4802
	No	88	0 (0.0)	NE [NE, NE)	179	2 (1.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.3516

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	0 (0.0)	NE [NE, NE)	250	3 (1.2)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.3072
	3	27	0 (0.0)	NE [NE, NE)	58	1 (1.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.5040
Prior proteasome inhibitor exposure per IXRS	Yes	138	0 (0.0)	NE [NE, NE)	276	3 (1.1)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.2767
	No	15	0 (0.0)	NE [NE, NE)	32	1 (3.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.5541

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	3 (2.3)	NE [NE, NE)	0.9998	>999.999 (<.001, NE)	0.2755
	>= 2	87	0 (0.0)	NE [NE, NE)	177	1 (0.6)	NE [NE, NE)		>999.999 (<.001, NE)	0.6303

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Thrombotic Microangiopathy (Carfilzomib) (AMQ) - Narrow										
Total subjects		153	2 (1.3)	NE [NE, NE)	308	2 (0.6)	NE [NE, NE)		0.472 (0.066, 3.352)	0.4421

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-512-sae-cox-eoi-cfz.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	1 (0.7)	NE [NE, NE)	283	2 (0.7)	NE [NE, NE)	0.9943	0.911 (0.083, 10.054)	0.9395
	> 75	18	1 (5.6)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.2305
Sex	Male	91	1 (1.1)	NE [NE, NE)	174	0 (0.0)	NE [NE, NE)	0.9954	<.001 (<.001, NE)	0.1635
	Female	62	1 (1.6)	NE [NE, NE)	134	2 (1.5)	NE [NE, NE)		0.852 (0.077, 9.415)	0.8962

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	2 (1.6)	NE [NE, NE)	240	1 (0.4)	NE [NE, NE)	1.0000	0.242 (0.022, 2.670)	0.2085
	Asian	20	0 (0.0)	NE [NE, NE)	46	1 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.5097
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	2 (2.0)	NE [NE, NE)	203	1 (0.5)	NE [NE, NE)		0.232 (0.021, 2.564)	0.1936
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	1 (1.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.4956
Baseline ECOG PS	0-1	146	2 (1.4)	NE [NE, NE)	294	2 (0.7)	NE [NE, NE)	0.9999	0.478 (0.067, 3.396)	0.4505
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	0 (0.0)	NE [NE, NE)	285	2 (0.7)	NE [NE, NE)	0.9964	>999.999 (<.001, NE)	0.3415
	No	17	2 (11.8)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.1024
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	1 (1.0)	NE [NE, NE)	0.9958	>999.999 (<.001, NE)	0.4744
	No	98	2 (2.0)	NE [NE, NE)	209	1 (0.5)	NE [NE, NE)		0.226 (0.020, 2.492)	0.1836

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	2 (2.7)	NE [NE, NE)	122	1 (0.8)	NE [NE, NE)	0.9941	0.274 (0.025, 3.022)	0.2575
	No	79	0 (0.0)	NE [NE, NE)	186	1 (0.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.5135
Refractory to Lenalidomide	Yes	55	1 (1.8)	NE [NE, NE)	98	1 (1.0)	NE [NE, NE)	0.9353	0.513 (0.032, 8.203)	0.6307
	No	98	1 (1.0)	NE [NE, NE)	210	1 (0.5)	NE [NE, NE)		0.462 (0.029, 7.382)	0.5753

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	2 (1.8)	NE [NE, NE)	205	2 (1.0)	NE [NE, NE)	0.9999	0.501 (0.071, 3.563)	0.4816
	No	43	0 (0.0)	NE [NE, NE)	103	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to IMiD	Yes	65	1 (1.5)	NE [NE, NE)	129	1 (0.8)	NE [NE, NE)	0.9949	0.454 (0.028, 7.256)	0.5663
	No	88	1 (1.1)	NE [NE, NE)	179	1 (0.6)	NE [NE, NE)		0.488 (0.031, 7.806)	0.6045

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	2 (1.6)	NE [NE, NE)	250	2 (0.8)	NE [NE, NE)	0.9999	0.488 (0.069, 3.468)	0.4642
	3	27	0 (0.0)	NE [NE, NE)	58	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Prior proteasome inhibitor exposure per IXRS	Yes	138	0 (0.0)	NE [NE, NE)	276	2 (0.7)	NE [NE, NE)	0.9947	>999.999 (<.001, NE)	0.3294
	No	15	2 (13.3)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0320

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	2 (3.0)	NE [NE, NE)	131	1 (0.8)	NE [NE, NE)	0.9946	0.245 (0.022, 2.705)	0.2134
	>= 2	87	0 (0.0)	NE [NE, NE)	177	1 (0.6)	NE [NE, NE)		>999.999 (<.001, NE)	0.5105

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Tumour lysis syndrome (SMQ) - Narrow										
Total subjects		153	1 (0.7)	NE [NE, NE)	308	2 (0.6)	NE [NE, NE)		0.998 (0.090, 11.004)	0.9986

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	1 (0.7)	NE [NE, NE)	283	2 (0.7)	NE [NE, NE)	1.0000	0.958 (0.087, 10.566)	0.9724
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	1 (1.1)	NE [NE, NE)	174	1 (0.6)	NE [NE, NE)	0.9958	0.523 (0.033, 8.364)	0.6411
	Female	62	0 (0.0)	NE [NE, NE)	134	1 (0.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.4964

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	0 (0.0)	NE [NE, NE)	240	2 (0.8)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.3118
	Asian	20	0 (0.0)	NE [NE, NE)	46	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
	Other or Unknown	11	1 (9.1)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.1573
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	1 (1.0)	NE [NE, NE)	203	2 (1.0)	NE [NE, NE)		1.012 (0.092, 11.156)	0.9925
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Baseline ECOG PS	0-1	146	1 (0.7)	NE [NE, NE)	294	2 (0.7)	NE [NE, NE)	1.0000	0.998 (0.090, 11.003)	0.9985
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-512-sae-cox-eoi-cfz.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	1 (0.7)	NE [NE, NE)	285	2 (0.7)	NE [NE, NE)	1.0000	0.958 (0.087, 10.569)	0.9726
	No	17	0 (0.0)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE
	No	98	1 (1.0)	NE [NE, NE)	209	2 (1.0)	NE [NE, NE)		0.941 (0.085, 10.373)	0.9601

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	1 (0.8)	NE [NE, NE)	0.9955	>999.999 (<.001, NE)	0.4361
	No	79	1 (1.3)	NE [NE, NE)	186	1 (0.5)	NE [NE, NE)		0.424 (0.027, 6.785)	0.5320
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	1 (1.0)	NE [NE, NE)	0.9960	>999.999 (<.001, NE)	0.4538
	No	98	1 (1.0)	NE [NE, NE)	210	1 (0.5)	NE [NE, NE)		0.467 (0.029, 7.459)	0.5807

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	1 (0.9)	NE [NE, NE)	205	1 (0.5)	NE [NE, NE)	0.9964	0.539 (0.034, 8.621)	0.6573
	No	43	0 (0.0)	NE [NE, NE)	103	1 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.5162
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	1 (0.8)	NE [NE, NE)	0.9957	>999.999 (<.001, NE)	0.4778
	No	88	1 (1.1)	NE [NE, NE)	179	1 (0.6)	NE [NE, NE)		0.492 (0.031, 7.859)	0.6081

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	0 (0.0)	NE [NE, NE)	250	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE
	3	27	1 (3.7)	NE [NE, NE)	58	2 (3.4)	NE [NE, NE)		0.941 (0.085, 10.381)	0.9605
Prior proteasome inhibitor exposure per IXRS	Yes	138	1 (0.7)	NE [NE, NE)	276	2 (0.7)	NE [NE, NE)	1.0000	1.005 (0.091, 11.082)	0.9968
	No	15	0 (0.0)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
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Table 14-6.1.512. Cox Regression of Serious Adverse Events of Interest for Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	1 (1.5)	NE [NE, NE)	131	2 (1.5)	NE [NE, NE)	1.0000	1.008 (0.091, 11.113)	0.9950
	>= 2	87	0 (0.0)	NE [NE, NE)	177	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of Interest for Carfilzomib. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
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Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Daratumumab-related infusion reaction (AMQ) - Narrow (event on same date or next date of any Daratumumab dosing)										
Total subjects		153	0 (0.0)	NE [NE, NE)	308	58 (18.8)	NE [NE, NE)		>999.999 (<.001, NE)	<.0001

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Output: t14-06-001-513-ae-cox-eoi-dar.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	0 (0.0)	NE [NE, NE)	283	54 (19.1)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	<.0001
	> 75	18	0 (0.0)	NE [NE, NE)	25	4 (16.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.0790
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	27 (15.5)	NE [NE, NE)	0.9998	>999.999 (<.001, NE)	<.0001
	Female	62	0 (0.0)	NE [NE, NE)	134	31 (23.1)	NE [NE, NE)		>999.999 (<.001, NE)	<.0001

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	0 (0.0)	NE [NE, NE)	240	39 (16.3)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	<.0001
	Asian	20	0 (0.0)	NE [NE, NE)	46	12 (26.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.0141
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	7 (31.8)	NE [0.1, NE)		>999.999 (<.001, NE)	0.0439
Region	North America	12	0 (0.0)	NE [NE, NE)	21	4 (19.0)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.1142

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	36 (17.7)	NE [NE, NE)		>999.999 (<.001, NE)	<.0001
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	18 (21.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.0022
Baseline ECOG PS	0-1	146	0 (0.0)	NE [NE, NE)	294	54 (18.4)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	<.0001
	2	7	0 (0.0)	NE [NE, NE)	13	3 (23.1)	NE [1.9, NE)		>999.999 (<.001, NE)	0.1934

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	0 (0.0)	NE [NE, NE)	285	51 (17.9)	NE [NE, NE)	0.9998	>999.999 (<.001, NE)	<.0001
	No	17	0 (0.0)	NE [NE, NE)	23	7 (30.4)	NE [11.0, NE)		>999.999 (<.001, NE)	0.0167
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	17 (17.2)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.0013
	No	98	0 (0.0)	NE [NE, NE)	209	41 (19.6)	NE [NE, NE)		>999.999 (<.001, NE)	<.0001

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	21 (17.2)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.0002
	No	79	0 (0.0)	NE [NE, NE)	186	37 (19.9)	NE [NE, NE)		>999.999 (<.001, NE)	<.0001
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	12 (12.2)	NE [NE, NE)	0.9997	>999.999 (<.001, NE)	0.0086
	No	98	0 (0.0)	NE [NE, NE)	210	46 (21.9)	NE [NE, NE)		>999.999 (<.001, NE)	<.0001

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	0 (0.0)	NE [NE, NE)	205	40 (19.5)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	<.0001
	No	43	0 (0.0)	NE [NE, NE)	103	18 (17.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.0042
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	15 (11.6)	NE [NE, NE)	0.9996	>999.999 (<.001, NE)	0.0052
	No	88	0 (0.0)	NE [NE, NE)	179	43 (24.0)	NE [NE, NE)		>999.999 (<.001, NE)	<.0001

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-513-ae-cox-eoi-dar.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	0 (0.0)	NE [NE, NE)	250	48 (19.2)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	<.0001
	3	27	0 (0.0)	NE [NE, NE)	58	10 (17.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.0294
Prior proteasome inhibitor exposure per IXRS	Yes	138	0 (0.0)	NE [NE, NE)	276	52 (18.8)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	<.0001
	No	15	0 (0.0)	NE [NE, NE)	32	6 (18.8)	NE [NE, NE)		>999.999 (<.001, NE)	0.0842

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
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Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	28 (21.4)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	<.0001
	>= 2	87	0 (0.0)	NE [NE, NE)	177	30 (16.9)	NE [NE, NE)		>999.999 (<.001, NE)	<.0001

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-513-ae-cox-eoi-dar.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Daratumumab-related infusion reaction (AMQ) - Narrow (event on same date or next date of first Daratumumab dosing)										
Total subjects		153	0 (0.0)	NE [NE, NE)	308	40 (13.0)	NE [NE, NE)		>999.999 (<.001, NE)	<.0001

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	0 (0.0)	NE [NE, NE)	283	37 (13.1)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	<.0001
	> 75	18	0 (0.0)	NE [NE, NE)	25	3 (12.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.1321
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	20 (11.5)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.0008
	Female	62	0 (0.0)	NE [NE, NE)	134	20 (14.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.0014

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Output: t14-06-001-513-ae-cox-eoi-dar.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	0 (0.0)	NE [NE, NE)	240	24 (10.0)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.0003
	Asian	20	0 (0.0)	NE [NE, NE)	46	10 (21.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.0247
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	6 (27.3)	NE [0.1, NE)		>999.999 (<.001, NE)	0.0612
Region	North America	12	0 (0.0)	NE [NE, NE)	21	3 (14.3)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.1763

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	22 (10.8)	NE [NE, NE)		>999.999 (<.001, NE)	0.0006
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	15 (17.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.0050
Baseline ECOG PS	0-1	146	0 (0.0)	NE [NE, NE)	294	37 (12.6)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	<.0001
	2	7	0 (0.0)	NE [NE, NE)	13	2 (15.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.2863

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	0 (0.0)	NE [NE, NE)	285	34 (11.9)	NE [NE, NE)	0.9998	>999.999 (<.001, NE)	<.0001
	No	17	0 (0.0)	NE [NE, NE)	23	6 (26.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.0241
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	10 (10.1)	NE [NE, NE)	0.9998	>999.999 (<.001, NE)	0.0151
	No	98	0 (0.0)	NE [NE, NE)	209	30 (14.4)	NE [NE, NE)		>999.999 (<.001, NE)	<.0001

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	15 (12.3)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.0018
	No	79	0 (0.0)	NE [NE, NE)	186	25 (13.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.0006
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	7 (7.1)	NE [NE, NE)	0.9997	>999.999 (<.001, NE)	0.0431
	No	98	0 (0.0)	NE [NE, NE)	210	33 (15.7)	NE [NE, NE)		>999.999 (<.001, NE)	<.0001

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	0 (0.0)	NE [NE, NE)	205	30 (14.6)	NE [NE, NE)	0.9998	>999.999 (<.001, NE)	<.0001
	No	43	0 (0.0)	NE [NE, NE)	103	10 (9.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.0349
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	10 (7.8)	NE [NE, NE)	0.9997	>999.999 (<.001, NE)	0.0215
	No	88	0 (0.0)	NE [NE, NE)	179	30 (16.8)	NE [NE, NE)		>999.999 (<.001, NE)	<.0001

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	0 (0.0)	NE [NE, NE)	250	35 (14.0)	NE [NE, NE)	0.9998	>999.999 (<.001, NE)	<.0001
	3	27	0 (0.0)	NE [NE, NE)	58	5 (8.6)	NE [NE, NE)		>999.999 (<.001, NE)	0.1190
Prior proteasome inhibitor exposure per IXRS	Yes	138	0 (0.0)	NE [NE, NE)	276	35 (12.7)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	<.0001
	No	15	0 (0.0)	NE [NE, NE)	32	5 (15.6)	NE [NE, NE)		>999.999 (<.001, NE)	0.1091

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	22 (16.8)	NE [NE, NE)	0.9998	>999.999 (<.001, NE)	0.0004
	>= 2	87	0 (0.0)	NE [NE, NE)	177	18 (10.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.0021

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Haemorrhage terms (excl laboratory terms) (SMQ) - Narrow										
Total subjects		153	19 (12.4)	NE [NE, NE)	308	46 (14.9)	NE [NE, NE)		1.039 (0.608, 1.776)	0.8871

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	15 (11.1)	NE [NE, NE)	283	40 (14.1)	NE [NE, NE)	0.8366	1.112 (0.613, 2.015)	0.7272
	> 75	18	4 (22.2)	NE [7.8, NE)	25	6 (24.0)	NE [11.7, NE)		0.933 (0.263, 3.315)	0.9151
Sex	Male	91	6 (6.6)	NE [NE, NE)	174	24 (13.8)	NE [NE, NE)	0.0817	1.810 (0.738, 4.438)	0.1884
	Female	62	13 (21.0)	NE [NE, NE)	134	22 (16.4)	NE [NE, NE)		0.669 (0.336, 1.330)	0.2483

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-513-ae-cox-eoi-dar.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	13 (10.7)	NE [NE, NE)	240	36 (15.0)	NE [NE, NE)	0.1411	1.246 (0.660, 2.351)	0.4975
	Asian	20	3 (15.0)	NE [NE, NE)	46	9 (19.6)	NE [NE, NE)		1.148 (0.310, 4.260)	0.8361
	Other or Unknown	11	3 (27.3)	NE [7.2, NE)	22	1 (4.5)	NE [NE, NE)		0.113 (0.012, 1.100)	0.0240
Region	North America	12	4 (33.3)	14.7 [6.9, 14.7)	21	7 (33.3)	NE [11.7, NE)	0.7658	0.658 (0.187, 2.320)	0.5127

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	8 (7.8)	NE [NE, NE)	203	22 (10.8)	NE [NE, NE)		1.224 (0.544, 2.751)	0.6246
	Asia Pacific	39	7 (17.9)	NE [19.8, NE)	84	17 (20.2)	NE [NE, NE)		0.964 (0.398, 2.337)	0.9356
Baseline ECOG PS	0-1	146	19 (13.0)	NE [NE, NE)	294	43 (14.6)	NE [NE, NE)	0.9844	0.991 (0.577, 1.703)	0.9750
	2	7	0 (0.0)	NE [NE, NE)	13	3 (23.1)	NE [8.2, NE)		>999.999 (<.001, NE)	0.4631

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	16 (11.8)	NE [NE, NE)	285	41 (14.4)	NE [NE, NE)	0.9247	1.049 (0.588, 1.871)	0.8716
	No	17	3 (17.6)	NE [19.8, NE)	23	5 (21.7)	NE [15.1, NE)		1.164 (0.276, 4.908)	0.8362
Refractory to Bortezomib or Ixazomib	Yes	55	3 (5.5)	NE [NE, NE)	99	18 (18.2)	NE [NE, NE)	0.0296	3.238 (0.953, 11.002)	0.0464
	No	98	16 (16.3)	NE [NE, NE)	209	28 (13.4)	NE [NE, NE)		0.670 (0.362, 1.240)	0.1995

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	13 (17.6)	NE [19.8, NE)	122	16 (13.1)	NE [NE, NE)	0.0416	0.612 (0.293, 1.279)	0.1874
	No	79	6 (7.6)	NE [NE, NE)	186	30 (16.1)	NE [NE, NE)		1.944 (0.809, 4.673)	0.1302
Refractory to Lenalidomide	Yes	55	9 (16.4)	NE [19.8, NE)	98	15 (15.3)	NE [NE, NE)	0.2558	0.727 (0.315, 1.678)	0.4530
	No	98	10 (10.2)	NE [NE, NE)	210	31 (14.8)	NE [NE, NE)		1.331 (0.652, 2.716)	0.4301

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	16 (14.5)	NE [NE, NE)	205	29 (14.1)	NE [NE, NE)	0.1735	0.840 (0.455, 1.550)	0.5757
	No	43	3 (7.0)	NE [NE, NE)	103	17 (16.5)	NE [NE, NE)		2.095 (0.613, 7.154)	0.2275
Refractory to IMiD	Yes	65	9 (13.8)	NE [19.8, NE)	129	18 (14.0)	NE [NE, NE)	0.4057	0.804 (0.359, 1.804)	0.5964
	No	88	10 (11.4)	NE [NE, NE)	179	28 (15.6)	NE [NE, NE)		1.256 (0.610, 2.588)	0.5345

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	18 (14.3)	NE [NE, NE)	250	36 (14.4)	NE [NE, NE)	0.2048	0.882 (0.500, 1.555)	0.6628
	3	27	1 (3.7)	NE [NE, NE)	58	10 (17.2)	NE [NE, NE)		3.450 (0.439, 27.081)	0.2100
Prior proteasome inhibitor exposure per IXRS	Yes	138	16 (11.6)	NE [NE, NE)	276	41 (14.9)	NE [NE, NE)	0.5686	1.103 (0.618, 1.969)	0.7402
	No	15	3 (20.0)	NE [19.8, NE)	32	5 (15.6)	NE [NE, NE)		0.732 (0.175, 3.070)	0.6686

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	8 (12.1)	NE [NE, NE)	131	20 (15.3)	NE [NE, NE)	0.8842	1.081 (0.475, 2.459)	0.8522
	>= 2	87	11 (12.6)	NE [NE, NE)	177	26 (14.7)	NE [NE, NE)		1.019 (0.502, 2.067)	0.9591

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Intravascular hemolysis (JMQ)										
Total subjects		153	5 (3.3)	NE [NE, NE)	308	4 (1.3)	NE [NE, NE)		0.302 (0.080, 1.136)	0.0607

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	4 (3.0)	NE [NE, NE)	283	4 (1.4)	NE [NE, NE)	0.9939	0.354 (0.088, 1.431)	0.1283
	> 75	18	1 (5.6)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.2305
Sex	Male	91	4 (4.4)	NE [NE, NE)	174	3 (1.7)	NE [NE, NE)	0.8919	0.270 (0.060, 1.227)	0.0701
	Female	62	1 (1.6)	NE [NE, NE)	134	1 (0.7)	NE [NE, NE)		0.409 (0.026, 6.534)	0.5129

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	5 (4.1)	NE [NE, NE)	240	3 (1.3)	NE [NE, NE)	1.0000	0.250 (0.059, 1.051)	0.0409
	Asian	20	0 (0.0)	NE [NE, NE)	46	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	1 (4.5)	NE [26.5, NE)		>999.999 (<.001, NE)	0.6171
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	0.4546	NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	2 (2.0)	NE [NE, NE)	203	3 (1.5)	NE [NE, NE)		0.595 (0.099, 3.568)	0.5655
	Asia Pacific	39	3 (7.7)	NE [NE, NE)	84	1 (1.2)	NE [NE, NE)		0.133 (0.014, 1.278)	0.0394
Baseline ECOG PS	0-1	146	5 (3.4)	NE [NE, NE)	294	3 (1.0)	NE [NE, NE)	0.9998	0.229 (0.054, 0.970)	0.0293
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	4 (2.9)	NE [NE, NE)	285	3 (1.1)	NE [NE, NE)	0.7135	0.266 (0.059, 1.201)	0.0650
	No	17	1 (5.9)	NE [NE, NE)	23	1 (4.3)	NE [NE, NE)		0.556 (0.035, 8.930)	0.6745
Refractory to Bortezomib or Ixazomib	Yes	55	1 (1.8)	NE [NE, NE)	99	1 (1.0)	NE [NE, NE)	0.7324	0.379 (0.023, 6.318)	0.4833
	No	98	4 (4.1)	NE [NE, NE)	209	3 (1.4)	NE [NE, NE)		0.270 (0.060, 1.215)	0.0676

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-513-ae-cox-eoi-dar.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	1 (1.4)	NE [NE, NE)	122	1 (0.8)	NE [NE, NE)	0.7534	0.530 (0.033, 8.478)	0.6482
	No	79	4 (5.1)	NE [NE, NE)	186	3 (1.6)	NE [NE, NE)		0.253 (0.056, 1.135)	0.0528
Refractory to Lenalidomide	Yes	55	1 (1.8)	NE [NE, NE)	98	0 (0.0)	NE [NE, NE)	0.9923	<.001 (<.001, NE)	0.1482
	No	98	4 (4.1)	NE [NE, NE)	210	4 (1.9)	NE [NE, NE)		0.384 (0.096, 1.540)	0.1606

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	3 (2.7)	NE [NE, NE)	205	4 (2.0)	NE [NE, NE)	0.9914	0.498 (0.110, 2.260)	0.3573
	No	43	2 (4.7)	NE [NE, NE)	103	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0241
Refractory to IMiD	Yes	65	1 (1.5)	NE [NE, NE)	129	0 (0.0)	NE [NE, NE)	0.9946	<.001 (<.001, NE)	0.1292
	No	88	4 (4.5)	NE [NE, NE)	179	4 (2.2)	NE [NE, NE)		0.406 (0.101, 1.629)	0.1885

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	5 (4.0)	NE [NE, NE)	250	4 (1.6)	NE [NE, NE)	0.9998	0.318 (0.085, 1.193)	0.0734
	3	27	0 (0.0)	NE [NE, NE)	58	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Prior proteasome inhibitor exposure per IXRS	Yes	138	4 (2.9)	NE [NE, NE)	276	2 (0.7)	NE [NE, NE)	0.4352	0.198 (0.036, 1.093)	0.0393
	No	15	1 (6.7)	NE [3.3, NE)	32	2 (6.3)	NE [NE, NE)		0.557 (0.050, 6.193)	0.6288

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	3 (4.5)	NE [NE, NE)	131	3 (2.3)	NE [NE, NE)	0.5978	0.381 (0.076, 1.900)	0.2214
	>= 2	87	2 (2.3)	NE [NE, NE)	177	1 (0.6)	NE [NE, NE)		0.216 (0.020, 2.383)	0.1685

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Opportunistic infections (JMQ)										
Total subjects		153	6 (3.9)	NE [NE, NE)	308	29 (9.4)	NE [NE, NE)		2.154 (0.894, 5.192)	0.0798

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	6 (4.4)	NE [NE, NE)	283	27 (9.5)	NE [NE, NE)	0.9895	1.938 (0.799, 4.697)	0.1359
	> 75	18	0 (0.0)	NE [NE, NE)	25	2 (8.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.2611
Sex	Male	91	4 (4.4)	NE [NE, NE)	174	13 (7.5)	NE [NE, NE)	0.3871	1.502 (0.489, 4.615)	0.4740
	Female	62	2 (3.2)	NE [NE, NE)	134	16 (11.9)	NE [NE, NE)		3.356 (0.771, 14.598)	0.0865

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	5 (4.1)	NE [NE, NE)	240	19 (7.9)	NE [NE, NE)	0.9253	1.703 (0.635, 4.566)	0.2848
	Asian	20	0 (0.0)	NE [NE, NE)	46	4 (8.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.2124
	Other or Unknown	11	1 (9.1)	NE [2.7, NE)	22	6 (27.3)	NE [3.7, NE)		2.610 (0.314, 21.689)	0.3563
Region	North America	12	1 (8.3)	NE [4.4, NE)	21	6 (28.6)	NE [5.6, NE)	0.7746	2.981 (0.352, 25.206)	0.2927

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	4 (3.9)	NE [NE, NE)	203	15 (7.4)	NE [NE, NE)		1.695 (0.562, 5.112)	0.3429
	Asia Pacific	39	1 (2.6)	NE [NE, NE)	84	8 (9.5)	NE [NE, NE)		3.310 (0.414, 26.486)	0.2315
Baseline ECOG PS	0-1	146	6 (4.1)	NE [NE, NE)	294	28 (9.5)	NE [NE, NE)	0.9998	2.130 (0.881, 5.146)	0.0855
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	6 (4.4)	NE [NE, NE)	285	28 (9.8)	NE [NE, NE)	0.9901	2.004 (0.829, 4.843)	0.1152
	No	17	0 (0.0)	NE [NE, NE)	23	1 (4.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.4583
Refractory to Bortezomib or Ixazomib	Yes	55	4 (7.3)	NE [NE, NE)	99	10 (10.1)	NE [NE, NE)	0.2234	1.278 (0.401, 4.080)	0.6776
	No	98	2 (2.0)	NE [NE, NE)	209	19 (9.1)	NE [NE, NE)		3.985 (0.927, 17.120)	0.0445

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	3 (4.1)	NE [NE, NE)	122	14 (11.5)	NE [NE, NE)	0.7739	2.429 (0.696, 8.482)	0.1509
	No	79	3 (3.8)	NE [NE, NE)	186	15 (8.1)	NE [NE, NE)		1.940 (0.561, 6.702)	0.2860
Refractory to Lenalidomide	Yes	55	1 (1.8)	NE [NE, NE)	98	12 (12.2)	NE [NE, NE)	0.2234	5.623 (0.728, 43.436)	0.0620
	No	98	5 (5.1)	NE [NE, NE)	210	17 (8.1)	NE [NE, NE)		1.454 (0.536, 3.942)	0.4590

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	4 (3.6)	NE [NE, NE)	205	22 (10.7)	NE [NE, NE)	0.4766	2.621 (0.902, 7.613)	0.0658
	No	43	2 (4.7)	NE [NE, NE)	103	7 (6.8)	NE [NE, NE)		1.309 (0.272, 6.314)	0.7362
Refractory to IMiD	Yes	65	3 (4.6)	NE [NE, NE)	129	16 (12.4)	NE [NE, NE)	0.8466	2.260 (0.656, 7.787)	0.1846
	No	88	3 (3.4)	NE [NE, NE)	179	13 (7.3)	NE [NE, NE)		1.958 (0.558, 6.873)	0.2850

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Output: t14-06-001-513-ae-cox-eoi-dar.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	5 (4.0)	NE [NE, NE)	250	27 (10.8)	NE [NE, NE)	0.3118	2.528 (0.973, 6.569)	0.0485
	3	27	1 (3.7)	NE [NE, NE)	58	2 (3.4)	NE [NE, NE)		0.599 (0.053, 6.786)	0.6755
Prior proteasome inhibitor exposure per IXRS	Yes	138	6 (4.3)	NE [NE, NE)	276	28 (10.1)	NE [NE, NE)	0.9911	2.109 (0.872, 5.097)	0.0900
	No	15	0 (0.0)	NE [NE, NE)	32	1 (3.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.5637

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-513-ae-cox-eoi-dar.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	2 (3.0)	NE [NE, NE)	131	9 (6.9)	NE [NE, NE)	0.9205	2.014 (0.435, 9.330)	0.3604
	>= 2	87	4 (4.6)	NE [NE, NE)	177	20 (11.3)	NE [NE, NE)		2.212 (0.755, 6.481)	0.1373

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Output: t14-06-001-513-ae-cox-eoi-dar.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Second primary malignancies: Malignant tumours (SMQ) - Narrow										
Total subjects		153	3 (2.0)	NE [NE, NE)	308	9 (2.9)	NE [NE, NE)		0.932 (0.250, 3.473)	0.9167

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	3 (2.2)	NE [NE, NE)	283	7 (2.5)	NE [NE, NE)	0.9913	0.666 (0.171, 2.593)	0.5553
	> 75	18	0 (0.0)	NE [NE, NE)	25	2 (8.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.2605
Sex	Male	91	3 (3.3)	NE [NE, NE)	174	6 (3.4)	NE [NE, NE)	0.9929	0.583 (0.143, 2.382)	0.4472
	Female	62	0 (0.0)	NE [NE, NE)	134	3 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.3102

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	3 (2.5)	NE [NE, NE)	240	8 (3.3)	NE [NE, NE)	1.0000	0.842 (0.221, 3.200)	0.8002
	Asian	20	0 (0.0)	NE [NE, NE)	46	1 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.5403
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	2 (9.5)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.5061

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	3 (2.9)	NE [NE, NE)	203	2 (1.0)	NE [NE, NE)		0.240 (0.040, 1.438)	0.0895
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	5 (6.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.3007
Baseline ECOG PS	0-1	146	3 (2.1)	NE [NE, NE)	294	9 (3.1)	NE [NE, NE)	1.0000	0.966 (0.260, 3.599)	0.9598
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Output: t14-06-001-513-ae-cox-eoi-dar.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	3 (2.2)	NE [NE, NE)	285	7 (2.5)	NE [NE, NE)	0.9936	0.715 (0.183, 2.791)	0.6284
	No	17	0 (0.0)	NE [NE, NE)	23	2 (8.7)	NE [29.6, NE)		>999.999 (<.001, NE)	0.3062
Refractory to Bortezomib or Ixazomib	Yes	55	2 (3.6)	NE [27.5, NE)	99	2 (2.0)	NE [NE, NE)	0.2368	0.369 (0.052, 2.642)	0.3016
	No	98	1 (1.0)	NE [NE, NE)	209	7 (3.3)	NE [NE, NE)		2.021 (0.246, 16.609)	0.5041

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	1 (1.4)	NE [NE, NE)	122	3 (2.5)	NE [NE, NE)	0.9109	1.031 (0.104, 10.181)	0.9790
	No	79	2 (2.5)	NE [NE, NE)	186	6 (3.2)	NE [NE, NE)		0.834 (0.166, 4.200)	0.8254
Refractory to Lenalidomide	Yes	55	1 (1.8)	NE [NE, NE)	98	3 (3.1)	NE [NE, NE)	0.8877	0.837 (0.083, 8.388)	0.8793
	No	98	2 (2.0)	NE [NE, NE)	210	6 (2.9)	NE [NE, NE)		0.957 (0.191, 4.791)	0.9575

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	1 (0.9)	NE [NE, NE)	205	6 (2.9)	NE [NE, NE)	0.2929	1.889 (0.226, 15.814)	0.5510
	No	43	2 (4.7)	NE [27.5, NE)	103	3 (2.9)	NE [NE, NE)		0.451 (0.075, 2.728)	0.3739
Refractory to IMiD	Yes	65	1 (1.5)	NE [NE, NE)	129	3 (2.3)	NE [NE, NE)	0.8128	0.748 (0.075, 7.497)	0.8046
	No	88	2 (2.3)	NE [NE, NE)	179	6 (3.4)	NE [NE, NE)		1.013 (0.202, 5.075)	0.9876

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	3 (2.4)	NE [NE, NE)	250	7 (2.8)	NE [NE, NE)	0.9923	0.789 (0.202, 3.087)	0.7328
	3	27	0 (0.0)	NE [NE, NE)	58	2 (3.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.5419
Prior proteasome inhibitor exposure per IXRS	Yes	138	3 (2.2)	NE [NE, NE)	276	7 (2.5)	NE [NE, NE)	0.9938	0.745 (0.191, 2.909)	0.6714
	No	15	0 (0.0)	NE [NE, NE)	32	2 (6.3)	NE [29.6, NE)		>999.999 (<.001, NE)	0.4618

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	1 (1.5)	NE [NE, NE)	131	4 (3.1)	NE [NE, NE)	0.6503	1.308 (0.144, 11.894)	0.8107
	>= 2	87	2 (2.3)	NE [27.5, NE)	177	5 (2.8)	NE [NE, NE)		0.714 (0.136, 3.752)	0.6895

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Tumour lysis syndrome (SMQ) - Narrow										
Total subjects		153	1 (0.7)	NE [NE, NE)	308	4 (1.3)	NE [NE, NE)		1.775 (0.196, 16.059)	0.6046

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	1 (0.7)	NE [NE, NE)	283	4 (1.4)	NE [NE, NE)	0.9999	1.705 (0.189, 15.426)	0.6308
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	1 (1.1)	NE [NE, NE)	174	2 (1.1)	NE [NE, NE)	0.9948	0.815 (0.071, 9.323)	0.8690
	Female	62	0 (0.0)	NE [NE, NE)	134	2 (1.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.3342

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-513-ae-cox-eoi-dar.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	0 (0.0)	NE [NE, NE)	240	3 (1.3)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.2146
	Asian	20	0 (0.0)	NE [NE, NE)	46	1 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.6949
	Other or Unknown	11	1 (9.1)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.1573
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	1 (1.0)	NE [NE, NE)	203	3 (1.5)	NE [NE, NE)		1.524 (0.159, 14.649)	0.7130
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	1 (1.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.7557
Baseline ECOG PS	0-1	146	1 (0.7)	NE [NE, NE)	294	4 (1.4)	NE [NE, NE)	0.9999	1.784 (0.197, 16.125)	0.6012
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	1 (0.7)	NE [NE, NE)	285	4 (1.4)	NE [NE, NE)	0.9999	1.713 (0.189, 15.480)	0.6279
	No	17	0 (0.0)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	2 (2.0)	NE [NE, NE)	0.9953	>999.999 (<.001, NE)	0.3653
	No	98	1 (1.0)	NE [NE, NE)	209	2 (1.0)	NE [NE, NE)		0.941 (0.085, 10.373)	0.9601

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	2 (1.6)	NE [NE, NE)	0.9945	>999.999 (<.001, NE)	0.2687
	No	79	1 (1.3)	NE [NE, NE)	186	2 (1.1)	NE [NE, NE)		0.707 (0.063, 7.950)	0.7782
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	2 (2.0)	NE [NE, NE)	0.9953	>999.999 (<.001, NE)	0.2869
	No	98	1 (1.0)	NE [NE, NE)	210	2 (1.0)	NE [NE, NE)		0.789 (0.070, 8.841)	0.8472

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	1 (0.9)	NE [NE, NE)	205	3 (1.5)	NE [NE, NE)	0.9959	1.377 (0.141, 13.486)	0.7828
	No	43	0 (0.0)	NE [NE, NE)	103	1 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.5162
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	2 (1.6)	NE [NE, NE)	0.9949	>999.999 (<.001, NE)	0.3135
	No	88	1 (1.1)	NE [NE, NE)	179	2 (1.1)	NE [NE, NE)		0.827 (0.074, 9.273)	0.8771

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	0 (0.0)	NE [NE, NE)	250	2 (0.8)	NE [NE, NE)	0.9940	>999.999 (<.001, NE)	0.3832
	3	27	1 (3.7)	NE [NE, NE)	58	2 (3.4)	NE [NE, NE)		0.941 (0.085, 10.381)	0.9605
Prior proteasome inhibitor exposure per IXRS	Yes	138	1 (0.7)	NE [NE, NE)	276	4 (1.4)	NE [NE, NE)	0.9999	1.791 (0.198, 16.195)	0.5989
	No	15	0 (0.0)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	1 (1.5)	NE [NE, NE)	131	2 (1.5)	NE [NE, NE)	0.9942	1.008 (0.091, 11.113)	0.9950
	>= 2	87	0 (0.0)	NE [NE, NE)	177	2 (1.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.4013

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Viral infection (JMQ)										
	Total subjects	153	24 (15.7)	NE [NE, NE)	308	73 (23.7)	NE [NE, NE)		1.303 (0.821, 2.069)	0.2604

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	22 (16.3)	NE [NE, NE)	283	68 (24.0)	NE [NE, NE)	0.7947	1.274 (0.787, 2.063)	0.3232
	> 75	18	2 (11.1)	NE [12.9, NE)	25	5 (20.0)	NE [22.0, NE)		1.502 (0.289, 7.811)	0.6264
Sex	Male	91	18 (19.8)	NE [21.5, NE)	174	41 (23.6)	NE [NE, NE)	0.1097	0.936 (0.536, 1.634)	0.8146
	Female	62	6 (9.7)	NE [NE, NE)	134	32 (23.9)	NE [NE, NE)		2.289 (0.957, 5.478)	0.0556

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	20 (16.4)	NE [NE, NE)	240	53 (22.1)	NE [NE, NE)	0.5769	1.142 (0.682, 1.912)	0.6143
	Asian	20	2 (10.0)	NE [12.9, NE)	46	12 (26.1)	NE [26.1, NE)		2.177 (0.482, 9.826)	0.2997
	Other or Unknown	11	2 (18.2)	NE [2.1, NE)	22	8 (36.4)	NE [3.7, NE)		1.853 (0.393, 8.734)	0.4284
Region	North America	12	3 (25.0)	NE [2.2, NE)	21	10 (47.6)	NE [4.1, NE)	0.2304	1.742 (0.474, 6.399)	0.3975

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	17 (16.7)	NE [NE, NE)	203	37 (18.2)	NE [NE, NE)		0.955 (0.537, 1.697)	0.8764
	Asia Pacific	39	4 (10.3)	NE [NE, NE)	84	26 (31.0)	NE [24.6, NE)		2.396 (0.830, 6.913)	0.0953
Baseline ECOG PS	0-1	146	24 (16.4)	NE [NE, NE)	294	68 (23.1)	NE [NE, NE)	0.9812	1.254 (0.787, 1.999)	0.3398
	2	7	0 (0.0)	NE [NE, NE)	13	5 (38.5)	22.0 [11.5, NE)		>999.999 (<.001, NE)	0.5002

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	22 (16.2)	NE [NE, NE)	285	69 (24.2)	NE [NE, NE)	0.9156	1.293 (0.799, 2.091)	0.2943
	No	17	2 (11.8)	NE [9.3, NE)	23	4 (17.4)	NE [NE, NE)		1.234 (0.223, 6.837)	0.8097
Refractory to Bortezomib or Ixazomib	Yes	55	8 (14.5)	NE [21.3, NE)	99	23 (23.2)	NE [23.6, NE)	0.7568	1.403 (0.626, 3.141)	0.4088
	No	98	16 (16.3)	NE [NE, NE)	209	50 (23.9)	NE [NE, NE)		1.259 (0.716, 2.215)	0.4221

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-513-ae-cox-eoi-dar.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	14 (18.9)	NE [NE, NE)	122	26 (21.3)	NE [NE, NE)	0.1231	0.882 (0.459, 1.697)	0.7083
	No	79	10 (12.7)	NE [NE, NE)	186	47 (25.3)	NE [NE, NE)		1.840 (0.929, 3.644)	0.0758
Refractory to Lenalidomide	Yes	55	11 (20.0)	NE [12.2, NE)	98	22 (22.4)	NE [NE, NE)	0.1439	0.859 (0.413, 1.784)	0.6834
	No	98	13 (13.3)	NE [NE, NE)	210	51 (24.3)	NE [NE, NE)		1.680 (0.913, 3.090)	0.0920

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-513-ae-cox-eoi-dar.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	17 (15.5)	NE [NE, NE)	205	49 (23.9)	NE [NE, NE)	0.9884	1.314 (0.755, 2.286)	0.3324
	No	43	7 (16.3)	NE [21.5, NE)	103	24 (23.3)	NE [NE, NE)		1.303 (0.561, 3.026)	0.5367
Refractory to IMiD	Yes	65	13 (20.0)	NE [12.2, NE)	129	31 (24.0)	NE [NE, NE)	0.1792	0.942 (0.490, 1.810)	0.8584
	No	88	11 (12.5)	NE [NE, NE)	179	42 (23.5)	NE [NE, NE)		1.721 (0.886, 3.346)	0.1051

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Output: t14-06-001-513-ae-cox-eoi-dar.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	18 (14.3)	NE [NE, NE)	250	61 (24.4)	NE [NE, NE)	0.0902	1.550 (0.915, 2.625)	0.0999
	3	27	6 (22.2)	NE [11.1, NE)	58	12 (20.7)	NE [22.0, NE)		0.555 (0.204, 1.513)	0.2438
Prior proteasome inhibitor exposure per IXRS	Yes	138	22 (15.9)	NE [NE, NE)	276	68 (24.6)	NE [NE, NE)	0.6927	1.343 (0.829, 2.174)	0.2290
	No	15	2 (13.3)	NE [9.3, NE)	32	5 (15.6)	NE [NE, NE)		0.998 (0.192, 5.191)	0.9986

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.513. Cox Regression of Adverse Events of Interest for Daratumumab
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	7 (10.6)	NE [NE, NE)	131	30 (22.9)	NE [NE, NE)	0.2100	1.916 (0.841, 4.366)	0.1152
	>= 2	87	17 (19.5)	NE [NE, NE)	177	43 (24.3)	NE [NE, NE)		1.044 (0.594, 1.835)	0.8811

Includes subjects with at least one adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-513-ae-cox-eoi-dar.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Daratumumab-related infusion reaction (AMQ) - Narrow (event on same date or next date of any Daratumumab dosing)										
Total subjects		153	0 (0.0)	NE [NE, NE)	308	7 (2.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.0673

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-514-ae-cox-eoi-dar-grd345.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	0 (0.0)	NE [NE, NE)	283	6 (2.1)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.0985
	> 75	18	0 (0.0)	NE [NE, NE)	25	1 (4.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.3961
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	5 (2.9)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.1168
	Female	62	0 (0.0)	NE [NE, NE)	134	2 (1.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.3416

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	0 (0.0)	NE [NE, NE)	240	4 (1.7)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.1675
	Asian	20	0 (0.0)	NE [NE, NE)	46	2 (4.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.3473
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	1 (4.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.5224
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	4 (2.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.1706
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	3 (3.6)	NE [NE, NE)		>999.999 (<.001, NE)	0.2358
Baseline ECOG PS	0-1	146	0 (0.0)	NE [NE, NE)	294	6 (2.0)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.0896
	2	7	0 (0.0)	NE [NE, NE)	13	1 (7.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.5002

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	0 (0.0)	NE [NE, NE)	285	5 (1.8)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.1247
	No	17	0 (0.0)	NE [NE, NE)	23	2 (8.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.2730
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	2 (2.0)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.3001
	No	98	0 (0.0)	NE [NE, NE)	209	5 (2.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.1315

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	5 (4.1)	NE [NE, NE)	0.9997	>999.999 (<.001, NE)	0.0921
	No	79	0 (0.0)	NE [NE, NE)	186	2 (1.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.3558
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	3 (3.1)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.2291
	No	98	0 (0.0)	NE [NE, NE)	210	4 (1.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.1698

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	0 (0.0)	NE [NE, NE)	205	6 (2.9)	NE [NE, NE)	0.9998	>999.999 (<.001, NE)	0.0802
	No	43	0 (0.0)	NE [NE, NE)	103	1 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.5182
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	3 (2.3)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.2544
	No	88	0 (0.0)	NE [NE, NE)	179	4 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.1585

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	0 (0.0)	NE [NE, NE)	250	7 (2.8)	NE [NE, NE)	0.9983	>999.999 (<.001, NE)	0.0624
	3	27	0 (0.0)	NE [NE, NE)	58	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Prior proteasome inhibitor exposure per IXRS	Yes	138	0 (0.0)	NE [NE, NE)	276	6 (2.2)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.0837
	No	15	0 (0.0)	NE [NE, NE)	32	1 (3.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.5637

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-514-ae-cox-eoi-dar-grd345.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	2 (1.5)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.3142
	>= 2	87	0 (0.0)	NE [NE, NE)	177	5 (2.8)	NE [NE, NE)		>999.999 (<.001, NE)	0.1276

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-514-ae-cox-eoi-dar-grd345.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Daratumumab-related infusion reaction (AMQ) - Narrow (event on same date or next date of first Daratumumab dosing)										
Total subjects		153	0 (0.0)	NE [NE, NE)	308	4 (1.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.1573

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-514-ae-cox-eoi-dar-grd345.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	0 (0.0)	NE [NE, NE)	283	3 (1.1)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.2305
	> 75	18	0 (0.0)	NE [NE, NE)	25	1 (4.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.3961
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	3 (1.7)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.2086
	Female	62	0 (0.0)	NE [NE, NE)	134	1 (0.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.4964

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-514-ae-cox-eoi-dar-grd345.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	0 (0.0)	NE [NE, NE)	240	2 (0.8)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.3126
	Asian	20	0 (0.0)	NE [NE, NE)	46	2 (4.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.3473
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-514-ae-cox-eoi-dar-grd345.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	2 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.3153
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	2 (2.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.3332
Baseline ECOG PS	0-1	146	0 (0.0)	NE [NE, NE)	294	4 (1.4)	NE [NE, NE)	0.9992	>999.999 (<.001, NE)	0.1573
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-514-ae-cox-eoi-dar-grd345.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	0 (0.0)	NE [NE, NE)	285	3 (1.1)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.2304
	No	17	0 (0.0)	NE [NE, NE)	23	1 (4.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.3899
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	0 (0.0)	NE [NE, NE)	0.9984	NE (NE, NE)	NE
	No	98	0 (0.0)	NE [NE, NE)	209	4 (1.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.1687

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	2 (1.6)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.2695
	No	79	0 (0.0)	NE [NE, NE)	186	2 (1.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.3558
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	0 (0.0)	NE [NE, NE)	0.9984	NE (NE, NE)	NE
	No	98	0 (0.0)	NE [NE, NE)	210	4 (1.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.1698

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
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Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	0 (0.0)	NE [NE, NE)	205	3 (1.5)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.2031
	No	43	0 (0.0)	NE [NE, NE)	103	1 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.5182
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	0 (0.0)	NE [NE, NE)	0.9984	NE (NE, NE)	NE
	No	88	0 (0.0)	NE [NE, NE)	179	4 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.1585

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	0 (0.0)	NE [NE, NE)	250	4 (1.6)	NE [NE, NE)	0.9986	>999.999 (<.001, NE)	0.1540
	3	27	0 (0.0)	NE [NE, NE)	58	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Prior proteasome inhibitor exposure per IXRS	Yes	138	0 (0.0)	NE [NE, NE)	276	4 (1.4)	NE [NE, NE)	0.9989	>999.999 (<.001, NE)	0.1558
	No	15	0 (0.0)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	2 (1.5)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.3142
	>= 2	87	0 (0.0)	NE [NE, NE)	177	2 (1.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.3205

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Haemorrhage terms (excl laboratory terms) (SMQ) - Narrow										
Total subjects		153	5 (3.3)	NE [NE, NE)	308	7 (2.3)	NE [NE, NE)		0.584 (0.184, 1.853)	0.3557

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	4 (3.0)	NE [NE, NE)	283	7 (2.5)	NE [NE, NE)	0.9917	0.697 (0.202, 2.402)	0.5660
	> 75	18	1 (5.6)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.2305
Sex	Male	91	2 (2.2)	NE [NE, NE)	174	4 (2.3)	NE [NE, NE)	0.4951	0.811 (0.146, 4.519)	0.8107
	Female	62	3 (4.8)	NE [NE, NE)	134	3 (2.2)	NE [NE, NE)		0.410 (0.083, 2.034)	0.2594

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	5 (4.1)	NE [NE, NE)	240	5 (2.1)	NE [NE, NE)	0.9999	0.415 (0.119, 1.446)	0.1543
	Asian	20	0 (0.0)	NE [NE, NE)	46	1 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.5097
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	1 (4.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.4795
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	0.9795	NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-514-ae-cox-eoi-dar-grd345.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	4 (3.9)	NE [NE, NE)	203	5 (2.5)	NE [NE, NE)		0.549 (0.147, 2.048)	0.3648
	Asia Pacific	39	1 (2.6)	NE [19.8, NE)	84	2 (2.4)	NE [NE, NE)		0.713 (0.062, 8.209)	0.7851
Baseline ECOG PS	0-1	146	5 (3.4)	NE [NE, NE)	294	6 (2.0)	NE [NE, NE)	0.9927	0.501 (0.152, 1.654)	0.2476
	2	7	0 (0.0)	NE [NE, NE)	13	1 (7.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.4631

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	2 (1.5)	NE [NE, NE)	285	6 (2.1)	NE [NE, NE)	0.1939	1.272 (0.255, 6.337)	0.7687
	No	17	3 (17.6)	NE [19.8, NE)	23	1 (4.3)	NE [NE, NE)		0.180 (0.018, 1.761)	0.0989
Refractory to Bortezomib or Ixazomib	Yes	55	1 (1.8)	NE [NE, NE)	99	4 (4.0)	NE [NE, NE)	0.1595	2.136 (0.239, 19.116)	0.4872
	No	98	4 (4.1)	NE [NE, NE)	209	3 (1.4)	NE [NE, NE)		0.266 (0.059, 1.206)	0.0659

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	4 (5.4)	NE [NE, NE)	122	3 (2.5)	NE [NE, NE)	0.2953	0.361 (0.079, 1.647)	0.1708
	No	79	1 (1.3)	NE [NE, NE)	186	4 (2.2)	NE [NE, NE)		1.463 (0.162, 13.192)	0.7325
Refractory to Lenalidomide	Yes	55	2 (3.6)	NE [19.8, NE)	98	3 (3.1)	NE [NE, NE)	0.8867	0.632 (0.101, 3.934)	0.6197
	No	98	3 (3.1)	NE [NE, NE)	210	4 (1.9)	NE [NE, NE)		0.551 (0.123, 2.477)	0.4310

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	4 (3.6)	NE [NE, NE)	205	4 (2.0)	NE [NE, NE)	0.4996	0.459 (0.114, 1.851)	0.2619
	No	43	1 (2.3)	NE [NE, NE)	103	3 (2.9)	NE [NE, NE)		1.035 (0.107, 10.037)	0.9764
Refractory to IMiD	Yes	65	2 (3.1)	NE [19.8, NE)	129	3 (2.3)	NE [NE, NE)	0.9891	0.559 (0.090, 3.477)	0.5273
	No	88	3 (3.4)	NE [NE, NE)	179	4 (2.2)	NE [NE, NE)		0.582 (0.129, 2.613)	0.4745

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	4 (3.2)	NE [NE, NE)	250	5 (2.0)	NE [NE, NE)	0.8765	0.523 (0.139, 1.967)	0.3295
	3	27	1 (3.7)	NE [NE, NE)	58	2 (3.4)	NE [NE, NE)		0.742 (0.067, 8.231)	0.8070
Prior proteasome inhibitor exposure per IXRS	Yes	138	2 (1.4)	NE [NE, NE)	276	6 (2.2)	NE [NE, NE)	0.0998	1.335 (0.268, 6.652)	0.7237
	No	15	3 (20.0)	NE [19.8, NE)	32	1 (3.1)	NE [NE, NE)		0.121 (0.013, 1.174)	0.0299

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	2 (3.0)	NE [NE, NE)	131	4 (3.1)	NE [NE, NE)	0.5353	0.847 (0.154, 4.670)	0.8489
	>= 2	87	3 (3.4)	NE [NE, NE)	177	3 (1.7)	NE [NE, NE)		0.404 (0.080, 2.029)	0.2550

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Intravascular hemolysis (JMQ)										
Total subjects		153	1 (0.7)	NE [NE, NE)	308	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.1343

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	1 (0.7)	NE [NE, NE)	283	0 (0.0)	NE [NE, NE)	0.9997	<.001 (<.001, NE)	0.1297
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	1 (1.1)	NE [NE, NE)	174	0 (0.0)	NE [NE, NE)	0.9994	<.001 (<.001, NE)	0.1534
	Female	62	0 (0.0)	NE [NE, NE)	134	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	1 (0.8)	NE [NE, NE)	240	0 (0.0)	NE [NE, NE)	1.0000	<.001 (<.001, NE)	0.1419
	Asian	20	0 (0.0)	NE [NE, NE)	46	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
	Asia Pacific	39	1 (2.6)	NE [NE, NE)	84	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.1172
Baseline ECOG PS	0-1	146	1 (0.7)	NE [NE, NE)	294	0 (0.0)	NE [NE, NE)	0.9998	<.001 (<.001, NE)	0.1380
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	0 (0.0)	NE [NE, NE)	285	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE
	No	17	1 (5.9)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.2037
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	0 (0.0)	NE [NE, NE)	0.9994	NE (NE, NE)	NE
	No	98	1 (1.0)	NE [NE, NE)	209	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.1157

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	1 (1.4)	NE [NE, NE)	122	0 (0.0)	NE [NE, NE)	0.9991	<.001 (<.001, NE)	0.1627
	No	79	0 (0.0)	NE [NE, NE)	186	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to Lenalidomide	Yes	55	1 (1.8)	NE [NE, NE)	98	0 (0.0)	NE [NE, NE)	0.9992	<.001 (<.001, NE)	0.1482
	No	98	0 (0.0)	NE [NE, NE)	210	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-514-ae-cox-eoi-dar-grd345.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	1 (0.9)	NE [NE, NE)	205	0 (0.0)	NE [NE, NE)	0.9993	<.001 (<.001, NE)	0.1419
	No	43	0 (0.0)	NE [NE, NE)	103	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to IMiD	Yes	65	1 (1.5)	NE [NE, NE)	129	0 (0.0)	NE [NE, NE)	0.9994	<.001 (<.001, NE)	0.1292
	No	88	0 (0.0)	NE [NE, NE)	179	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	1 (0.8)	NE [NE, NE)	250	0 (0.0)	NE [NE, NE)	0.9996	<.001 (<.001, NE)	0.1431
	3	27	0 (0.0)	NE [NE, NE)	58	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Prior proteasome inhibitor exposure per IXRS	Yes	138	0 (0.0)	NE [NE, NE)	276	0 (0.0)	NE [NE, NE)	NE	NE (NE, NE)	NE
	No	15	1 (6.7)	NE [3.3, NE)	32	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0833

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	0 (0.0)	NE [NE, NE)	0.9992	NE (NE, NE)	NE
	>= 2	87	1 (1.1)	NE [NE, NE)	177	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.1297

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Opportunistic infections (JMQ)										
Total subjects		153	0 (0.0)	NE [NE, NE)	308	3 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.2693

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	0 (0.0)	NE [NE, NE)	283	3 (1.1)	NE [NE, NE)	0.9991	>999.999 (<.001, NE)	0.2770
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	1 (0.6)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.5279
	Female	62	0 (0.0)	NE [NE, NE)	134	2 (1.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.3739

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	0 (0.0)	NE [NE, NE)	240	2 (0.8)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.3694
	Asian	20	0 (0.0)	NE [NE, NE)	46	1 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.5453
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	2 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.3725
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	1 (1.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.5375
Baseline ECOG PS	0-1	146	0 (0.0)	NE [NE, NE)	294	3 (1.0)	NE [NE, NE)	0.9998	>999.999 (<.001, NE)	0.2600
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	0 (0.0)	NE [NE, NE)	285	3 (1.1)	NE [NE, NE)	0.9991	>999.999 (<.001, NE)	0.2772
	No	17	0 (0.0)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	0 (0.0)	NE [NE, NE)	0.9986	NE (NE, NE)	NE
	No	98	0 (0.0)	NE [NE, NE)	209	3 (1.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.2810

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	0 (0.0)	NE [NE, NE)	0.9986	NE (NE, NE)	NE
	No	79	0 (0.0)	NE [NE, NE)	186	3 (1.6)	NE [NE, NE)		>999.999 (<.001, NE)	0.2984
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	0 (0.0)	NE [NE, NE)	0.9986	NE (NE, NE)	NE
	No	98	0 (0.0)	NE [NE, NE)	210	3 (1.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.2747

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	0 (0.0)	NE [NE, NE)	205	0 (0.0)	NE [NE, NE)	0.9991	NE (NE, NE)	NE
	No	43	0 (0.0)	NE [NE, NE)	103	3 (2.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.3229
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	0 (0.0)	NE [NE, NE)	0.9986	NE (NE, NE)	NE
	No	88	0 (0.0)	NE [NE, NE)	179	3 (1.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.2658

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	0 (0.0)	NE [NE, NE)	250	3 (1.2)	NE [NE, NE)	0.9991	>999.999 (<.001, NE)	0.2488
	3	27	0 (0.0)	NE [NE, NE)	58	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Prior proteasome inhibitor exposure per IXRS	Yes	138	0 (0.0)	NE [NE, NE)	276	3 (1.1)	NE [NE, NE)	0.9991	>999.999 (<.001, NE)	0.2652
	No	15	0 (0.0)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	1 (0.8)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.5260
	>= 2	87	0 (0.0)	NE [NE, NE)	177	2 (1.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.3696

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-514-ae-cox-eoi-dar-grd345.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Second primary malignancies: Malignant tumours (SMQ) - Narrow										
Total subjects		153	3 (2.0)	NE [NE, NE)	308	4 (1.3)	NE [NE, NE)		0.431 (0.096, 1.941)	0.2592

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-514-ae-cox-eoi-dar-grd345.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	3 (2.2)	NE [NE, NE)	283	4 (1.4)	NE [NE, NE)	0.9999	0.412 (0.091, 1.854)	0.2328
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	3 (3.3)	NE [NE, NE)	174	2 (1.1)	NE [NE, NE)	0.9928	0.205 (0.034, 1.247)	0.0578
	Female	62	0 (0.0)	NE [NE, NE)	134	2 (1.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.4039

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	3 (2.5)	NE [NE, NE)	240	3 (1.3)	NE [NE, NE)	1.0000	0.322 (0.065, 1.608)	0.1459
	Asian	20	0 (0.0)	NE [NE, NE)	46	1 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.5403
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	1 (4.8)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.5403

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	3 (2.9)	NE [NE, NE)	203	2 (1.0)	NE [NE, NE)		0.240 (0.040, 1.438)	0.0895
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	1 (1.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.5930
Baseline ECOG PS	0-1	146	3 (2.1)	NE [NE, NE)	294	4 (1.4)	NE [NE, NE)	NE	0.449 (0.100, 2.024)	0.2848
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	3 (2.2)	NE [NE, NE)	285	3 (1.1)	NE [NE, NE)	0.9952	0.306 (0.061, 1.535)	0.1283
	No	17	0 (0.0)	NE [NE, NE)	23	1 (4.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.5329
Refractory to Bortezomib or Ixazomib	Yes	55	2 (3.6)	NE [27.5, NE)	99	2 (2.0)	NE [NE, NE)	0.7554	0.369 (0.052, 2.642)	0.3016
	No	98	1 (1.0)	NE [NE, NE)	209	2 (1.0)	NE [NE, NE)		0.638 (0.057, 7.082)	0.7123

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	1 (1.4)	NE [NE, NE)	122	2 (1.6)	NE [NE, NE)	0.6127	0.754 (0.066, 8.587)	0.8198
	No	79	2 (2.5)	NE [NE, NE)	186	2 (1.1)	NE [NE, NE)		0.297 (0.042, 2.126)	0.1995
Refractory to Lenalidomide	Yes	55	1 (1.8)	NE [NE, NE)	98	2 (2.0)	NE [NE, NE)	0.7761	0.628 (0.054, 7.257)	0.7072
	No	98	2 (2.0)	NE [NE, NE)	210	2 (1.0)	NE [NE, NE)		0.337 (0.047, 2.407)	0.2551

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	1 (0.9)	NE [NE, NE)	205	3 (1.5)	NE [NE, NE)	0.2613	1.093 (0.113, 10.596)	0.9390
	No	43	2 (4.7)	NE [27.5, NE)	103	1 (1.0)	NE [NE, NE)		0.144 (0.013, 1.603)	0.0673
Refractory to IMiD	Yes	65	1 (1.5)	NE [NE, NE)	129	2 (1.6)	NE [NE, NE)	0.8440	0.560 (0.048, 6.477)	0.6383
	No	88	2 (2.3)	NE [NE, NE)	179	2 (1.1)	NE [NE, NE)		0.356 (0.050, 2.544)	0.2823

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	3 (2.4)	NE [NE, NE)	250	3 (1.2)	NE [NE, NE)	0.9941	0.356 (0.071, 1.785)	0.1902
	3	27	0 (0.0)	NE [NE, NE)	58	1 (1.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.6911
Prior proteasome inhibitor exposure per IXRS	Yes	138	3 (2.2)	NE [NE, NE)	276	3 (1.1)	NE [NE, NE)	0.9953	0.319 (0.064, 1.596)	0.1428
	No	15	0 (0.0)	NE [NE, NE)	32	1 (3.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.5892

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	1 (1.5)	NE [NE, NE)	131	1 (0.8)	NE [NE, NE)	0.8965	0.429 (0.027, 6.878)	0.5382
	>= 2	87	2 (2.3)	NE [27.5, NE)	177	3 (1.7)	NE [NE, NE)		0.391 (0.064, 2.385)	0.2918

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Tumour lysis syndrome (SMQ) - Narrow										
Total subjects		153	1 (0.7)	NE [NE, NE)	308	4 (1.3)	NE [NE, NE)		1.775 (0.196, 16.059)	0.6046

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	1 (0.7)	NE [NE, NE)	283	4 (1.4)	NE [NE, NE)	0.9999	1.705 (0.189, 15.426)	0.6308
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	1 (1.1)	NE [NE, NE)	174	2 (1.1)	NE [NE, NE)	0.9948	0.815 (0.071, 9.323)	0.8690
	Female	62	0 (0.0)	NE [NE, NE)	134	2 (1.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.3342

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	0 (0.0)	NE [NE, NE)	240	3 (1.3)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.2146
	Asian	20	0 (0.0)	NE [NE, NE)	46	1 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.6949
	Other or Unknown	11	1 (9.1)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.1573
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	1 (1.0)	NE [NE, NE)	203	3 (1.5)	NE [NE, NE)		1.524 (0.159, 14.649)	0.7130
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	1 (1.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.7557
Baseline ECOG PS	0-1	146	1 (0.7)	NE [NE, NE)	294	4 (1.4)	NE [NE, NE)	0.9999	1.784 (0.197, 16.125)	0.6012
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-514-ae-cox-eoi-dar-grd345.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	1 (0.7)	NE [NE, NE)	285	4 (1.4)	NE [NE, NE)	0.9999	1.713 (0.189, 15.480)	0.6279
	No	17	0 (0.0)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	2 (2.0)	NE [NE, NE)	0.9953	>999.999 (<.001, NE)	0.3653
	No	98	1 (1.0)	NE [NE, NE)	209	2 (1.0)	NE [NE, NE)		0.941 (0.085, 10.373)	0.9601

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	2 (1.6)	NE [NE, NE)	0.9945	>999.999 (<.001, NE)	0.2687
	No	79	1 (1.3)	NE [NE, NE)	186	2 (1.1)	NE [NE, NE)		0.707 (0.063, 7.950)	0.7782
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	2 (2.0)	NE [NE, NE)	0.9953	>999.999 (<.001, NE)	0.2869
	No	98	1 (1.0)	NE [NE, NE)	210	2 (1.0)	NE [NE, NE)		0.789 (0.070, 8.841)	0.8472

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	1 (0.9)	NE [NE, NE)	205	3 (1.5)	NE [NE, NE)	0.9959	1.377 (0.141, 13.486)	0.7828
	No	43	0 (0.0)	NE [NE, NE)	103	1 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.5162
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	2 (1.6)	NE [NE, NE)	0.9949	>999.999 (<.001, NE)	0.3135
	No	88	1 (1.1)	NE [NE, NE)	179	2 (1.1)	NE [NE, NE)		0.827 (0.074, 9.273)	0.8771

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	0 (0.0)	NE [NE, NE)	250	2 (0.8)	NE [NE, NE)	0.9940	>999.999 (<.001, NE)	0.3832
	3	27	1 (3.7)	NE [NE, NE)	58	2 (3.4)	NE [NE, NE)		0.941 (0.085, 10.381)	0.9605
Prior proteasome inhibitor exposure per IXRS	Yes	138	1 (0.7)	NE [NE, NE)	276	4 (1.4)	NE [NE, NE)	0.9999	1.791 (0.198, 16.195)	0.5989
	No	15	0 (0.0)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	1 (1.5)	NE [NE, NE)	131	2 (1.5)	NE [NE, NE)	0.9942	1.008 (0.091, 11.113)	0.9950
	>= 2	87	0 (0.0)	NE [NE, NE)	177	2 (1.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.4013

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Viral infection (JMQ)										
Total subjects		153	3 (2.0)	NE [NE, NE)	308	21 (6.8)	NE [NE, NE)		2.876 (0.856, 9.662)	0.0737

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	3 (2.2)	NE [NE, NE)	283	20 (7.1)	NE [NE, NE)	0.9918	2.593 (0.769, 8.747)	0.1110
	> 75	18	0 (0.0)	NE [NE, NE)	25	1 (4.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.3961
Sex	Male	91	1 (1.1)	NE [NE, NE)	174	12 (6.9)	NE [NE, NE)	0.4258	4.985 (0.647, 38.440)	0.0871
	Female	62	2 (3.2)	NE [NE, NE)	134	9 (6.7)	NE [NE, NE)		1.789 (0.386, 8.301)	0.4511

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	3 (2.5)	NE [NE, NE)	240	16 (6.7)	NE [NE, NE)	0.9999	2.266 (0.659, 7.795)	0.1821
	Asian	20	0 (0.0)	NE [NE, NE)	46	4 (8.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.2618
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	1 (4.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.5727
Region	North America	12	1 (8.3)	NE [16.2, NE)	21	3 (14.3)	NE [NE, NE)	0.8550	0.877 (0.081, 9.496)	0.9142

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	2 (2.0)	NE [NE, NE)	203	11 (5.4)	NE [NE, NE)		2.346 (0.519, 10.597)	0.2535
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	7 (8.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.1087
Baseline ECOG PS	0-1	146	3 (2.1)	NE [NE, NE)	294	21 (7.1)	NE [NE, NE)	0.9998	2.957 (0.880, 9.929)	0.0657
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	3 (2.2)	NE [NE, NE)	285	21 (7.4)	NE [NE, NE)	0.9997	2.768 (0.824, 9.300)	0.0858
	No	17	0 (0.0)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	7 (7.1)	NE [NE, NE)	0.9906	>999.999 (<.001, NE)	0.0744
	No	98	3 (3.1)	NE [NE, NE)	209	14 (6.7)	NE [NE, NE)		1.821 (0.522, 6.351)	0.3401

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	3 (4.1)	NE [NE, NE)	122	7 (5.7)	NE [NE, NE)	0.9874	1.017 (0.260, 3.980)	0.9806
	No	79	0 (0.0)	NE [NE, NE)	186	14 (7.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.0213
Refractory to Lenalidomide	Yes	55	3 (5.5)	NE [NE, NE)	98	6 (6.1)	NE [NE, NE)	0.9860	0.742 (0.182, 3.024)	0.6763
	No	98	0 (0.0)	NE [NE, NE)	210	15 (7.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.0124

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	3 (2.7)	NE [NE, NE)	205	16 (7.8)	NE [NE, NE)	0.9914	2.325 (0.674, 8.012)	0.1691
	No	43	0 (0.0)	NE [NE, NE)	103	5 (4.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.1970
Refractory to IMiD	Yes	65	3 (4.6)	NE [NE, NE)	129	9 (7.0)	NE [NE, NE)	0.9868	1.091 (0.292, 4.082)	0.8966
	No	88	0 (0.0)	NE [NE, NE)	179	12 (6.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.0220

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-514-ae-cox-eoi-dar-grd345.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	3 (2.4)	NE [NE, NE)	250	18 (7.2)	NE [NE, NE)	0.9916	2.622 (0.771, 8.922)	0.1091
	3	27	0 (0.0)	NE [NE, NE)	58	3 (5.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.4109
Prior proteasome inhibitor exposure per IXRS	Yes	138	3 (2.2)	NE [NE, NE)	276	21 (7.6)	NE [NE, NE)	0.9997	2.895 (0.861, 9.726)	0.0719
	No	15	0 (0.0)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-514-ae-cox-eoi-dar-grd345.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.514. Cox Regression of Grade ≥3 Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	9 (6.9)	NE [NE, NE)	0.9889	>999.999 (<.001, NE)	0.0521
	>= 2	87	3 (3.4)	NE [NE, NE)	177	12 (6.8)	NE [NE, NE)		1.615 (0.454, 5.744)	0.4553

Includes subjects with at least one CTCAE Grade ≥3 adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-514-ae-cox-eoi-dar-grd345.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Daratumumab-related infusion reaction (AMQ) - Narrow (event on same date or next date of any Daratumumab dosing)										
Total subjects		153	0 (0.0)	NE [NE, NE)	308	4 (1.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.1667

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-515-sae-cox-eoi-dar.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	0 (0.0)	NE [NE, NE)	283	4 (1.4)	NE [NE, NE)	0.9989	>999.999 (<.001, NE)	0.1741
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	2 (1.1)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.3090
	Female	62	0 (0.0)	NE [NE, NE)	134	2 (1.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.3555

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-515-sae-cox-eoi-dar.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	0 (0.0)	NE [NE, NE)	240	2 (0.8)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.3271
	Asian	20	0 (0.0)	NE [NE, NE)	46	1 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.5097
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	1 (4.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.5224
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Output: t14-06-001-515-sae-cox-eoi-dar.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	2 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.3322
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	2 (2.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.3355
Baseline ECOG PS	0-1	146	0 (0.0)	NE [NE, NE)	294	3 (1.0)	NE [NE, NE)	0.9997	>999.999 (<.001, NE)	0.2293
	2	7	0 (0.0)	NE [NE, NE)	13	1 (7.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.5002

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-515-sae-cox-eoi-dar.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	0 (0.0)	NE [NE, NE)	285	4 (1.4)	NE [NE, NE)	0.9989	>999.999 (<.001, NE)	0.1753
	No	17	0 (0.0)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	1 (1.0)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.4637
	No	98	0 (0.0)	NE [NE, NE)	209	3 (1.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.2472

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-515-sae-cox-eoi-dar.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	2 (1.6)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.2758
	No	79	0 (0.0)	NE [NE, NE)	186	2 (1.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.3681
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	1 (1.0)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.4637
	No	98	0 (0.0)	NE [NE, NE)	210	3 (1.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.2453

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-515-sae-cox-eoi-dar.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	0 (0.0)	NE [NE, NE)	205	3 (1.5)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.2074
	No	43	0 (0.0)	NE [NE, NE)	103	1 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.5338
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	1 (0.8)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.4884
	No	88	0 (0.0)	NE [NE, NE)	179	3 (1.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.2318

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Output: t14-06-001-515-sae-cox-eoi-dar.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	0 (0.0)	NE [NE, NE)	250	4 (1.6)	NE [NE, NE)	0.9987	>999.999 (<.001, NE)	0.1599
	3	27	0 (0.0)	NE [NE, NE)	58	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Prior proteasome inhibitor exposure per IXRS	Yes	138	0 (0.0)	NE [NE, NE)	276	4 (1.4)	NE [NE, NE)	0.9989	>999.999 (<.001, NE)	0.1646
	No	15	0 (0.0)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	2 (1.5)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.3319
	>= 2	87	0 (0.0)	NE [NE, NE)	177	2 (1.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.3260

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Daratumumab-related infusion reaction (AMQ) - Narrow (event on same date or next date of first Daratumumab dosing)										
Total subjects		153	0 (0.0)	NE [NE, NE)	308	2 (0.6)	NE [NE, NE)		>999.999 (<.001, NE)	0.3184

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-515-sae-cox-eoi-dar.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	0 (0.0)	NE [NE, NE)	283	2 (0.7)	NE [NE, NE)	0.9992	>999.999 (<.001, NE)	0.3281
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	1 (0.6)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.4696
	Female	62	0 (0.0)	NE [NE, NE)	134	1 (0.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.4964

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-515-sae-cox-eoi-dar.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	0 (0.0)	NE [NE, NE)	240	1 (0.4)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.4759
	Asian	20	0 (0.0)	NE [NE, NE)	46	1 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.5097
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-515-sae-cox-eoi-dar.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	1 (0.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.4784
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	1 (1.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.4956
Baseline ECOG PS	0-1	146	0 (0.0)	NE [NE, NE)	294	2 (0.7)	NE [NE, NE)	0.9995	>999.999 (<.001, NE)	0.3184
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-515-sae-cox-eoi-dar.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	0 (0.0)	NE [NE, NE)	285	2 (0.7)	NE [NE, NE)	0.9992	>999.999 (<.001, NE)	0.3280
	No	17	0 (0.0)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	0 (0.0)	NE [NE, NE)	0.9988	NE (NE, NE)	NE
	No	98	0 (0.0)	NE [NE, NE)	209	2 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.3321

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-515-sae-cox-eoi-dar.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	1 (0.8)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.4361
	No	79	0 (0.0)	NE [NE, NE)	186	1 (0.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.5146
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	0 (0.0)	NE [NE, NE)	0.9988	NE (NE, NE)	NE
	No	98	0 (0.0)	NE [NE, NE)	210	2 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.3332

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-515-sae-cox-eoi-dar.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	0 (0.0)	NE [NE, NE)	205	2 (1.0)	NE [NE, NE)	0.9989	>999.999 (<.001, NE)	0.2995
	No	43	0 (0.0)	NE [NE, NE)	103	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	0 (0.0)	NE [NE, NE)	0.9989	NE (NE, NE)	NE
	No	88	0 (0.0)	NE [NE, NE)	179	2 (1.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.3205

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
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Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	0 (0.0)	NE [NE, NE)	250	2 (0.8)	NE [NE, NE)	0.9990	>999.999 (<.001, NE)	0.3147
	3	27	0 (0.0)	NE [NE, NE)	58	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Prior proteasome inhibitor exposure per IXRS	Yes	138	0 (0.0)	NE [NE, NE)	276	2 (0.7)	NE [NE, NE)	0.9992	>999.999 (<.001, NE)	0.3167
	No	15	0 (0.0)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-515-sae-cox-eoi-dar.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	1 (0.8)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.4778
	>= 2	87	0 (0.0)	NE [NE, NE)	177	1 (0.6)	NE [NE, NE)		>999.999 (<.001, NE)	0.4832

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-515-sae-cox-eoi-dar.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Haemorrhage terms (excl laboratory terms) (SMQ) - Narrow										
Total subjects		153	5 (3.3)	NE [NE, NE)	308	7 (2.3)	NE [NE, NE)		0.586 (0.185, 1.860)	0.3590

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
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Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	4 (3.0)	NE [NE, NE)	283	7 (2.5)	NE [NE, NE)	0.9917	0.699 (0.203, 2.407)	0.5684
	> 75	18	1 (5.6)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.2305
Sex	Male	91	2 (2.2)	NE [NE, NE)	174	5 (2.9)	NE [NE, NE)	0.2484	0.991 (0.189, 5.193)	0.9919
	Female	62	3 (4.8)	NE [NE, NE)	134	2 (1.5)	NE [NE, NE)		0.281 (0.047, 1.682)	0.1374

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	5 (4.1)	NE [NE, NE)	240	5 (2.1)	NE [NE, NE)	0.9999	0.418 (0.120, 1.456)	0.1577
	Asian	20	0 (0.0)	NE [NE, NE)	46	1 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.5097
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	1 (4.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.4795
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	0.9791	NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	4 (3.9)	NE [NE, NE)	203	5 (2.5)	NE [NE, NE)		0.548 (0.147, 2.045)	0.3637
	Asia Pacific	39	1 (2.6)	NE [21.9, NE)	84	2 (2.4)	NE [NE, NE)		0.703 (0.061, 8.137)	0.7771
Baseline ECOG PS	0-1	146	5 (3.4)	NE [NE, NE)	294	6 (2.0)	NE [NE, NE)	0.9928	0.502 (0.152, 1.658)	0.2493
	2	7	0 (0.0)	NE [NE, NE)	13	1 (7.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.4631

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-515-sae-cox-eoi-dar.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	2 (1.5)	NE [NE, NE)	285	7 (2.5)	NE [NE, NE)	0.9932	1.453 (0.300, 7.028)	0.6403
	No	17	3 (17.6)	NE [21.9, NE)	23	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0258
Refractory to Bortezomib or Ixazomib	Yes	55	1 (1.8)	NE [NE, NE)	99	4 (4.0)	NE [NE, NE)	0.1636	2.136 (0.239, 19.116)	0.4872
	No	98	4 (4.1)	NE [NE, NE)	209	3 (1.4)	NE [NE, NE)		0.271 (0.060, 1.224)	0.0695

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-515-sae-cox-eoi-dar.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	4 (5.4)	NE [NE, NE)	122	3 (2.5)	NE [NE, NE)	0.2992	0.366 (0.080, 1.662)	0.1753
	No	79	1 (1.3)	NE [NE, NE)	186	4 (2.2)	NE [NE, NE)		1.463 (0.162, 13.182)	0.7329
Refractory to Lenalidomide	Yes	55	2 (3.6)	NE [21.9, NE)	98	3 (3.1)	NE [NE, NE)	0.8790	0.639 (0.103, 3.962)	0.6278
	No	98	3 (3.1)	NE [NE, NE)	210	4 (1.9)	NE [NE, NE)		0.551 (0.123, 2.474)	0.4298

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	4 (3.6)	NE [NE, NE)	205	4 (2.0)	NE [NE, NE)	0.4981	0.458 (0.114, 1.850)	0.2613
	No	43	1 (2.3)	NE [NE, NE)	103	3 (2.9)	NE [NE, NE)		1.031 (0.106, 9.999)	0.9790
Refractory to IMiD	Yes	65	2 (3.1)	NE [21.9, NE)	129	3 (2.3)	NE [NE, NE)	0.9780	0.565 (0.091, 3.502)	0.5347
	No	88	3 (3.4)	NE [NE, NE)	179	4 (2.2)	NE [NE, NE)		0.579 (0.129, 2.600)	0.4701

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	4 (3.2)	NE [NE, NE)	250	5 (2.0)	NE [NE, NE)	0.8797	0.526 (0.140, 1.979)	0.3344
	3	27	1 (3.7)	NE [NE, NE)	58	2 (3.4)	NE [NE, NE)		0.742 (0.067, 8.231)	0.8070
Prior proteasome inhibitor exposure per IXRS	Yes	138	2 (1.4)	NE [NE, NE)	276	7 (2.5)	NE [NE, NE)	0.9927	1.523 (0.315, 7.367)	0.5983
	No	15	3 (20.0)	NE [21.9, NE)	32	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0056

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	2 (3.0)	NE [NE, NE)	131	3 (2.3)	NE [NE, NE)	0.8945	0.665 (0.110, 4.018)	0.6542
	>= 2	87	3 (3.4)	NE [NE, NE)	177	4 (2.3)	NE [NE, NE)		0.536 (0.119, 2.420)	0.4104

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Opportunistic infections (JMQ)										
Total subjects		153	0 (0.0)	NE [NE, NE)	308	3 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.2523

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	0 (0.0)	NE [NE, NE)	283	2 (0.7)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.3614
	> 75	18	0 (0.0)	NE [NE, NE)	25	1 (4.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.4193
Sex	Male	91	0 (0.0)	NE [NE, NE)	174	1 (0.6)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.4781
	Female	62	0 (0.0)	NE [NE, NE)	134	2 (1.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.3776

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	0 (0.0)	NE [NE, NE)	240	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE
	Asian	20	0 (0.0)	NE [NE, NE)	46	3 (6.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.2793
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	0 (0.0)	NE [NE, NE)	203	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	3 (3.6)	NE [NE, NE)		>999.999 (<.001, NE)	0.2728
Baseline ECOG PS	0-1	146	0 (0.0)	NE [NE, NE)	294	3 (1.0)	NE [NE, NE)	0.9996	>999.999 (<.001, NE)	0.2462
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	0 (0.0)	NE [NE, NE)	285	3 (1.1)	NE [NE, NE)	0.9991	>999.999 (<.001, NE)	0.2598
	No	17	0 (0.0)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	2 (2.0)	NE [NE, NE)	0.9998	>999.999 (<.001, NE)	0.3067
	No	98	0 (0.0)	NE [NE, NE)	209	1 (0.5)	NE [NE, NE)		>999.999 (<.001, NE)	0.5407

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	1 (0.8)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.4664
	No	79	0 (0.0)	NE [NE, NE)	186	2 (1.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.3872
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	1 (1.0)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.4843
	No	98	0 (0.0)	NE [NE, NE)	210	2 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.3679

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	0 (0.0)	NE [NE, NE)	205	2 (1.0)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.3339
	No	43	0 (0.0)	NE [NE, NE)	103	1 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.5551
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	2 (1.6)	NE [NE, NE)	0.9999	>999.999 (<.001, NE)	0.3486
	No	88	0 (0.0)	NE [NE, NE)	179	1 (0.6)	NE [NE, NE)		>999.999 (<.001, NE)	0.5178

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-515-sae-cox-eoi-dar.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	0 (0.0)	NE [NE, NE)	250	3 (1.2)	NE [NE, NE)	0.9990	>999.999 (<.001, NE)	0.2402
	3	27	0 (0.0)	NE [NE, NE)	58	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Prior proteasome inhibitor exposure per IXRS	Yes	138	0 (0.0)	NE [NE, NE)	276	3 (1.1)	NE [NE, NE)	0.9991	>999.999 (<.001, NE)	0.2467
	No	15	0 (0.0)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-515-sae-cox-eoi-dar.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	0 (0.0)	NE [NE, NE)	0.9986	NE (NE, NE)	NE
	>= 2	87	0 (0.0)	NE [NE, NE)	177	3 (1.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.2558

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-515-sae-cox-eoi-dar.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Second primary malignancies: Malignant tumours (SMQ) - Narrow										
Total subjects		153	1 (0.7)	NE [NE, NE)	308	4 (1.3)	NE [NE, NE)		1.192 (0.132, 10.741)	0.8752

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-515-sae-cox-eoi-dar.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	1 (0.7)	NE [NE, NE)	283	3 (1.1)	NE [NE, NE)	0.9947	0.877 (0.090, 8.496)	0.9095
	> 75	18	0 (0.0)	NE [NE, NE)	25	1 (4.0)	NE [22.6, NE)		>999.999 (<.001, NE)	0.4386
Sex	Male	91	1 (1.1)	NE [NE, NE)	174	3 (1.7)	NE [NE, NE)	0.9956	0.770 (0.080, 7.456)	0.8213
	Female	62	0 (0.0)	NE [NE, NE)	134	1 (0.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.5332

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-515-sae-cox-eoi-dar.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	1 (0.8)	NE [NE, NE)	240	3 (1.3)	NE [NE, NE)	1.0000	0.866 (0.090, 8.355)	0.9008
	Asian	20	0 (0.0)	NE [NE, NE)	46	1 (2.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.5403
	Other or Unknown	11	0 (0.0)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Region	North America	12	0 (0.0)	NE [NE, NE)	21	2 (9.5)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.5061

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Output: t14-06-001-515-sae-cox-eoi-dar.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	1 (1.0)	NE [NE, NE)	203	1 (0.5)	NE [NE, NE)		0.322 (0.020, 5.161)	0.3989
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	1 (1.2)	NE [NE, NE)		>999.999 (<.001, NE)	0.5930
Baseline ECOG PS	0-1	146	1 (0.7)	NE [NE, NE)	294	4 (1.4)	NE [NE, NE)	NE	1.244 (0.138, 11.209)	0.8452
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Output: t14-06-001-515-sae-cox-eoi-dar.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	1 (0.7)	NE [NE, NE)	285	3 (1.1)	NE [NE, NE)	0.9962	0.825 (0.085, 8.013)	0.8683
	No	17	0 (0.0)	NE [NE, NE)	23	1 (4.3)	NE [NE, NE)		>999.999 (<.001, NE)	0.5329
Refractory to Bortezomib or Ixazomib	Yes	55	1 (1.8)	NE [27.5, NE)	99	2 (2.0)	NE [NE, NE)	0.9952	0.683 (0.062, 7.570)	0.7547
	No	98	0 (0.0)	NE [NE, NE)	209	2 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.4469

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	3 (2.5)	NE [NE, NE)	0.9958	>999.999 (<.001, NE)	0.3345
	No	79	1 (1.3)	NE [NE, NE)	186	1 (0.5)	NE [NE, NE)		0.268 (0.017, 4.340)	0.3206
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	3 (3.1)	NE [NE, NE)	0.9950	>999.999 (<.001, NE)	0.3885
	No	98	1 (1.0)	NE [NE, NE)	210	1 (0.5)	NE [NE, NE)		0.310 (0.019, 5.008)	0.3834

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	0 (0.0)	NE [NE, NE)	205	4 (2.0)	NE [NE, NE)	0.9949	>999.999 (<.001, NE)	0.2559
	No	43	1 (2.3)	NE [27.5, NE)	103	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.0374
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	3 (2.3)	NE [NE, NE)	0.9943	>999.999 (<.001, NE)	0.4119
	No	88	1 (1.1)	NE [NE, NE)	179	1 (0.6)	NE [NE, NE)		0.326 (0.020, 5.268)	0.4060

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	1 (0.8)	NE [NE, NE)	250	2 (0.8)	NE [NE, NE)	0.9959	0.677 (0.060, 7.588)	0.7501
	3	27	0 (0.0)	NE [NE, NE)	58	2 (3.4)	NE [NE, NE)		>999.999 (<.001, NE)	0.5419
Prior proteasome inhibitor exposure per IXRS	Yes	138	1 (0.7)	NE [NE, NE)	276	3 (1.1)	NE [NE, NE)	0.9960	0.855 (0.088, 8.305)	0.8928
	No	15	0 (0.0)	NE [NE, NE)	32	1 (3.1)	NE [NE, NE)		>999.999 (<.001, NE)	0.5892

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	0 (0.0)	NE [NE, NE)	131	1 (0.8)	NE [NE, NE)	0.9954	>999.999 (<.001, NE)	0.5292
	>= 2	87	1 (1.1)	NE [27.5, NE)	177	3 (1.7)	NE [NE, NE)		0.712 (0.073, 6.939)	0.7690

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Tumour lysis syndrome (SMQ) - Narrow										
Total subjects		153	1 (0.7)	NE [NE, NE)	308	2 (0.6)	NE [NE, NE)		0.998 (0.090, 11.004)	0.9986

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	1 (0.7)	NE [NE, NE)	283	2 (0.7)	NE [NE, NE)	1.0000	0.958 (0.087, 10.566)	0.9724
	> 75	18	0 (0.0)	NE [NE, NE)	25	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Sex	Male	91	1 (1.1)	NE [NE, NE)	174	1 (0.6)	NE [NE, NE)	0.9958	0.523 (0.033, 8.364)	0.6411
	Female	62	0 (0.0)	NE [NE, NE)	134	1 (0.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.4964

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-515-sae-cox-eoi-dar.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	0 (0.0)	NE [NE, NE)	240	2 (0.8)	NE [NE, NE)	1.0000	>999.999 (<.001, NE)	0.3118
	Asian	20	0 (0.0)	NE [NE, NE)	46	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
	Other or Unknown	11	1 (9.1)	NE [NE, NE)	22	0 (0.0)	NE [NE, NE)		<.001 (<.001, NE)	0.1573
Region	North America	12	0 (0.0)	NE [NE, NE)	21	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	1 (1.0)	NE [NE, NE)	203	2 (1.0)	NE [NE, NE)		1.012 (0.092, 11.156)	0.9925
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Baseline ECOG PS	0-1	146	1 (0.7)	NE [NE, NE)	294	2 (0.7)	NE [NE, NE)	1.0000	0.998 (0.090, 11.003)	0.9985
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
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Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	1 (0.7)	NE [NE, NE)	285	2 (0.7)	NE [NE, NE)	1.0000	0.958 (0.087, 10.569)	0.9726
	No	17	0 (0.0)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to Bortezomib or Ixazomib	Yes	55	0 (0.0)	NE [NE, NE)	99	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE
	No	98	1 (1.0)	NE [NE, NE)	209	2 (1.0)	NE [NE, NE)		0.941 (0.085, 10.373)	0.9601

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	0 (0.0)	NE [NE, NE)	122	1 (0.8)	NE [NE, NE)	0.9955	>999.999 (<.001, NE)	0.4361
	No	79	1 (1.3)	NE [NE, NE)	186	1 (0.5)	NE [NE, NE)		0.424 (0.027, 6.785)	0.5320
Refractory to Lenalidomide	Yes	55	0 (0.0)	NE [NE, NE)	98	1 (1.0)	NE [NE, NE)	0.9960	>999.999 (<.001, NE)	0.4538
	No	98	1 (1.0)	NE [NE, NE)	210	1 (0.5)	NE [NE, NE)		0.467 (0.029, 7.459)	0.5807

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	1 (0.9)	NE [NE, NE)	205	1 (0.5)	NE [NE, NE)	0.9964	0.539 (0.034, 8.621)	0.6573
	No	43	0 (0.0)	NE [NE, NE)	103	1 (1.0)	NE [NE, NE)		>999.999 (<.001, NE)	0.5162
Refractory to IMiD	Yes	65	0 (0.0)	NE [NE, NE)	129	1 (0.8)	NE [NE, NE)	0.9957	>999.999 (<.001, NE)	0.4778
	No	88	1 (1.1)	NE [NE, NE)	179	1 (0.6)	NE [NE, NE)		0.492 (0.031, 7.859)	0.6081

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	0 (0.0)	NE [NE, NE)	250	0 (0.0)	NE [NE, NE)	1.0000	NE (NE, NE)	NE
	3	27	1 (3.7)	NE [NE, NE)	58	2 (3.4)	NE [NE, NE)		0.941 (0.085, 10.381)	0.9605
Prior proteasome inhibitor exposure per IXRS	Yes	138	1 (0.7)	NE [NE, NE)	276	2 (0.7)	NE [NE, NE)	1.0000	1.005 (0.091, 11.082)	0.9968
	No	15	0 (0.0)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	1 (1.5)	NE [NE, NE)	131	2 (1.5)	NE [NE, NE)	1.0000	1.008 (0.091, 11.113)	0.9950
	>= 2	87	0 (0.0)	NE [NE, NE)	177	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
EOI Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Viral infection (JMQ)										
Total subjects		153	4 (2.6)	NE [NE, NE)	308	19 (6.2)	NE [NE, NE)		1.952 (0.662, 5.755)	0.2172

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Age - at baseline (years)	<= 75	135	3 (2.2)	NE [NE, NE)	283	18 (6.4)	NE [NE, NE)	0.3849	2.377 (0.698, 8.093)	0.1533
	> 75	18	1 (5.6)	NE [21.5, NE)	25	1 (4.0)	NE [NE, NE)		0.627 (0.039, 10.086)	0.7394
Sex	Male	91	3 (3.3)	NE [NE, NE)	174	10 (5.7)	NE [NE, NE)	0.4469	1.356 (0.371, 4.959)	0.6438
	Female	62	1 (1.6)	NE [NE, NE)	134	9 (6.7)	NE [NE, NE)		3.613 (0.457, 28.572)	0.1928

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	White	122	3 (2.5)	NE [NE, NE)	240	12 (5.0)	NE [NE, NE)	0.8525	1.661 (0.467, 5.905)	0.4285
	Asian	20	0 (0.0)	NE [NE, NE)	46	5 (10.9)	NE [NE, NE)		>999.999 (<.001, NE)	0.1958
	Other or Unknown	11	1 (9.1)	NE [2.1, NE)	22	2 (9.1)	NE [NE, NE)		0.775 (0.070, 8.583)	0.8350
Region	North America	12	1 (8.3)	NE [16.2, NE)	21	4 (19.0)	NE [NE, NE)	0.9198	1.463 (0.152, 14.058)	0.7402

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
	Europe	102	3 (2.9)	NE [NE, NE)	203	6 (3.0)	NE [NE, NE)		0.876 (0.219, 3.512)	0.8520
	Asia Pacific	39	0 (0.0)	NE [NE, NE)	84	9 (10.7)	NE [NE, NE)		>999.999 (<.001, NE)	0.0689
Baseline ECOG PS	0-1	146	4 (2.7)	NE [NE, NE)	294	19 (6.5)	NE [NE, NE)	0.9999	2.003 (0.680, 5.905)	0.1989
	2	7	0 (0.0)	NE [NE, NE)	13	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	4 (2.9)	NE [NE, NE)	285	19 (6.7)	NE [NE, NE)	0.9998	1.878 (0.637, 5.537)	0.2459
	No	17	0 (0.0)	NE [NE, NE)	23	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE
Refractory to Bortezomib or Ixazomib	Yes	55	1 (1.8)	NE [NE, NE)	99	7 (7.1)	NE [NE, NE)	0.5372	3.362 (0.412, 27.443)	0.2297
	No	98	3 (3.1)	NE [NE, NE)	209	12 (5.7)	NE [NE, NE)		1.520 (0.427, 5.405)	0.5146

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-515-sae-cox-eoi-dar.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	3 (4.1)	NE [NE, NE)	122	8 (6.6)	NE [NE, NE)	0.3374	1.235 (0.324, 4.706)	0.7562
	No	79	1 (1.3)	NE [NE, NE)	186	11 (5.9)	NE [NE, NE)		4.077 (0.525, 31.628)	0.1450
Refractory to Lenalidomide	Yes	55	2 (3.6)	NE [NE, NE)	98	7 (7.1)	NE [NE, NE)	0.6387	1.389 (0.284, 6.796)	0.6839
	No	98	2 (2.0)	NE [NE, NE)	210	12 (5.7)	NE [NE, NE)		2.460 (0.550, 11.011)	0.2234

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-515-sae-cox-eoi-dar.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd No. of Events (%)	Kd Median (months) (95%CI)	KdD (N = 308) N	KdD No. of Events (%)	KdD Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	3 (2.7)	NE [NE, NE)	205	16 (7.8)	NE [NE, NE)	0.5677	2.334 (0.677, 8.045)	0.1669
	No	43	1 (2.3)	NE [NE, NE)	103	3 (2.9)	NE [NE, NE)		1.095 (0.113, 10.575)	0.9373
Refractory to IMiD	Yes	65	3 (4.6)	NE [NE, NE)	129	11 (8.5)	NE [NE, NE)	0.4590	1.435 (0.397, 5.192)	0.5797
	No	88	1 (1.1)	NE [NE, NE)	179	8 (4.5)	NE [NE, NE)		3.397 (0.424, 27.203)	0.2205

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-515-sae-cox-eoi-dar.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	3 (2.4)	NE [NE, NE)	250	15 (6.0)	NE [NE, NE)	0.6834	2.132 (0.615, 7.394)	0.2219
	3	27	1 (3.7)	NE [NE, NE)	58	4 (6.9)	NE [NE, NE)		1.107 (0.122, 10.075)	0.9279
Prior proteasome inhibitor exposure per IXRS	Yes	138	4 (2.9)	NE [NE, NE)	276	19 (6.9)	NE [NE, NE)	0.9998	1.963 (0.665, 5.789)	0.2133
	No	15	0 (0.0)	NE [NE, NE)	32	0 (0.0)	NE [NE, NE)		NE (NE, NE)	NE

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-515-sae-cox-eoi-dar.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.515. Cox Regression of Serious Adverse Events of Interest for Daratumumab <Safety Population>

EOI Characteristics	Subgroup	Kd (N = 153) N	Kd (N = 153) No. of Events (%)	Kd (N = 153) Median (months) (95%CI)	KdD (N = 308) N	KdD (N = 308) No. of Events (%)	KdD (N = 308) Median (months) (95%CI)	p-value[a] Interaction with Treatment	Hazard Ratio (KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	1 (1.5)	NE [NE, NE)	131	9 (6.9)	NE [NE, NE)	0.3976	3.794 (0.479, 30.025)	0.1743
	>= 2	87	3 (3.4)	NE [NE, NE)	177	10 (5.6)	NE [NE, NE)		1.366 (0.374, 4.988)	0.6358

Includes subjects with at least one serious adverse event of interest for Daratumumab. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-eoi-cfz.sas
Output: t14-06-001-515-sae-cox-eoi-dar.rtf (Date Generated: 27AUG2020:00:31) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.516. Cox Regression of Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	148 (96.7)	0.5 [0.3, 0.5)	308	307 (99.7)	0.3 [0.2, 0.3)		1.420 (1.165, 1.729)	0.0007
Age - at baseline (years)	<= 75	135	130 (96.3)	0.5 [0.3, 0.5)	283	283 (100.0)	0.3 [0.2, 0.3)	0.1871	1.475 (1.197, 1.819)	0.0004
	> 75	18	18 (100.0)	0.4 [0.1, 0.9)	25	24 (96.0)	0.3 [0.1, 1.0)		0.897 (0.480, 1.678)	0.7035

Includes subjects with at least one adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-sub.sas
Output: t14-06-001-516-ae-cox-excl-dpe.rtf (Date Generated: 27AUG2020:00:35) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.516. Cox Regression of Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Sex	Male	91	88 (96.7)	0.5 [0.4, 1.0)	174	174 (100.0)	0.3 [0.2, 0.4)	0.2038	1.596 (1.232, 2.068)	0.0004
	Female	62	60 (96.8)	0.3 [0.2, 0.5)	134	133 (99.3)	0.2 [0.1, 0.3)		1.230 (0.905, 1.673)	0.2580
Race	White	122	117 (95.9)	0.5 [0.4, 0.7)	240	239 (99.6)	0.3 [0.3, 0.4)	0.4597	1.385 (1.108, 1.730)	0.0051

Includes subjects with at least one adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.516. Cox Regression of Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	Asian	20	20 (100.0)	0.2 [0.1, 0.4)	46	46 (100.0)	0.0 [0.0, 0.1)		2.387 (1.351, 4.219)	0.0023
	Other or Unknown	11	11 (100.0)	0.3 [0.0, 1.2)	22	22 (100.0)	0.1 [0.0, 0.4)		1.653 (0.747, 3.660)	0.2206
Region	North America	12	12 (100.0)	0.2 [0.1, 0.4)	21	21 (100.0)	0.0 [0.0, 0.1)	0.2998	2.323 (1.102, 4.899)	0.0325

Includes subjects with at least one adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.516. Cox Regression of Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Region	Europe	102	97 (95.1)	0.5 [0.4, 0.8)	203	202 (99.5)	0.4 [0.3, 0.5)		1.361 (1.066, 1.738)	0.0142
	Asia Pacific	39	39 (100.0)	0.3 [0.1, 0.5)	84	84 (100.0)	0.1 [0.0, 0.1)		1.823 (1.235, 2.691)	0.0031
Baseline ECOG PS	0-1	146	142 (97.3)	0.5 [0.3, 0.5)	294	293 (99.7)	0.3 [0.2, 0.3)	0.8030	1.425 (1.164, 1.743)	0.0008

Includes subjects with at least one adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.516. Cox Regression of Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Baseline ECOG PS	2	7	6 (85.7)	0.2 [0.0, 0.5)	13	13 (100.0)	0.1 [0.0, 0.7)		1.111 (0.414, 2.978)	0.8758
Prior Bortezomib or Ixazomib exposure	Yes	136	133 (97.8)	0.4 [0.3, 0.5)	285	284 (99.6)	0.3 [0.2, 0.3)	0.2756	1.363 (1.108, 1.677)	0.0046
	No	17	15 (88.2)	0.5 [0.2, 1.4)	23	23 (100.0)	0.1 [0.0, 0.7)		1.532 (0.796, 2.948)	0.2423

Includes subjects with at least one adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.516. Cox Regression of Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Refractory to Bortezomib or Ixazomib	Yes	55	53 (96.4)	0.5 [0.3, 1.3)	99	99 (100.0)	0.3 [0.2, 0.4)	0.5168	1.518 (1.083, 2.129)	0.0159
	No	98	95 (96.9)	0.4 [0.3, 0.5)	209	208 (99.5)	0.2 [0.1, 0.3)		1.327 (1.039, 1.694)	0.0317
Prior Lenalidomide exposure	Yes	74	70 (94.6)	0.3 [0.2, 0.5)	122	122 (100.0)	0.2 [0.1, 0.3)	0.2170	1.608 (1.195, 2.164)	0.0022

Includes subjects with at least one adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.516. Cox Regression of Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	No	79	78 (98.7)	0.5 [0.4, 0.7)	186	185 (99.5)	0.3 [0.2, 0.4)		1.323 (1.014, 1.727)	0.0494
Refractory to Lenalidomide	Yes	55	53 (96.4)	0.3 [0.2, 0.5)	98	98 (100.0)	0.2 [0.1, 0.3)	0.9250	1.379 (0.983, 1.934)	0.0760
	No	98	95 (96.9)	0.5 [0.3, 0.6)	210	209 (99.5)	0.3 [0.2, 0.3)		1.430 (1.120, 1.827)	0.0053

Includes subjects with at least one adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.516. Cox Regression of Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	106 (96.4)	0.3 [0.3, 0.5)	205	205 (100.0)	0.2 [0.1, 0.3)	0.7496	1.457 (1.150, 1.846)	0.0026
	No	43	42 (97.7)	0.7 [0.5, 1.3)	103	102 (99.0)	0.3 [0.2, 0.5)		1.388 (0.966, 1.993)	0.0827
Refractory to IMiD	Yes	65	63 (96.9)	0.3 [0.2, 0.5)	129	129 (100.0)	0.2 [0.1, 0.3)	0.9148	1.399 (1.031, 1.898)	0.0371

Includes subjects with at least one adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-sub.sas
Output: t14-06-001-516-ae-cox-excl-dpe.rtf (Date Generated: 27AUG2020:00:35) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.516. Cox Regression of Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Refractory to IMiD	No	88	85 (96.6)	0.5 [0.4, 0.7)	179	178 (99.4)	0.3 [0.1, 0.4)		1.422 (1.097, 1.843)	0.0098
ISS stage per IXRS	1 or 2	126	121 (96.0)	0.5 [0.3, 0.6)	250	249 (99.6)	0.3 [0.1, 0.3)	0.2631	1.480 (1.189, 1.842)	0.0007
	3	27	27 (100.0)	0.3 [0.0, 0.5)	58	58 (100.0)	0.3 [0.1, 0.3)		1.140 (0.719, 1.808)	0.5492

Includes subjects with at least one adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.516. Cox Regression of Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior proteasome inhibitor exposure per IXRS	Yes	138	134 (97.1)	0.5 [0.3, 0.5)	276	276 (100.0)	0.3 [0.2, 0.3)	0.8878	1.431 (1.162, 1.761)	0.0010
	No	15	14 (93.3)	0.5 [0.1, 1.0)	32	31 (96.9)	0.2 [0.0, 0.8)		1.175 (0.623, 2.214)	0.6789
Number of prior lines of therapy per IXRS	1	66	64 (97.0)	0.5 [0.4, 0.7)	131	130 (99.2)	0.3 [0.1, 0.3)	0.8723	1.426 (1.054, 1.929)	0.0267

Includes subjects with at least one adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.516. Cox Regression of Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	>= 2	87	84 (96.6)	0.3 [0.3, 0.5)	177	177 (100.0)	0.3 [0.1, 0.3)		1.401 (1.078, 1.820)	0.0137

Includes subjects with at least one adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.517. Cox Regression of Grade ≥3 Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	116 (75.8)	2.6 [1.9, 3.5)	308	267 (86.7)	1.7 [1.1, 2.5)		1.215 (0.977, 1.512)	0.0800
Age - at baseline (years)	<= 75	135	100 (74.1)	2.8 [1.9, 4.1)	283	246 (86.9)	1.6 [1.0, 2.4)	0.2273	1.277 (1.012, 1.611)	0.0395
	> 75	18	16 (88.9)	1.7 [0.5, 3.9)	25	21 (84.0)	3.1 [0.7, 4.2)		0.820 (0.427, 1.574)	0.5382

Includes subjects with at least one CTCAE Grade ≥3 adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.517. Cox Regression of Grade ≥3 Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Sex	Male	91	70 (76.9)	2.8 [1.9, 4.1)	174	153 (87.9)	1.5 [1.0, 2.8)	0.9662	1.218 (0.917, 1.618)	0.1748
	Female	62	46 (74.2)	2.3 [0.5, 4.4)	134	114 (85.1)	2.1 [0.8, 3.1)		1.209 (0.858, 1.704)	0.2738
Race	White	122	91 (74.6)	2.9 [2.1, 5.0)	240	201 (83.8)	2.5 [1.4, 4.0)	0.5096	1.148 (0.896, 1.471)	0.2763

Includes subjects with at least one CTCAE Grade ≥3 adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.517. Cox Regression of Grade ≥3 Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	Asian	20	18 (90.0)	0.5 [0.2, 2.6)	46	45 (97.8)	0.5 [0.2, 0.6)		1.400 (0.807, 2.430)	0.2287
	Other or Unknown	11	7 (63.6)	4.1 [0.7, NE)	22	21 (95.5)	2.5 [0.7, 7.0)		1.823 (0.770, 4.315)	0.1668
Region	North America	12	10 (83.3)	3.6 [0.4, 11.5)	21	19 (90.5)	0.7 [0.5, 6.3)	0.9154	1.253 (0.567, 2.766)	0.5875

Includes subjects with at least one CTCAE Grade ≥3 adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.517. Cox Regression of Grade ≥3 Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Region	Europe	102	72 (70.6)	3.2 [2.2, 7.0)	203	170 (83.7)	2.8 [1.6, 4.2)		1.245 (0.945, 1.640)	0.1178
	Asia Pacific	39	34 (87.2)	1.4 [0.7, 2.1)	84	78 (92.9)	0.7 [0.5, 1.4)		1.133 (0.755, 1.698)	0.5582
Baseline ECOG PS	0-1	146	111 (76.0)	2.6 [1.9, 3.7)	294	254 (86.4)	1.7 [1.2, 2.5)	0.3813	1.234 (0.987, 1.543)	0.0644

Includes subjects with at least one CTCAE Grade ≥3 adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.517. Cox Regression of Grade ≥3 Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Baseline ECOG PS	2	7	5 (71.4)	0.5 [0.2, NE)	13	12 (92.3)	0.7 [0.3, 4.0)		0.853 (0.289, 2.521)	0.7890
Prior Bortezomib or Ixazomib exposure	Yes	136	102 (75.0)	2.6 [1.9, 4.1)	285	245 (86.0)	1.7 [1.0, 2.5)	0.9006	1.217 (0.965, 1.533)	0.0963
	No	17	14 (82.4)	2.2 [1.0, 3.9)	23	22 (95.7)	1.7 [0.5, 6.5)		1.211 (0.616, 2.381)	0.5768

Includes subjects with at least one CTCAE Grade ≥3 adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.517. Cox Regression of Grade ≥3 Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Refractory to Bortezomib or Ixazomib	Yes	55	42 (76.4)	2.6 [1.2, 4.0)	99	81 (81.8)	2.2 [0.6, 3.9)	0.2741	1.039 (0.714, 1.511)	0.8588
	No	98	74 (75.5)	2.4 [1.5, 4.4)	209	186 (89.0)	1.6 [1.0, 2.4)		1.322 (1.009, 1.731)	0.0414
Prior Lenalidomide exposure	Yes	74	56 (75.7)	2.4 [1.5, 4.4)	122	108 (88.5)	0.9 [0.5, 1.5)	0.2803	1.422 (1.029, 1.966)	0.0335

Includes subjects with at least one CTCAE Grade ≥3 adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.1.517. Cox Regression of Grade ≥3 Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	No	79	60 (75.9)	2.6 [1.2, 4.1)	186	159 (85.5)	2.8 [1.6, 4.1)		1.100 (0.817, 1.481)	0.5289
Refractory to Lenalidomide	Yes	55	42 (76.4)	2.4 [1.4, 4.4)	98	84 (85.7)	1.1 [0.6, 2.3)	0.7041	1.165 (0.803, 1.691)	0.4295
	No	98	74 (75.5)	2.6 [1.4, 4.1)	210	183 (87.1)	2.1 [1.2, 3.2)		1.252 (0.956, 1.640)	0.1016

Includes subjects with at least one CTCAE Grade ≥3 adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
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[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.517. Cox Regression of Grade ≥3 Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	84 (76.4)	2.1 [1.4, 3.2)	205	180 (87.8)	1.2 [0.7, 1.7)	0.6039	1.296 (1.000, 1.680)	0.0512
	No	43	32 (74.4)	3.9 [1.9, 12.0)	103	87 (84.5)	4.0 [2.1, 5.1)		1.099 (0.732, 1.652)	0.6467
Refractory to IMiD	Yes	65	50 (76.9)	2.1 [1.4, 3.5)	129	109 (84.5)	1.3 [0.6, 2.4)	0.5010	1.131 (0.808, 1.582)	0.4813

Includes subjects with at least one CTCAE Grade ≥3 adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.517. Cox Regression of Grade ≥3 Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Refractory to IMiD	No	88	66 (75.0)	2.9 [1.9, 5.1)	179	158 (88.3)	2.1 [1.1, 3.2)		1.287 (0.966, 1.716)	0.0835
ISS stage per IXRS	1 or 2	126	93 (73.8)	2.9 [2.1, 4.0)	250	215 (86.0)	2.3 [1.4, 3.3)	0.7709	1.227 (0.961, 1.565)	0.1002
	3	27	23 (85.2)	0.5 [0.3, 5.0)	58	52 (89.7)	0.5 [0.4, 0.7)		1.124 (0.688, 1.838)	0.6372

Includes subjects with at least one CTCAE Grade ≥3 adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-sub.sas
Output: t14-06-001-517-ae-cox-grd345-excl-dpe.rtf (Date Generated: 27AUG2020:00:35) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.517. Cox Regression of Grade ≥3 Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior proteasome inhibitor exposure per IXRS	Yes	138	103 (74.6)	2.4 [1.6, 4.0)	276	238 (86.2)	1.5 [1.0, 2.4)	0.5855	1.245 (0.988, 1.569)	0.0635
	No	15	13 (86.7)	2.6 [1.3, 3.9)	32	29 (90.6)	3.8 [0.7, 8.7)		0.909 (0.468, 1.765)	0.7647
Number of prior lines of therapy per IXRS	1	66	49 (74.2)	2.9 [1.8, 5.8)	131	116 (88.5)	2.5 [1.1, 4.1)	0.7915	1.266 (0.906, 1.768)	0.1648

Includes subjects with at least one CTCAE Grade ≥3 adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-sub.sas
Output: t14-06-001-517-ae-cox-grd345-excl-dpe.rtf (Date Generated: 27AUG2020:00:35) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.517. Cox Regression of Grade ≥3 Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	>= 2	87	67 (77.0)	2.3 [1.4, 3.5)	177	151 (85.3)	1.3 [0.8, 2.3)		1.196 (0.896, 1.596)	0.2295

Includes subjects with at least one CTCAE Grade ≥3 adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-sub.sas
Output: t14-06-001-517-ae-cox-grd345-excl-dpe.rtf (Date Generated: 27AUG2020:00:35) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.518. Cox Regression of Serious Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Total subjects		153	75 (49.0)	13.2 [7.6, 28.7)	308	192 (62.3)	10.4 [8.5, 13.7)		1.159 (0.887, 1.514)	0.2786
Age - at baseline (years)	<= 75	135	64 (47.4)	13.2 [9.0, 32.9)	283	175 (61.8)	10.5 [8.7, 14.7)	0.6519	1.193 (0.895, 1.590)	0.2260
	> 75	18	11 (61.1)	7.0 [2.1, NE)	25	17 (68.0)	7.6 [3.0, 28.5)		0.977 (0.455, 2.095)	0.9546

Includes subjects with at least one serious adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Output: t14-06-001-518-sae-cox-excl-dpe.rtf (Date Generated: 27AUG2020:00:35) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.518. Cox Regression of Serious Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Sex	Male	91	44 (48.4)	13.2 [7.0, 32.9)	174	111 (63.8)	11.2 [7.0, 14.8)	0.7394	1.198 (0.844, 1.700)	0.3102
	Female	62	31 (50.0)	16.2 [2.7, NE)	134	81 (60.4)	9.8 [7.0, 17.8)		1.102 (0.728, 1.669)	0.6426
Race	White	122	62 (50.8)	12.5 [7.0, 27.5)	240	145 (60.4)	10.5 [8.1, 14.8)	0.4614	1.078 (0.800, 1.453)	0.6193

Includes subjects with at least one serious adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Output: t14-06-001-518-sae-cox-excl-dpe.rtf (Date Generated: 27AUG2020:00:35) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.518. Cox Regression of Serious Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Race	Asian	20	8 (40.0)	NE [2.4, NE)	46	33 (71.7)	9.7 [3.9, 17.6)		1.842 (0.849, 3.997)	0.1165
	Other or Unknown	11	5 (45.5)	NE [0.9, NE)	22	14 (63.6)	17.4 [1.2, 24.0)		1.263 (0.453, 3.526)	0.6554
Region	North America	12	4 (33.3)	16.2 [2.5, NE)	21	14 (66.7)	14.7 [4.1, NE)	0.8103	1.464 (0.470, 4.558)	0.5081

Includes subjects with at least one serious adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Output: t14-06-001-518-sae-cox-excl-dpe.rtf (Date Generated: 27AUG2020:00:35) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.518. Cox Regression of Serious Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Region	Europe	102	50 (49.0)	19.4 [7.0, 32.9)	203	121 (59.6)	11.4 [8.7, 17.3)		1.130 (0.813, 1.572)	0.4649
	Asia Pacific	39	21 (53.8)	8.3 [3.0, NE)	84	57 (67.9)	8.7 [3.8, 12.7)		1.136 (0.688, 1.877)	0.6189
Baseline ECOG PS	0-1	146	72 (49.3)	13.2 [8.3, 28.7)	294	184 (62.6)	10.4 [8.5, 13.7)	0.4412	1.181 (0.899, 1.552)	0.2299

Includes subjects with at least one serious adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.518. Cox Regression of Serious Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Baseline ECOG PS	2	7	3 (42.9)	NE [0.0, NE)	13	8 (61.5)	6.2 [0.3, NE)		0.932 (0.235, 3.699)	0.9138
Prior Bortezomib or Ixazomib exposure	Yes	136	65 (47.8)	16.2 [8.3, 28.7)	285	177 (62.1)	10.5 [8.1, 14.7)	0.7216	1.181 (0.888, 1.570)	0.2510
	No	17	10 (58.8)	9.0 [2.1, NE)	23	15 (65.2)	9.7 [2.3, NE)		1.018 (0.455, 2.277)	0.9691

Includes subjects with at least one serious adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.518. Cox Regression of Serious Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Refractory to Bortezomib or Ixazomib	Yes	55	26 (47.3)	13.2 [5.3, 28.7)	99	61 (61.6)	11.2 [4.6, 17.2)	0.8902	1.181 (0.744, 1.875)	0.4808
	No	98	49 (50.0)	16.2 [5.8, NE)	209	131 (62.7)	10.3 [8.2, 16.7)		1.153 (0.830, 1.602)	0.3908
Prior Lenalidomide exposure	Yes	74	35 (47.3)	16.2 [5.3, NE)	122	81 (66.4)	9.8 [6.3, 15.8)	0.7220	1.246 (0.837, 1.855)	0.2766

Includes subjects with at least one serious adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.518. Cox Regression of Serious Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior Lenalidomide exposure	No	79	40 (50.6)	13.2 [7.3, 27.5)	186	111 (59.7)	10.9 [8.7, 17.2)		1.125 (0.784, 1.616)	0.5221
Refractory to Lenalidomide	Yes	55	26 (47.3)	11.6 [3.5, NE)	98	62 (63.3)	11.4 [7.6, 19.9)	0.6154	1.033 (0.651, 1.641)	0.8859
	No	98	49 (50.0)	19.4 [7.3, 32.9)	210	130 (61.9)	9.7 [7.0, 13.5)		1.219 (0.878, 1.694)	0.2354

Includes subjects with at least one serious adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.518. Cox Regression of Serious Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	53 (48.2)	13.2 [5.8, NE)	205	132 (64.4)	9.5 [6.4, 12.2)	0.5936	1.235 (0.897, 1.699)	0.1933
	No	43	22 (51.2)	21.5 [5.1, NE)	103	60 (58.3)	16.7 [9.5, 18.8)		1.048 (0.643, 1.710)	0.8497
Refractory to IMiD	Yes	65	32 (49.2)	11.4 [3.5, NE)	129	83 (64.3)	10.4 [6.5, 15.8)	0.6667	1.057 (0.702, 1.594)	0.7886

Includes subjects with at least one serious adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.518. Cox Regression of Serious Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Refractory to IMiD	No	88	43 (48.9)	21.5 [5.8, 32.9)	179	109 (60.9)	10.3 [7.0, 17.2)		1.224 (0.860, 1.743)	0.2602
ISS stage per IXRS	1 or 2	126	58 (46.0)	19.4 [11.4, 32.9)	250	146 (58.4)	12.7 [9.7, 17.8)	0.7510	1.152 (0.849, 1.562)	0.3625
	3	27	17 (63.0)	1.6 [0.5, 7.0)	58	46 (79.3)	3.5 [1.0, 9.5)		1.107 (0.633, 1.935)	0.7185

Includes subjects with at least one serious adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

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Table 14-6.1.518. Cox Regression of Serious Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Prior proteasome inhibitor exposure per IXRS	Yes	138	65 (47.1)	16.2 [8.3, 28.7)	276	172 (62.3)	10.5 [8.1, 14.7)	0.3932	1.204 (0.904, 1.602)	0.2022
	No	15	10 (66.7)	5.3 [2.0, NE)	32	20 (62.5)	9.7 [2.9, NE)		0.843 (0.393, 1.806)	0.6593
Number of prior lines of therapy per IXRS	1	66	34 (51.5)	12.5 [5.1, NE)	131	78 (59.5)	9.8 [7.4, 17.2)	0.5997	1.089 (0.728, 1.630)	0.6764

Includes subjects with at least one serious adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-sub.sas
Output: t14-06-001-518-sae-cox-excl-dpe.rtf (Date Generated: 27AUG2020:00:35) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.1.518. Cox Regression of Serious Adverse Events Excluding Disease Progression Events <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Hazard Ratio	
Characteristics	Subgroup	N	No. of Events (%)	Median (months) (95%CI)	N	No. of Events (%)	Median (months) (95%CI)	Interaction with Treatment	(KdD/Kd) (95%CI)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	>= 2	87	41 (47.1)	13.2 [7.6, 32.9)	177	114 (64.4)	11.3 [6.5, 16.7)		1.222 (0.854, 1.749)	0.2712

Includes subjects with at least one serious adverse event excluding disease progression events. If a subject has no event, the censoring is as follows: earliest between withdrawal of consent date, lost to follow-up date, study treatment end date + 30 days, cut-off date and death date.
Disease progression events were defined as preferred terms of plasma cell myeloma and plasmacytoma.
CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a Cox regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using the unstratified log-rank test.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-ae-cox-sub.sas
Output: t14-06-001-518-sae-cox-excl-dpe.rtf (Date Generated: 27AUG2020:00:35) Source Data: adam.adsl, adam.adbase, adam.adae, sdtm.ds

Table 14-6.2.501. Logistic Regression of TEAEs Leading to any Study Treatment Discontinuation <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Total subjects		153	38 (24.8)	(18.2, 32.5)	308	85 (27.6)	(22.7, 33.0)		0.028 (-0.057, 0.112)	1.154 (0.740, 1.798)	1.111 (0.799, 1.545)	0.5768
Age - at baseline (years)	<= 75	135	32 (23.7)	(16.8, 31.8)	283	73 (25.8)	(20.8, 31.3)	0.4652	0.021 (-0.067, 0.109)	1.119 (0.694, 1.804)	1.088 (0.758, 1.562)	0.7179
	> 75	18	6 (33.3)	(13.3, 59.0)	25	12 (48.0)	(27.8, 68.7)		0.147 (-0.146, 0.440)	1.846 (0.526, 6.478)	1.440 (0.667, 3.111)	0.3684

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-teae-logr-distrt.sas
Output: t14-06-002-501-teae-logr-disany.rtf (Date Generated: 27AUG2020:00:38) Source Data: adam.adsl, adam.adae, adam.adbase

Table 14-6.2.501. Logistic Regression of TEAEs Leading to any Study Treatment Discontinuation <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Sex	Male	91	28 (30.8)	(21.5, 41.3)	174	47 (27.0)	(20.6, 34.3)	0.0629	-0.038 (-0.153, 0.078)	0.833 (0.477, 1.453)	0.878 (0.592, 1.301)	0.5665
	Female	62	10 (16.1)	(8.0, 27.7)	134	38 (28.4)	(20.9, 36.8)		0.122 (0.003, 0.241)	2.058 (0.949, 4.463)	1.758 (0.938, 3.295)	0.0749

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-teae-logr-distrt.sas
Output: t14-06-002-501-teae-logr-disany.rtf (Date Generated: 27AUG2020:00:38) Source Data: adam.adsl, adam.adae, adam.adbase

Table 14-6.2.501. Logistic Regression of TEAEs Leading to any Study Treatment Discontinuation <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Race	White	122	30 (24.6)	(17.2, 33.2)	240	68 (28.3)	(22.7, 34.5)	0.8873	0.037 (-0.058, 0.133)	1.212 (0.736, 1.996)	1.152 (0.796, 1.668)	0.5317
	Asian	20	4 (20.0)	(5.7, 43.7)	46	10 (21.7)	(10.9, 36.4)		0.017 (-0.195, 0.229)	1.111 (0.303, 4.079)	1.087 (0.387, 3.057)	1.0000
	Other or Unknown	11	4 (36.4)	(10.9, 69.2)	22	7 (31.8)	(13.9, 54.9)		-0.045 (-0.390, 0.299)	0.817 (0.178, 3.738)	0.875 (0.324, 2.361)	1.0000

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-teae-logr-distrt.sas
Output: t14-06-002-501-teae-logr-disany.rtf (Date Generated: 27AUG2020:00:38) Source Data: adam.adsl, adam.adae, adam.adbase

Table 14-6.2.501. Logistic Regression of TEAEs Leading to any Study Treatment Discontinuation <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Region	North America	12	3 (25.0)	(5.5, 57.2)	21	7 (33.3)	(14.6, 57.0)	0.7348	0.083 (-0.234, 0.401)	1.500 (0.306, 7.361)	1.333 (0.422, 4.218)	0.7098
	Europe	102	25 (24.5)	(16.5, 34.0)	203	50 (24.6)	(18.9, 31.2)		0.001 (-0.101, 0.104)	1.007 (0.579, 1.749)	1.005 (0.662, 1.525)	1.0000
	Asia Pacific	39	10 (25.6)	(13.0, 42.1)	84	28 (33.3)	(23.4, 44.5)		0.077 (-0.093, 0.247)	1.450 (0.620, 3.392)	1.300 (0.703, 2.402)	0.5296

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-teae-logr-distrt.sas
Output: t14-06-002-501-teae-logr-disany.rtf (Date Generated: 27AUG2020:00:38) Source Data: adam.adsl, adam.adae, adam.adbase

Table 14-6.2.501. Logistic Regression of TEAEs Leading to any Study Treatment Discontinuation <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Baseline ECOG PS	0-1	146	37 (25.3)	(18.5, 33.2)	294	79 (26.9)	(21.9, 32.3)	0.2077	0.015 (-0.072, 0.102)	1.082 (0.688, 1.703)	1.060 (0.758, 1.484)	0.8184
	2	7	1 (14.3)	(0.4, 57.9)	13	6 (46.2)	(19.2, 74.9)		0.319 (-0.056, 0.694)	5.143 (0.475, 55.642)	3.231 (0.480, 21.757)	0.3285

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-teae-logr-distrt.sas
Output: t14-06-002-501-teae-logr-disany.rtf (Date Generated: 27AUG2020:00:38) Source Data: adam.adsl, adam.adae, adam.adbase

Table 14-6.2.501. Logistic Regression of TEAEs Leading to any Study Treatment Discontinuation <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	32 (23.5)	(16.7, 31.6)	285	74 (26.0)	(21.0, 31.5)	0.5798	0.024 (-0.063, 0.112)	1.140 (0.708, 1.836)	1.104 (0.769, 1.583)	0.6323
	No	17	6 (35.3)	(14.2, 61.7)	23	11 (47.8)	(26.8, 69.4)		0.125 (-0.180, 0.431)	1.681 (0.464, 6.093)	1.355 (0.626, 2.933)	0.5254

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-teae-logr-distrt.sas
Output: t14-06-002-501-teae-logr-disany.rtf (Date Generated: 27AUG2020:00:38) Source Data: adam.adsl, adam.adae, adam.adbase

Table 14-6.2.501. Logistic Regression of TEAEs Leading to any Study Treatment Discontinuation <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Refractory to Bortezomib or Ixazomib	Yes	55	9 (16.4)	(7.8, 28.8)	99	23 (23.2)	(15.3, 32.8)	0.3974	0.069 (-0.060, 0.197)	1.547 (0.659, 3.630)	1.420 (0.707, 2.849)	0.4080
	No	98	29 (29.6)	(20.8, 39.7)	209	62 (29.7)	(23.6, 36.4)		0.001 (-0.109, 0.110)	1.004 (0.593, 1.697)	1.002 (0.692, 1.451)	1.0000

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-teae-logr-distrt.sas
Output: t14-06-002-501-teae-logr-disany.rtf (Date Generated: 27AUG2020:00:38) Source Data: adam.adsl, adam.adae, adam.adbase

Table 14-6.2.501. Logistic Regression of TEAEs Leading to any Study Treatment Discontinuation <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	22 (29.7)	(19.7, 41.5)	122	34 (27.9)	(20.1, 36.7)	0.2883	-0.019 (-0.150, 0.112)	0.913 (0.483, 1.726)	0.937 (0.597, 1.473)	0.8706
	No	79	16 (20.3)	(12.0, 30.8)	186	51 (27.4)	(21.1, 34.4)		0.072 (-0.038, 0.181)	1.488 (0.787, 2.811)	1.354 (0.824, 2.223)	0.2794

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-teae-logr-distrt.sas
Output: t14-06-002-501-teae-logr-disany.rtf (Date Generated: 27AUG2020:00:38) Source Data: adam.adsl, adam.adae, adam.adbase

Table 14-6.2.501. Logistic Regression of TEAEs Leading to any Study Treatment Discontinuation <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Refractory to Lenalidomide	Yes	55	15 (27.3)	(16.1, 41.0)	98	27 (27.6)	(19.0, 37.5)	0.6652	0.003 (-0.144, 0.150)	1.014 (0.484, 2.127)	1.010 (0.590, 1.730)	1.0000
	No	98	23 (23.5)	(15.5, 33.1)	210	58 (27.6)	(21.7, 34.2)		0.041 (-0.062, 0.145)	1.244 (0.713, 2.171)	1.177 (0.774, 1.790)	0.4888

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-teae-logr-distrt.sas
Output: t14-06-002-501-teae-logr-disany.rtf (Date Generated: 27AUG2020:00:38) Source Data: adam.adsl, adam.adae, adam.adbase

Table 14-6.2.501. Logistic Regression of TEAEs Leading to any Study Treatment Discontinuation <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	28 (25.5)	(17.6, 34.6)	205	59 (28.8)	(22.7, 35.5)	0.9047	0.033 (-0.069, 0.136)	1.183 (0.700, 2.000)	1.131 (0.769, 1.663)	0.5976
	No	43	10 (23.3)	(11.8, 38.6)	103	26 (25.2)	(17.2, 34.8)		0.020 (-0.132, 0.171)	1.114 (0.483, 2.570)	1.085 (0.574, 2.052)	1.0000

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-teae-logr-distrt.sas
Output: t14-06-002-501-teae-logr-disany.rtf (Date Generated: 27AUG2020:00:38) Source Data: adam.adsl, adam.adae, adam.adbase

Table 14-6.2.501. Logistic Regression of TEAEs Leading to any Study Treatment Discontinuation <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Refractory to IMiD	Yes	65	16 (24.6)	(14.8, 36.9)	129	40 (31.0)	(23.2, 39.7)	0.4953	0.064 (-0.068, 0.196)	1.376 (0.700, 2.707)	1.260 (0.766, 2.071)	0.4037
	No	88	22 (25.0)	(16.4, 35.4)	179	45 (25.1)	(19.0, 32.2)		0.001 (-0.109, 0.112)	1.007 (0.559, 1.816)	1.006 (0.647, 1.564)	1.0000

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-teae-logr-distrt.sas
Output: t14-06-002-501-teae-logr-disany.rtf (Date Generated: 27AUG2020:00:38) Source Data: adam.adsl, adam.adae, adam.adbase

Table 14-6.2.501. Logistic Regression of TEAEs Leading to any Study Treatment Discontinuation <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	29 (23.0)	(16.0, 31.4)	250	69 (27.6)	(22.2, 33.6)	0.3609	0.046 (-0.046, 0.138)	1.275 (0.774, 2.100)	1.199 (0.822, 1.749)	0.3844
	3	27	9 (33.3)	(16.5, 54.0)	58	16 (27.6)	(16.7, 40.9)		-0.057 (-0.269, 0.154)	0.762 (0.284, 2.042)	0.828 (0.421, 1.629)	0.6160

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-teae-logr-distrt.sas
Output: t14-06-002-501-teae-logr-disany.rtf (Date Generated: 27AUG2020:00:38) Source Data: adam.adsl, adam.adae, adam.adbase

Table 14-6.2.501. Logistic Regression of TEAEs Leading to any Study Treatment Discontinuation <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Prior proteasome inhibitor exposure per IXRS	Yes	138	33 (23.9)	(17.1, 31.9)	276	73 (26.4)	(21.3, 32.1)	0.9456	0.025 (-0.063, 0.114)	1.144 (0.712, 1.838)	1.106 (0.774, 1.580)	0.6335
	No	15	5 (33.3)	(11.8, 61.6)	32	12 (37.5)	(21.1, 56.3)		0.042 (-0.250, 0.333)	1.200 (0.330, 4.360)	1.125 (0.484, 2.616)	1.0000

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-teae-logr-distrt.sas
Output: t14-06-002-501-teae-logr-disany.rtf (Date Generated: 27AUG2020:00:38) Source Data: adam.adsl, adam.adae, adam.adbase

Table 14-6.2.501. Logistic Regression of TEAEs Leading to any Study Treatment Discontinuation <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	18 (27.3)	(17.0, 39.6)	131	39 (29.8)	(22.1, 38.4)	0.9304	0.025 (-0.108, 0.158)	1.130 (0.585, 2.184)	1.092 (0.680, 1.753)	0.7425
	>= 2	87	20 (23.0)	(14.6, 33.2)	177	46 (26.0)	(19.7, 33.1)		0.030 (-0.080, 0.140)	1.176 (0.644, 2.147)	1.131 (0.715, 1.787)	0.6519

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

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Table 14-6.2.502. Logistic Regression of TEAEs Leading to Discontinuation of Carfilzomib
<Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Total subjects		153	34 (22.2)	(15.9, 29.6)	308	80 (26.0)	(21.2, 31.3)		0.038 (-0.045, 0.120)	1.228 (0.777, 1.942)	1.169 (0.823, 1.661)	0.4230
Age - at baseline (years)	<= 75	135	28 (20.7)	(14.2, 28.6)	283	68 (24.0)	(19.2, 29.4)	0.5387	0.033 (-0.052, 0.117)	1.209 (0.735, 1.988)	1.159 (0.785, 1.710)	0.5343
	> 75	18	6 (33.3)	(13.3, 59.0)	25	12 (48.0)	(27.8, 68.7)		0.147 (-0.146, 0.440)	1.846 (0.526, 6.478)	1.440 (0.667, 3.111)	0.3684

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

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Table 14-6.2.502. Logistic Regression of TEAEs Leading to Discontinuation of Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Sex	Male	91	26 (28.6)	(19.6, 39.0)	174	43 (24.7)	(18.5, 31.8)	0.0265	-0.039 (-0.151, 0.074)	0.821 (0.464, 1.452)	0.865 (0.571, 1.311)	0.5559
	Female	62	8 (12.9)	(5.7, 23.9)	134	37 (27.6)	(20.2, 36.0)		0.147 (0.034, 0.260)	2.575 (1.119, 5.925)	2.140 (1.060, 4.320)	0.0279

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

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Table 14-6.2.502. Logistic Regression of TEAEs Leading to Discontinuation of Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Race	White	122	28 (23.0)	(15.8, 31.4)	240	66 (27.5)	(22.0, 33.6)	0.4358	0.045 (-0.048, 0.139)	1.273 (0.766, 2.117)	1.198 (0.816, 1.760)	0.3770
	Asian	20	2 (10.0)	(1.2, 31.7)	46	9 (19.6)	(9.4, 33.9)		0.096 (-0.079, 0.270)	2.189 (0.428, 11.200)	1.957 (0.464, 8.253)	0.4816
	Other or Unknown	11	4 (36.4)	(10.9, 69.2)	22	5 (22.7)	(7.8, 45.4)		-0.136 (-0.470, 0.198)	0.515 (0.106, 2.504)	0.625 (0.209, 1.873)	0.4376

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

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Table 14-6.2.502. Logistic Regression of TEAEs Leading to Discontinuation of Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Region	North America	12	1 (8.3)	(0.2, 38.5)	21	6 (28.6)	(11.3, 52.2)	0.3884	0.202 (-0.046, 0.451)	4.400 (0.461, 41.974)	3.429 (0.466, 25.199)	0.2233
	Europe	102	24 (23.5)	(15.7, 33.0)	203	48 (23.6)	(18.0, 30.1)		0.001 (-0.100, 0.102)	1.006 (0.575, 1.763)	1.005 (0.655, 1.542)	1.0000
	Asia Pacific	39	9 (23.1)	(11.1, 39.3)	84	26 (31.0)	(21.3, 42.0)		0.079 (-0.086, 0.244)	1.494 (0.622, 3.591)	1.341 (0.696, 2.585)	0.3997

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

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Table 14-6.2.502. Logistic Regression of TEAEs Leading to Discontinuation of Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Baseline ECOG PS	0-1	146	33 (22.6)	(16.1, 30.3)	294	75 (25.5)	(20.6, 30.9)	0.3503	0.029 (-0.055, 0.113)	1.173 (0.734, 1.873)	1.129 (0.789, 1.615)	0.5571
	2	7	1 (14.3)	(0.4, 57.9)	13	5 (38.5)	(13.9, 68.4)		0.242 (-0.129, 0.612)	3.750 (0.342, 41.081)	2.692 (0.387, 18.744)	0.3544

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

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Table 14-6.2.502. Logistic Regression of TEAEs Leading to Discontinuation of Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	28 (20.6)	(14.1, 28.4)	285	70 (24.6)	(19.7, 30.0)	0.8695	0.040 (-0.045, 0.124)	1.256 (0.765, 2.061)	1.193 (0.810, 1.758)	0.3905
	No	17	6 (35.3)	(14.2, 61.7)	23	10 (43.5)	(23.2, 65.5)		0.082 (-0.223, 0.386)	1.410 (0.387, 5.133)	1.232 (0.557, 2.727)	0.7471

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

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Table 14-6.2.502. Logistic Regression of TEAEs Leading to Discontinuation of Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Refractory to Bortezomib or Ixazomib	Yes	55	7 (12.7)	(5.3, 24.5)	99	22 (22.2)	(14.5, 31.7)	0.2242	0.095 (-0.025, 0.215)	1.959 (0.778, 4.935)	1.746 (0.797, 3.824)	0.1974
	No	98	27 (27.6)	(19.0, 37.5)	209	58 (27.8)	(21.8, 34.3)		0.002 (-0.105, 0.109)	1.010 (0.591, 1.728)	1.007 (0.683, 1.485)	1.0000

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

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Table 14-6.2.502. Logistic Regression of TEAEs Leading to Discontinuation of Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	18 (24.3)	(15.1, 35.7)	122	31 (25.4)	(18.0, 34.1)	0.5471	0.011 (-0.114, 0.135)	1.060 (0.543, 2.070)	1.045 (0.631, 1.729)	1.0000
	No	79	16 (20.3)	(12.0, 30.8)	186	49 (26.3)	(20.2, 33.3)		0.061 (-0.048, 0.170)	1.408 (0.744, 2.666)	1.301 (0.790, 2.143)	0.3499

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

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Table 14-6.2.502. Logistic Regression of TEAEs Leading to Discontinuation of Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Refractory to Lenalidomide	Yes	55	12 (21.8)	(11.8, 35.0)	98	24 (24.5)	(16.4, 34.2)	0.8750	0.027 (-0.112, 0.165)	1.162 (0.528, 2.556)	1.122 (0.610, 2.064)	0.8430
	No	98	22 (22.4)	(14.6, 32.0)	210	56 (26.7)	(20.8, 33.2)		0.042 (-0.060, 0.144)	1.256 (0.714, 2.209)	1.188 (0.772, 1.828)	0.4831

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.2.502. Logistic Regression of TEAEs Leading to Discontinuation of Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	24 (21.8)	(14.5, 30.7)	205	54 (26.3)	(20.5, 32.9)	0.7841	0.045 (-0.053, 0.143)	1.281 (0.740, 2.219)	1.207 (0.792, 1.840)	0.4132
	No	43	10 (23.3)	(11.8, 38.6)	103	26 (25.2)	(17.2, 34.8)		0.020 (-0.132, 0.171)	1.114 (0.483, 2.570)	1.085 (0.574, 2.052)	1.0000

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
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Table 14-6.2.502. Logistic Regression of TEAEs Leading to Discontinuation of Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Refractory to IMiD	Yes	65	13 (20.0)	(11.1, 31.8)	129	37 (28.7)	(21.1, 37.3)	0.3276	0.087 (-0.038, 0.212)	1.609 (0.785, 3.297)	1.434 (0.821, 2.504)	0.2255
	No	88	21 (23.9)	(15.4, 34.1)	179	43 (24.0)	(18.0, 31.0)		0.002 (-0.107, 0.110)	1.009 (0.555, 1.835)	1.007 (0.639, 1.587)	1.0000

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

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Table 14-6.2.502. Logistic Regression of TEAEs Leading to Discontinuation of Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	25 (19.8)	(13.3, 27.9)	250	64 (25.6)	(20.3, 31.5)	0.2906	0.058 (-0.031, 0.146)	1.390 (0.825, 2.343)	1.290 (0.857, 1.944)	0.2480
	3	27	9 (33.3)	(16.5, 54.0)	58	16 (27.6)	(16.7, 40.9)		-0.057 (-0.269, 0.154)	0.762 (0.284, 2.042)	0.828 (0.421, 1.629)	0.6160

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-teae-logr-distrt.sas
Output: t14-06-002-502-teae-logr-discfz.rtf (Date Generated: 27AUG2020:00:38) Source Data: adam.adsl, adam.adae, adam.adbase

Table 14-6.2.502. Logistic Regression of TEAEs Leading to Discontinuation of Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Prior proteasome inhibitor exposure per IXRS	Yes	138	29 (21.0)	(14.5, 28.8)	276	70 (25.4)	(20.3, 30.9)	0.6333	0.043 (-0.042, 0.129)	1.277 (0.782, 2.087)	1.207 (0.824, 1.768)	0.3924
	No	15	5 (33.3)	(11.8, 61.6)	32	10 (31.3)	(16.1, 50.0)		-0.021 (-0.308, 0.267)	0.909 (0.246, 3.363)	0.938 (0.388, 2.263)	1.0000

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

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Table 14-6.2.502. Logistic Regression of TEAEs Leading to Discontinuation of Carfilzomib <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	17 (25.8)	(15.8, 38.0)	131	36 (27.5)	(20.0, 36.0)	0.6386	0.017 (-0.113, 0.148)	1.092 (0.558, 2.139)	1.067 (0.650, 1.750)	0.8658
	>= 2	87	17 (19.5)	(11.8, 29.4)	177	44 (24.9)	(18.7, 31.9)		0.053 (-0.052, 0.158)	1.362 (0.725, 2.558)	1.272 (0.774, 2.092)	0.3563

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

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Table 14-6.2.503. Logistic Regression of TEAEs Leading to Discontinuation of Dexamethasone <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Total subjects		153	37 (24.2)	(17.6, 31.8)	308	43 (14.0)	(10.3, 18.3)		-0.102 (-0.180, -0.024)	0.509 (0.311, 0.831)	0.577 (0.389, 0.856)	0.0087
Age - at baseline (years)	<= 75	135	31 (23.0)	(16.2, 31.0)	283	37 (13.1)	(9.4, 17.6)	0.7605	-0.099 (-0.180, -0.018)	0.505 (0.297, 0.857)	0.569 (0.370, 0.876)	0.0154
	> 75	18	6 (33.3)	(13.3, 59.0)	25	6 (24.0)	(9.4, 45.1)		-0.093 (-0.368, 0.181)	0.632 (0.165, 2.419)	0.720 (0.277, 1.872)	0.5157

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

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Table 14-6.2.503. Logistic Regression of TEAEs Leading to Discontinuation of Dexamethasone <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Sex	Male	91	27 (29.7)	(20.5, 40.2)	174	27 (15.5)	(10.5, 21.8)	0.3679	-0.142 (-0.250, -0.033)	0.435 (0.237, 0.800)	0.523 (0.327, 0.836)	0.0098
	Female	62	10 (16.1)	(8.0, 27.7)	134	16 (11.9)	(7.0, 18.7)		-0.042 (-0.149, 0.065)	0.705 (0.300, 1.658)	0.740 (0.357, 1.537)	0.4976

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

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Table 14-6.2.503. Logistic Regression of TEAEs Leading to Discontinuation of Dexamethasone <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Race	White	122	30 (24.6)	(17.2, 33.2)	240	34 (14.2)	(10.0, 19.2)	0.8800	-0.104 (-0.192, -0.016)	0.506 (0.292, 0.876)	0.576 (0.371, 0.894)	0.0192
	Asian	20	3 (15.0)	(3.2, 37.9)	46	5 (10.9)	(3.6, 23.6)		-0.041 (-0.222, 0.139)	0.691 (0.148, 3.220)	0.725 (0.191, 2.744)	0.6901
	Other or Unknown	11	4 (36.4)	(10.9, 69.2)	22	4 (18.2)	(5.2, 40.3)		-0.182 (-0.509, 0.145)	0.389 (0.076, 2.001)	0.500 (0.153, 1.630)	0.3915

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

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Table 14-6.2.503. Logistic Regression of TEAEs Leading to Discontinuation of Dexamethasone <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Region	North America	12	3 (25.0)	(5.5, 57.2)	21	1 (4.8)	(0.1, 23.8)	0.4471	-0.202 (-0.464, 0.059)	0.150 (0.014, 1.647)	0.190 (0.022, 1.634)	0.1250
	Europe	102	25 (24.5)	(16.5, 34.0)	203	27 (13.3)	(9.0, 18.8)		-0.112 (-0.208, -0.016)	0.473 (0.258, 0.866)	0.543 (0.333, 0.885)	0.0161
	Asia Pacific	39	9 (23.1)	(11.1, 39.3)	84	15 (17.9)	(10.4, 27.7)		-0.052 (-0.208, 0.103)	0.725 (0.286, 1.838)	0.774 (0.371, 1.612)	0.6253

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

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Table 14-6.2.503. Logistic Regression of TEAEs Leading to Discontinuation of Dexamethasone <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Baseline ECOG PS	0-1	146	36 (24.7)	(17.9, 32.5)	294	37 (12.6)	(9.0, 16.9)	0.0478	-0.121 (-0.200, -0.041)	0.440 (0.264, 0.733)	0.510 (0.337, 0.772)	0.0017
	2	7	1 (14.3)	(0.4, 57.9)	13	6 (46.2)	(19.2, 74.9)		0.319 (-0.056, 0.694)	5.143 (0.475, 55.642)	3.231 (0.480, 21.757)	0.3285

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

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Table 14-6.2.503. Logistic Regression of TEAEs Leading to Discontinuation of Dexamethasone <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Prior Bortezomib or Ixazomib exposure	Yes	136	31 (22.8)	(16.0, 30.8)	285	39 (13.7)	(9.9, 18.2)	0.6778	-0.091 (-0.172, -0.010)	0.537 (0.318, 0.907)	0.600 (0.392, 0.918)	0.0247
	No	17	6 (35.3)	(14.2, 61.7)	23	4 (17.4)	(5.0, 38.8)		-0.179 (-0.454, 0.096)	0.386 (0.089, 1.674)	0.493 (0.164, 1.479)	0.2743

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

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Table 14-6.2.503. Logistic Regression of TEAEs Leading to Discontinuation of Dexamethasone <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Refractory to Bortezomib or Ixazomib	Yes	55	8 (14.5)	(6.5, 26.7)	99	15 (15.2)	(8.7, 23.8)	0.0620	0.006 (-0.111, 0.123)	1.049 (0.414, 2.657)	1.042 (0.472, 2.300)	1.0000
	No	98	29 (29.6)	(20.8, 39.7)	209	28 (13.4)	(9.1, 18.8)		-0.162 (-0.263, -0.060)	0.368 (0.204, 0.663)	0.453 (0.286, 0.718)	0.0014

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

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Table 14-6.2.503. Logistic Regression of TEAEs Leading to Discontinuation of Dexamethasone <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Prior Lenalidomide exposure	Yes	74	21 (28.4)	(18.5, 40.1)	122	19 (15.6)	(9.6, 23.2)	0.6552	-0.128 (-0.249, -0.007)	0.466 (0.230, 0.941)	0.549 (0.317, 0.951)	0.0435
	No	79	16 (20.3)	(12.0, 30.8)	186	24 (12.9)	(8.4, 18.6)		-0.073 (-0.174, 0.027)	0.583 (0.291, 1.170)	0.637 (0.358, 1.132)	0.1363

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

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Table 14-6.2.503. Logistic Regression of TEAEs Leading to Discontinuation of Dexamethasone <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Refractory to Lenalidomide	Yes	55	14 (25.5)	(14.7, 39.0)	98	17 (17.3)	(10.4, 26.3)	0.5776	-0.081 (-0.218, 0.056)	0.615 (0.276, 1.369)	0.681 (0.365, 1.274)	0.2948
	No	98	23 (23.5)	(15.5, 33.1)	210	26 (12.4)	(8.2, 17.6)		-0.111 (-0.206, -0.016)	0.461 (0.247, 0.858)	0.528 (0.318, 0.876)	0.0186

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

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Table 14-6.2.503. Logistic Regression of TEAEs Leading to Discontinuation of Dexamethasone <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Prior IMiD exposure	Yes	110	27 (24.5)	(16.8, 33.7)	205	31 (15.1)	(10.5, 20.8)	0.6804	-0.094 (-0.188, -0.000)	0.548 (0.307, 0.977)	0.616 (0.389, 0.977)	0.0475
	No	43	10 (23.3)	(11.8, 38.6)	103	12 (11.7)	(6.2, 19.5)		-0.116 (-0.257, 0.025)	0.435 (0.172, 1.102)	0.501 (0.234, 1.071)	0.0818

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

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Table 14-6.2.503. Logistic Regression of TEAEs Leading to Discontinuation of Dexamethasone <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Refractory to IMiD	Yes	65	15 (23.1)	(13.5, 35.2)	129	22 (17.1)	(11.0, 24.7)	0.2844	-0.060 (-0.181, 0.061)	0.685 (0.328, 1.432)	0.739 (0.412, 1.326)	0.3367
	No	88	22 (25.0)	(16.4, 35.4)	179	21 (11.7)	(7.4, 17.4)		-0.133 (-0.235, -0.031)	0.399 (0.205, 0.774)	0.469 (0.273, 0.806)	0.0077

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-teae-logr-distrt.sas
Output: t14-06-002-503-teae-logr-disdex.rtf (Date Generated: 27AUG2020:00:38) Source Data: adam.adsl, adam.adae, adam.adbase

Table 14-6.2.503. Logistic Regression of TEAEs Leading to Discontinuation of Dexamethasone <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
ISS stage per IXRS	1 or 2	126	29 (23.0)	(16.0, 31.4)	250	33 (13.2)	(9.3, 18.0)	0.9641	-0.098 (-0.183, -0.014)	0.509 (0.292, 0.885)	0.574 (0.365, 0.900)	0.0186
	3	27	8 (29.6)	(13.8, 50.2)	58	10 (17.2)	(8.6, 29.4)		-0.124 (-0.322, 0.074)	0.495 (0.170, 1.444)	0.582 (0.259, 1.308)	0.2549

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-teae-logr-distrt.sas
Output: t14-06-002-503-teae-logr-disdex.rtf (Date Generated: 27AUG2020:00:38) Source Data: adam.adsl, adam.adae, adam.adbase

Table 14-6.2.503. Logistic Regression of TEAEs Leading to Discontinuation of Dexamethasone <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Prior proteasome inhibitor exposure per IXRS	Yes	138	32 (23.2)	(16.4, 31.1)	276	37 (13.4)	(9.6, 18.0)	0.8897	-0.098 (-0.179, -0.017)	0.513 (0.303, 0.867)	0.578 (0.377, 0.886)	0.0169
	No	15	5 (33.3)	(11.8, 61.6)	32	6 (18.8)	(7.2, 36.4)		-0.146 (-0.420, 0.128)	0.462 (0.115, 1.859)	0.563 (0.204, 1.554)	0.2923

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-teae-logr-distrt.sas
Output: t14-06-002-503-teae-logr-disdex.rtf (Date Generated: 27AUG2020:00:38) Source Data: adam.adsl, adam.adae, adam.adbase

Table 14-6.2.503. Logistic Regression of TEAEs Leading to Discontinuation of Dexamethasone <Safety Population>

		Kd (N = 153)			KdD (N = 308)			p-value[a]	Absolute Risk Difference (95% CI)	Odds Ratio (95% CI)	Relative Risk (95% CI)	
Characteristics	Subgroup	N	No. of Subjects (%)	95% CI	N	No. of Subjects (%)	95% CI	Interaction with Treatment	(KdD-Kd)	(KdD/Kd)	(KdD/Kd)	p-value (2-sided)[b]
Number of prior lines of therapy per IXRS	1	66	18 (27.3)	(17.0, 39.6)	131	16 (12.2)	(7.1, 19.1)	0.2779	-0.151 (-0.272, -0.029)	0.371 (0.175, 0.788)	0.448 (0.245, 0.820)	0.0154
	>= 2	87	19 (21.8)	(13.7, 32.0)	177	27 (15.3)	(10.3, 21.4)		-0.066 (-0.168, 0.036)	0.644 (0.335, 1.238)	0.698 (0.412, 1.184)	0.2267

CI: confidence interval; NE: not estimable; ECOG PS: Eastern Cooperative Oncology Group Performance Status; Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Unstratified analysis was conducted for total subjects and subgroups.
[a] The p-value (2-sided) for interaction was from a logistic regression model with baseline characteristic, treatment group and interaction term between baseline characteristic and treatment as covariates.
[b] 2-sided p-values were calculated using Fisher's exact test for 'Total subjects' and subgroups.

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-teae-logr-distrt.sas
Output: t14-06-002-503-teae-logr-disdex.rtf (Date Generated: 27AUG2020:00:38) Source Data: adam.adsl, adam.adae, adam.adbase

Table 14-6.3.501. Subgroup Analyses (Age < 75, Age ≥ 75) of Subject Incidence of Treatment-emergent Adverse Events <Safety Population>

	Kd n (%)			KdD n (%)		
	< 75 years	≥ 75 years	Total	< 75 years	≥ 75 years	Total
Analysis set: safety	131	22	153	280	28	308
Any TEAE	126 (96.2%)	22 (100.0%)	148 (96.7%)	280 (100.0%)	27 (96.4%)	307 (99.7%)
Maximum toxicity grade						
Grade 1	5 (3.8%)	0 (0.0%)	5 (3.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Grade 2	25 (19.1%)	2 (9.1%)	27 (17.6%)	34 (12.1%)	5 (17.9%)	39 (12.7%)
Grade 3	68 (51.9%)	17 (77.3%)	85 (55.6%)	163 (58.2%)	11 (39.3%)	174 (56.5%)
Grade 4	19 (14.5%)	3 (13.6%)	22 (14.4%)	56 (20.0%)	7 (25.0%)	63 (20.5%)
Grade 5	9 (6.9%)	0 (0.0%)	9 (5.9%)	27 (9.6%)	4 (14.3%)	31 (10.1%)

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab;
Treatment-emergent adverse events are defined as any adverse event with an onset after the administration of the first dose of any study treatment and within the end of study or 30 days of the last dose of any study treatment, whichever occurs earlier. Adverse events were coded using MedDRA (version 23.0) and graded using NCI-CTCAE (version 4.03).

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-teae-sum-sub-age.sas
Output: t14-06-003-501-teae-sum-sub-age.rtf (Date Generated: 28AUG2020:02:53) Source Data: adam.adsl, adam.adae

Table 14-6.3.501. Subgroup Analyses (Age < 75, Age ≥ 75) of Subject Incidence of Treatment-emergent Adverse Events <Safety Population>

	Kd n (%)			KdD n (%)		
	< 75 years	≥ 75 years	Total	< 75 years	≥ 75 years	Total
Any serious TEAE	62 (47.3%)	14 (63.6%)	76 (49.7%)	176 (62.9%)	18 (64.3%)	194 (63.0%)
TEAE leading to discontinuation of carfilzomib	27 (20.6%)	7 (31.8%)	34 (22.2%)	68 (24.3%)	12 (42.9%)	80 (26.0%)
TEAE leading to discontinuation of dexamethasone	30 (22.9%)	7 (31.8%)	37 (24.2%)	37 (13.2%)	6 (21.4%)	43 (14.0%)
TEAE leading to discontinuation of daratumumab	0 (0.0%)	0 (0.0%)	0 (0.0%)	28 (10.0%)	5 (17.9%)	33 (10.7%)
TEAE leading to discontinuation of all study treatment	25 (19.1%)	6 (27.3%)	31 (20.3%)	24 (8.6%)	5 (17.9%)	29 (9.4%)

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab;
Treatment-emergent adverse events are defined as any adverse event with an onset after the administration of the first dose of any study treatment and within the end of study or 30 days of the last dose of any study treatment, whichever occurs earlier. Adverse events were coded using MedDRA (version 23.0) and graded using NCI-CTCAE (version 4.03).

Program: /userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/tables/t-teae-sum-sub-age.sas
Output: t14-06-003-501-teae-sum-sub-age.rtf (Date Generated: 28AUG2020:02:53) Source Data: adam.adsl, adam.adae

Table 14-6.7.4. Treatment-emergent Adverse Events Leading to Any Study Treatment Discontinuation by System Organ Class and Preferred Term <Safety Population>

System Organ Class Preferred Term	Kd (N = 153) n (%)	KdD (N = 308) n (%)
Number of subjects reporting treatment-emergent adverse events leading to any study treatment discontinuation	38 (24.8)	85 (27.6)
Blood and lymphatic system disorders	3 (2.0)	4 (1.3)
Thrombotic thrombocytopenic purpura	2 (1.3)	2 (0.6)
Haemolytic anaemia	1 (0.7)	1 (0.3)
Thrombocytopenia	0 (0.0)	1 (0.3)
Cardiac disorders	6 (3.9)	21 (6.8)
Cardiac failure	3 (2.0)	8 (2.6)
Cardiac failure acute	1 (0.7)	2 (0.6)
Atrial fibrillation	0 (0.0)	2 (0.6)
Cardiac failure congestive	0 (0.0)	2 (0.6)
Acute coronary syndrome	0 (0.0)	1 (0.3)
Acute myocardial infarction	0 (0.0)	1 (0.3)
Angina pectoris	0 (0.0)	1 (0.3)
Arrhythmia	0 (0.0)	1 (0.3)
Atrial enlargement	0 (0.0)	1 (0.3)
Atrial flutter	0 (0.0)	1 (0.3)
Cardiac arrest	0 (0.0)	1 (0.3)
Left ventricular dysfunction	0 (0.0)	1 (0.3)
Cardiomyopathy	1 (0.7)	0 (0.0)
Extrasystoles	1 (0.7)	0 (0.0)
Eye disorders	1 (0.7)	1 (0.3)
Eyelid oedema	0 (0.0)	1 (0.3)
Cataract	1 (0.7)	0 (0.0)
Gastrointestinal disorders	1 (0.7)	1 (0.3)
Upper gastrointestinal haemorrhage	0 (0.0)	1 (0.3)
Abdominal pain upper	1 (0.7)	0 (0.0)
General disorders and administration site conditions	4 (2.6)	11 (3.6)
Fatigue	1 (0.7)	8 (2.6)
Asthenia	1 (0.7)	3 (1.0)

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Treatment-emergent adverse events (TEAE) are events with an onset after the administration of the first dose of any study treatment and within the end of study or 30 days of the last dose of any study treatment, whichever occurs earlier.
Adverse events were coded using MedDRA (version 23.0).

Program: /userdata/stat/amg981/onc/20160275/analysis/os_interim_2020_ub/tables/t-ae-sum-soc-pref-trtdis.sas Output: t14-06-007-004-ae-sum-soc-pref-trtdis.rtf (Date Generated: 17AUG20:02:20:42) Source: adam.adsl, adam.adae

Table 14-6.7.4. Treatment-emergent Adverse Events Leading to Any Study Treatment Discontinuation by System Organ Class and Preferred Term <Safety Population>

System Organ Class Preferred Term	Kd (N = 153) n (%)	KdD (N = 308) n (%)
Death	1 (0.7)	0 (0.0)
Oedema peripheral	1 (0.7)	0 (0.0)
Hepatobiliary disorders	1 (0.7)	2 (0.6)
Hepatic function abnormal	0 (0.0)	1 (0.3)
Liver disorder	0 (0.0)	1 (0.3)
Venoocclusive liver disease	1 (0.7)	0 (0.0)
Infections and infestations	4 (2.6)	14 (4.5)
Pneumonia	0 (0.0)	4 (1.3)
Septic shock	0 (0.0)	3 (1.0)
Sepsis	0 (0.0)	2 (0.6)
Influenza	1 (0.7)	1 (0.3)
Acinetobacter infection	0 (0.0)	1 (0.3)
Bronchitis	0 (0.0)	1 (0.3)
Hepatitis viral	0 (0.0)	1 (0.3)
Pneumonia cytomegaloviral	0 (0.0)	1 (0.3)
Upper respiratory tract infection	0 (0.0)	1 (0.3)
COVID-19 pneumonia	1 (0.7)	0 (0.0)
Respiratory tract infection	1 (0.7)	0 (0.0)
Urinary tract infection	1 (0.7)	0 (0.0)
Injury, poisoning and procedural complications	1 (0.7)	1 (0.3)
Infusion related reaction	0 (0.0)	1 (0.3)
Humerus fracture	1 (0.7)	0 (0.0)
Investigations	1 (0.7)	2 (0.6)
Weight increased	0 (0.0)	2 (0.6)
Ejection fraction decreased	1 (0.7)	0 (0.0)
Metabolism and nutrition disorders	1 (0.7)	6 (1.9)
Hyperglycaemia	0 (0.0)	2 (0.6)
Tumour lysis syndrome	1 (0.7)	1 (0.3)
Decreased appetite	0 (0.0)	1 (0.3)
Diabetes mellitus	0 (0.0)	1 (0.3)

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Treatment-emergent adverse events (TEAE) are events with an onset after the administration of the first dose of any study treatment and within the end of study or 30 days of the last dose of any study treatment, whichever occurs earlier.
Adverse events were coded using MedDRA (version 23.0).

Program: /userdata/stat/amg981/onc/20160275/analysis/os_interim_2020_ub/tables/t-ae-sum-soc-pref-trtdis.sas Output: t14-06-007-004-ae-sum-soc-pref-trtdis.rtf (Date Generated: 17AUG20:02:20:42) Source: adam.adsl, adam.adae

Table 14-6.7.4. Treatment-emergent Adverse Events Leading to Any Study Treatment Discontinuation by System Organ Class and Preferred Term <Safety Population>

System Organ Class Preferred Term	Kd (N = 153) n (%)	KdD (N = 308) n (%)
Type 2 diabetes mellitus	0 (0.0)	1 (0.3)
Musculoskeletal and connective tissue disorders	0 (0.0)	2 (0.6)
Muscular weakness	0 (0.0)	1 (0.3)
Spinal osteoarthritis	0 (0.0)	1 (0.3)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4 (2.6)	4 (1.3)
Plasma cell myeloma	2 (1.3)	2 (0.6)
Metastases to liver	1 (0.7)	2 (0.6)
Metastases to lung	1 (0.7)	0 (0.0)
Pancreatic carcinoma	1 (0.7)	0 (0.0)
Transitional cell carcinoma	1 (0.7)	0 (0.0)
Nervous system disorders	2 (1.3)	10 (3.2)
Neuropathy peripheral	0 (0.0)	6 (1.9)
Lethargy	0 (0.0)	1 (0.3)
Neuralgia	0 (0.0)	1 (0.3)
Polyneuropathy	0 (0.0)	1 (0.3)
Posterior reversible encephalopathy syndrome	0 (0.0)	1 (0.3)
Cognitive disorder	1 (0.7)	0 (0.0)
Spinal cord compression	1 (0.7)	0 (0.0)
Psychiatric disorders	2 (1.3)	5 (1.6)
Insomnia	0 (0.0)	3 (1.0)
Agitation	1 (0.7)	1 (0.3)
Hypomania	0 (0.0)	1 (0.3)
Mania	1 (0.7)	0 (0.0)
Renal and urinary disorders	6 (3.9)	4 (1.3)
Acute kidney injury	3 (2.0)	2 (0.6)
Proteinuria	2 (1.3)	1 (0.3)
Chronic kidney disease	0 (0.0)	1 (0.3)
Renal impairment	1 (0.7)	0 (0.0)
Respiratory, thoracic and mediastinal disorders	3 (2.0)	11 (3.6)

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Treatment-emergent adverse events (TEAE) are events with an onset after the administration of the first dose of any study treatment and within the end of study or 30 days of the last dose of any study treatment, whichever occurs earlier.
Adverse events were coded using MedDRA (version 23.0).

Program: /userdata/stat/amg981/onc/20160275/analysis/os_interim_2020_ub/tables/t-ae-sum-soc-pref-trtdis.sas Output: t14-06-007-004-ae-sum-soc-pref-trtdis.rtf (Date Generated: 17AUG20:02:20:42) Source: adam.adsl, adam.adae

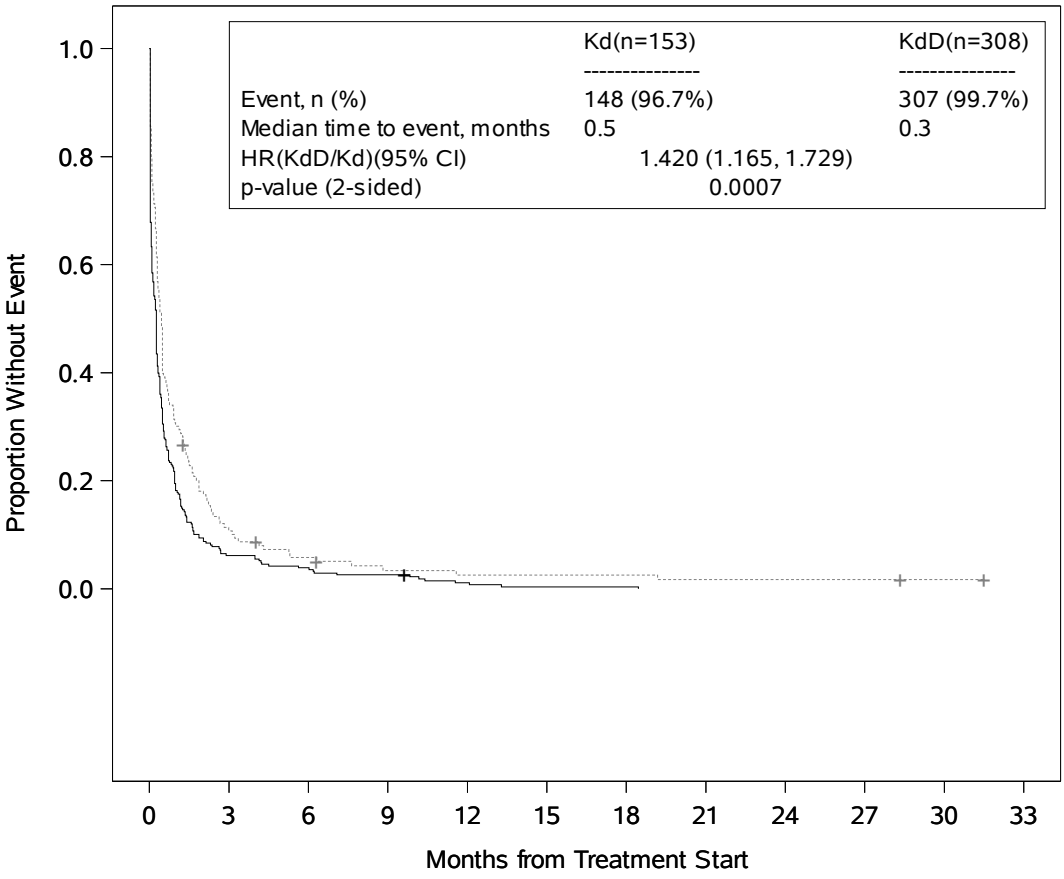
Table 14-6.7.4. Treatment-emergent Adverse Events Leading to Any Study Treatment Discontinuation by System Organ Class and Preferred Term <Safety Population>

System Organ Class Preferred Term	Kd (N = 153) n (%)	KdD (N = 308) n (%)
Dyspnoea	1 (0.7)	4 (1.3)
Pulmonary oedema	2 (1.3)	2 (0.6)
Pulmonary hypertension	0 (0.0)	2 (0.6)
Hiccups	0 (0.0)	1 (0.3)
Pulmonary embolism	0 (0.0)	1 (0.3)
Respiratory failure	0 (0.0)	1 (0.3)
Vascular disorders	3 (2.0)	4 (1.3)
Hypertension	3 (2.0)	4 (1.3)

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
Treatment-emergent adverse events (TEAE) are events with an onset after the administration of the first dose of any study treatment and within the end of study or 30 days of the last dose of any study treatment, whichever occurs earlier.
Adverse events were coded using MedDRA (version 23.0).

Program:
/userdata/stat/amg981/onc/20160275/analysis/os_interim_2020_ub/tables/t-ae-sum-soc-pref-trtdis.sas
Output: t14-06-007-004-ae-sum-soc-pref-trtdis.rtf (Date Generated: 17AUG20:02:20:42) Source: adam.adsl, adam.adae

Figure 14-6.1.501. KM Curves of Adverse Events
<Safety Population>

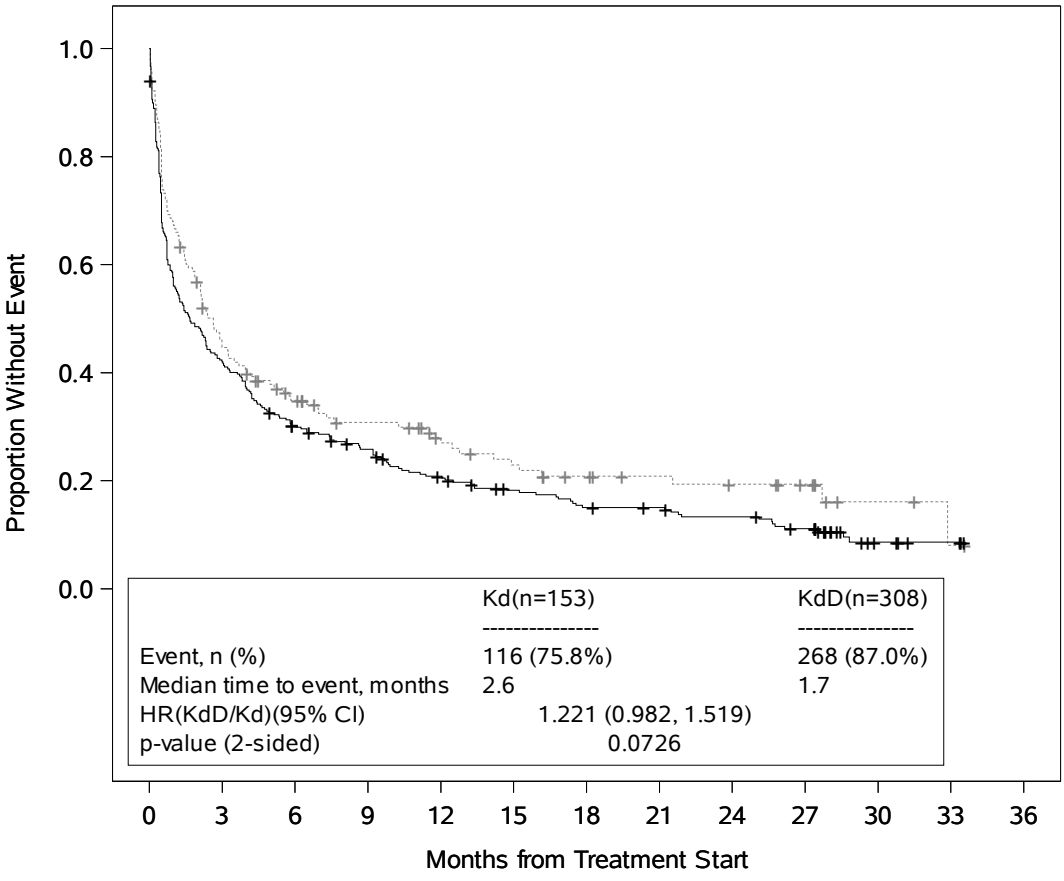


Number of Subjects at Risk:

Kd	153	16	8	4	3	3	3	2	2	2	1	0
KdD	308	19	12	8	3	1	1	0				

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-km-all.sas.
Output: f14-06-001-501-ae-km.rtf (Date Generated: 17SEP20:01:04:24).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.2.501. KM Curves of Grade ≥3 Adverse Events <Safety Population>

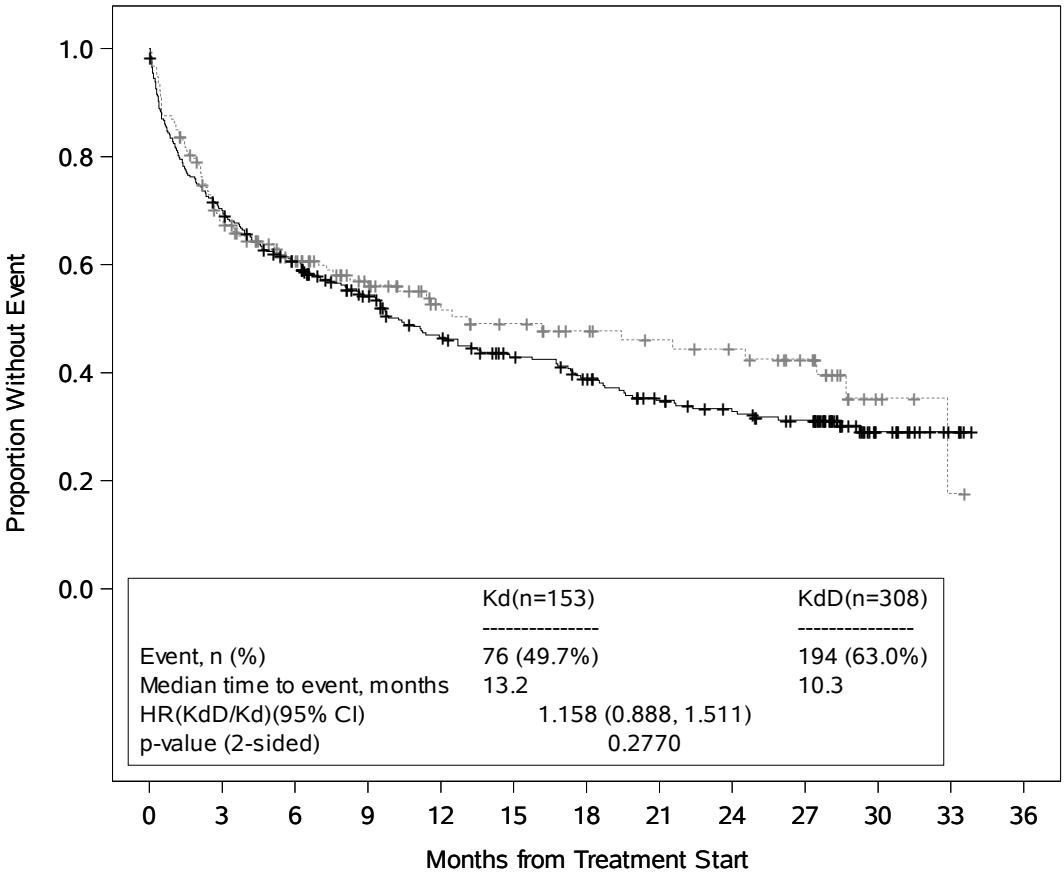


Number of Subjects at Risk:

Kd	153	66	47	36	28	22	17	14	12	9	3	1	0
KdD	308	129	90	74	57	46	38	36	31	24	6	3	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-km-all.sas.
Output: f14-06-002-501-ae-km-grd345.rtf (Date Generated: 17SEP20:01:04:26).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.3.501. KM Curves of Serious Adverse Events
<Safety Population>

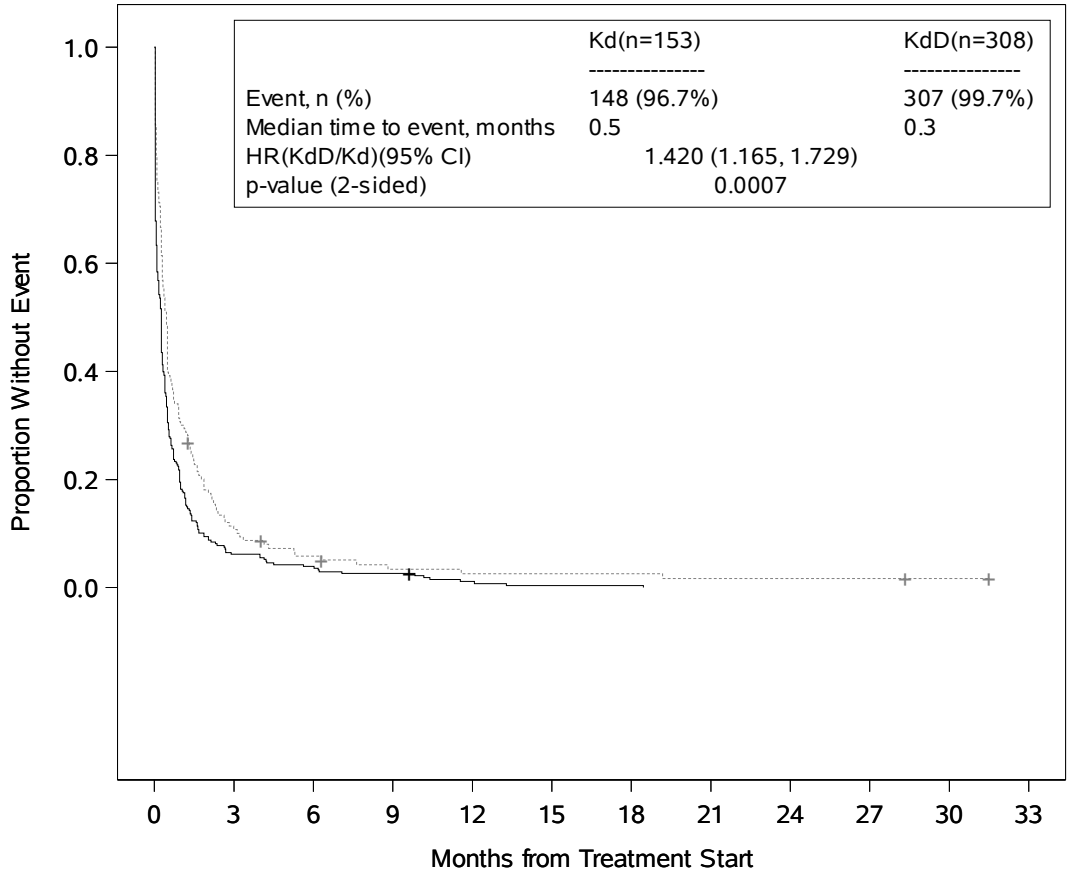


Number of Subjects at Risk:

Kd	153	99	77	58	43	37	31	27	24	18	4	1	0
KdD	308	214	179	144	118	101	88	72	63	55	16	5	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-km-all.sas.
Output: f14-06-003-501-sae-km.rtf (Date Generated: 17SEP20:01:04:27).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.16.501. KM Curves of Adverse Events Excluding Disease Progression Events
<Safety Population>

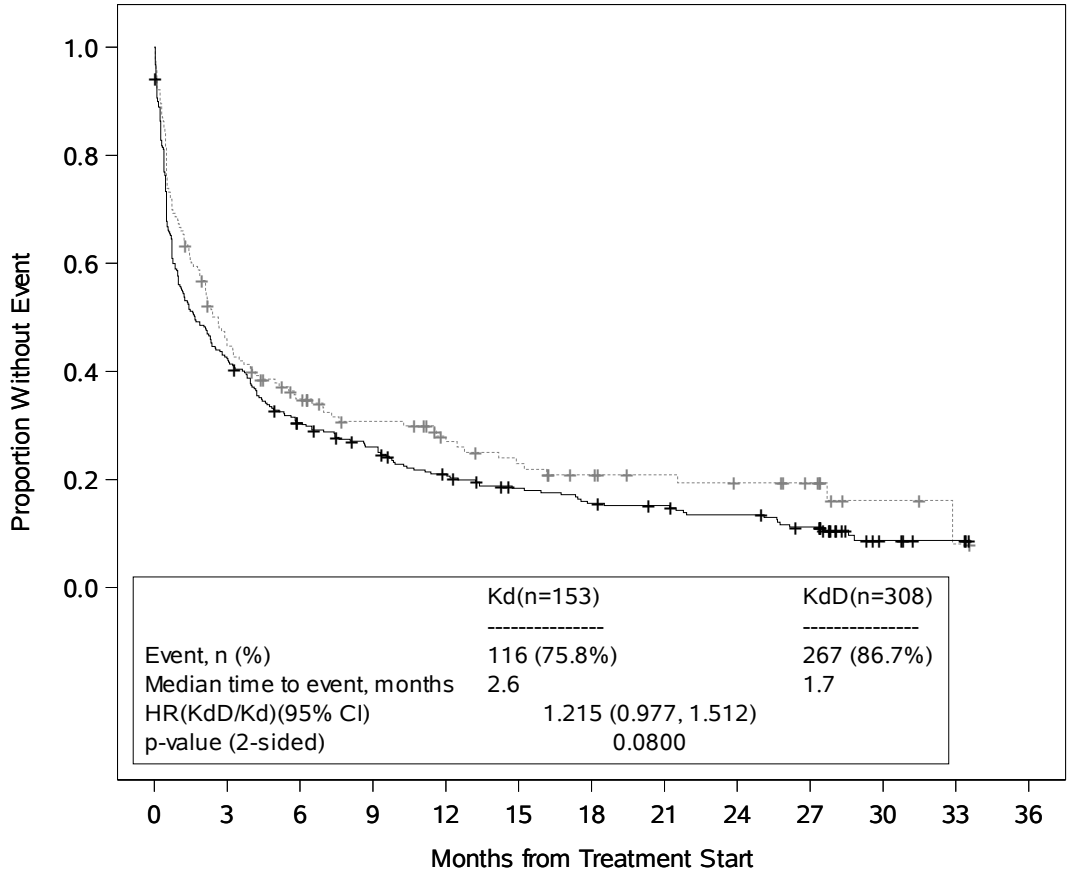


Number of Subjects at Risk:

Kd	153	16	8	4	3	3	3	2	2	2	1	0
KdD	308	19	12	8	3	1	1	0				

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-km-all.sas.
Output: f14-06-016-501-ae-km-excl-dpe.rtf (Date Generated: 17SEP20:01:04:29).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.17.501. KM Curves of Grade ≥3 Adverse Events Excluding Disease Progression Events
<Safety Population>

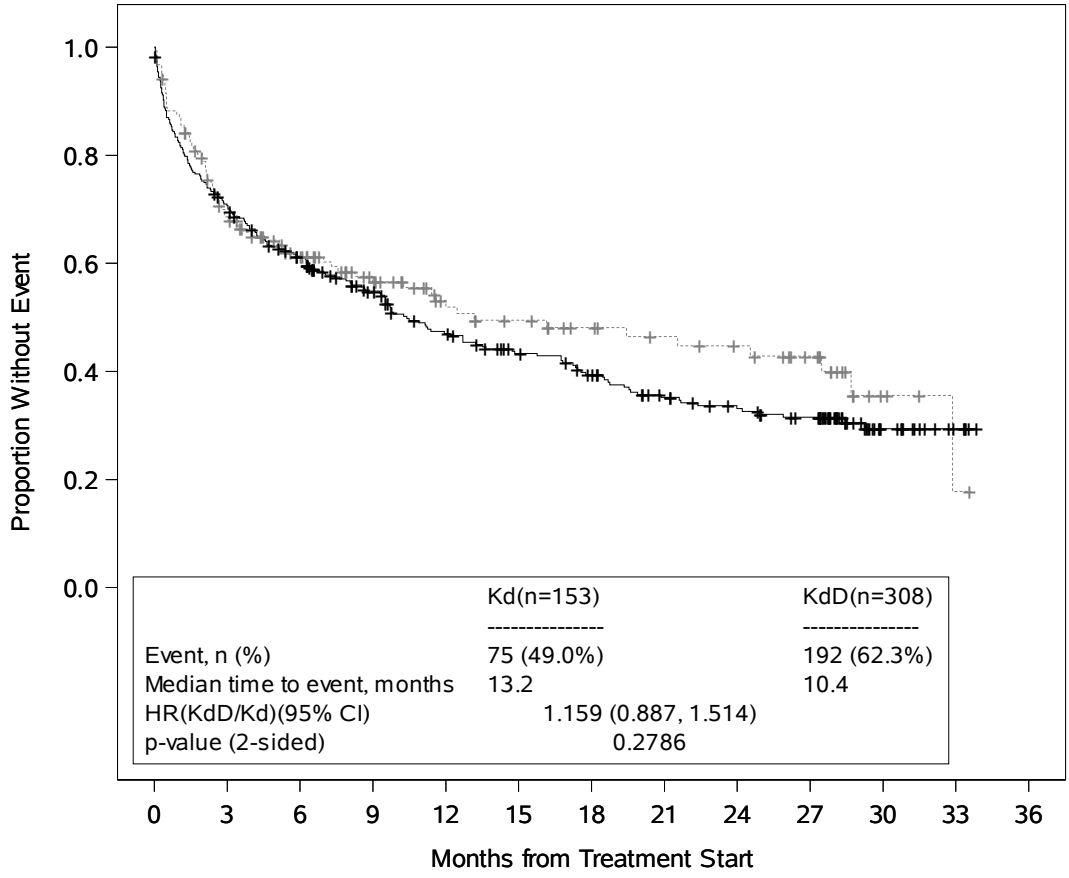


Number of Subjects at Risk:

Kd	153	66	47	36	28	22	17	14	12	9	3	1	0
KdD	308	130	90	74	57	46	39	36	31	24	6	3	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-km-all.sas.
Output: f14-06-017-501-ae-km-grd345-excl-dpe.rtf (Date Generated: 17SEP20:01:04:30).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.18.501. KM Curves of Serious Adverse Events Excluding Disease Progression Events
<Safety Population>

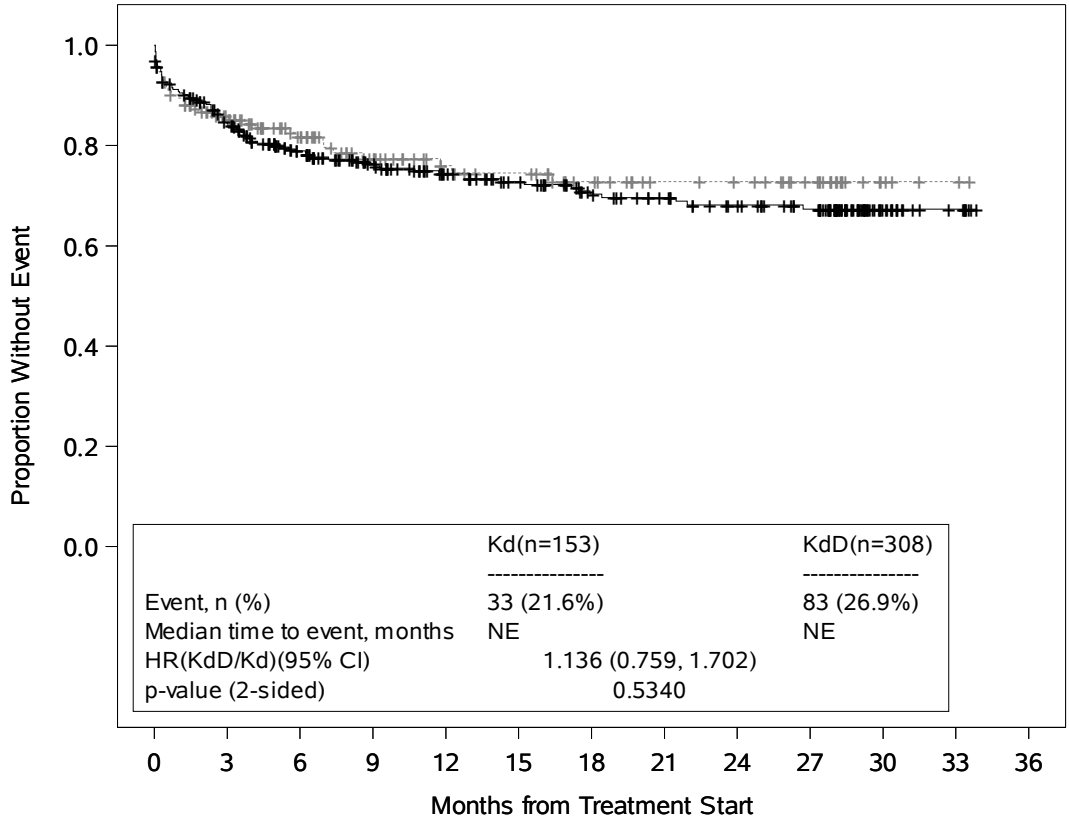


Number of Subjects at Risk:

Kd	153	99	77	58	43	37	31	27	24	18	4	1	0
KdD	308	215	179	144	118	101	88	72	63	55	16	5	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-km-all.sas.
Output: f14-06-018-501-sae-km-excl-dpe.rtf (Date Generated: 17SEP20:01:04:32).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.4.517. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Psychiatric Disorders)
<Safety Population>

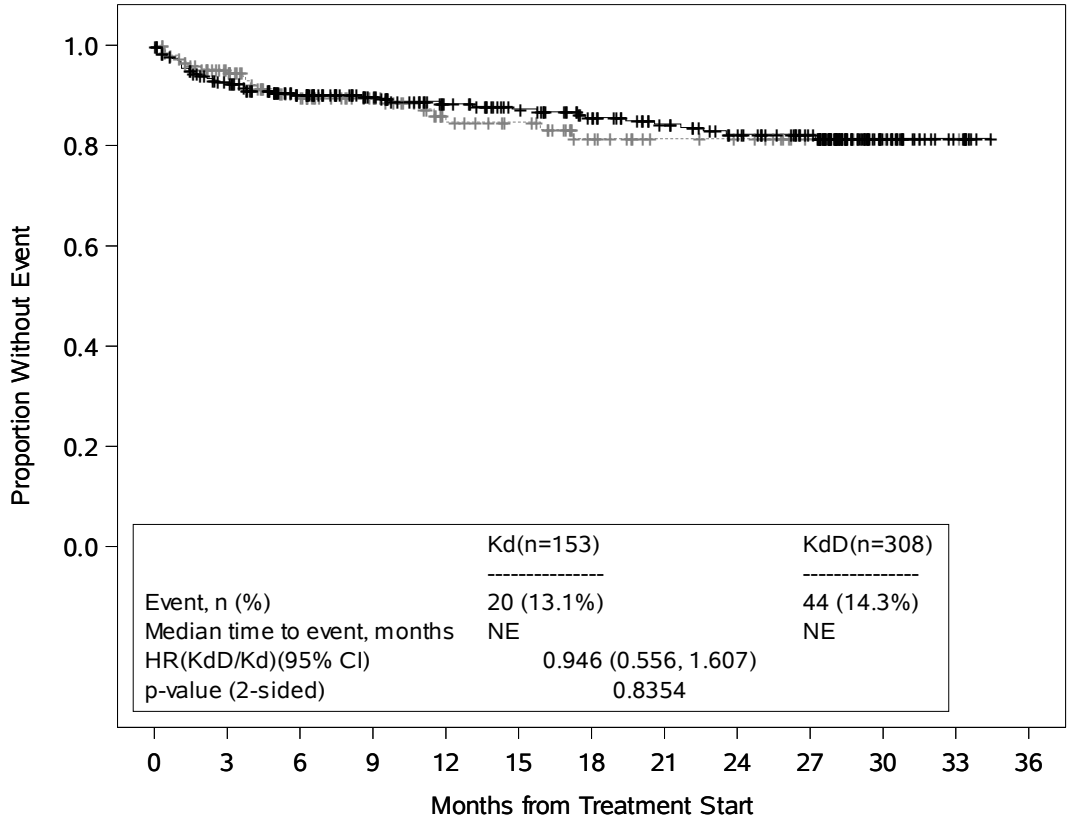


Number of Subjects at Risk:

Kd	153	114	87	66	52	48	38	30	28	21	5	2	0
KdD	308	244	199	165	141	125	107	98	88	77	22	8	0

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-ge10.sas.
Output: f14-06-004-517-ae-km-soc-psych-ge10.rtf (Date Generated: 16SEP20:01:19:26).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.4.518. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Renal and Urinary Disorders)
<Safety Population>

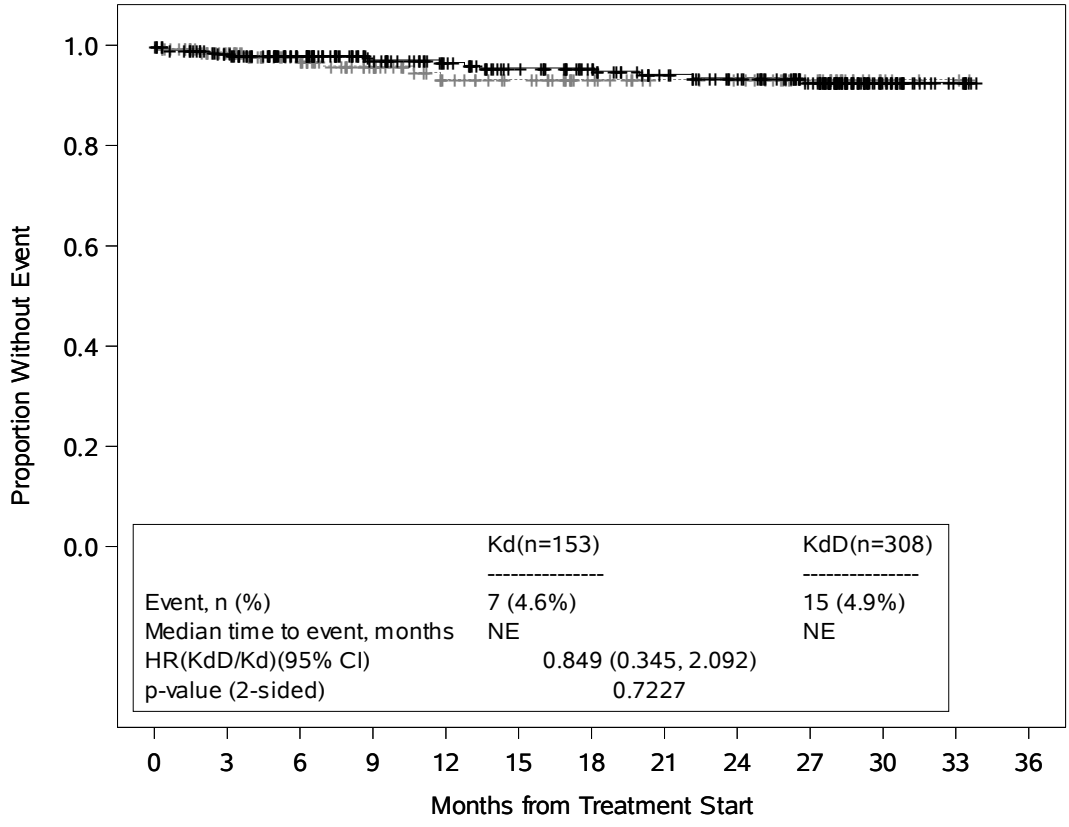


Number of Subjects at Risk:

Kd	153	127	103	85	64	57	43	35	33	25	6	2	0
KdD	308	270	234	200	176	161	144	128	116	100	31	10	0

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-ge10.sas.
Output: f14-06-004-518-ae-km-soc-renal-ge10.rtf (Date Generated: 16SEP20:01:19:28).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.4.519. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Reproductive System and Breast Disorders) <Safety Population>

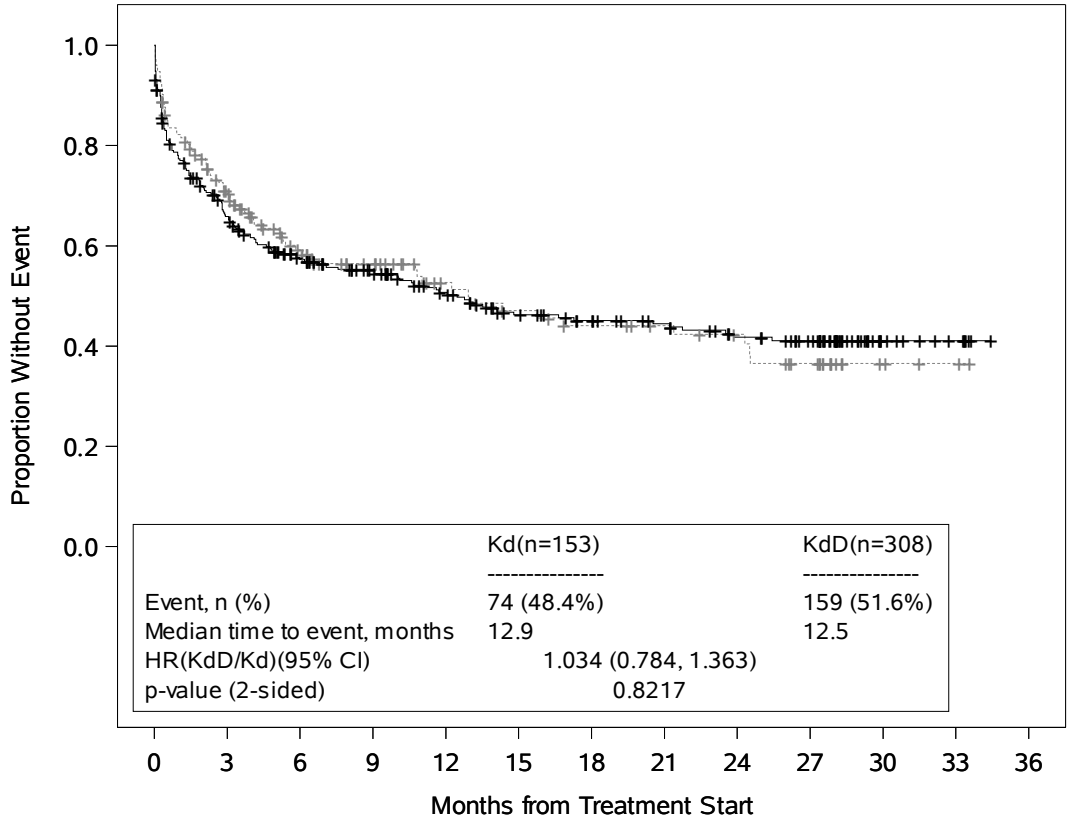


Number of Subjects at Risk:

Kd	153	131	105	84	65	58	45	37	35	25	5	2	0
KdD	308	284	247	206	185	167	153	137	125	102	34	9	0

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-ge10.sas.
Output: f14-06-004-519-ae-km-soc-repro-ge10.rtf (Date Generated: 16SEP20:01:19:30).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.4.520. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Respiratory, Thoracic and Mediastinal Disorders) <Safety Population>

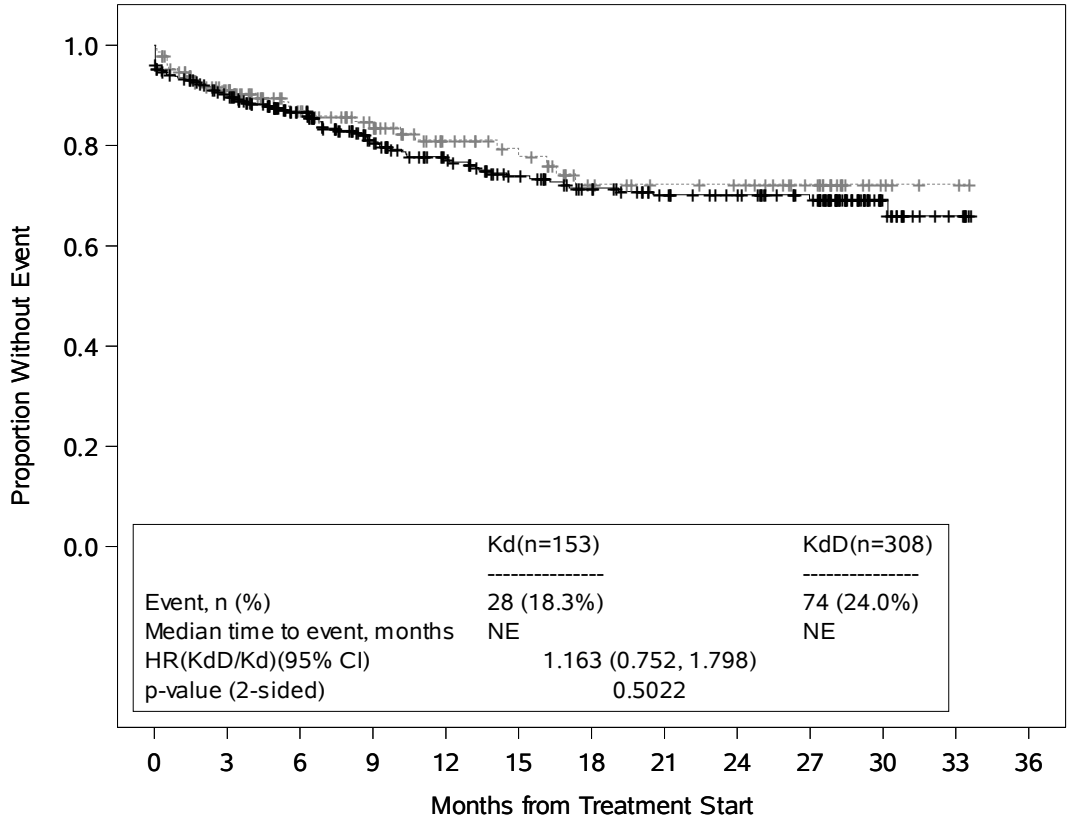


Number of Subjects at Risk:

Kd	153	97	67	53	38	32	28	25	22	16	4	2	0
KdD	308	191	151	129	106	87	78	70	60	51	13	7	0

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-ge10.sas.
Output: f14-06-004-520-ae-km-soc-respi-ge10.rtf (Date Generated: 16SEP20:01:19:32).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.4.521. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Skin and Subcutaneous Tissue Disorders)
<Safety Population>

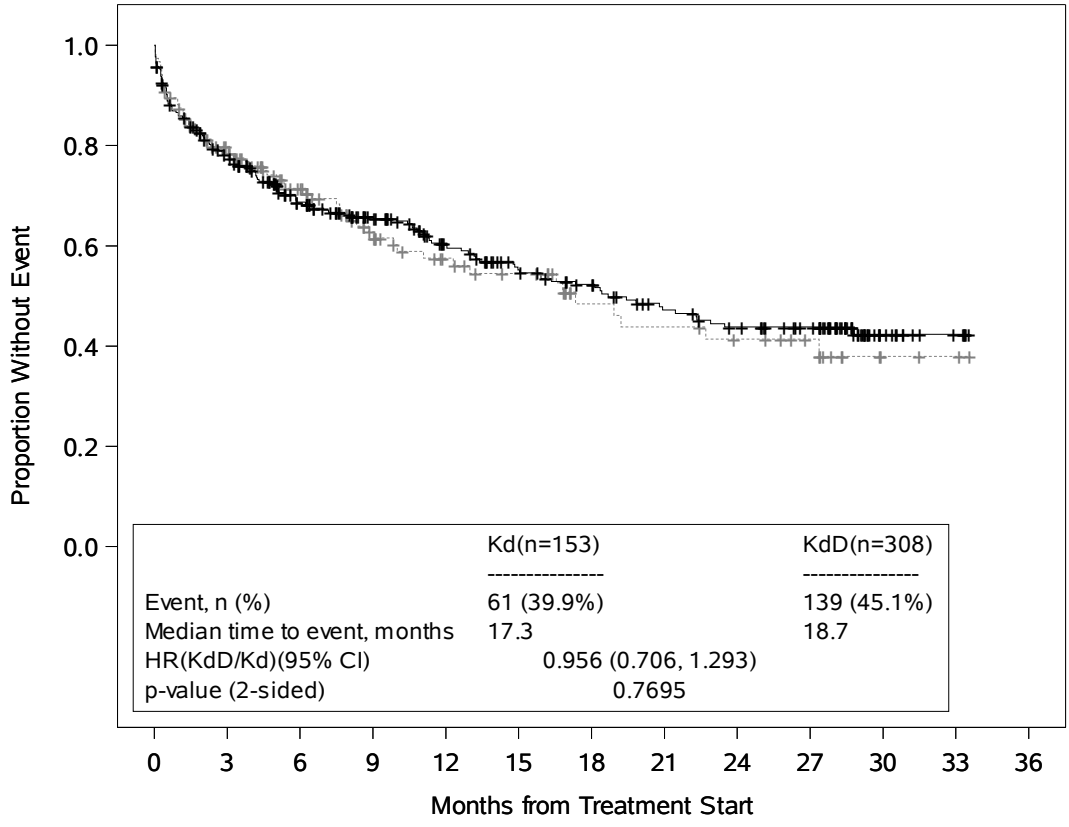


Number of Subjects at Risk:

Kd	153	123	95	75	55	48	35	31	29	21	5	2	0
KdD	308	261	218	173	147	127	112	99	92	79	22	7	0

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-ge10.sas.
Output: f14-06-004-521-ae-km-soc-skin-ge10.rtf (Date Generated: 16SEP20:01:19:34).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.4.522. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Vascular Disorders)
<Safety Population>

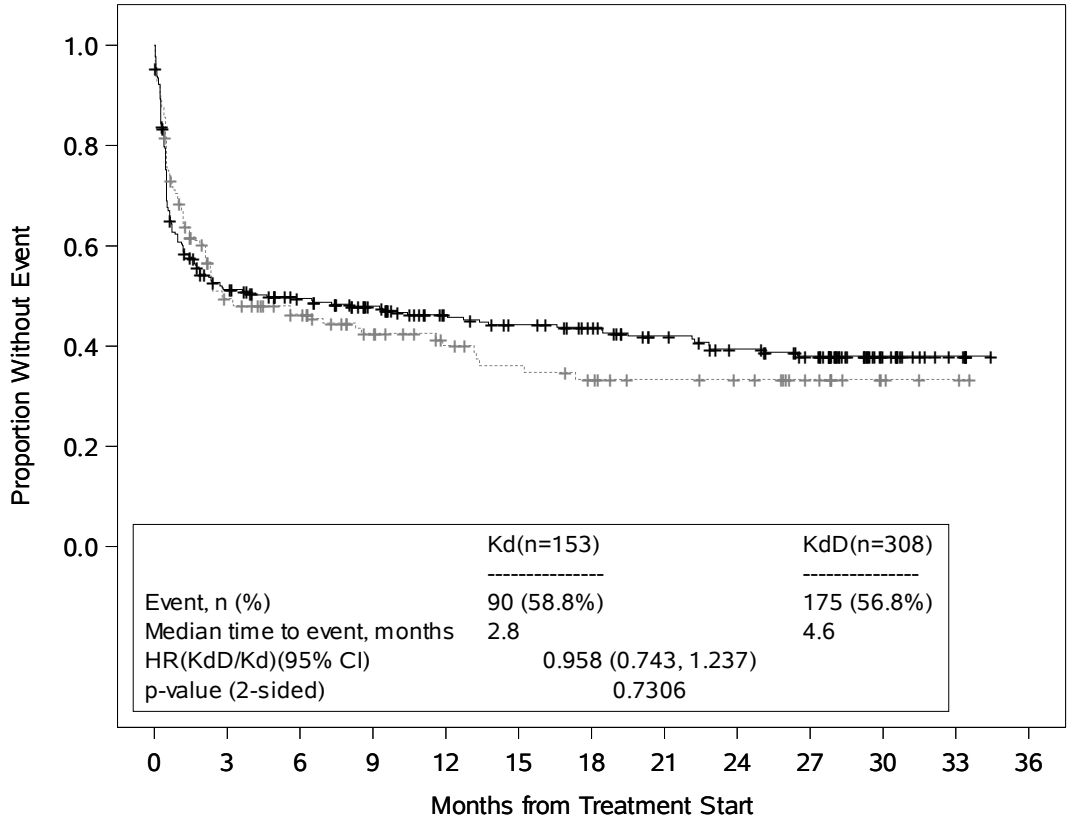


Number of Subjects at Risk:

Kd	153	106	75	52	39	33	21	19	16	12	3	2	0
KdD	308	227	177	147	117	97	86	71	63	54	14	5	0

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-ge10.sas.
Output: f14-06-004-522-ae-km-soc-vascu-ge10.rtf (Date Generated: 16SEP20:01:19:37).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.4.501. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Blood and Lymphatic System Disorders)
<Safety Population>

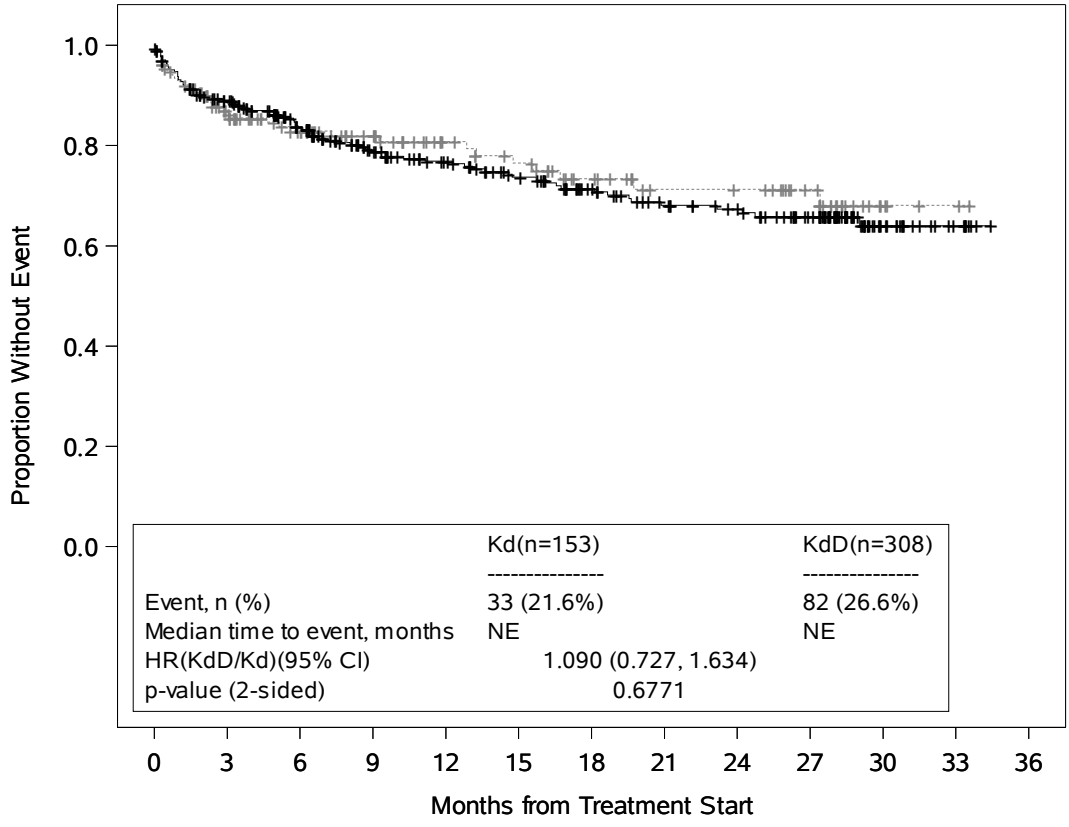


Number of Subjects at Risk:

Kd	153	67	56	41	32	27	23	19	17	11	4	2	0
KdD	308	149	131	114	95	87	79	67	58	49	19	6	0

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-ge10.sas.
Output: f14-06-004-501-ae-km-soc-blood-ge10.rtf (Date Generated: 16SEP20:01:18:54).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.4.502. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Cardiac Disorders)
<Safety Population>

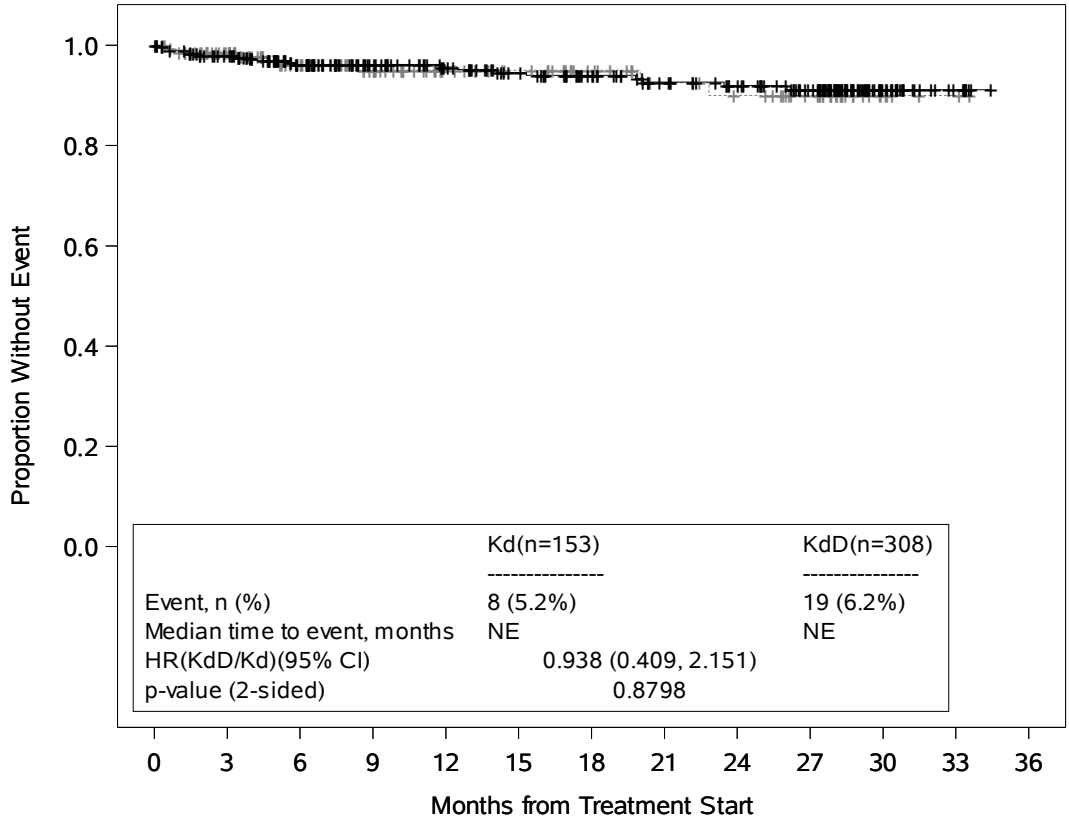


Number of Subjects at Risk:

Kd	153	115	92	76	59	52	41	32	31	23	5	2	0
KdD	308	258	213	171	151	133	113	98	90	74	22	8	0

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-ge10.sas.
Output: f14-06-004-502-ae-km-soc-cardi-ge10.rtf (Date Generated: 16SEP20:01:18:57).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.4.503. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Ear and Labyrinth Disorders)
<Safety Population>

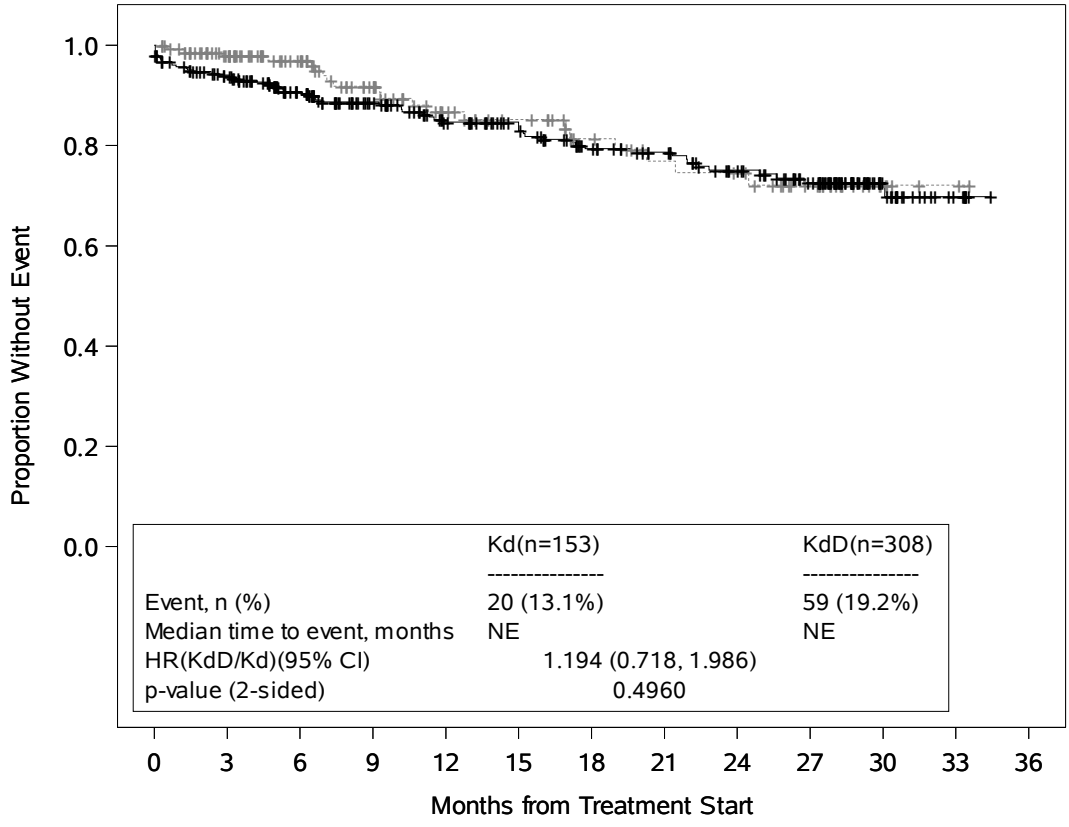


Number of Subjects at Risk:

Kd	153	130	104	83	63	56	45	37	34	26	6	2	0
KdD	308	284	243	205	184	167	150	133	122	102	31	9	0

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-ge10.sas.
Output: f14-06-004-503-ae-km-soc-ear-ge10.rtf (Date Generated: 16SEP20:01:18:59).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.4.505. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Eye Disorders)
<Safety Population>

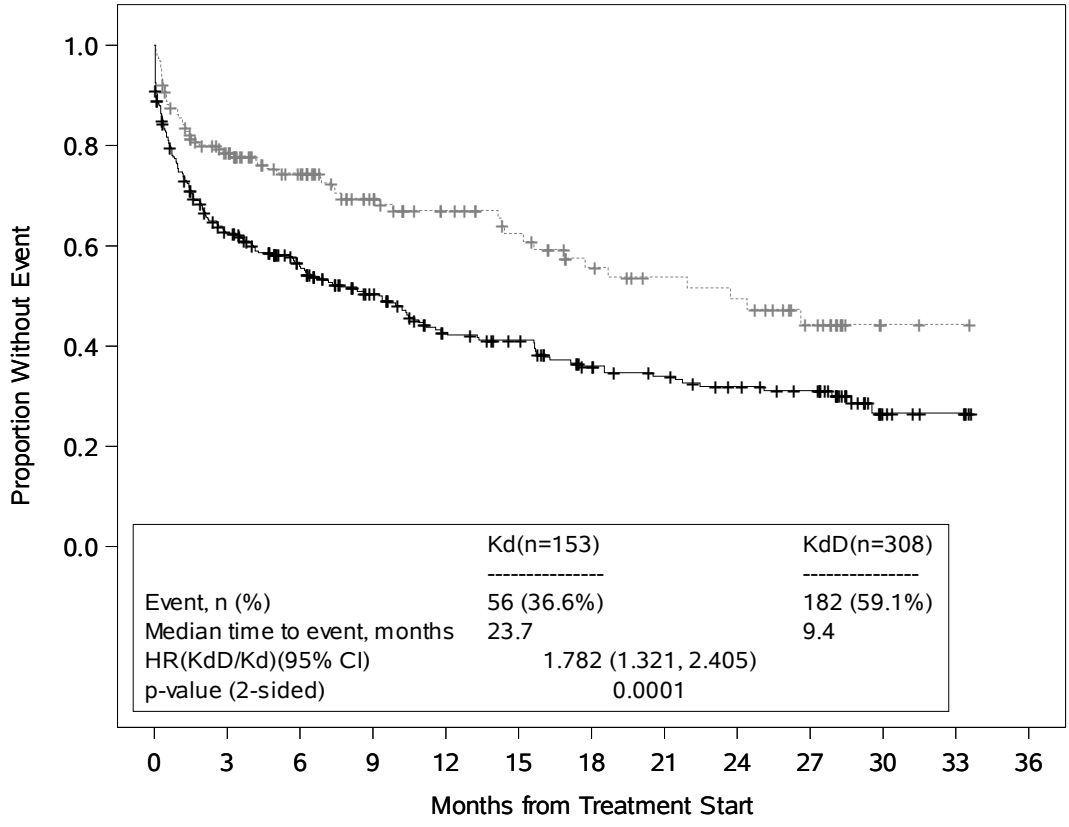


Number of Subjects at Risk:

Kd	153	129	104	80	59	51	39	33	31	22	6	2	0
KdD	308	272	229	190	162	147	125	114	98	80	27	8	0

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-ge10.sas.
Output: f14-06-004-505-ae-km-soc-eye-ge10.rtf (Date Generated: 16SEP20:01:19:02).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.4.506. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Gastrointestinal Disorders)
<Safety Population>

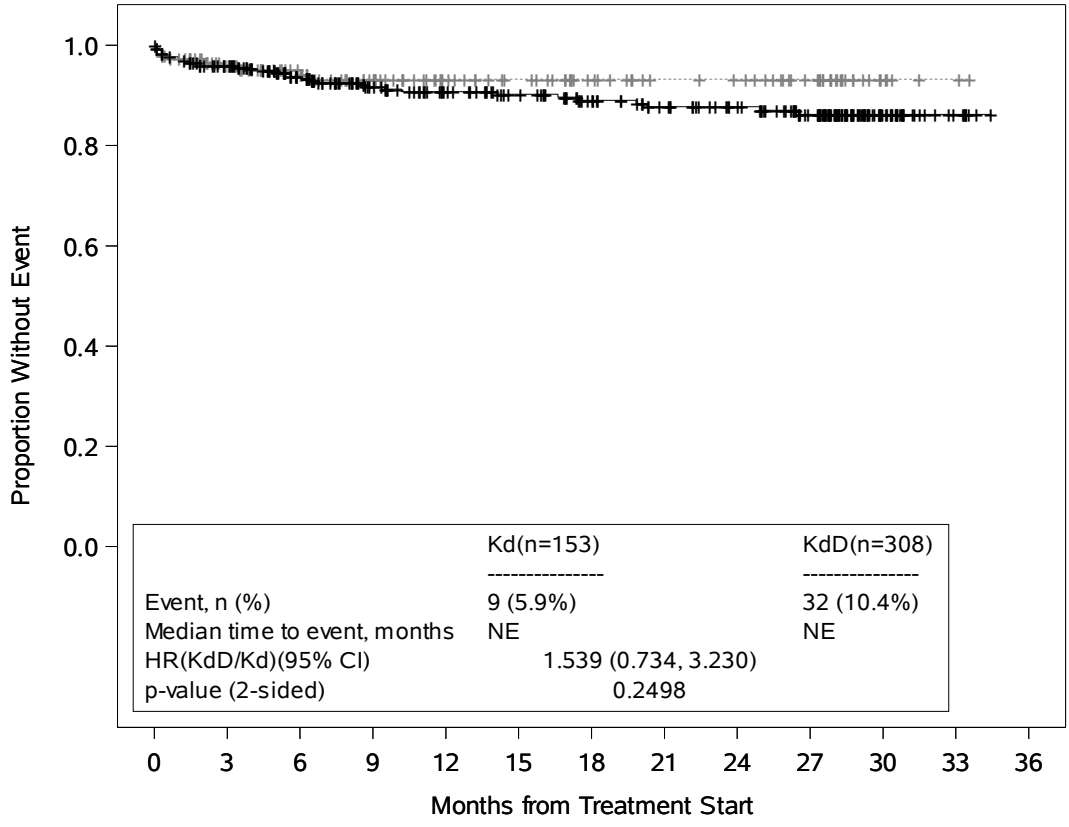


Number of Subjects at Risk:

Kd	153	107	84	61	48	40	30	25	23	14	2	1	0
KdD	308	180	142	110	83	75	57	50	43	38	10	5	0

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-ge10.sas.
Output: f14-06-004-506-ae-km-soc-gastr-ge10.rtf (Date Generated: 16SEP20:01:19:05).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.4.508. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Hepatobiliary Disorders)
<Safety Population>

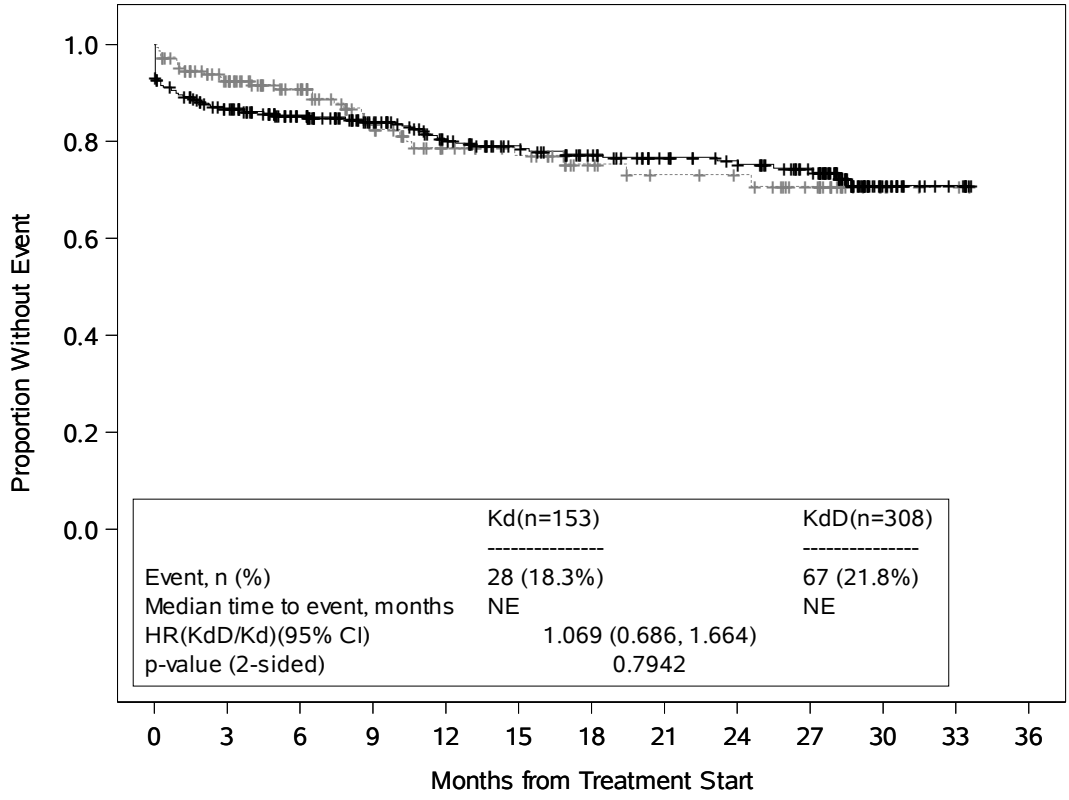


Number of Subjects at Risk:

Kd	153	127	105	84	65	57	46	38	36	27	6	2	0
KdD	308	277	239	199	179	164	146	132	120	98	33	8	0

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-ge10.sas.
Output: f14-06-004-508-ae-km-soc-hepat-ge10.rtf (Date Generated: 16SEP20:01:19:09).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.4.511. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Injury, Poisoning and Procedural Complications) <Safety Population>

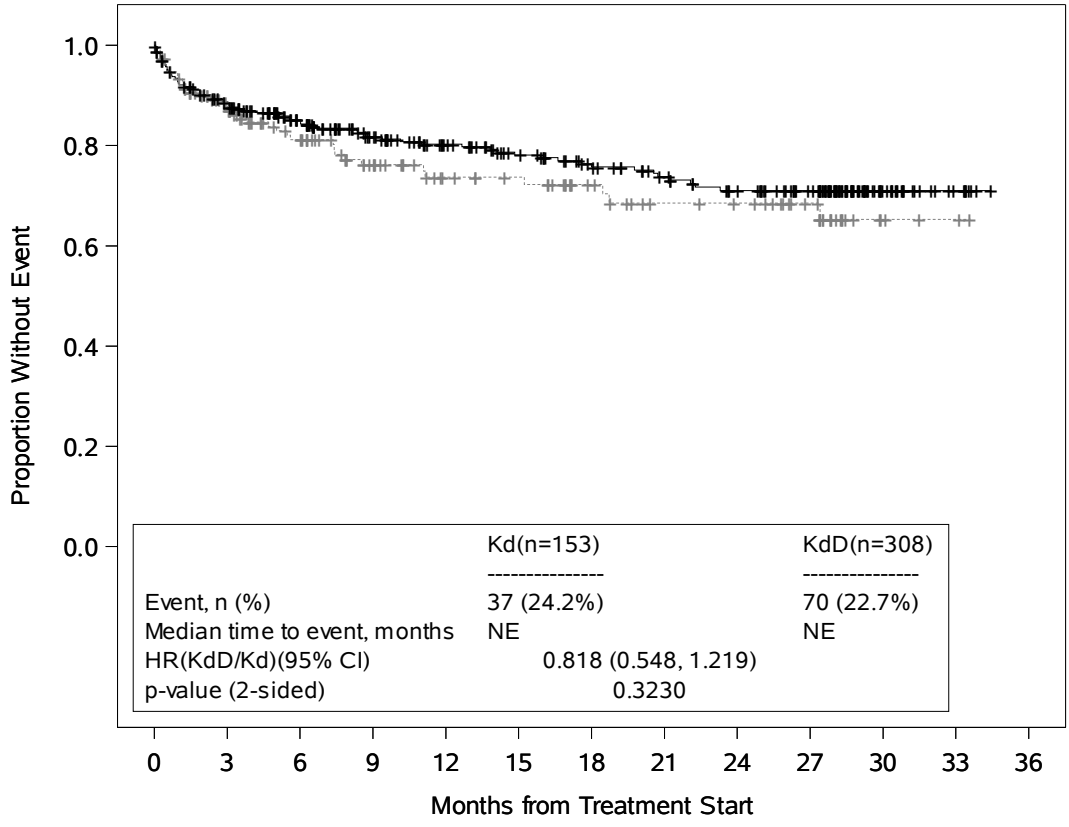


Number of Subjects at Risk:

Kd	153	124	101	75	55	49	37	32	30	22	5	2	0
KdD	308	252	216	182	156	139	125	111	103	87	23	7	0

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm.Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-ge10.sas.
Output: f14-06-004-511-ae-km-soc-injur-ge10.rtf (Date Generated: 16SEP20:01:19:15).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.4.512. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Investigations)
<Safety Population>

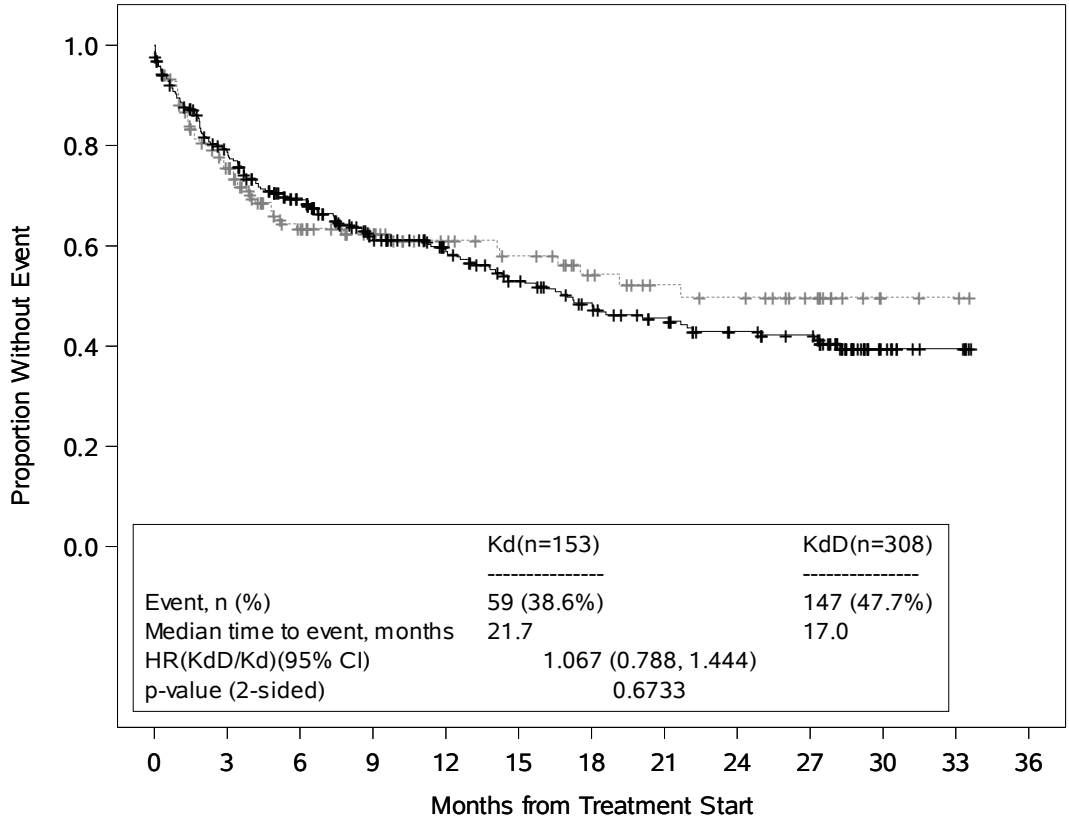


Number of Subjects at Risk:

Kd	153	117	93	70	55	51	40	32	30	22	4	2	0
KdD	308	258	217	181	157	139	123	111	99	83	27	8	0

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-ge10.sas.
Output: f14-06-004-512-ae-km-soc-inves-ge10.rtf (Date Generated: 16SEP20:01:19:16).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.4.514. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Musculoskeletal and Connective Tissue Disorders) <Safety Population>

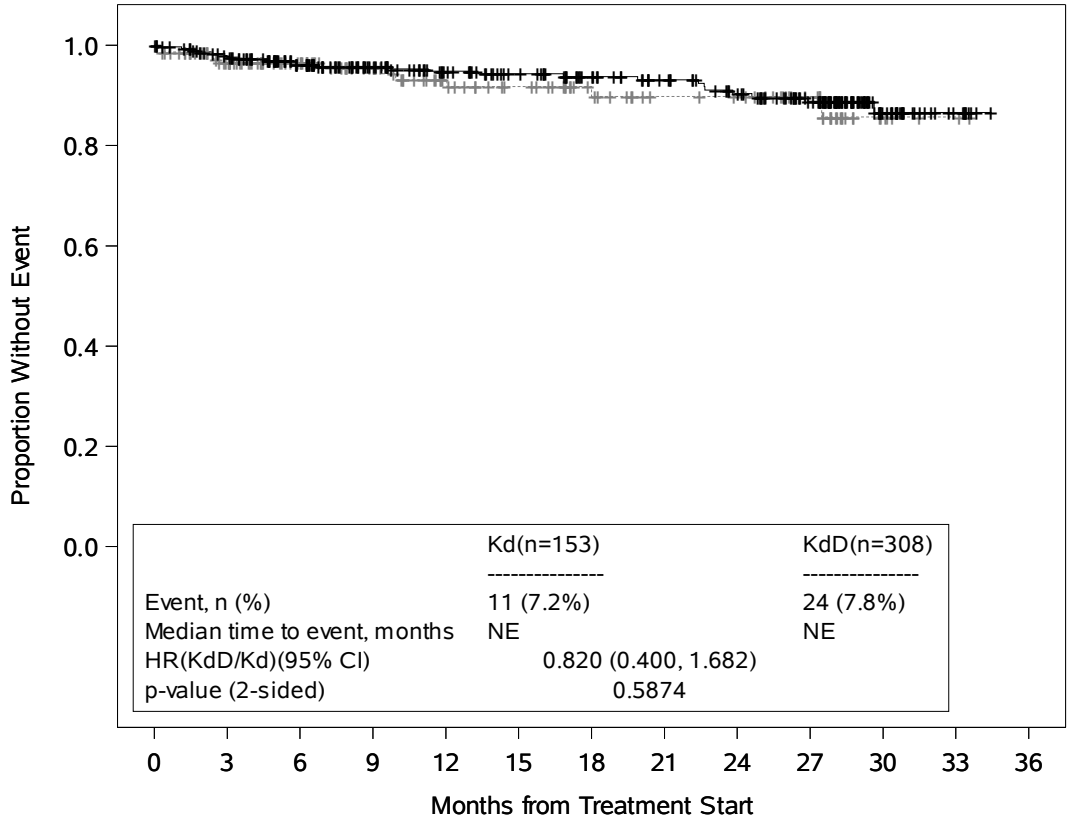


Number of Subjects at Risk:

Kd	153	105	70	55	42	36	27	21	19	13	3	2	0
KdD	308	229	183	138	118	98	83	71	59	54	13	6	0

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-ge10.sas.
Output: f14-06-004-514-ae-km-soc-muscu-ge10.rtf (Date Generated: 16SEP20:01:19:20).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.4.515. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps)) <Safety Population>

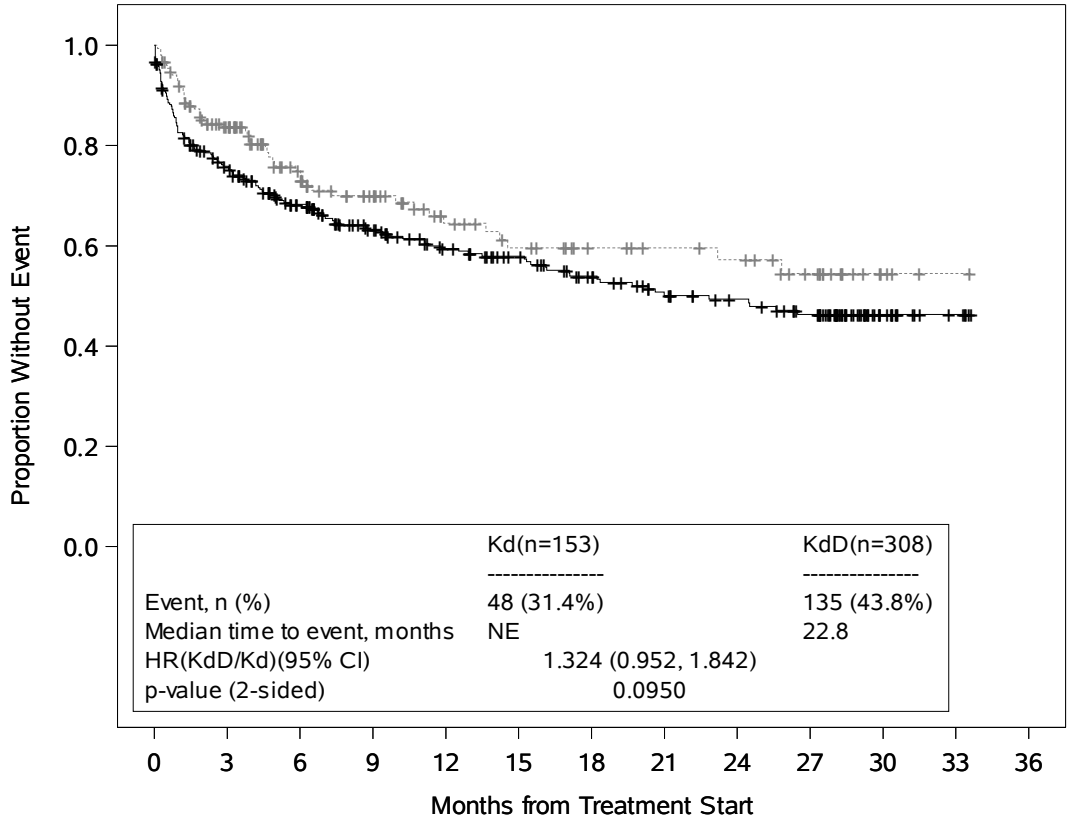


Number of Subjects at Risk:

Kd	153	129	107	87	67	58	46	38	36	26	6	2	0
KdD	308	286	249	212	189	173	157	143	129	106	33	9	0

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-ge10.sas.
Output: f14-06-004-515-ae-km-soc-neopl-ge10.rtf (Date Generated: 16SEP20:01:19:21).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.4.516. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Nervous System Disorders)
<Safety Population>

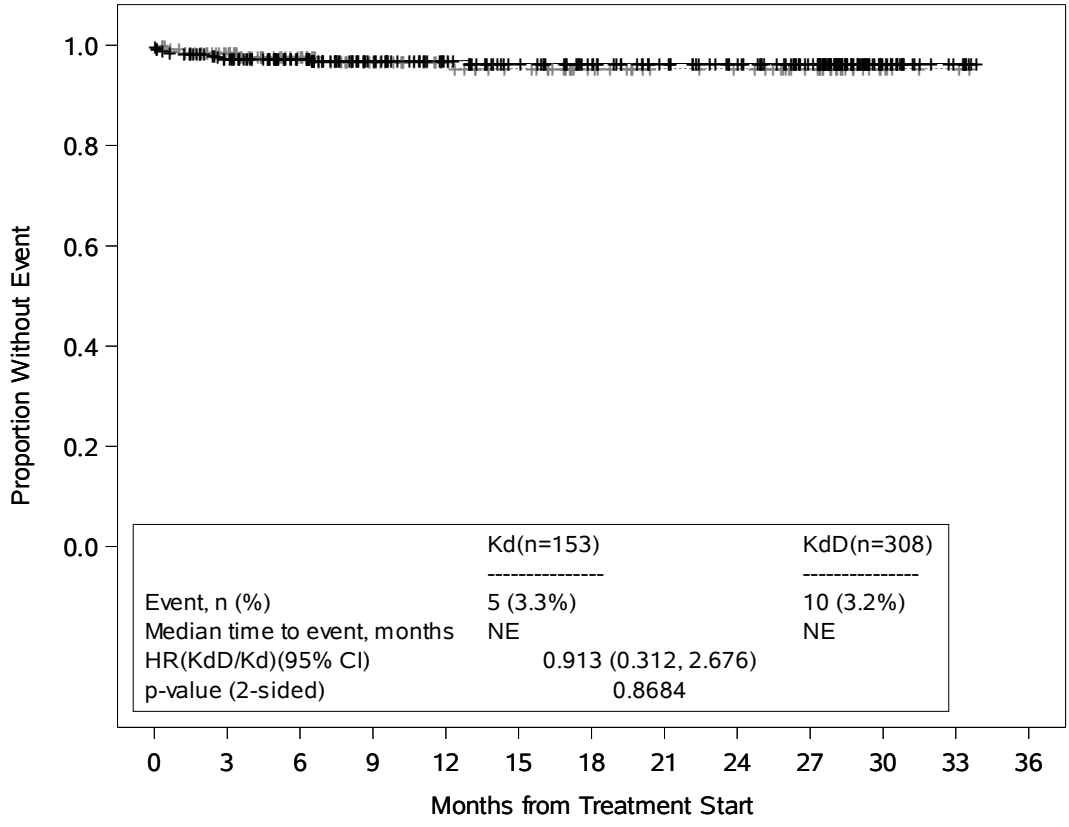


Number of Subjects at Risk:

Kd	153	111	79	60	43	36	29	26	24	17	4	1	0
KdD	308	220	177	141	119	105	89	75	67	57	16	5	0

Includes SOC where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-ge10.sas.
Output: f14-06-004-516-ae-km-soc-nervo-ge10.rtf (Date Generated: 16SEP20:01:19:23).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.564. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Psychiatric Disorders) and PT (Agitation) <Safety Population>

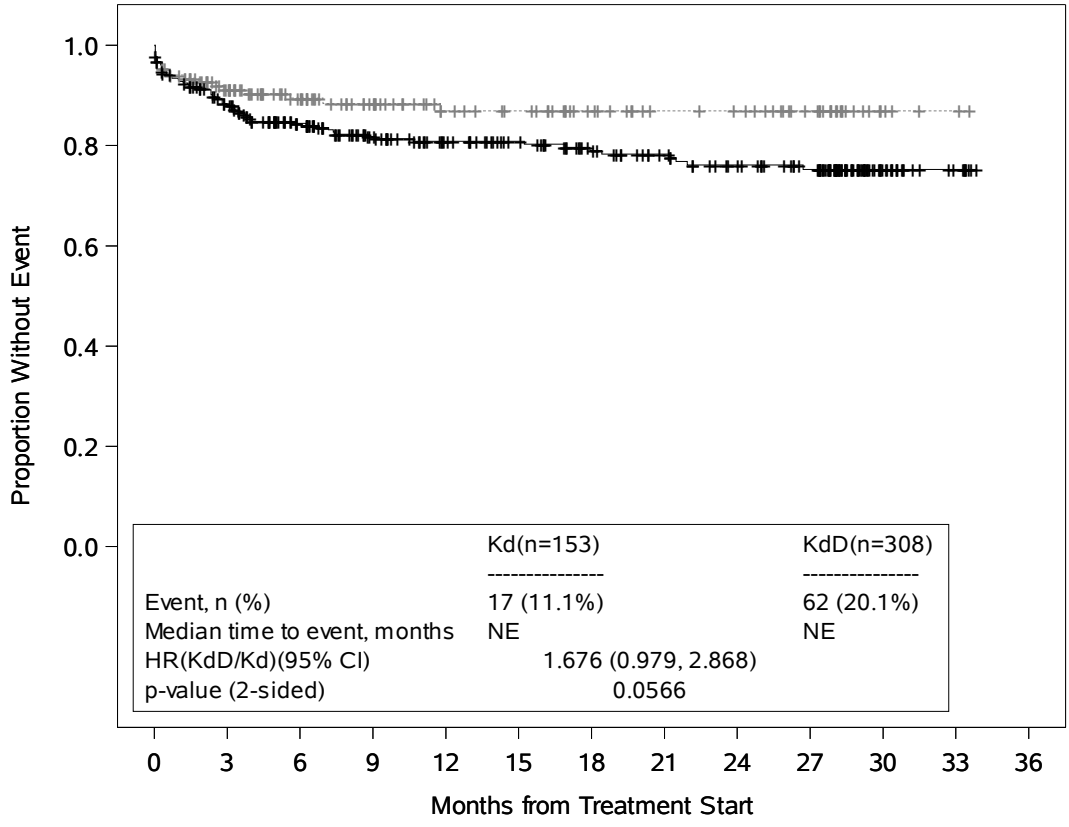


Number of Subjects at Risk:

Kd	153	131	106	85	67	59	46	38	36	27	6	2	0
KdD	308	282	246	207	186	169	153	138	126	105	31	8	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-564-ae-km-soc-psych-pt-agita-ge10.rtf (Date Generated: 16SEP20:20:38:11).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.565. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Psychiatric Disorders) and PT (Insomnia)
<Safety Population>

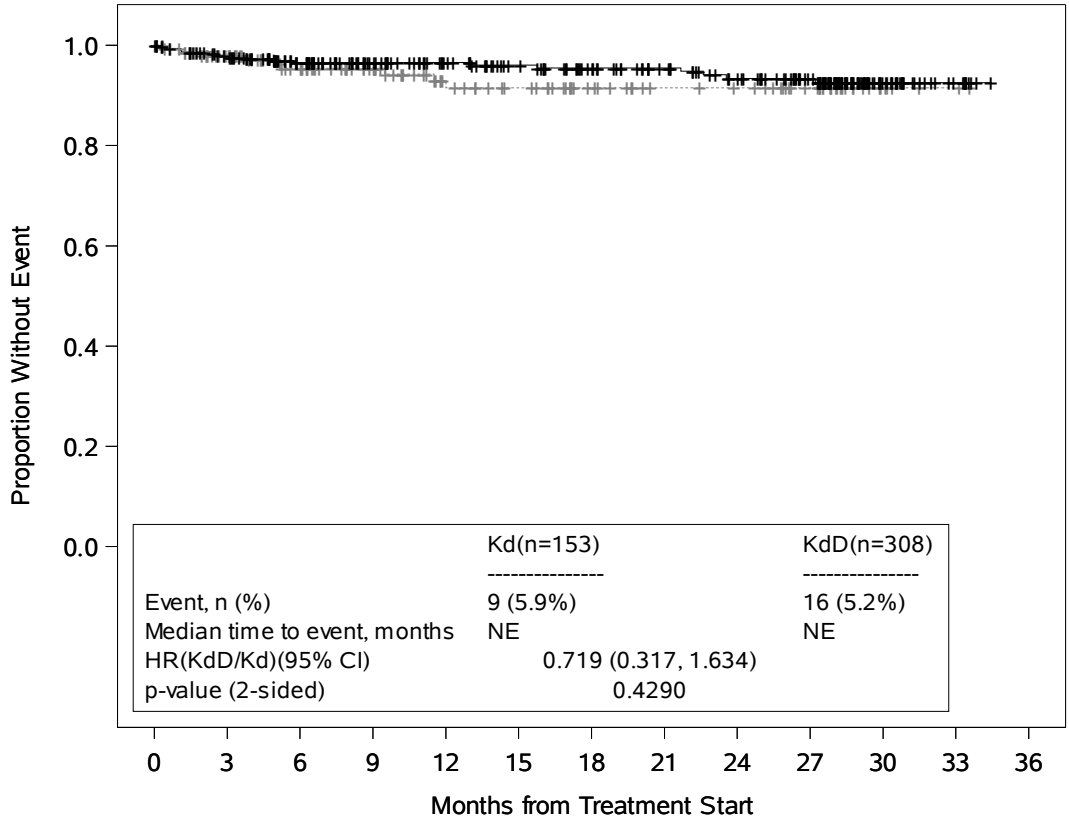


Number of Subjects at Risk:

Kd	153	119	94	74	58	53	42	34	32	23	5	2	0
KdD	308	253	210	174	152	138	121	109	97	85	24	8	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-565-ae-km-soc-psych-pt-insom-ge10.rtf (Date Generated: 16SEP20:20:38:12).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.566. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Renal and Urinary Disorders) and PT (Acute Kidney Injury) <Safety Population>

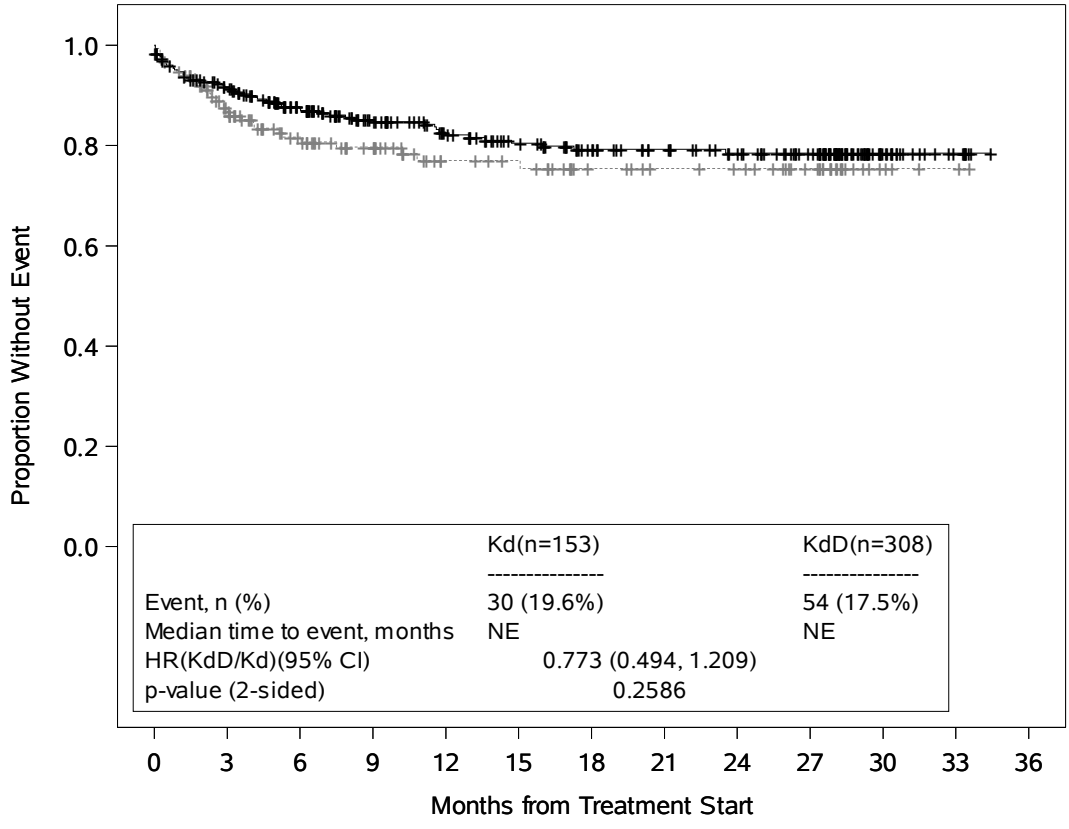


Number of Subjects at Risk:

Kd	153	131	107	87	66	58	46	38	36	27	6	2	0
KdD	308	286	250	212	191	174	158	143	129	108	34	10	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-566-ae-km-soc-renal-pt-acute-ge10.rtf (Date Generated: 16SEP20:20:38:14).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.567. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Respiratory, Thoracic and Mediastinal Disorders) and PT (Cough) <Safety Population>

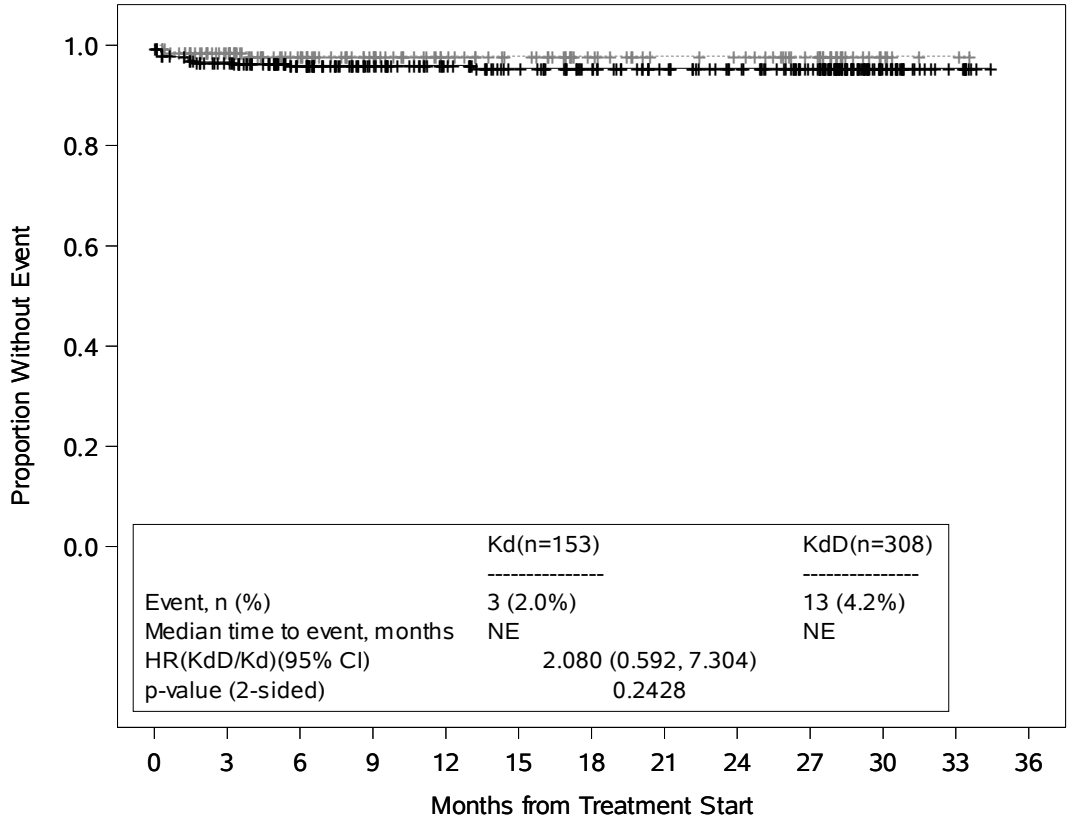


Number of Subjects at Risk:

Kd	153	114	87	71	51	48	37	33	31	23	5	2	0
KdD	308	266	221	181	155	138	121	110	100	84	24	8	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-567-ae-km-soc-respi-pt-cough-ge10.rtf (Date Generated: 16SEP20:20:38:15).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.568. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Respiratory, Thoracic and Mediastinal Disorders) and PT (Dysphonia) <Safety Population>

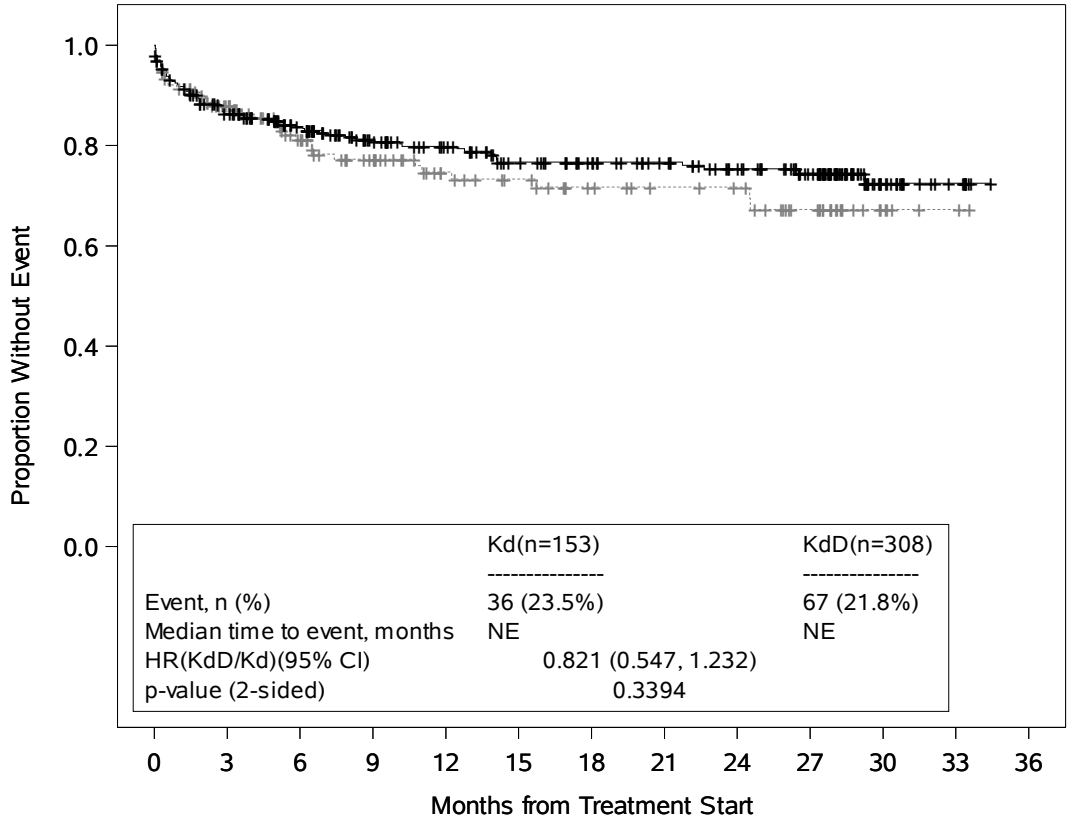


Number of Subjects at Risk:

Kd	153	130	105	85	67	59	46	38	36	26	6	2	0
KdD	308	280	243	208	187	170	155	140	128	108	35	10	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-568-ae-km-soc-respi-pt-dysph-ge10.rtf (Date Generated: 16SEP20:20:38:17).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.569. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Respiratory, Thoracic and Mediastinal Disorders) and PT (Dyspnoea) <Safety Population>

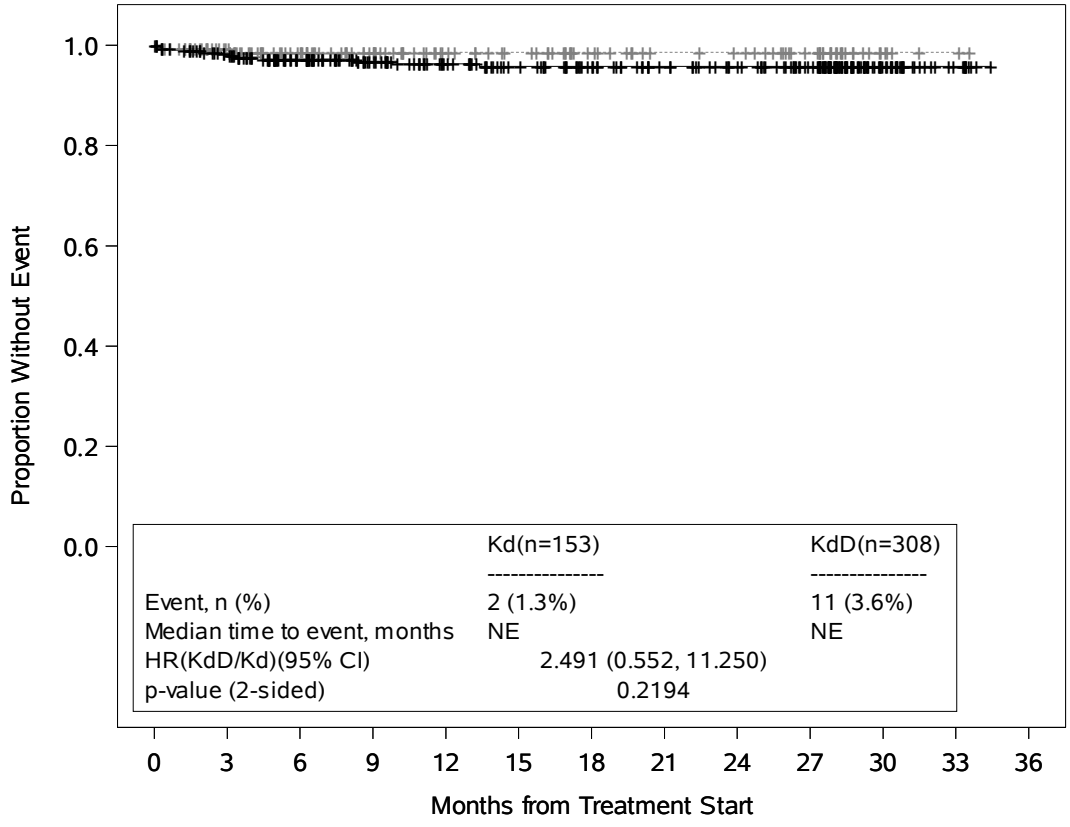


Number of Subjects at Risk:

Kd	153	119	90	70	53	47	39	35	33	23	6	2	0
KdD	308	249	214	178	160	140	128	117	104	85	24	9	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-569-ae-km-soc-respi-pt-dyspn-ge10.rtf (Date Generated: 16SEP20:20:38:18).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.570. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Respiratory, Thoracic and Mediastinal Disorders) and PT (Dyspnoea Exertional) <Safety Population>

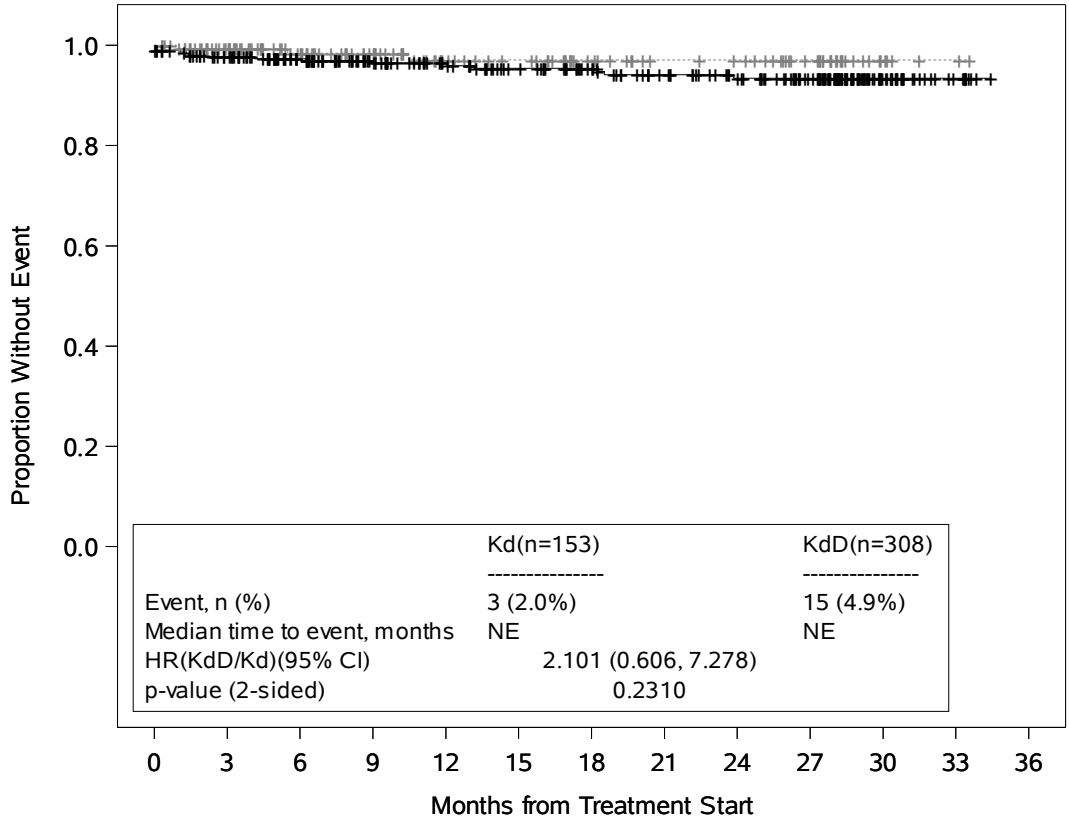


Number of Subjects at Risk:

Kd	153	131	106	86	67	60	47	39	37	27	6	2	0
KdD	308	284	245	206	184	167	151	136	125	106	36	10	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-570-ae-km-soc-respi-pt-dysexe-ge10.rtf (Date Generated: 16SEP20:20:38:20).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.571. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Respiratory, Thoracic and Mediastinal Disorders) and PT (Oropharyngeal Pain) <Safety Population>

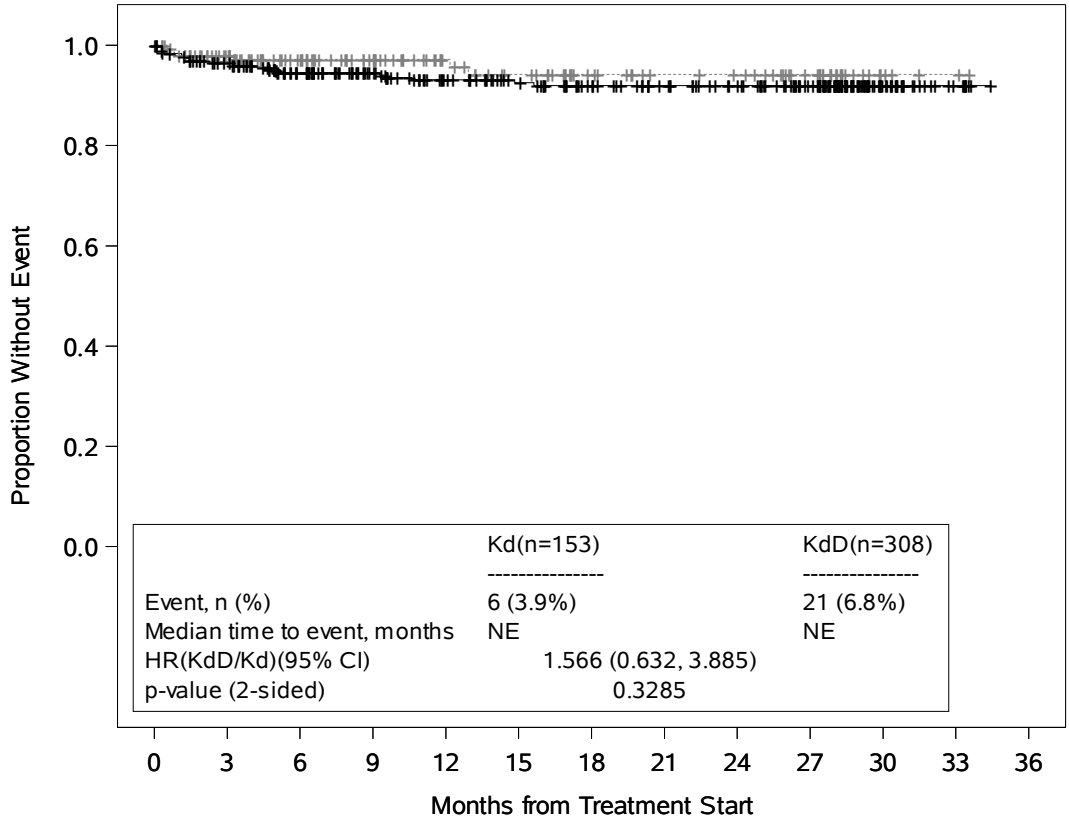


Number of Subjects at Risk:

Kd	153	131	106	86	65	59	46	38	36	26	6	2	0
KdD	308	282	246	208	187	170	154	138	125	104	35	10	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-571-ae-km-soc-respi-pt-oroph-ge10.rtf (Date Generated: 16SEP20:20:38:21).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.572. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Respiratory, Thoracic and Mediastinal Disorders) and PT (Productive Cough) <Safety Population>

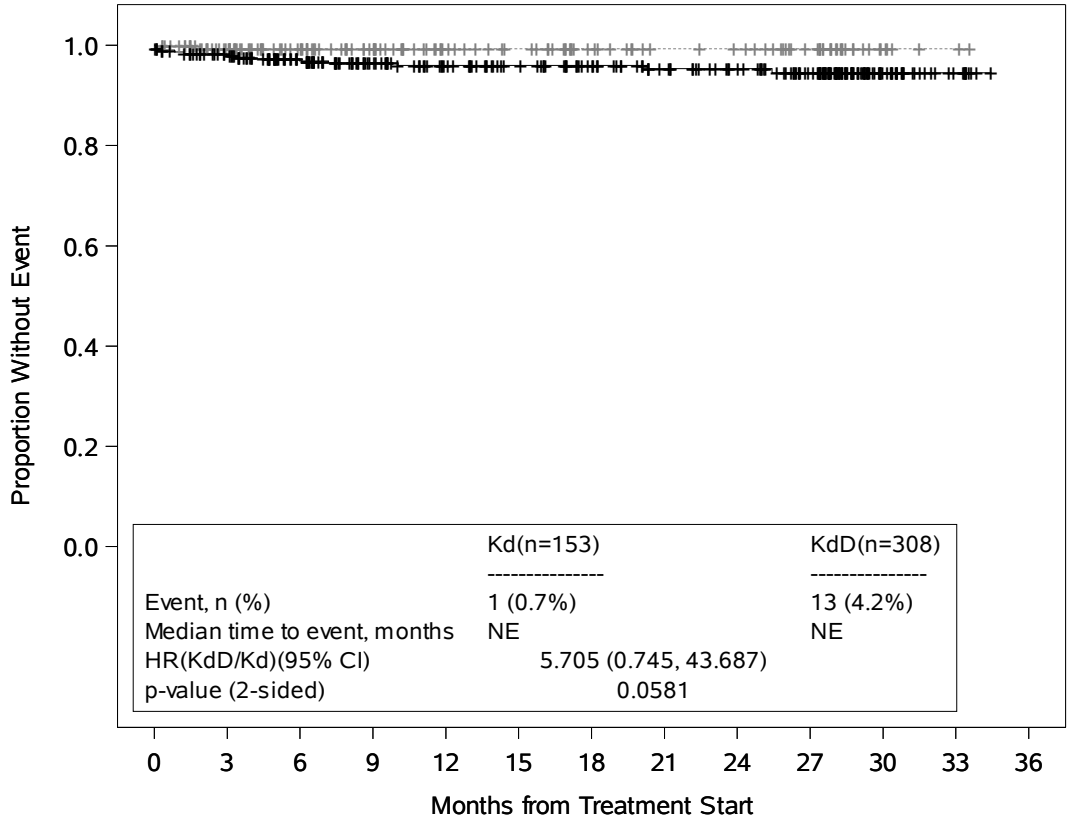


Number of Subjects at Risk:

Kd	153	130	105	85	66	57	44	37	35	25	5	2	0
KdD	308	280	240	204	180	164	148	135	124	102	33	9	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-572-ae-km-soc-respi-pt-produ-ge10.rtf (Date Generated: 16SEP20:20:38:23).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.573. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Respiratory, Thoracic and Mediastinal Disorders) and PT (Rhinorrhoea) <Safety Population>

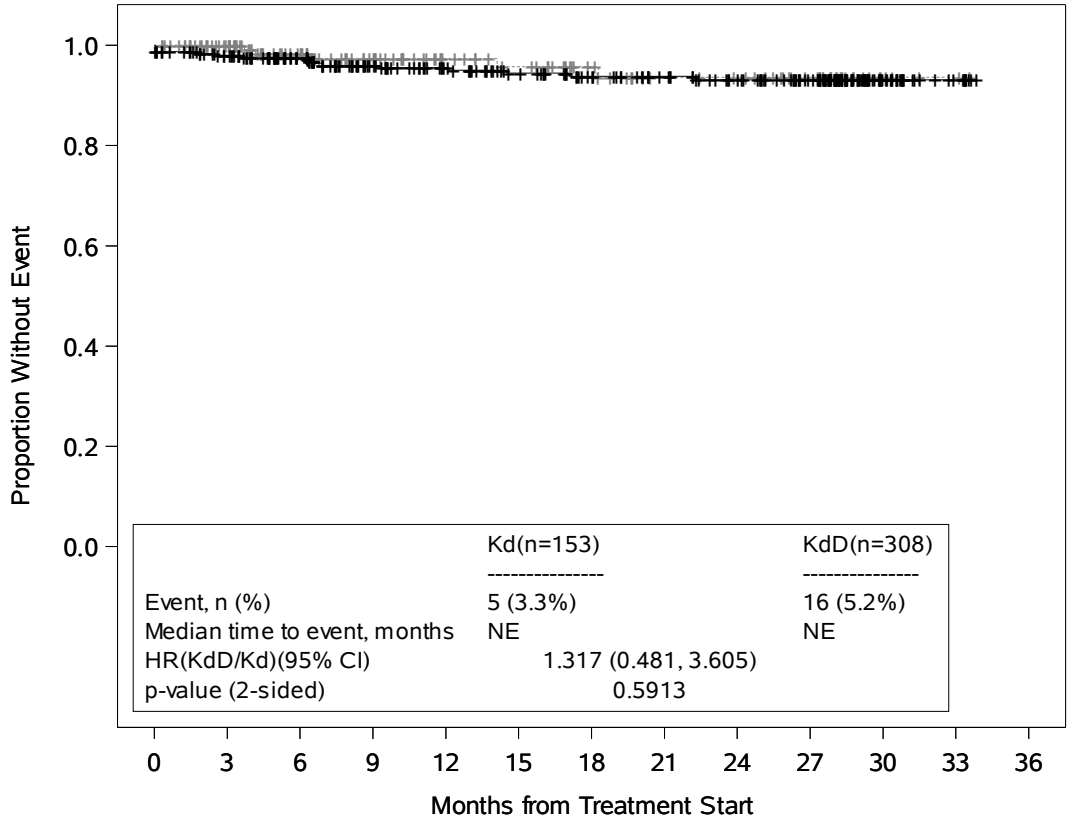


Number of Subjects at Risk:

Kd	153	131	107	87	67	60	47	39	37	27	6	2	0
KdD	308	283	245	206	185	170	155	139	127	105	33	10	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-573-ae-km-soc-respi-pt-rhino-ge10.rtf (Date Generated: 16SEP20:20:38:24).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.574. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Skin and Subcutaneous Tissue Disorders) and PT (Pruritus) <Safety Population>

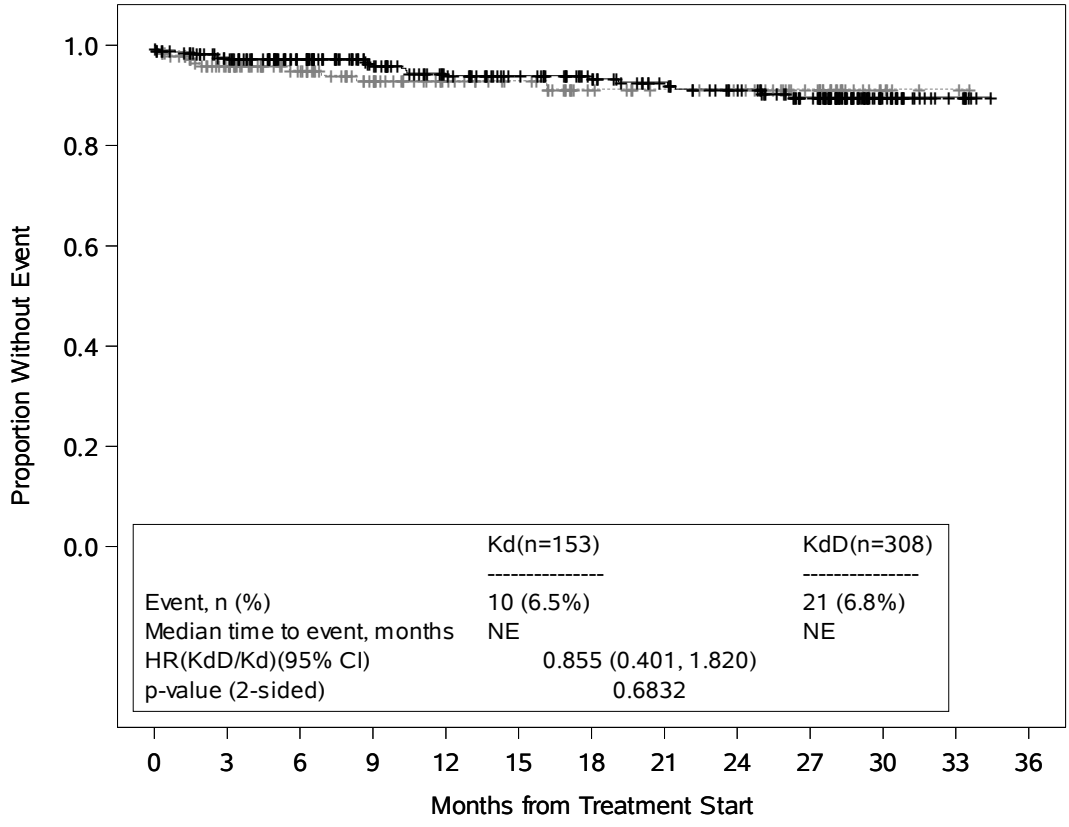


Number of Subjects at Risk:

Kd	153	132	106	85	65	58	46	37	35	26	5	2	0
KdD	308	283	246	206	184	166	150	137	124	103	32	9	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-574-ae-km-soc-skin-pt-pruri-ge10.rtf (Date Generated: 16SEP20:20:38:26).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.575. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Skin and Subcutaneous Tissue Disorders) and PT (Rash) <Safety Population>

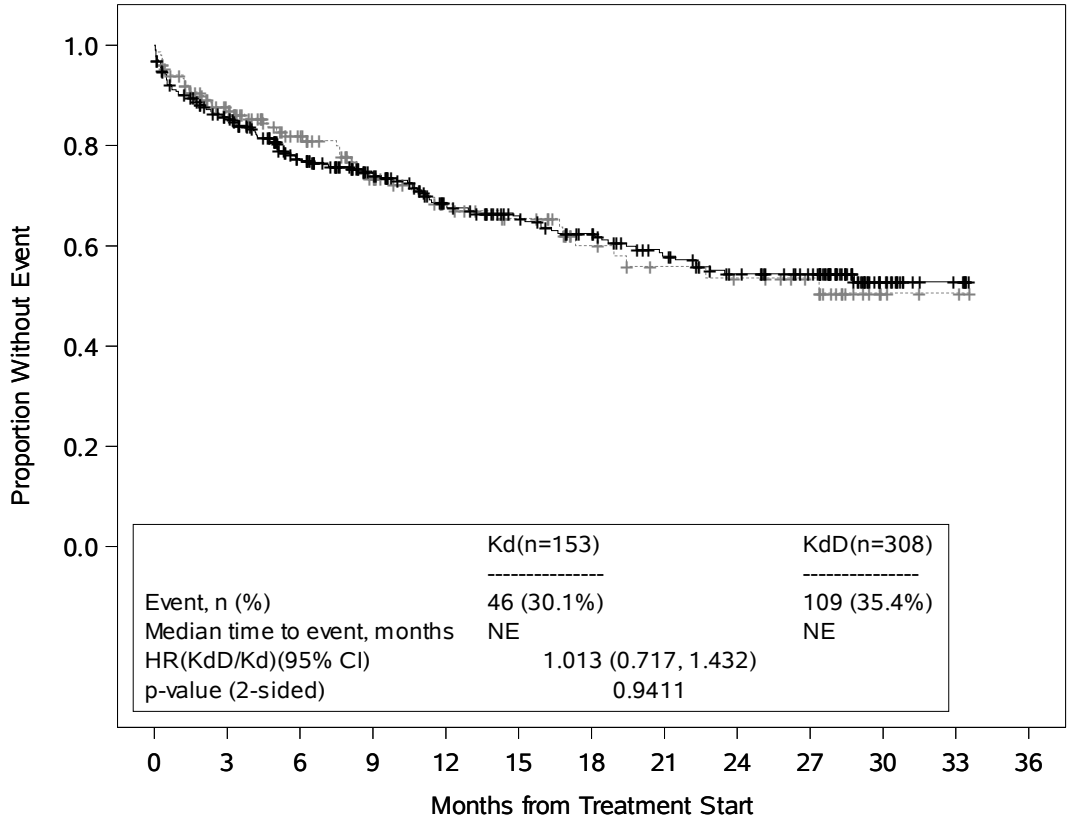


Number of Subjects at Risk:

Kd	153	128	104	83	65	57	43	38	36	26	6	2	0
KdD	308	282	245	205	180	164	148	134	122	102	32	9	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-575-ae-km-soc-skin-pt-rash-ge10.rtf (Date Generated: 16SEP20:20:38:28).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.576. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Vascular Disorders) and PT (Hypertension) <Safety Population>

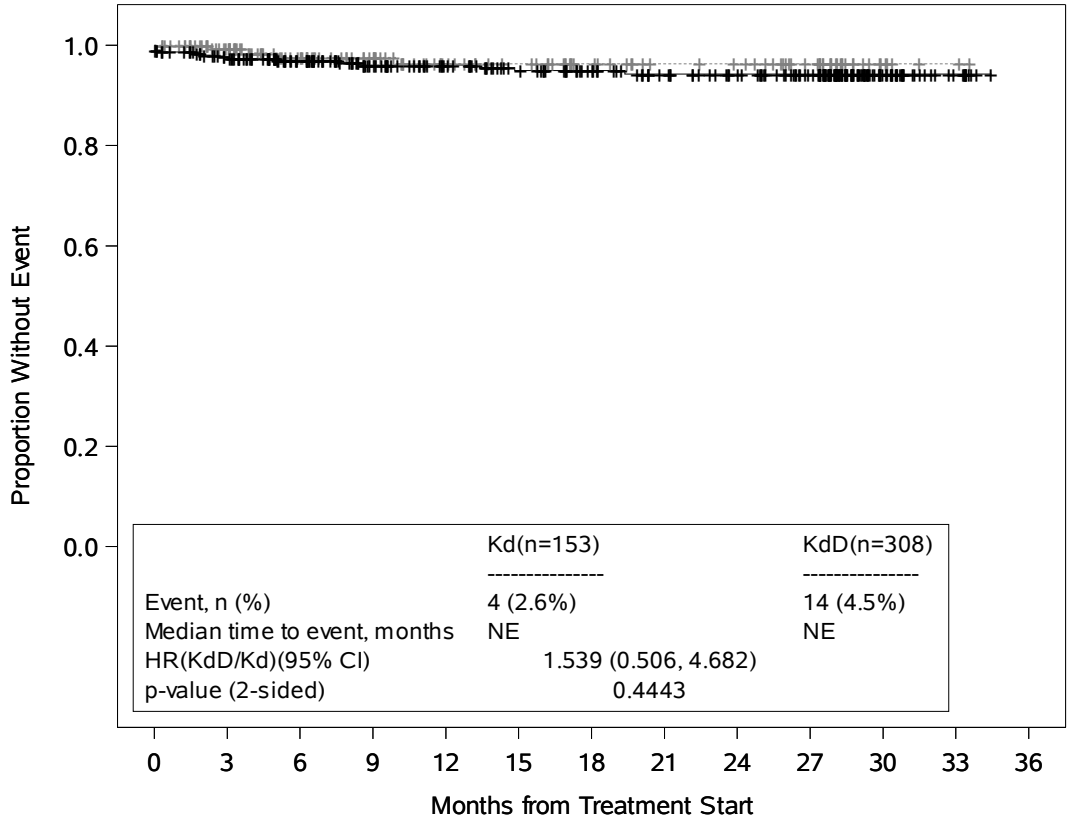


Number of Subjects at Risk:

Kd	153	116	88	64	49	42	30	25	22	18	4	2	0
KdD	308	249	198	164	132	115	102	86	73	63	19	6	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-576-ae-km-soc-vascu-pt-hyper-ge10.rtf (Date Generated: 16SEP20:20:38:29).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.577. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Vascular Disorders) and PT (Hypotension) <Safety Population>

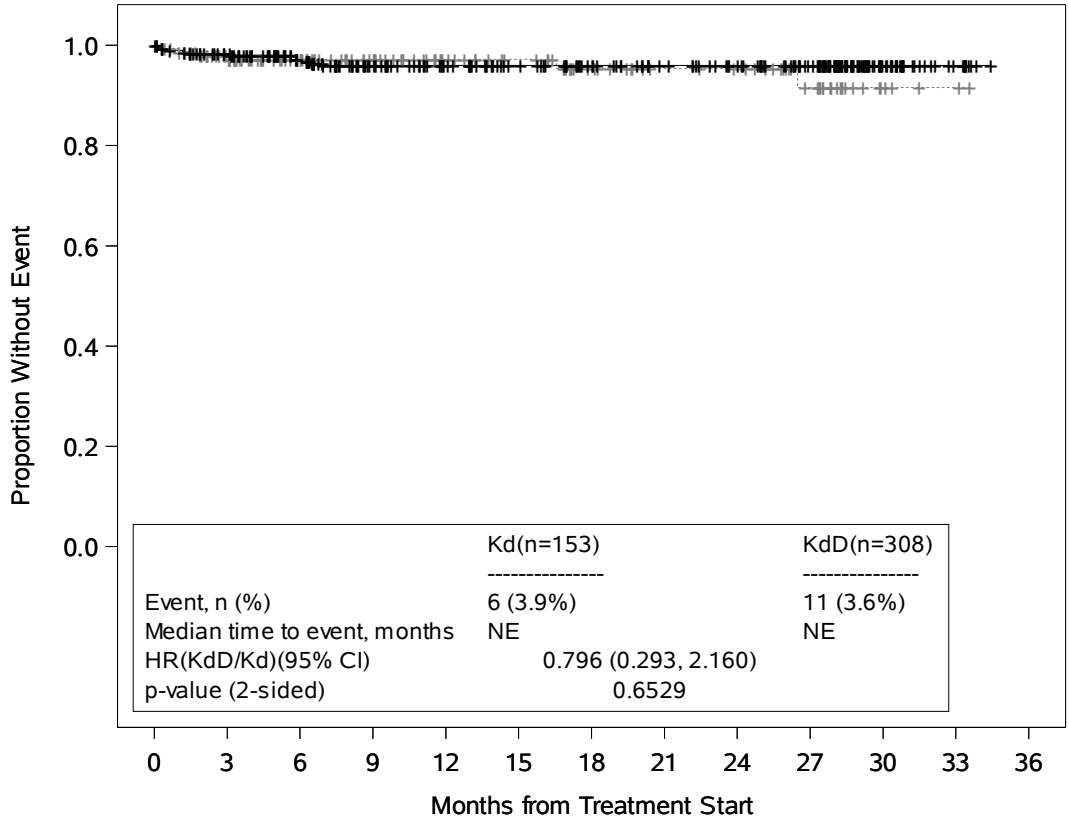


Number of Subjects at Risk:

Kd	153	131	105	86	66	59	47	39	37	27	6	2	0
KdD	308	282	244	205	184	166	151	136	125	106	35	10	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-577-ae-km-soc-vascu-pt-hypot-ge10.rtf (Date Generated: 16SEP20:20:38:31).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.578. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Vascular Disorders) and PT (Phlebitis) <Safety Population>

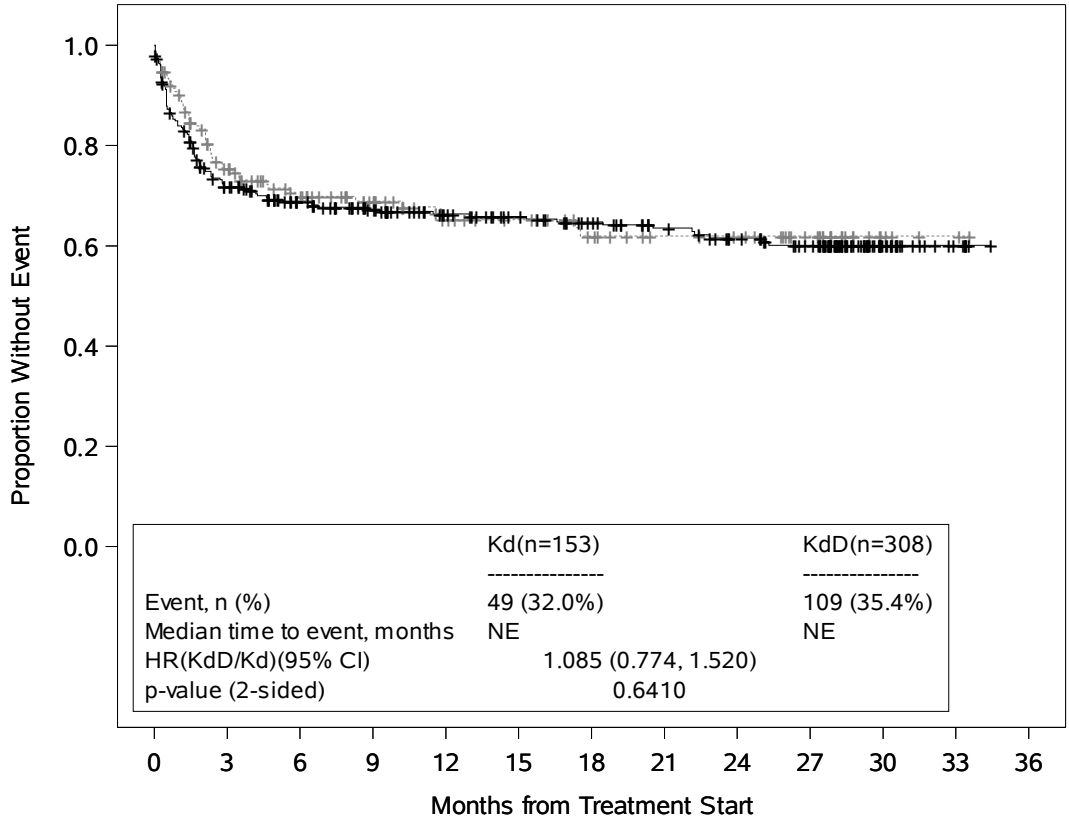


Number of Subjects at Risk:

Kd	153	129	104	84	65	57	44	36	34	23	5	2	0
KdD	308	284	245	204	184	168	153	139	129	109	35	10	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-578-ae-km-soc-vascu-pt-phleb-ge10.rtf (Date Generated: 16SEP20:20:38:32).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.501. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Blood and Lymphatic System Disorders) and PT (Anaemia) <Safety Population>

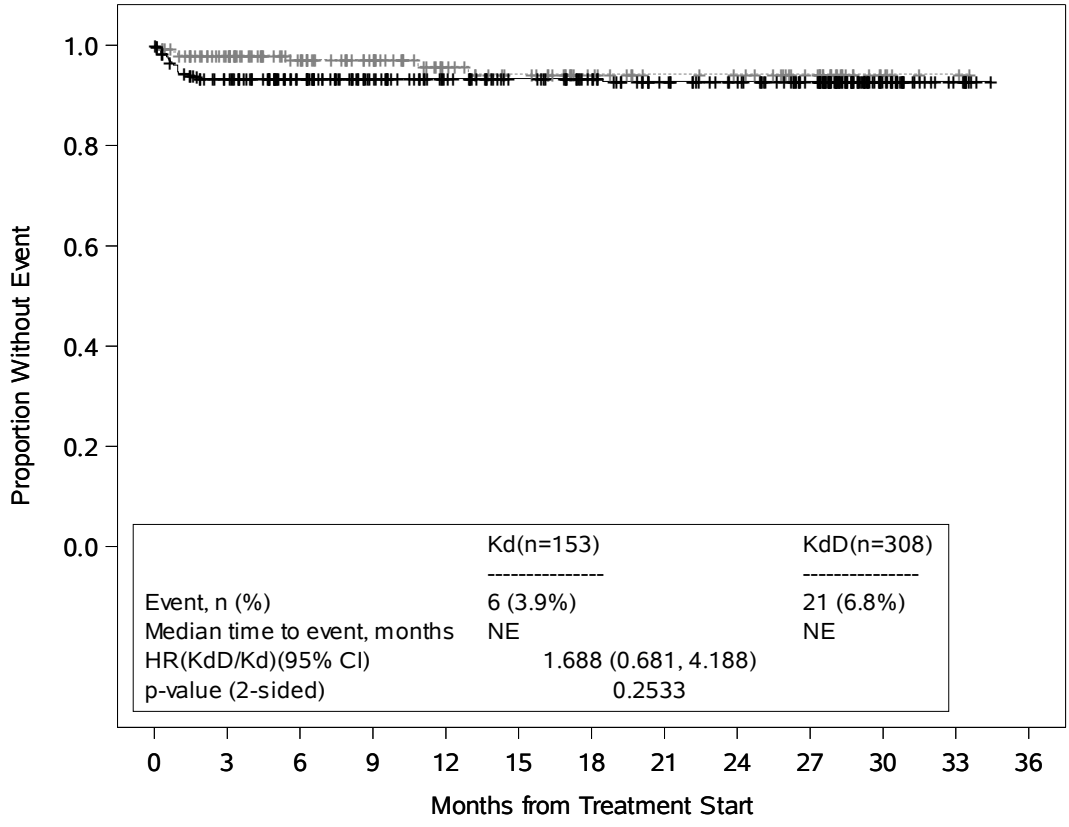


Number of Subjects at Risk:

Kd	153	103	84	67	50	45	37	31	29	21	5	2	0
KdD	308	207	177	155	135	123	111	98	88	77	25	7	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-501-ae-km-soc-blood-pt-anaem-ge10.rtf (Date Generated: 16SEP20:20:36:32).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.502. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Blood and Lymphatic System Disorders) and PT (Leukopenia) <Safety Population>

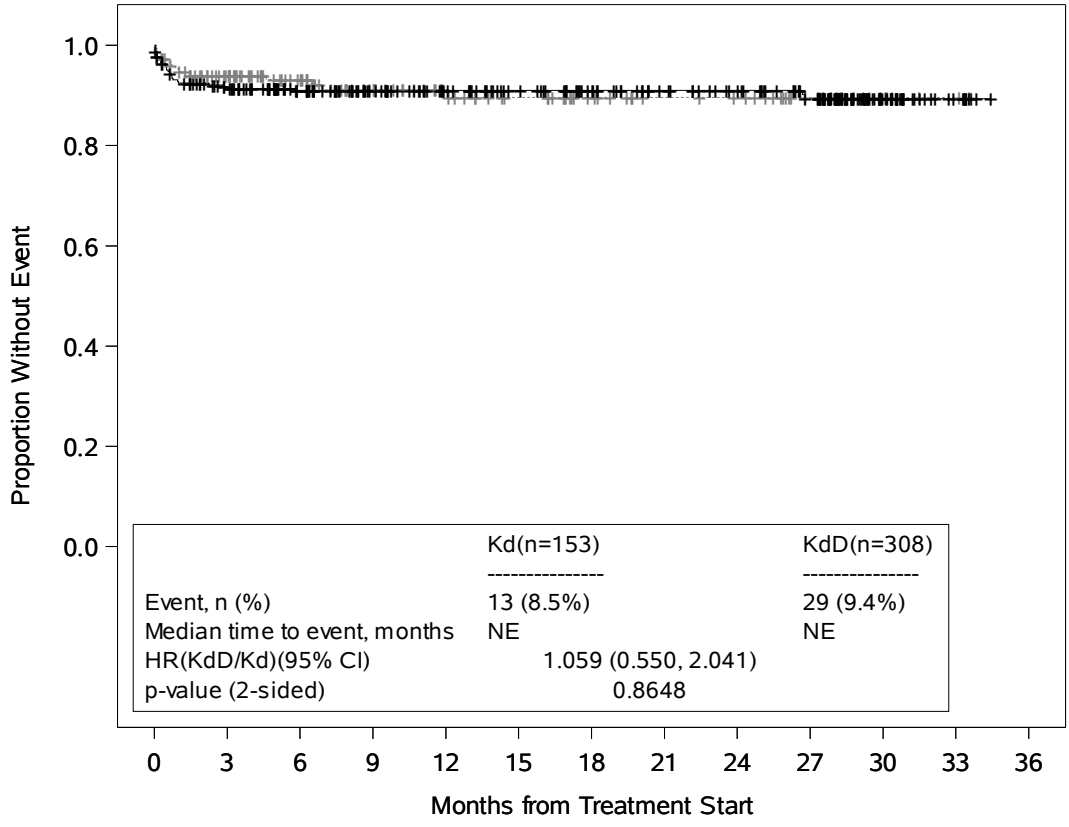


Number of Subjects at Risk:

Kd	153	131	106	87	66	57	44	37	35	26	6	2	0
KdD	308	270	237	205	184	168	154	138	127	108	36	10	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-502-ae-km-soc-blood-pt-leuko-ge10.rtf (Date Generated: 16SEP20:20:36:34).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.503. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Blood and Lymphatic System Disorders) and PT (Lymphopenia) <Safety Population>

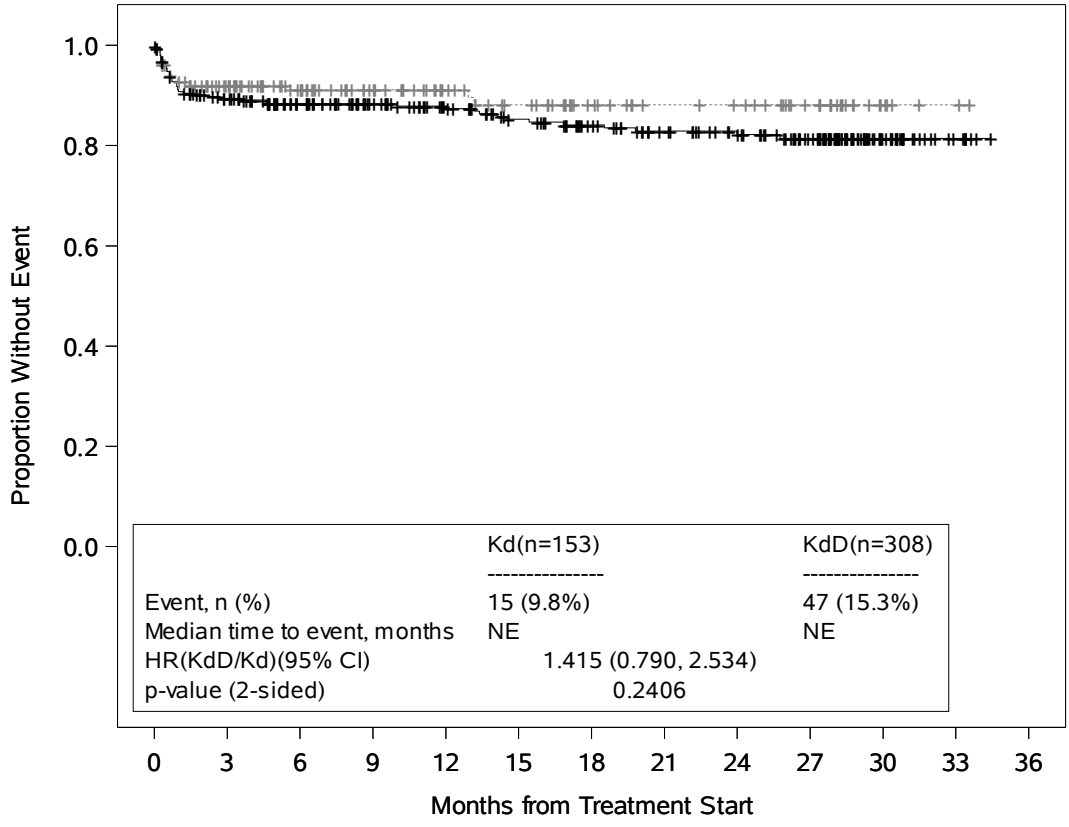


Number of Subjects at Risk:

Kd	153	125	100	78	62	53	43	36	34	24	6	2	0
KdD	308	263	229	198	178	162	147	132	123	105	36	10	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-503-ae-km-soc-blood-pt-lymph-ge10.rtf (Date Generated: 16SEP20:20:36:36).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.504. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Blood and Lymphatic System Disorders) and PT (Neutropenia) <Safety Population>

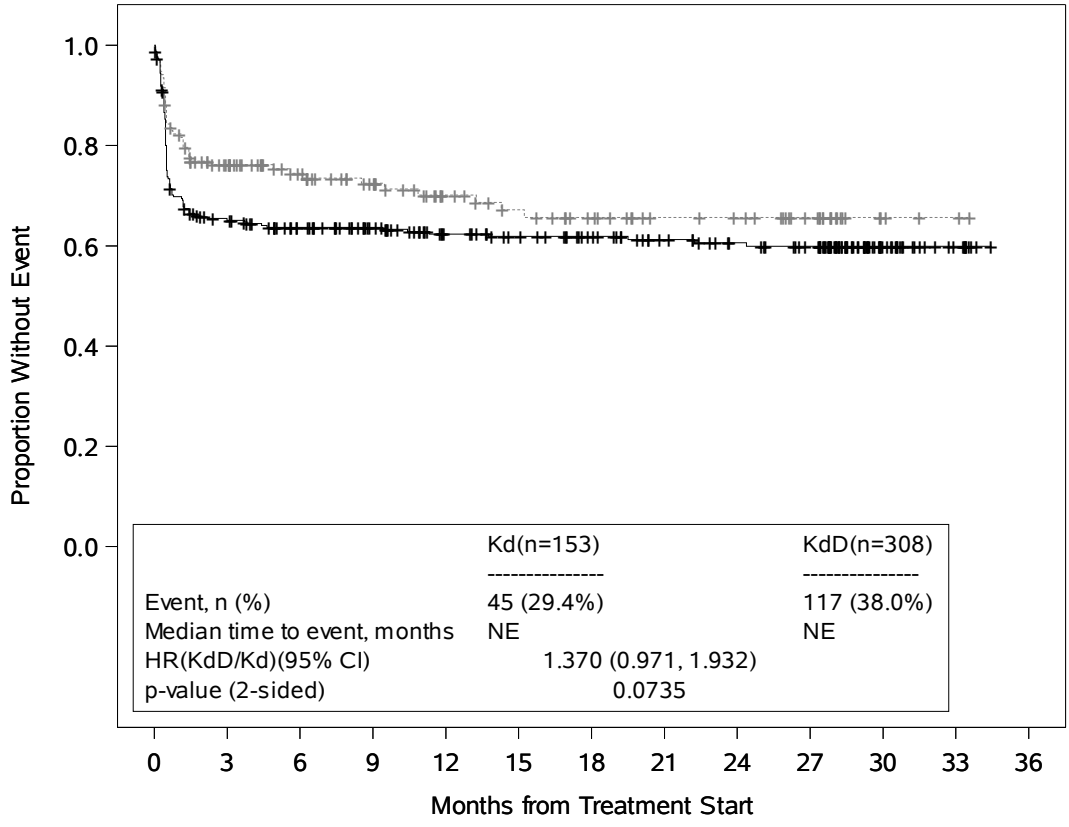


Number of Subjects at Risk:

Kd	153	122	99	79	63	53	40	33	31	22	6	2	0
KdD	308	258	224	195	174	156	141	126	115	95	33	8	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-504-ae-km-soc-blood-pt-neutr-ge10.rtf (Date Generated: 16SEP20:20:36:38).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.505. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Blood and Lymphatic System Disorders) and PT (Thrombocytopenia) <Safety Population>

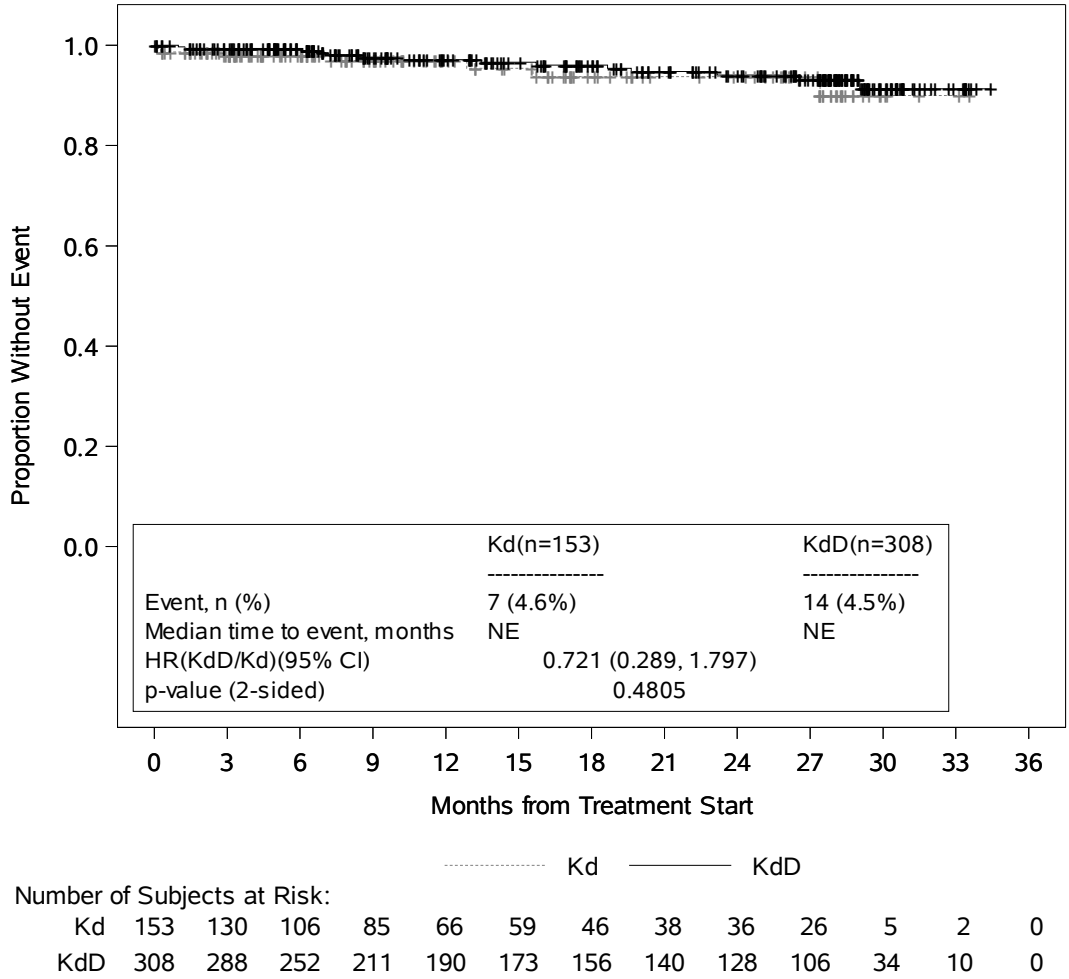


Number of Subjects at Risk:

Kd	153	102	82	67	51	44	37	29	27	19	4	2	0
KdD	308	190	170	151	129	120	110	98	89	81	28	10	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-505-ae-km-soc-blood-pt-throm-ge10.rtf (Date Generated: 16SEP20:20:36:40).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.506. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Cardiac Disorders) and PT (Cardiac Failure) <Safety Population>

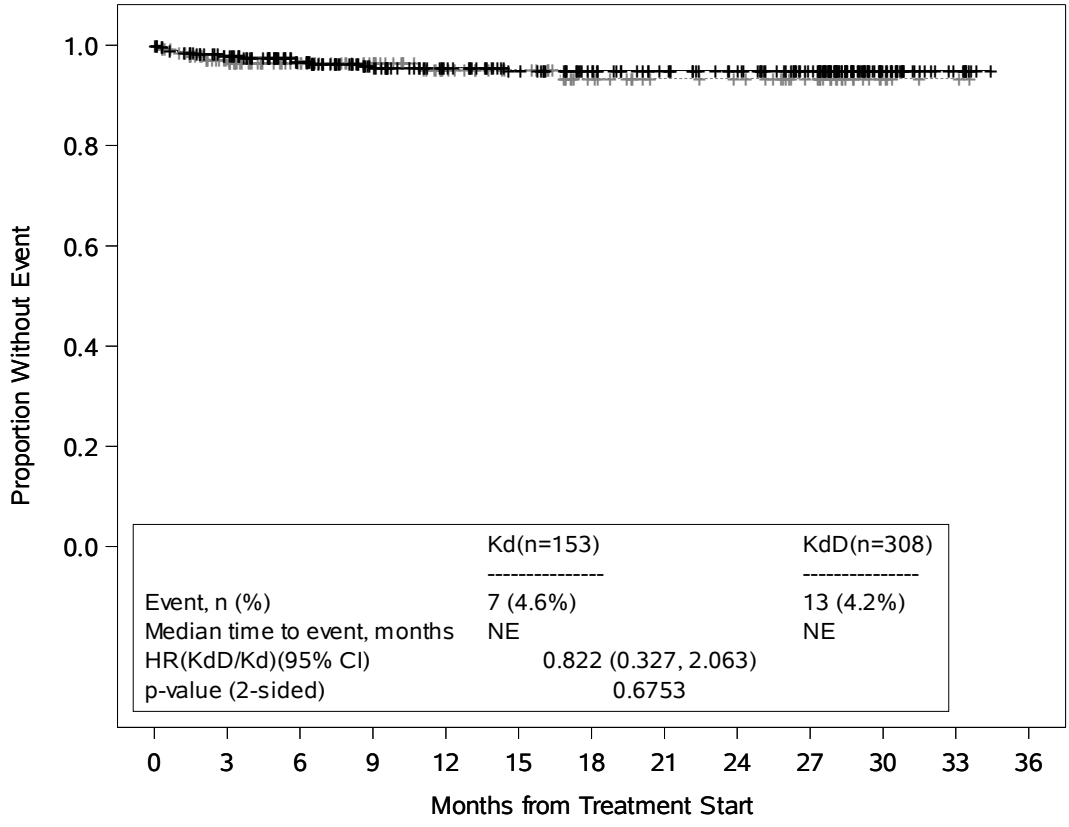


Number of Subjects at Risk:

Kd	153	130	106	85	66	59	46	38	36	26	5	2	0
KdD	308	288	252	211	190	173	156	140	128	106	34	10	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-506-ae-km-soc-cardi-pt-cardi-ge10.rtf (Date Generated: 16SEP20:20:36:41).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.507. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Cardiac Disorders) and PT (Tachycardia) <Safety Population>

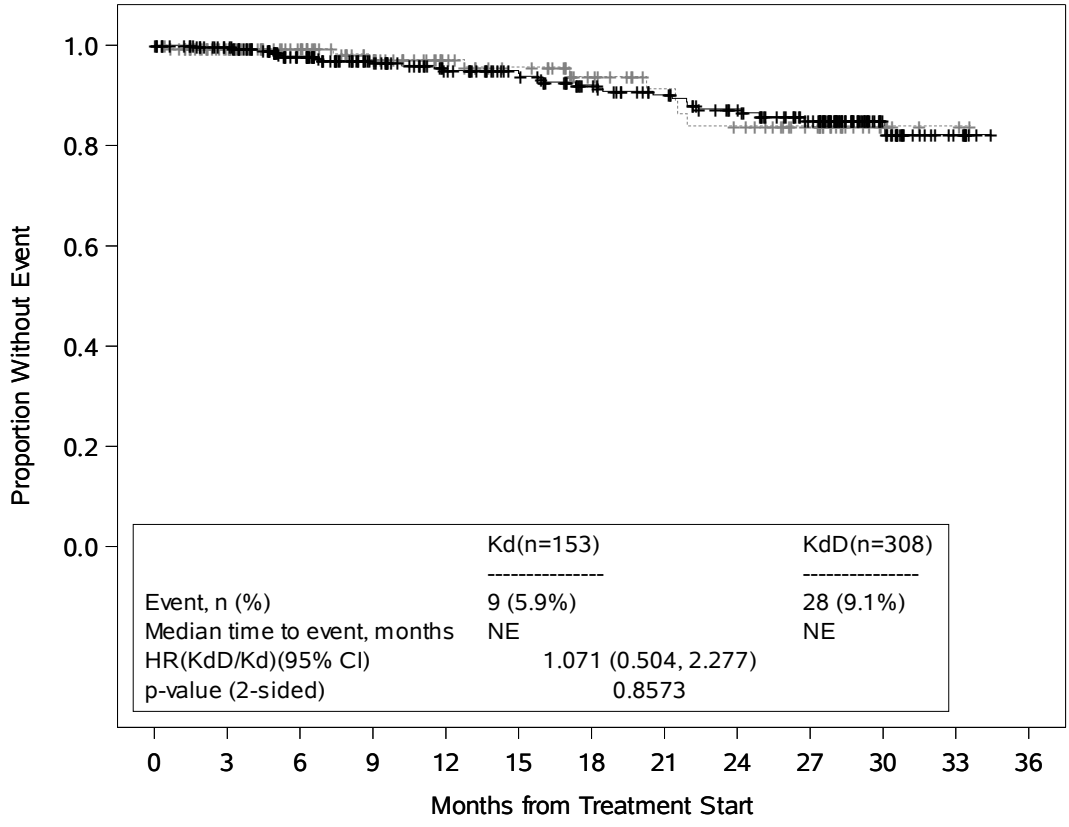


Number of Subjects at Risk:

Kd	153	128	104	86	65	57	44	36	34	25	6	2	0
KdD	308	283	244	203	182	165	149	136	126	105	35	10	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-507-ae-km-soc-cardi-pt-tachy-ge10.rtf (Date Generated: 16SEP20:20:36:43).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.508. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Eye Disorders) and PT (Cataract)
<Safety Population>

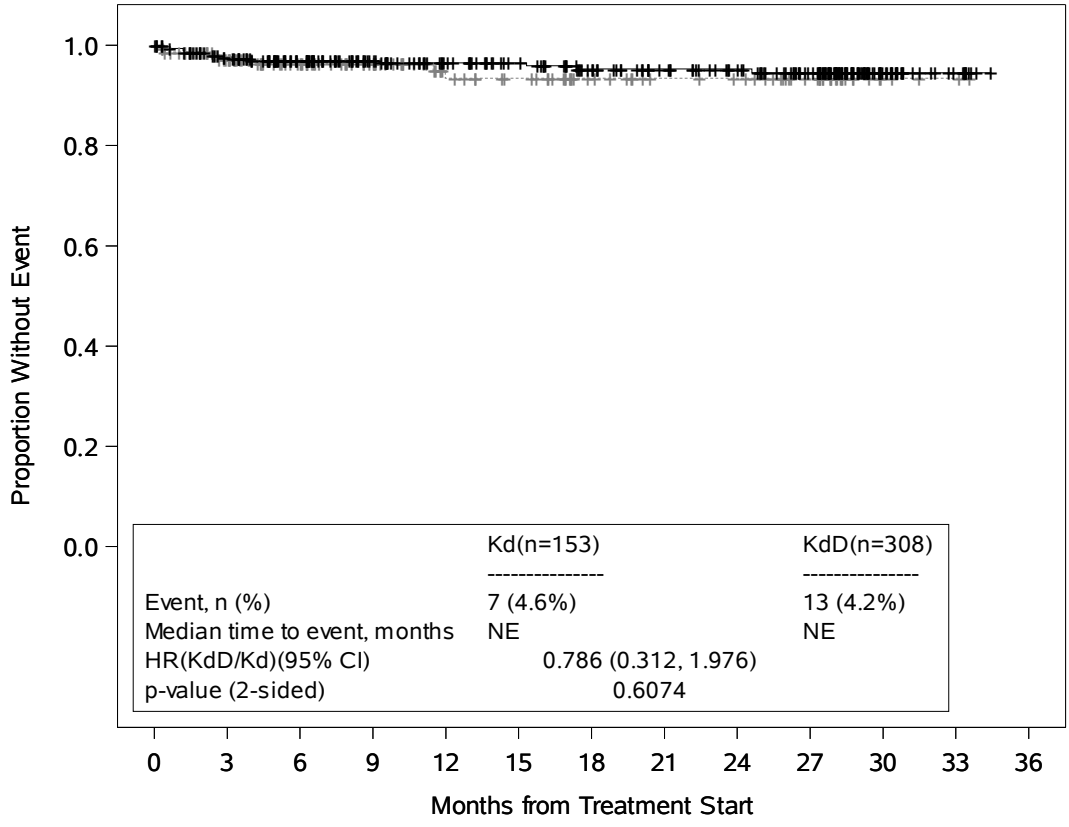


Number of Subjects at Risk:

Kd	153	131	107	85	66	58	45	37	33	24	6	2	0
KdD	308	288	248	206	182	166	146	132	117	96	32	9	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-508-ae-km-soc-eye-pt-catar-ge10.rtf (Date Generated: 16SEP20:20:36:45).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.509. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Gastrointestinal Disorders) and PT (Abdominal Pain) <Safety Population>

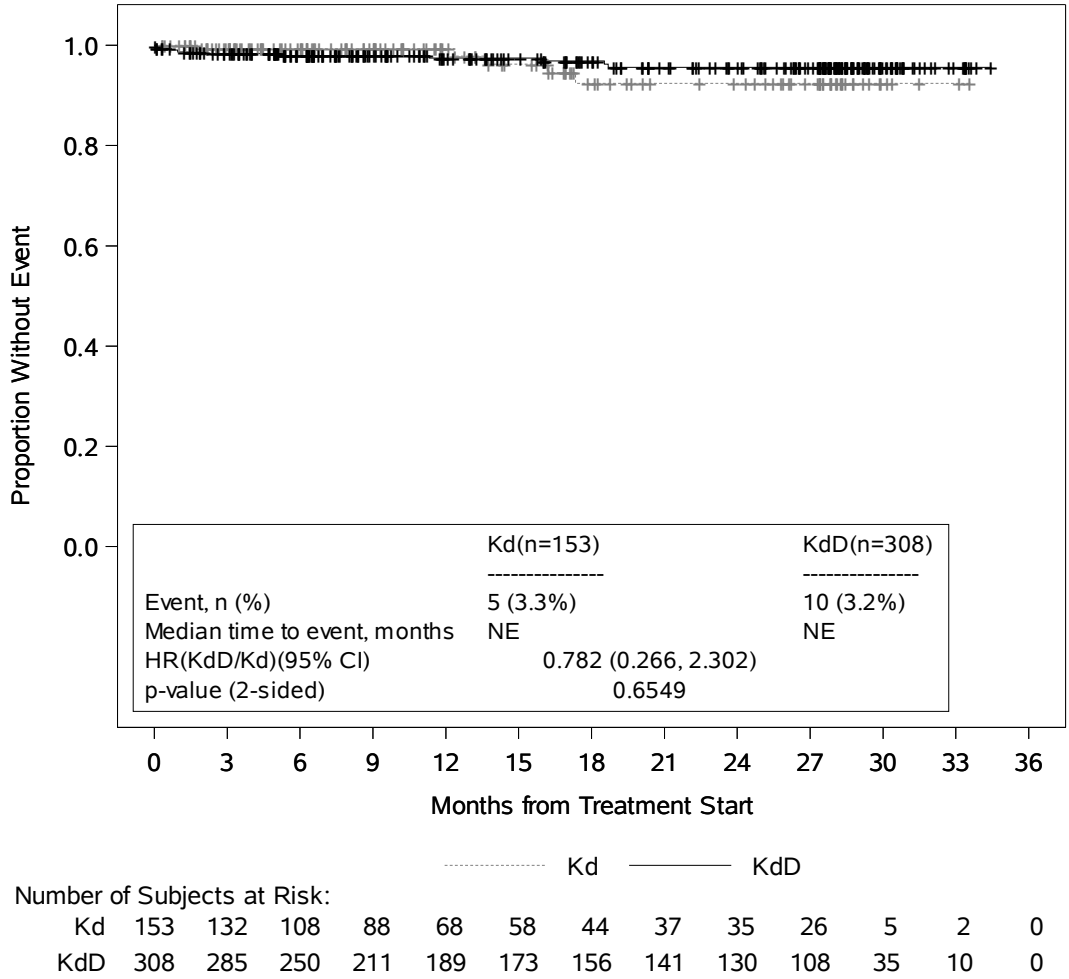


Number of Subjects at Risk:

Kd	153	128	104	84	62	56	43	36	34	24	4	2	0
KdD	308	282	246	208	186	171	153	138	126	103	32	10	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-509-ae-km-soc-gastr-pt-abdom-ge10.rtf (Date Generated: 16SEP20:20:36:46).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.510. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Gastrointestinal Disorders) and PT (Abdominal Pain Upper) <Safety Population>

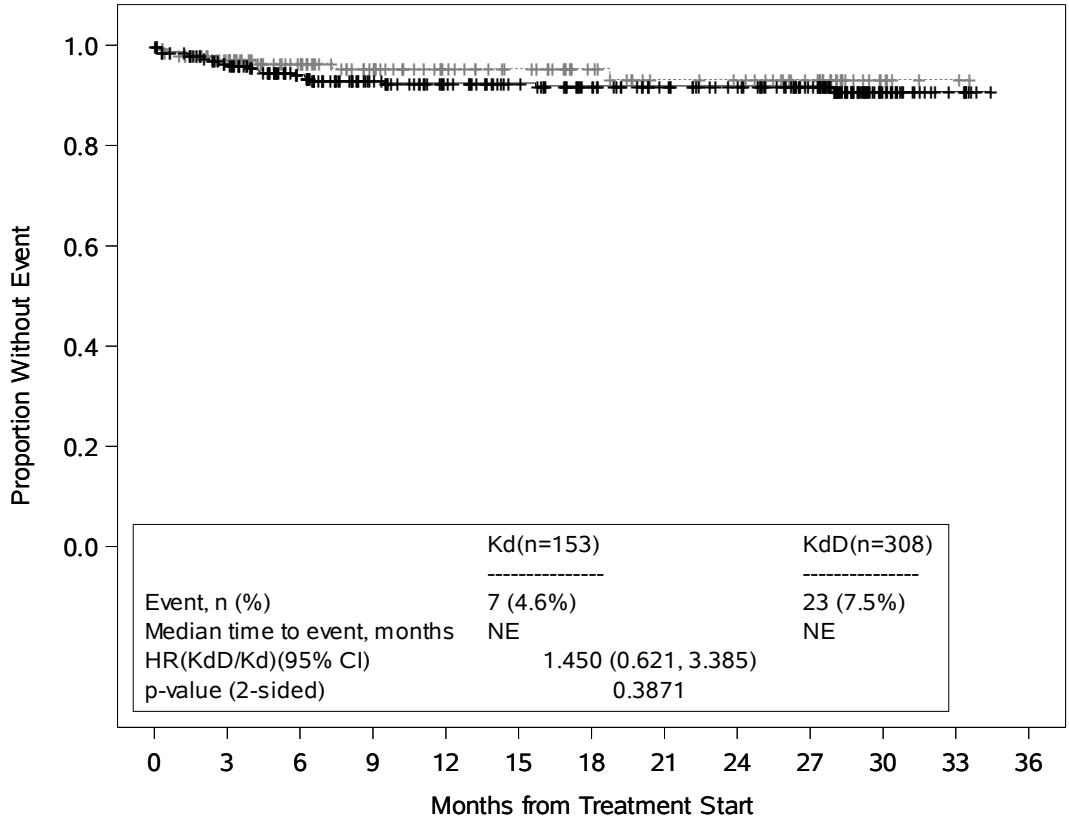


Number of Subjects at Risk:

Kd	153	132	108	88	68	58	44	37	35	26	5	2	0
KdD	308	285	250	211	189	173	156	141	130	108	35	10	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-510-ae-km-soc-gastr-pt-abdpai-ge10.rtf (Date Generated: 16SEP20:20:36:48).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.511. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Gastrointestinal Disorders) and PT (Constipation) <Safety Population>

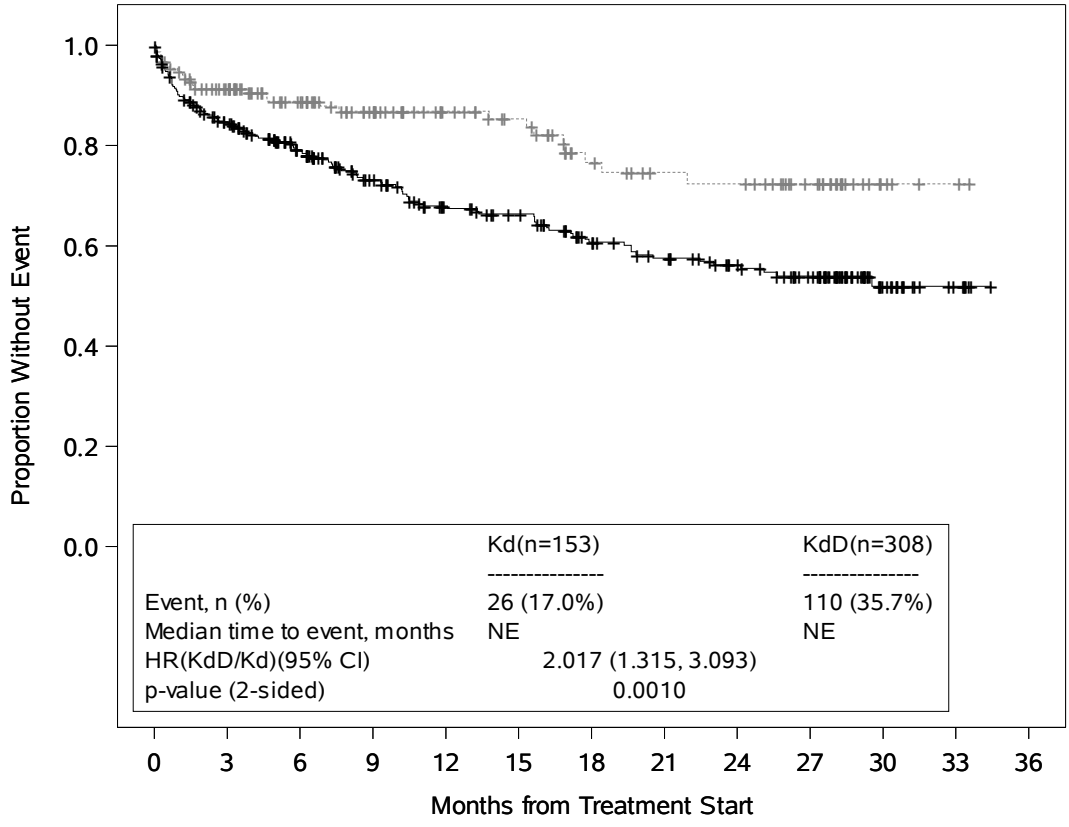


Number of Subjects at Risk:

Kd	153	128	103	83	66	58	46	37	35	26	6	2	0
KdD	308	277	238	202	181	165	149	134	124	102	30	9	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-511-ae-km-soc-gastr-pt-const-ge10.rtf (Date Generated: 16SEP20:20:36:49).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.512. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Gastrointestinal Disorders) and PT (Diarrhoea)
<Safety Population>

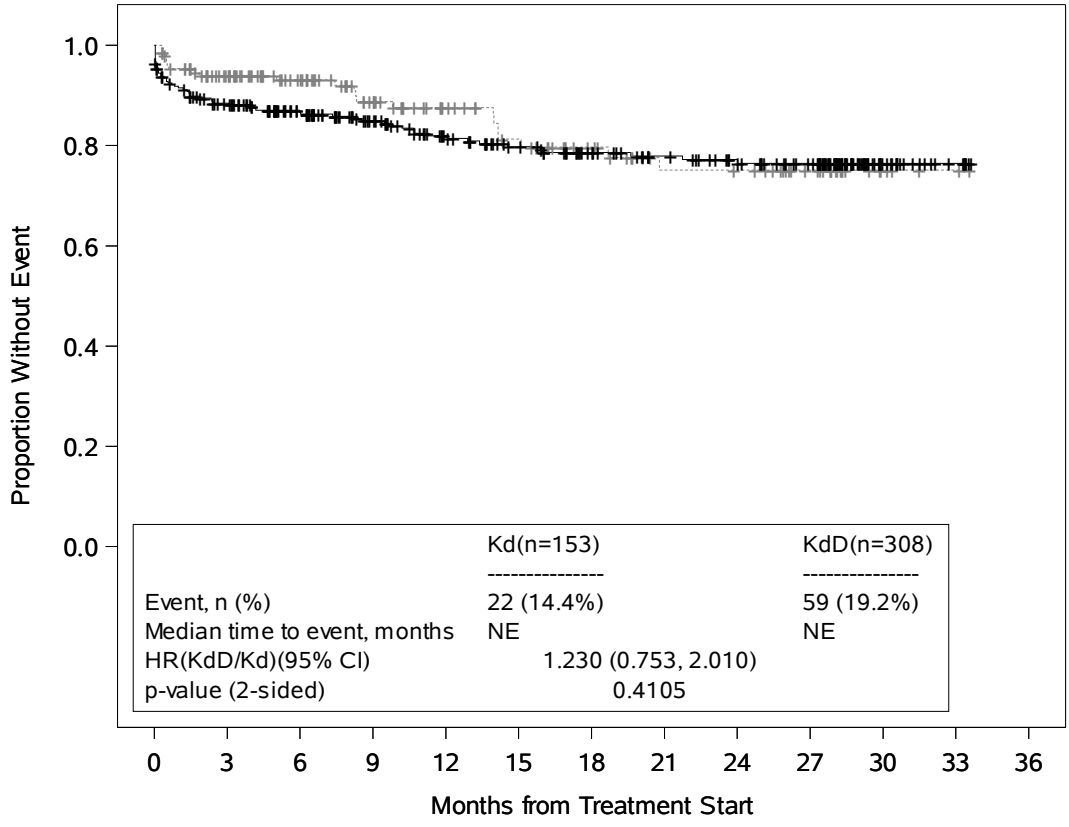


Number of Subjects at Risk:

Kd	153	124	100	80	62	54	39	33	32	22	5	2	0
KdD	308	244	199	159	133	123	101	90	78	64	22	7	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-512-ae-km-soc-gastr-pt-diarr-ge10.rtf (Date Generated: 16SEP20:20:36:51).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.513. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Gastrointestinal Disorders) and PT (Nausea)
<Safety Population>

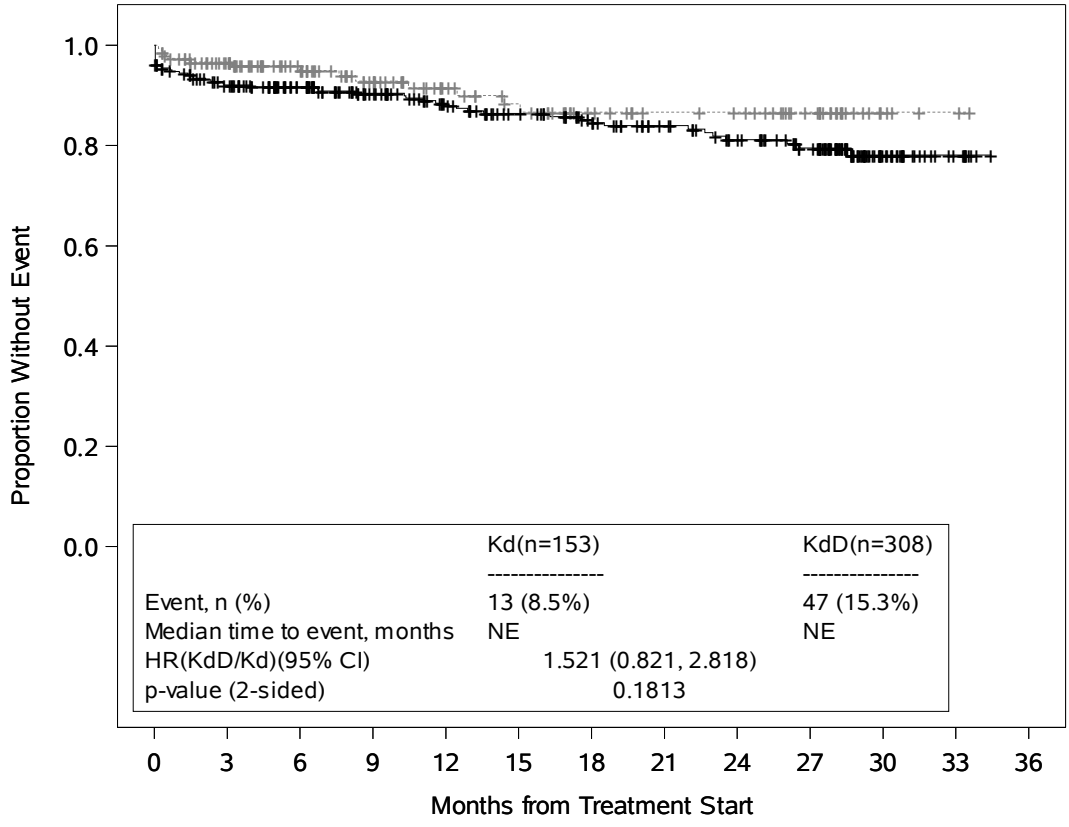


Number of Subjects at Risk:

Kd	153	125	101	78	61	51	40	30	29	20	5	2	0
KdD	308	256	219	182	156	139	123	110	100	87	23	7	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-513-ae-km-soc-gastr-pt-nause-ge10.rtf (Date Generated: 16SEP20:20:36:52).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.514. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Gastrointestinal Disorders) and PT (Vomiting) <Safety Population>

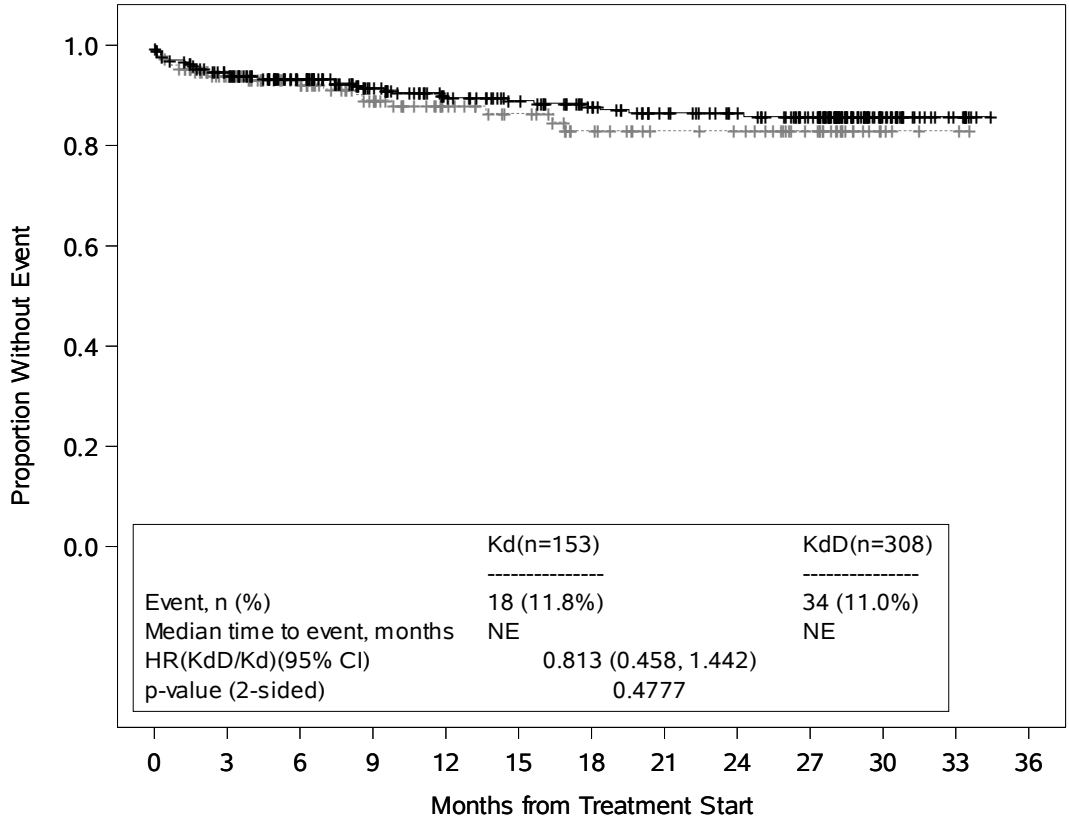


Number of Subjects at Risk:

Kd	153	129	103	81	62	53	41	35	33	23	5	2	0
KdD	308	267	233	196	172	154	139	124	111	94	31	9	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-514-ae-km-soc-gastr-pt-vomit-ge10.rtf (Date Generated: 16SEP20:20:36:54).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.515. KM Curves of Most Frequent Adverse Events by MedDRA SOC (General Disorders and Administration Site Conditions) and PT (Asthenia) <Safety Population>

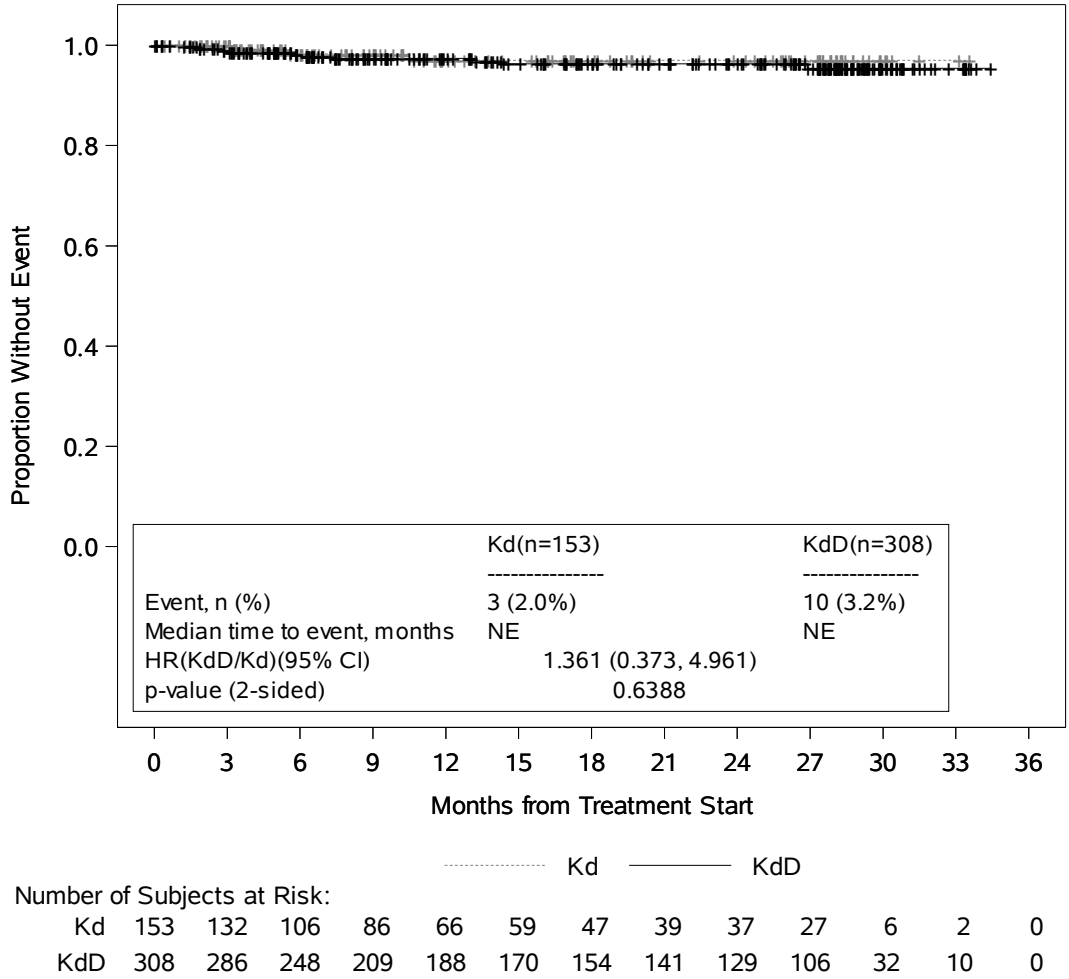


Number of Subjects at Risk:

Kd	153	125	101	81	63	54	43	35	33	23	5	2	0
KdD	308	275	237	196	173	158	142	127	117	100	34	10	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-515-ae-km-soc-gastr-pt-asthe-ge10.rtf (Date Generated: 16SEP20:20:36:55).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.516. KM Curves of Most Frequent Adverse Events by MedDRA SOC (General Disorders and Administration Site Conditions) and PT (Chest Discomfort) <Safety Population>

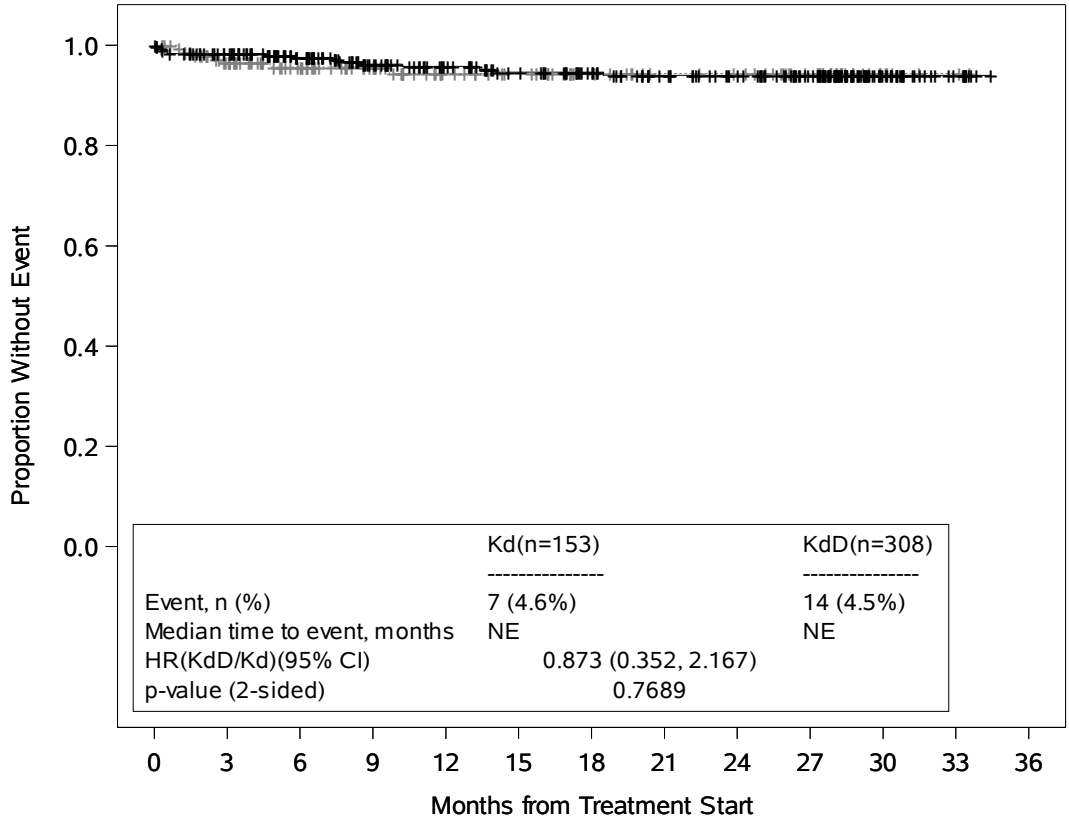


Number of Subjects at Risk:

Kd	153	132	106	86	66	59	47	39	37	27	6	2	0
KdD	308	286	248	209	188	170	154	141	129	106	32	10	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-516-ae-km-soc-gener-pt-chest-ge10.rtf (Date Generated: 16SEP20:20:36:57).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.517. KM Curves of Most Frequent Adverse Events by MedDRA SOC (General Disorders and Administration Site Conditions) and PT (Chest Pain) <Safety Population>

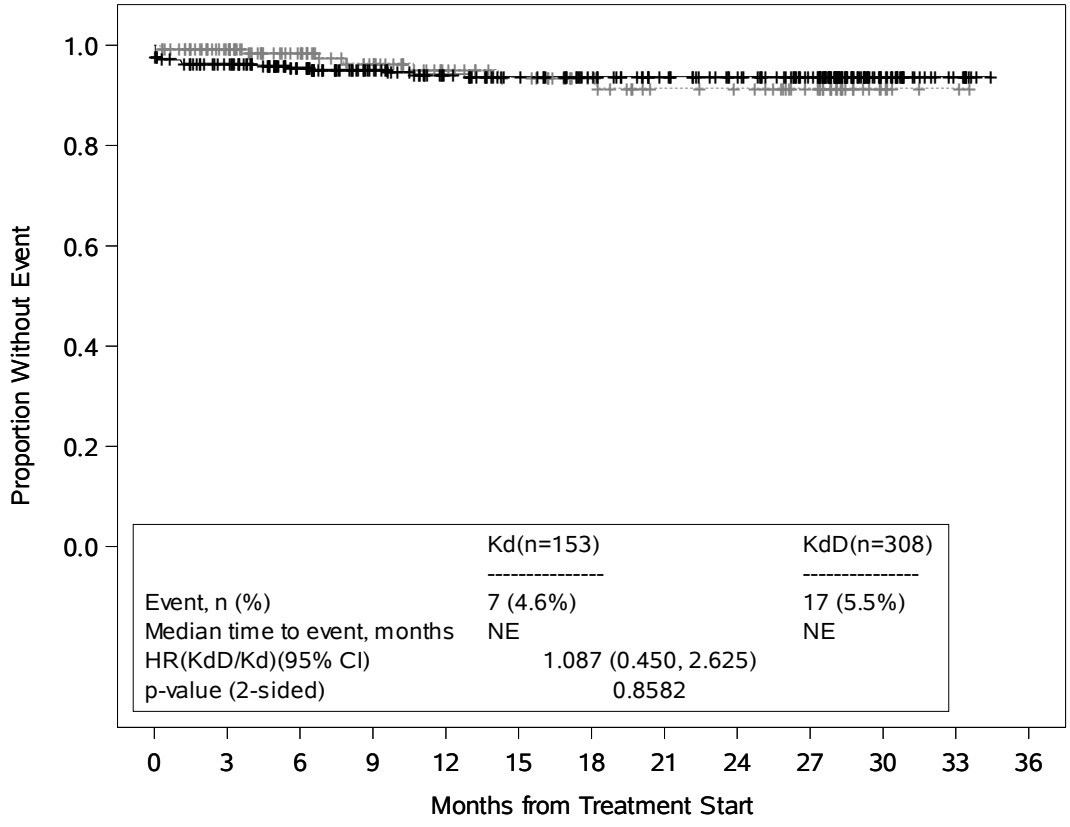


Number of Subjects at Risk:

Kd	153	129	105	85	65	58	46	39	37	27	6	2	0
KdD	308	284	246	205	183	167	152	136	124	104	34	10	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-517-ae-km-soc-gener-pt-chepai-ge10.rtf (Date Generated: 16SEP20:20:36:58).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.518. KM Curves of Most Frequent Adverse Events by MedDRA SOC (General Disorders and Administration Site Conditions) and PT (Chills) <Safety Population>

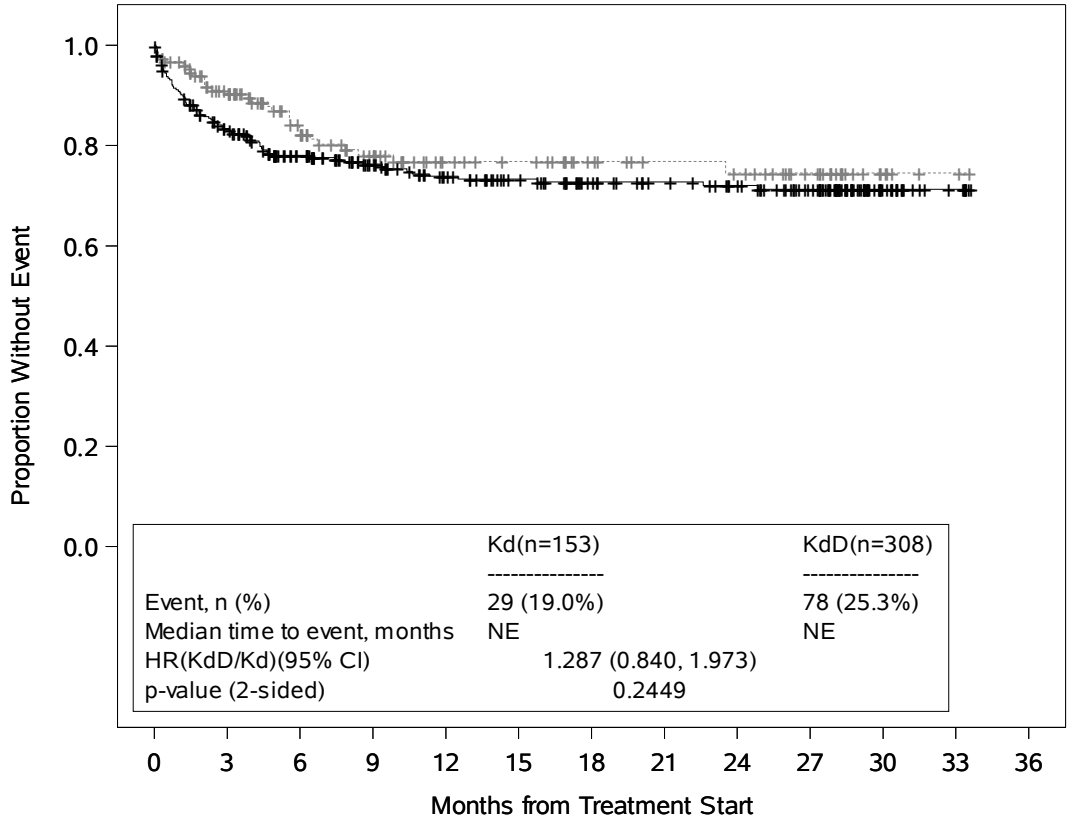


Number of Subjects at Risk:

Kd	153	131	106	86	66	58	46	37	35	26	6	2	0
KdD	308	280	242	204	182	167	152	138	126	105	34	10	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-518-ae-km-soc-gener-pt-chill-ge10.rtf (Date Generated: 16SEP20:20:37:00).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.519. KM Curves of Most Frequent Adverse Events by MedDRA SOC (General Disorders and Administration Site Conditions) and PT (Fatigue) <Safety Population>

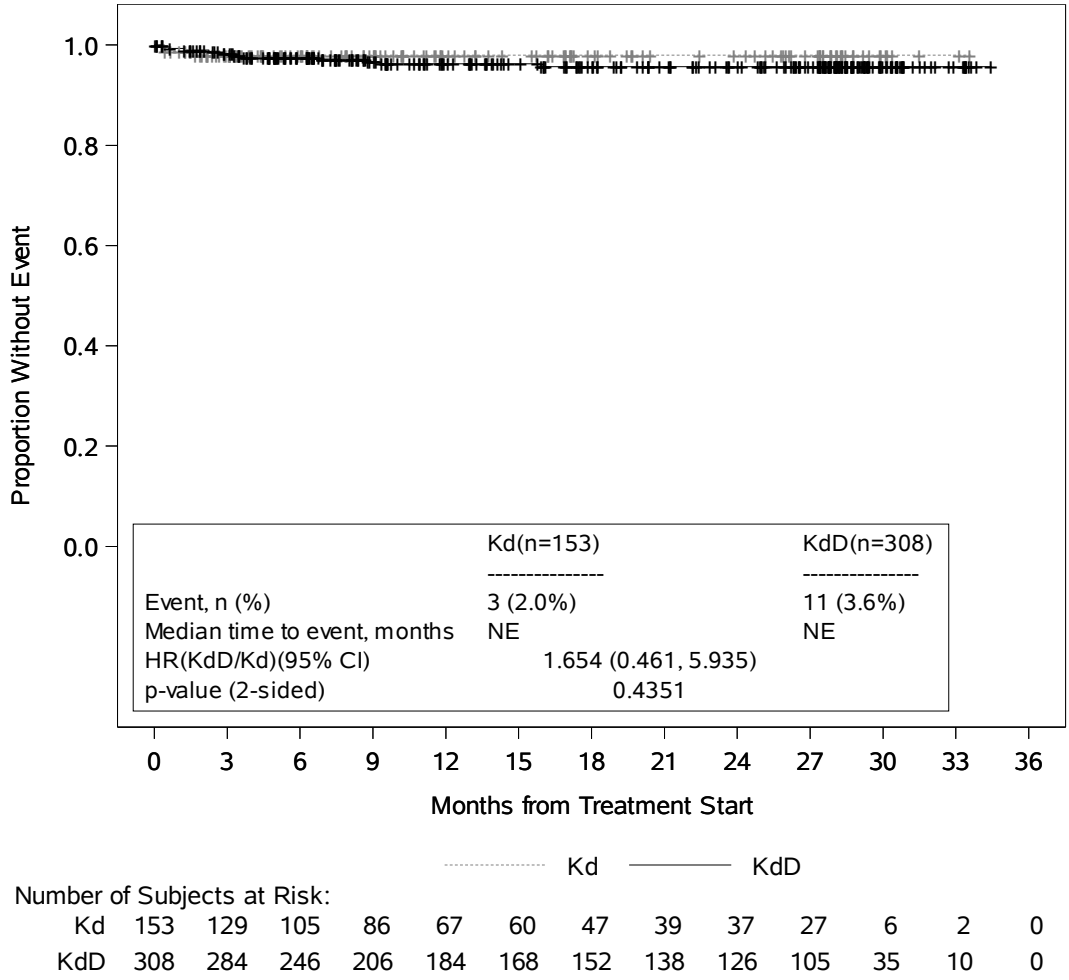


Number of Subjects at Risk:

Kd	153	121	89	69	51	47	38	33	31	22	6	2	0
KdD	308	241	197	164	144	129	113	104	96	79	25	8	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-519-ae-km-soc-gener-pt-fatig-ge10.rtf (Date Generated: 16SEP20:20:37:02).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.520. KM Curves of Most Frequent Adverse Events by MedDRA SOC (General Disorders and Administration Site Conditions) and PT (Influenza Like Illness)
<Safety Population>

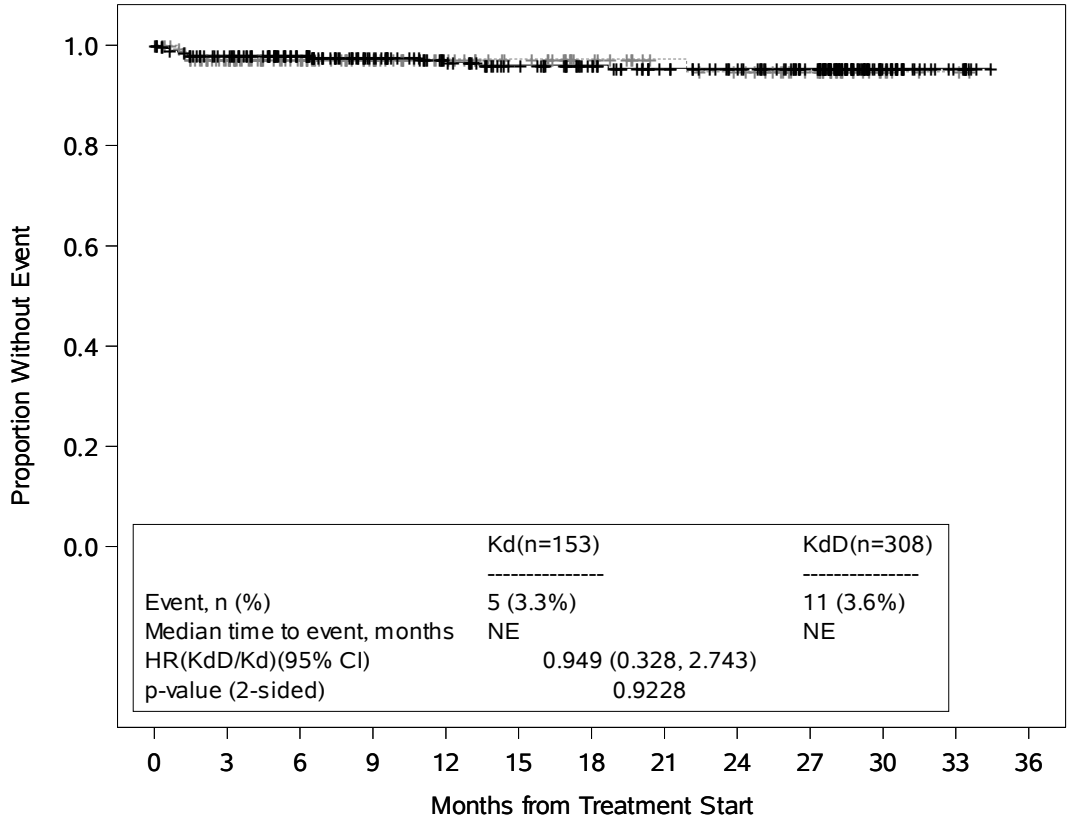


Number of Subjects at Risk:

Kd	153	129	105	86	67	60	47	39	37	27	6	2	0
KdD	308	284	246	206	184	168	152	138	126	105	35	10	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-520-ae-km-soc-gener-pt-influ-ge10.rtf (Date Generated: 16SEP20:20:37:03).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.521. KM Curves of Most Frequent Adverse Events by MedDRA SOC (General Disorders and Administration Site Conditions) and PT (Malaise) <Safety Population>

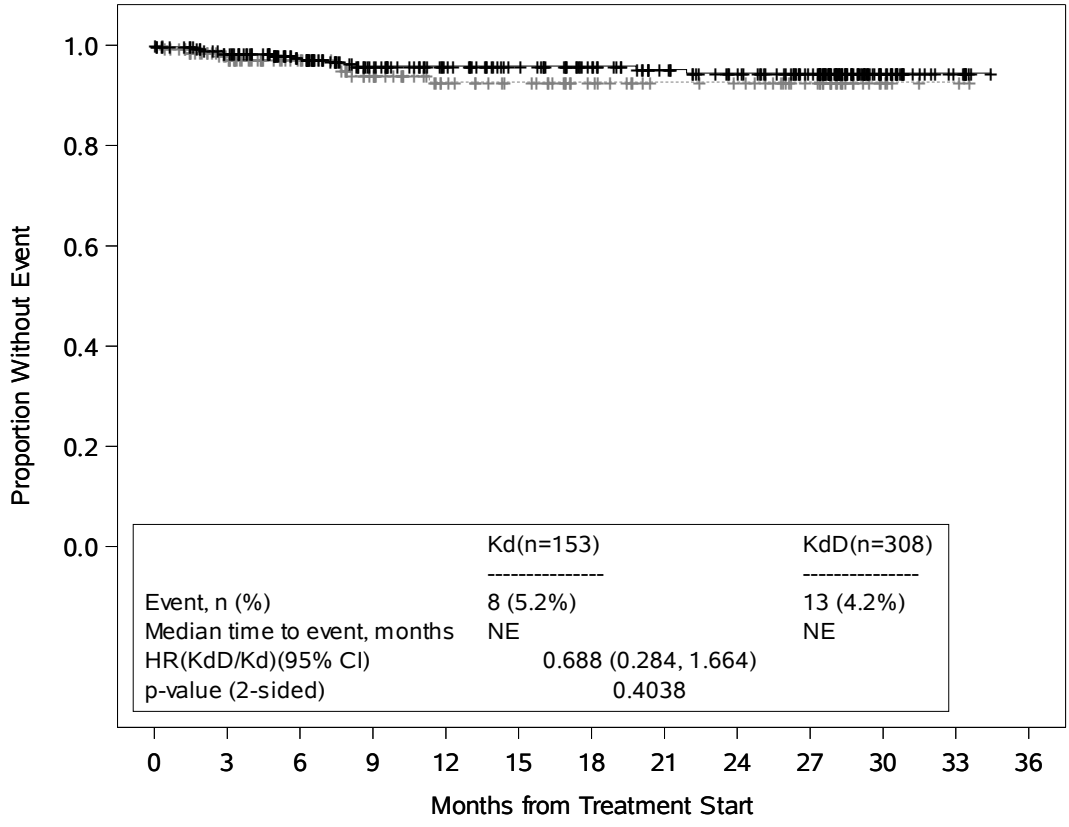


Number of Subjects at Risk:

Kd	153	129	105	85	65	57	46	38	35	26	6	2	0
KdD	308	284	248	210	188	170	154	138	128	107	35	10	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-521-ae-km-soc-gener-pt-malai-ge10.rtf (Date Generated: 16SEP20:20:37:05).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.522. KM Curves of Most Frequent Adverse Events by MedDRA SOC (General Disorders and Administration Site Conditions) and PT (Oedema) <Safety Population>

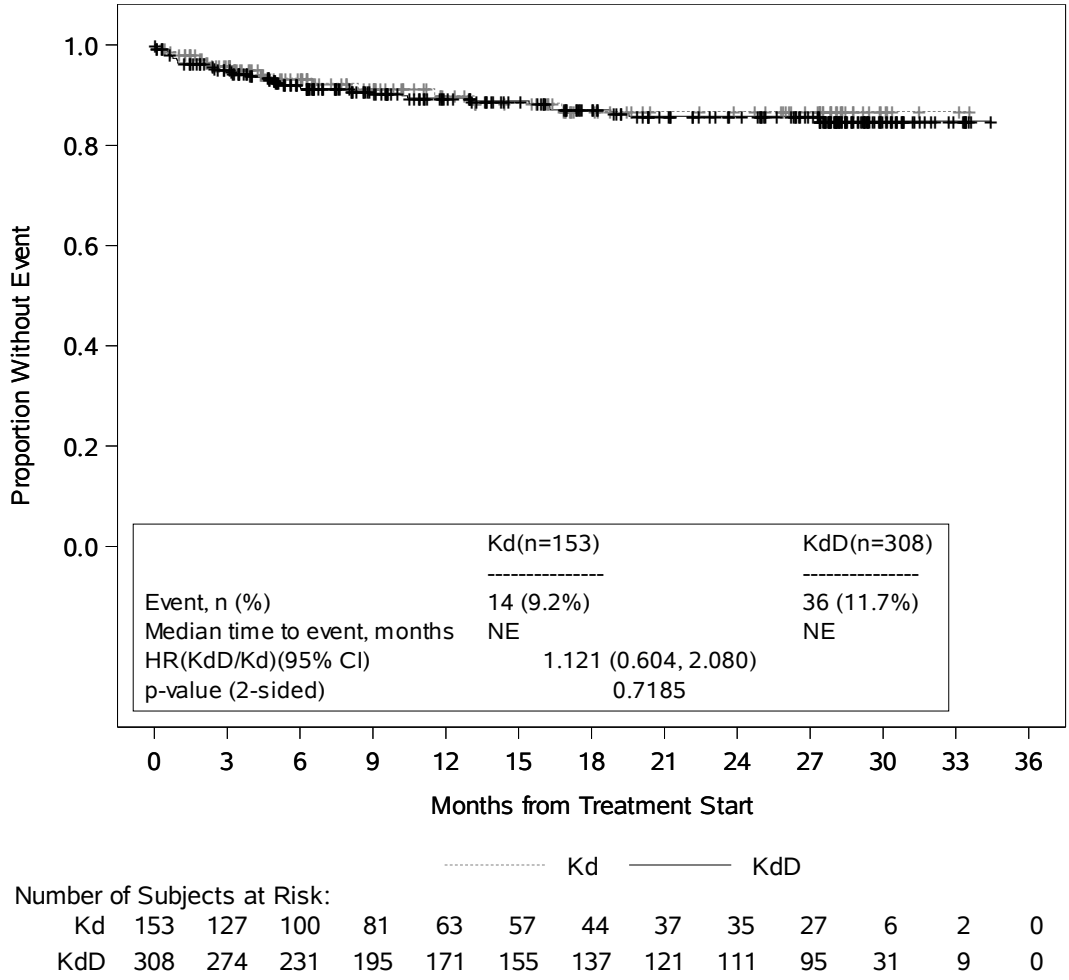


Number of Subjects at Risk:

Kd	153	130	106	83	64	57	46	38	36	26	6	2	0
KdD	308	285	247	206	185	169	153	137	125	104	33	9	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-522-ae-km-soc-gener-pt-oedem-ge10.rtf (Date Generated: 16SEP20:20:37:07).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.523. KM Curves of Most Frequent Adverse Events by MedDRA SOC (General Disorders and Administration Site Conditions) and PT (Oedema Peripheral)
<Safety Population>

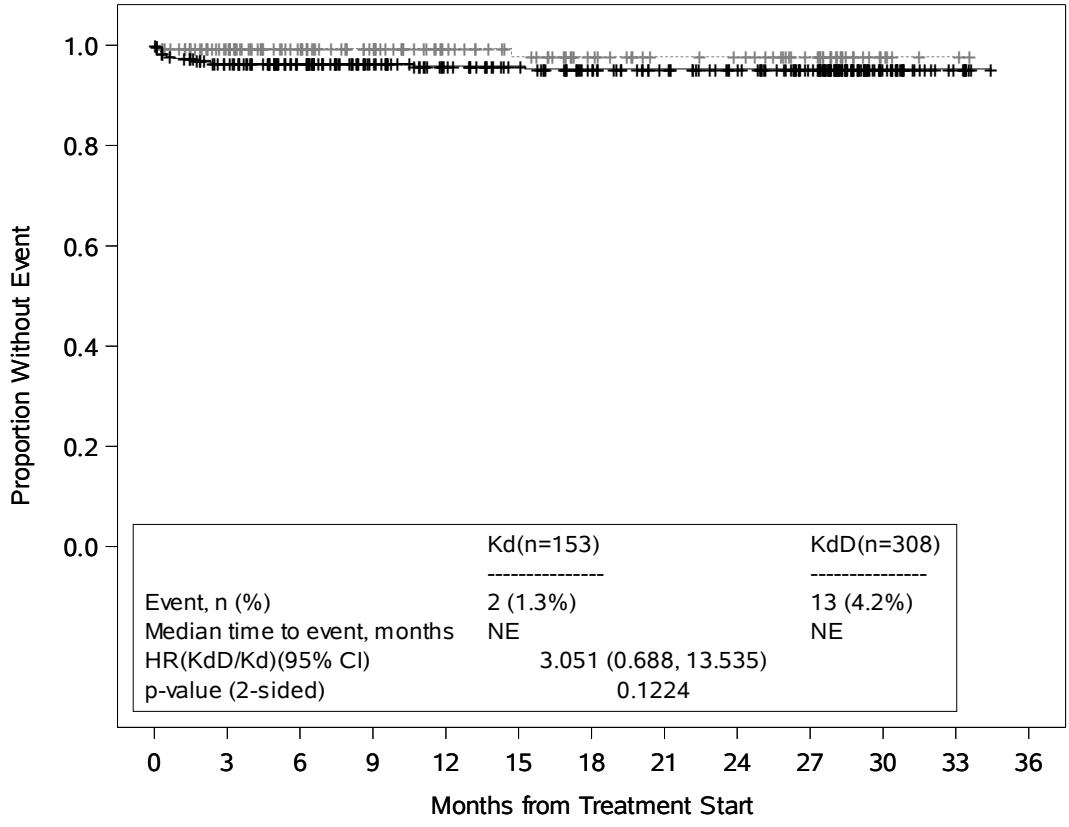


Number of Subjects at Risk:

Kd	153	127	100	81	63	57	44	37	35	27	6	2	0
KdD	308	274	231	195	171	155	137	121	111	95	31	9	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-523-ae-km-soc-gener-pt-oedper-ge10.rtf (Date Generated: 16SEP20:20:37:08).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.524. KM Curves of Most Frequent Adverse Events by MedDRA SOC (General Disorders and Administration Site Conditions) and PT (Pain) <Safety Population>

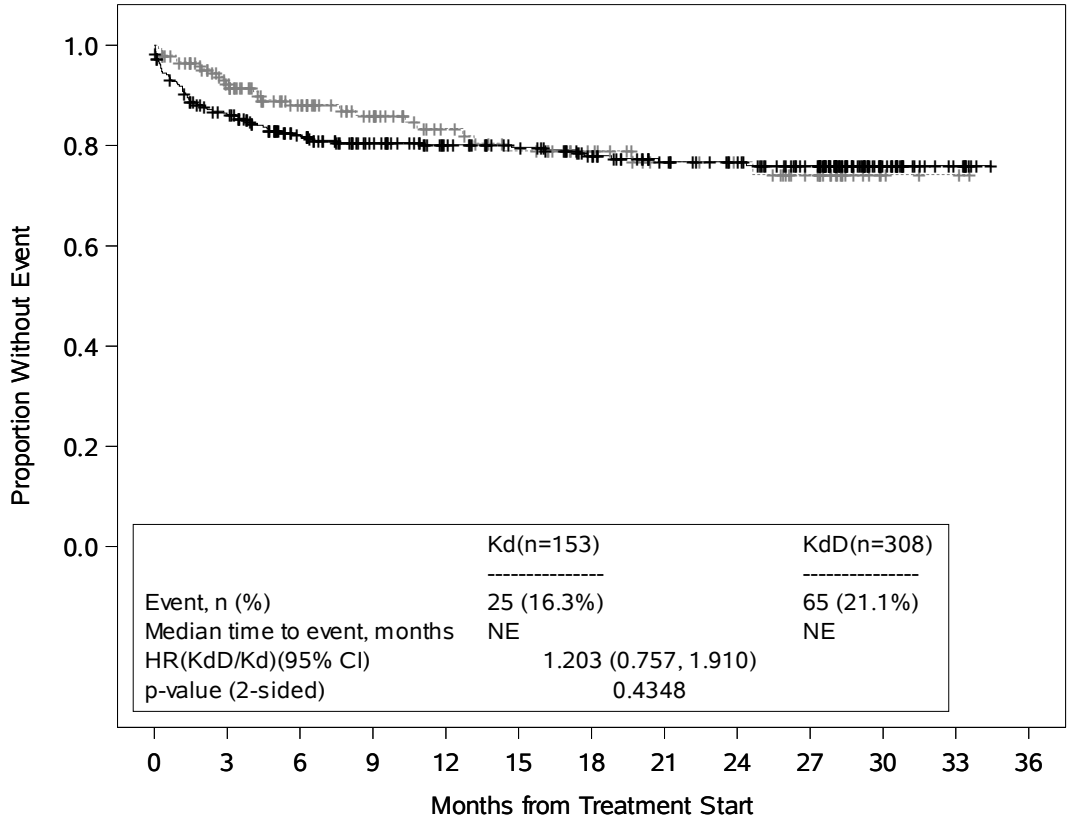


Number of Subjects at Risk:

Kd	153	131	107	88	68	59	47	39	37	27	6	2	0
KdD	308	278	245	206	184	170	153	139	127	106	33	9	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-524-ae-km-soc-gener-pt-pain-ge10.rtf (Date Generated: 16SEP20:20:37:10).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.525. KM Curves of Most Frequent Adverse Events by MedDRA SOC (General Disorders and Administration Site Conditions) and PT (Pyrexia) <Safety Population>

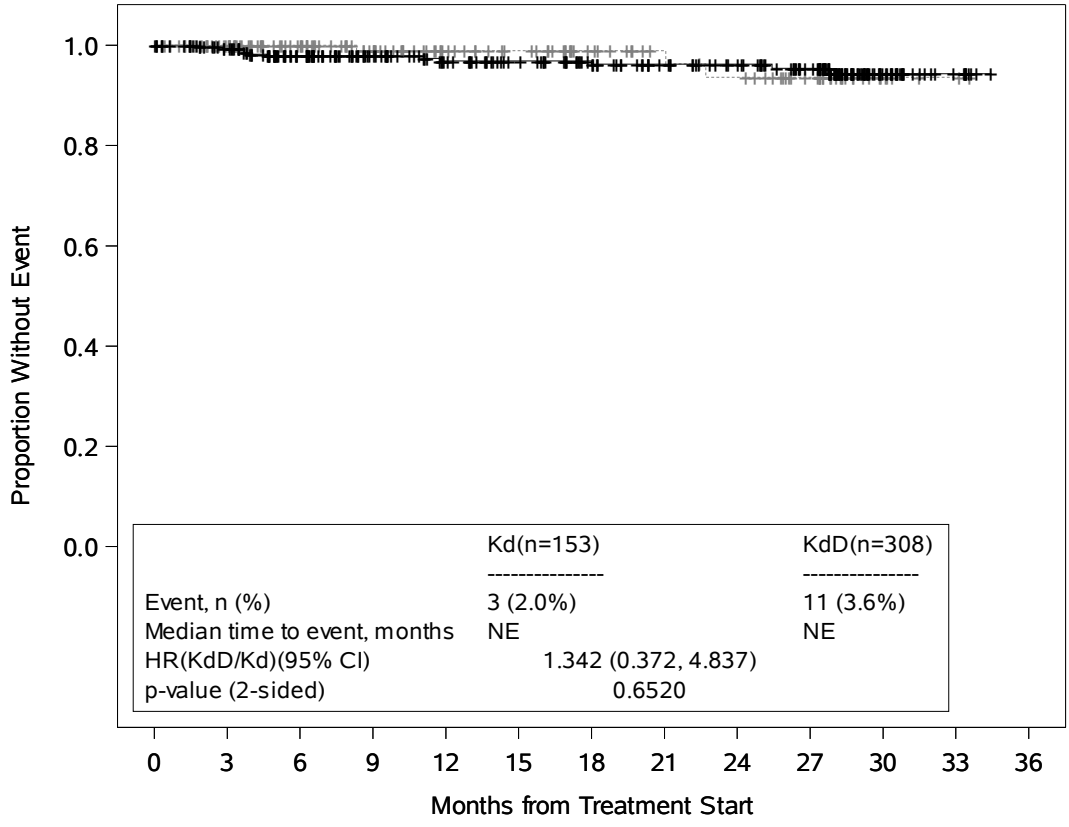


Number of Subjects at Risk:

Kd	153	123	95	76	59	51	41	32	30	22	4	2	0
KdD	308	253	214	184	164	152	136	119	110	92	31	9	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-525-ae-km-soc-gener-pt-pyrex-ge10.rtf (Date Generated: 16SEP20:20:37:11).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.526. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Immune System Disorders) and PT (Hypogammaglobulinaemia) <Safety Population>

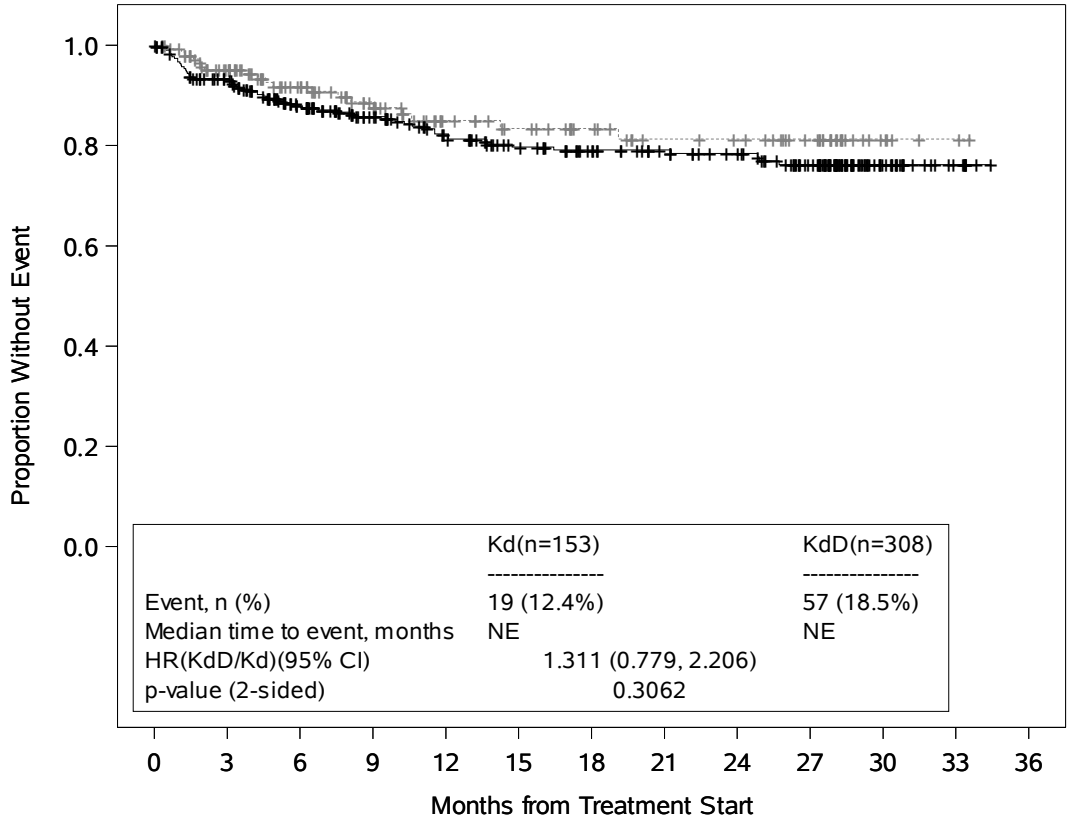


Number of Subjects at Risk:

Kd	153	132	108	87	67	59	46	38	35	25	6	2	0
KdD	308	287	247	208	186	170	153	138	127	107	33	9	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-526-ae-km-soc-immun-pt-hypog-ge10.rtf (Date Generated: 16SEP20:20:37:13).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.527. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Infections and Infestations) and PT (Bronchitis) <Safety Population>

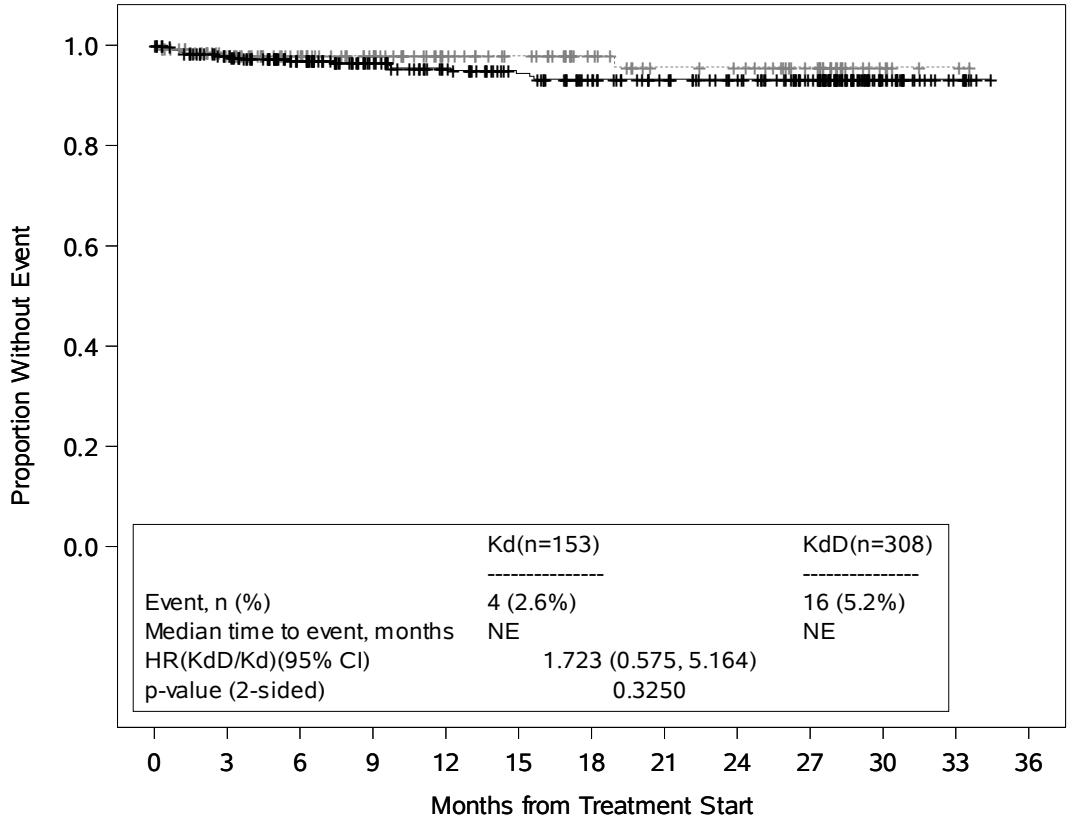


Number of Subjects at Risk:

Kd	153	126	99	79	57	50	42	34	32	24	6	2	0
KdD	308	270	222	185	162	143	129	117	109	87	27	8	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-527-ae-km-soc-infec-pt-bronc-ge10.rtf (Date Generated: 16SEP20:20:37:14).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.528. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Infections and Infestations) and PT (Conjunctivitis) <Safety Population>

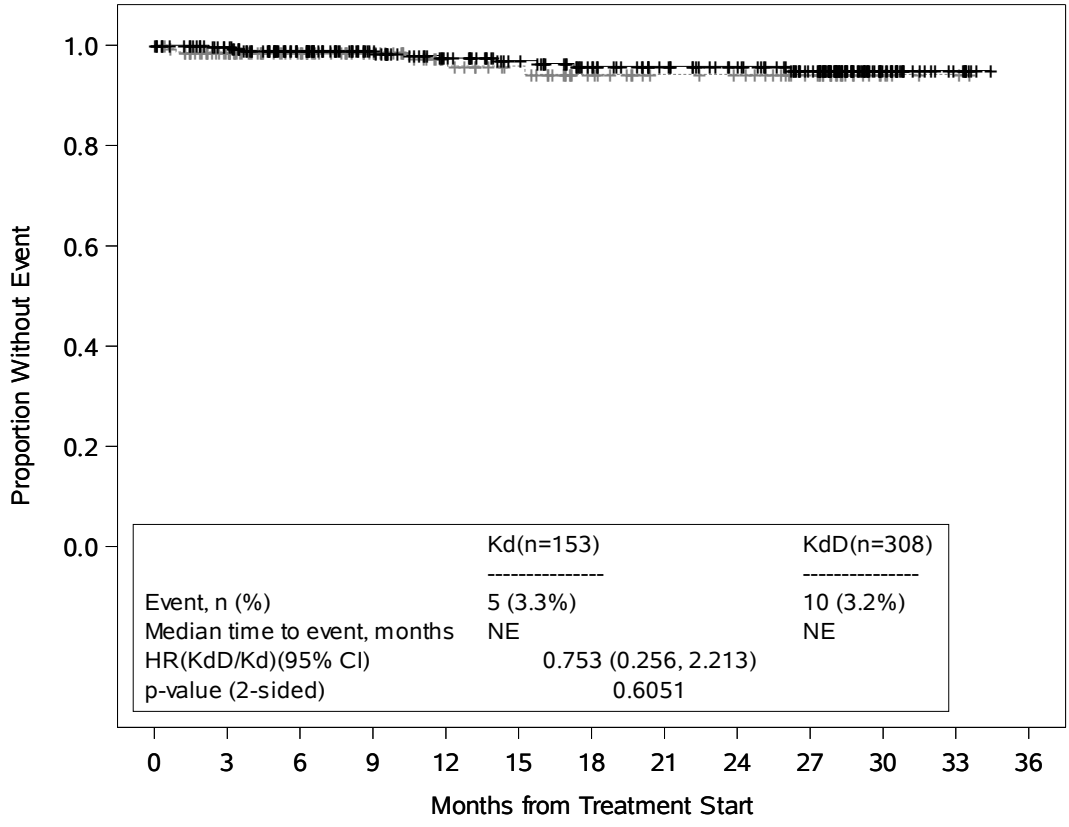


Number of Subjects at Risk:

Kd	153	129	105	87	67	59	46	37	35	25	6	2	0
KdD	308	283	245	205	183	165	148	134	122	101	32	9	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-528-ae-km-soc-infec-pt-conju-ge10.rtf (Date Generated: 16SEP20:20:37:16).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.529. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Infections and Infestations) and PT (Gastroenteritis) <Safety Population>

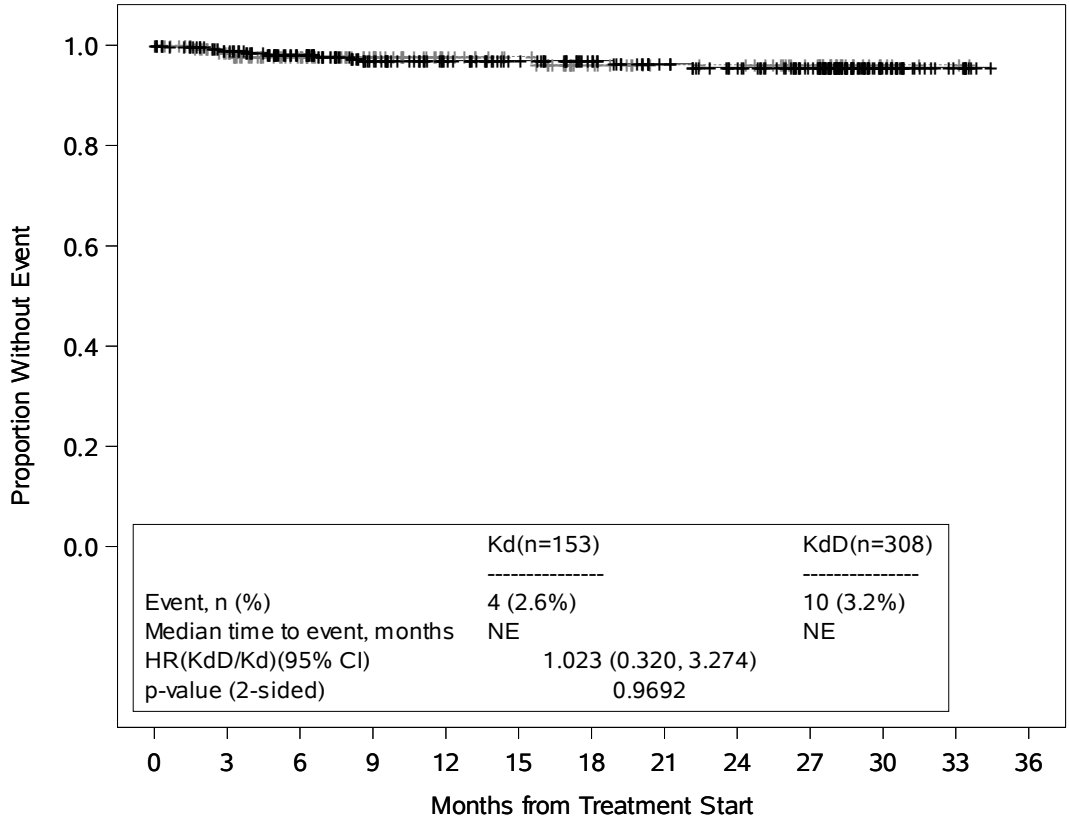


Number of Subjects at Risk:

Kd	153	131	107	87	66	58	45	37	35	26	6	2	0
KdD	308	288	250	211	188	171	154	140	129	108	34	10	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-529-ae-km-soc-infec-pt-gastr-ge10.rtf (Date Generated: 16SEP20:20:37:17).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.530. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Infections and Infestations) and PT (Infection) <Safety Population>

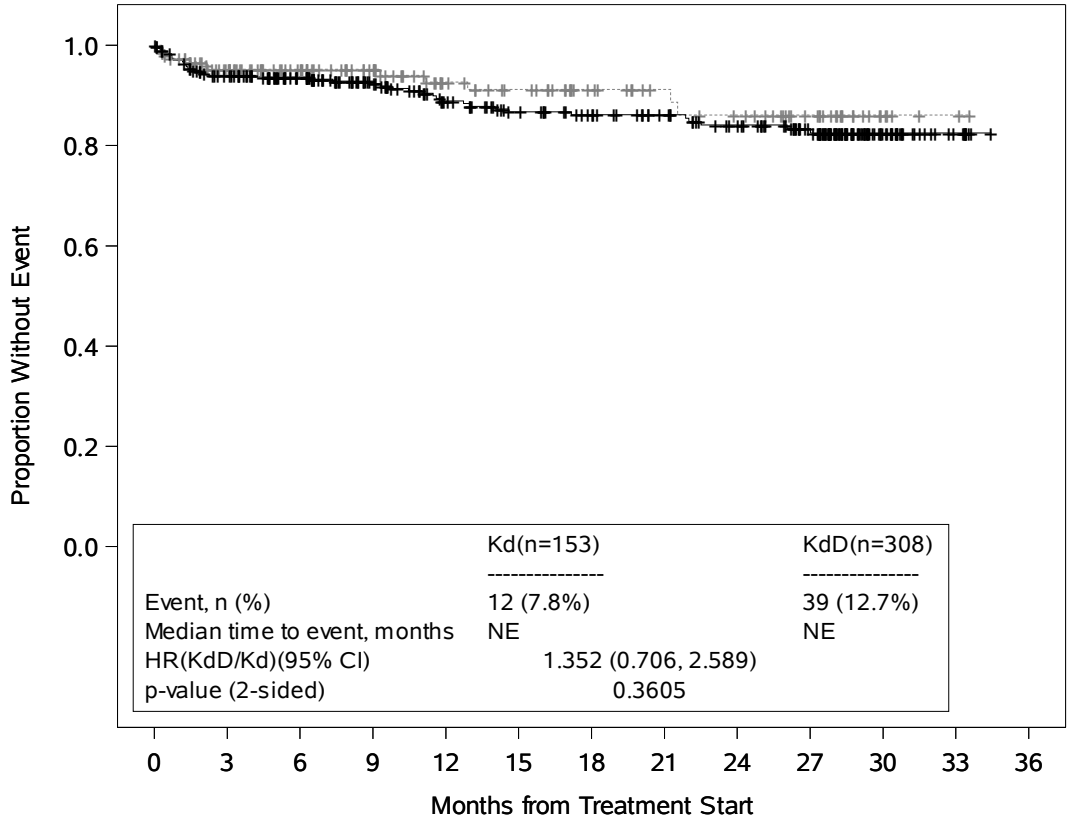


Number of Subjects at Risk:

Kd	153	130	107	87	67	59	45	37	36	26	5	2	0
KdD	308	286	251	209	188	173	157	141	130	109	36	10	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-530-ae-km-soc-infec-pt-infec-ge10.rtf (Date Generated: 16SEP20:20:37:19).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.531. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Infections and Infestations) and PT (Influenza)
<Safety Population>

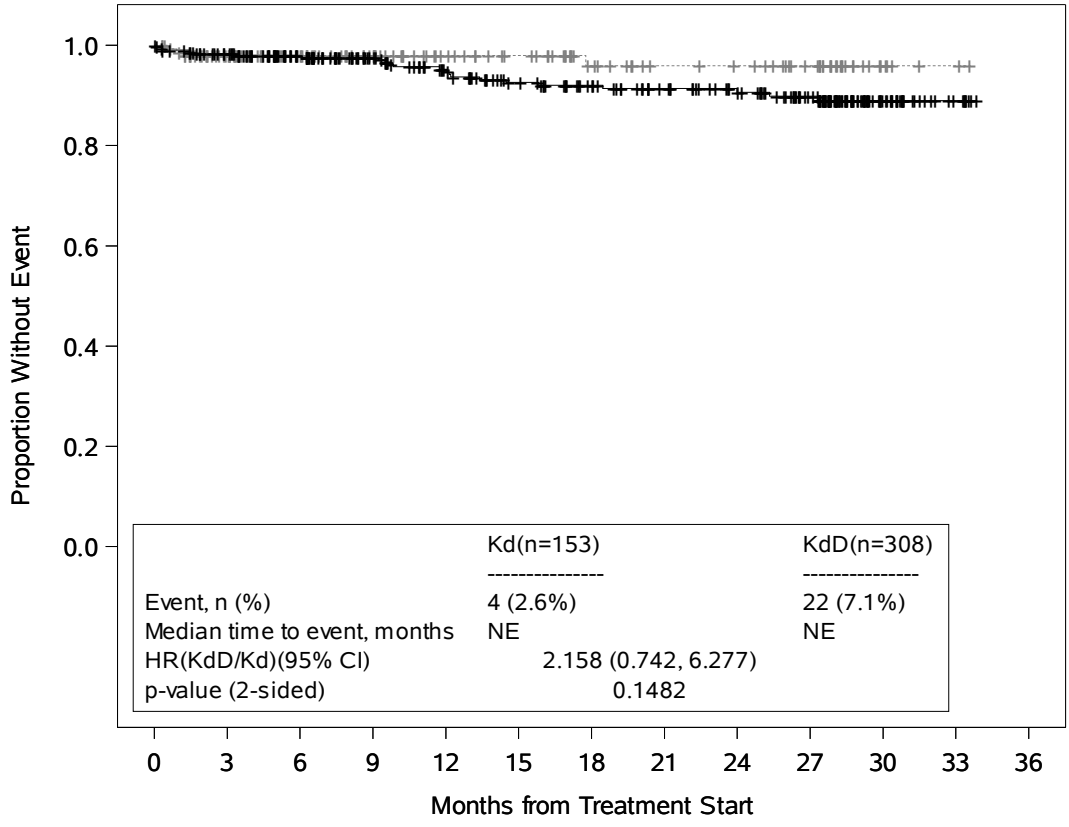


Number of Subjects at Risk:

Kd	153	125	103	84	63	55	43	36	32	22	6	2	0
KdD	308	272	239	200	171	154	143	132	119	98	33	9	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-531-ae-km-soc-infec-pt-influ-ge10.rtf (Date Generated: 16SEP20:20:37:20).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.532. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Infections and Infestations) and PT (Lower Respiratory Tract Infection) <Safety Population>

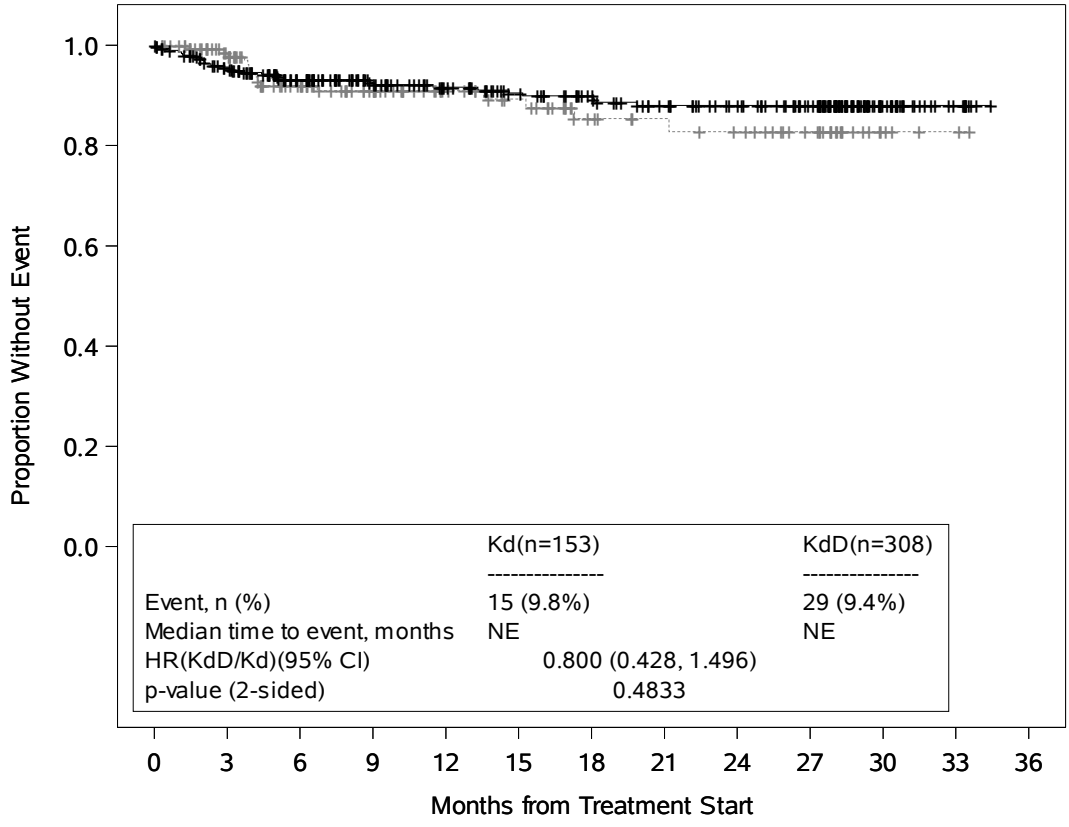


Number of Subjects at Risk:

Kd	153	129	105	85	67	59	45	37	35	27	6	2	0
KdD	308	285	249	210	186	166	151	136	123	101	33	8	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-532-ae-km-soc-infec-pt-lower-ge10.rtf (Date Generated: 16SEP20:20:37:22).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.533. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Infections and Infestations) and PT (Nasopharyngitis) <Safety Population>

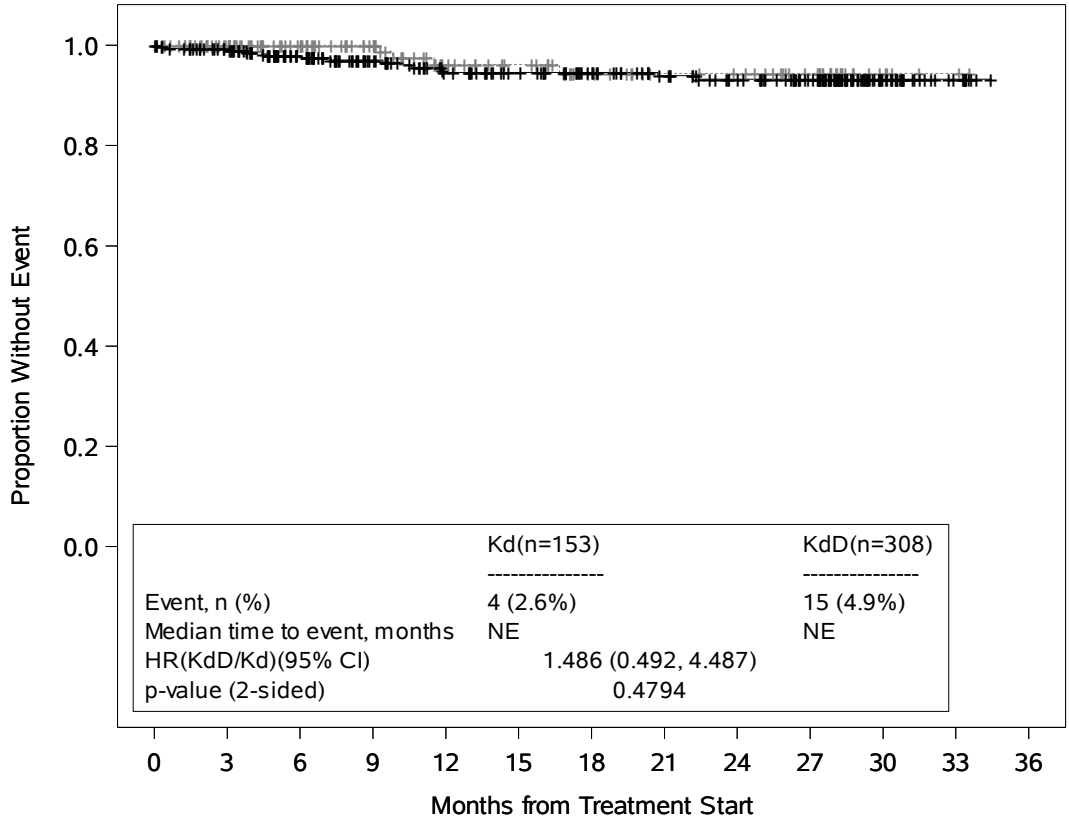


Number of Subjects at Risk:

Kd	153	130	98	78	59	51	37	33	30	22	5	2	0
KdD	308	276	233	194	173	156	143	129	118	100	33	10	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-533-ae-km-soc-infec-pt-nasop-ge10.rtf (Date Generated: 16SEP20:20:37:24).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.534. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Infections and Infestations) and PT (Pharyngitis) <Safety Population>

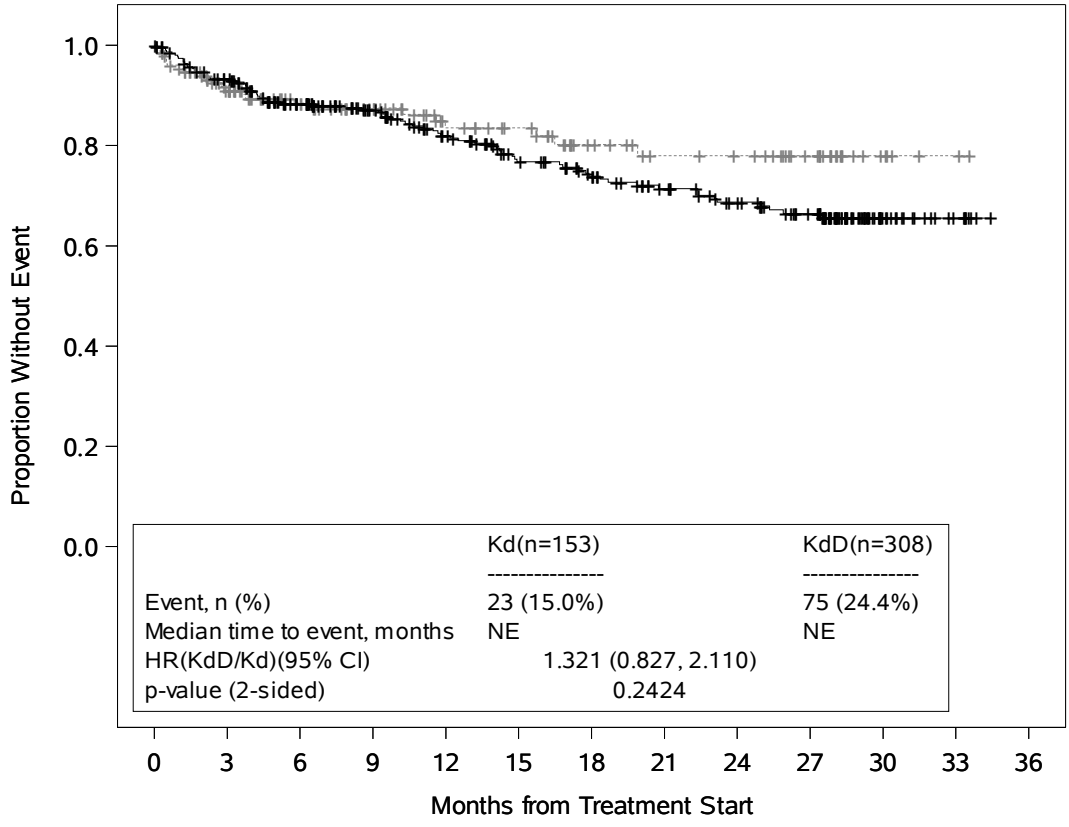


Number of Subjects at Risk:

Kd	153	132	108	88	66	58	44	36	34	25	6	2	0
KdD	308	286	246	207	182	168	153	138	125	106	35	10	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-534-ae-km-soc-infec-pt-phary-ge10.rtf (Date Generated: 16SEP20:20:37:25).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.535. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Infections and Infestations) and PT (Pneumonia)
<Safety Population>

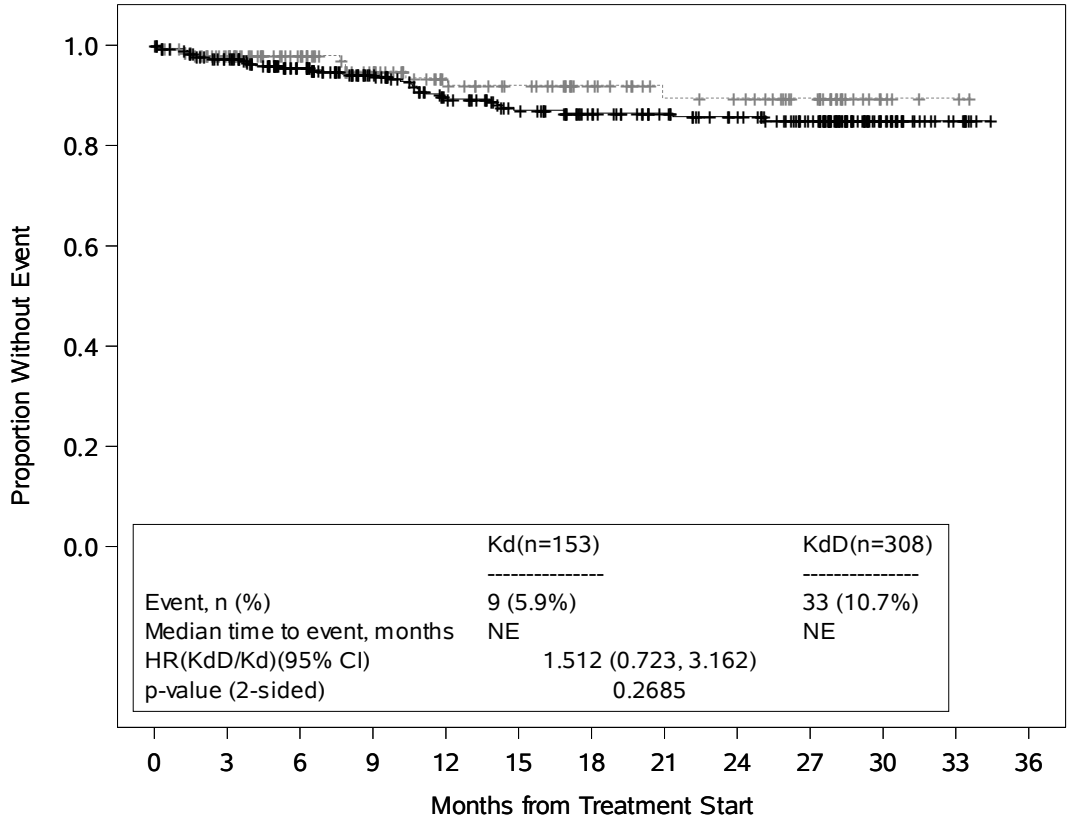


Number of Subjects at Risk:

Kd	153	120	96	78	60	54	40	33	31	22	6	2	0
KdD	308	274	231	195	167	142	126	110	97	81	23	8	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-535-ae-km-soc-infec-pt-pneum-ge10.rtf (Date Generated: 16SEP20:20:37:27).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.536. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Infections and Infestations) and PT (Respiratory Tract Infection) <Safety Population>

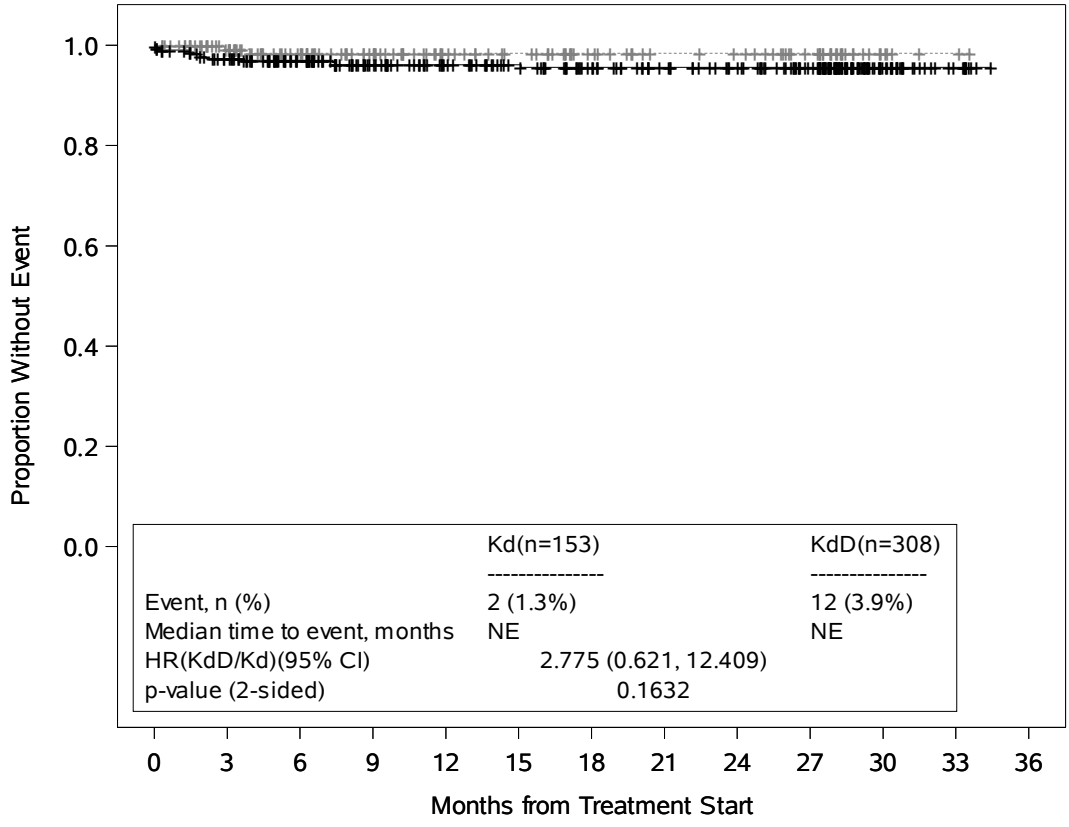


Number of Subjects at Risk:

Kd	153	129	105	84	64	56	44	35	33	24	5	2	0
KdD	308	282	241	202	172	153	136	122	111	92	31	9	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-536-ae-km-soc-infec-pt-respi-ge10.rtf (Date Generated: 16SEP20:20:37:28).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.537. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Infections and Infestations) and PT (Sepsis) <Safety Population>

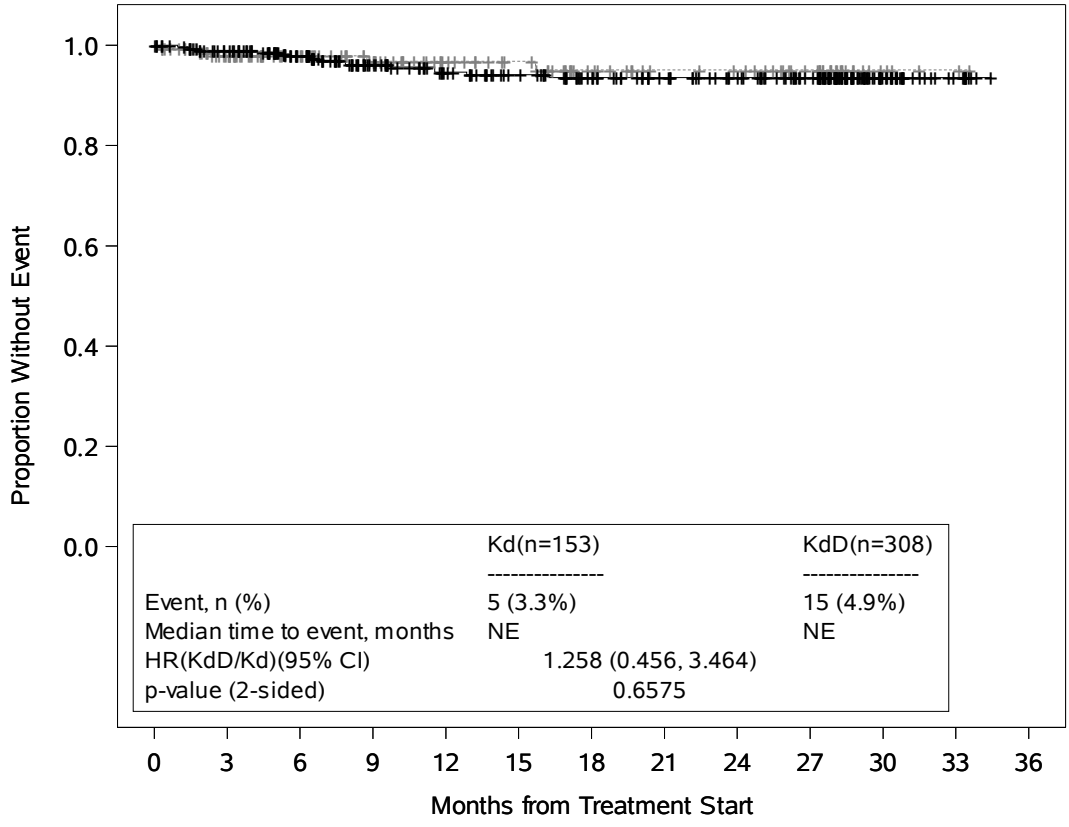


Number of Subjects at Risk:

Kd	153	132	108	88	68	60	47	39	37	27	6	2	0
KdD	308	283	248	209	188	173	156	141	130	108	34	10	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-537-ae-km-soc-infec-pt-sepsi-ge10.rtf (Date Generated: 16SEP20:20:37:30).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.538. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Infections and Infestations) and PT (Sinusitis) <Safety Population>

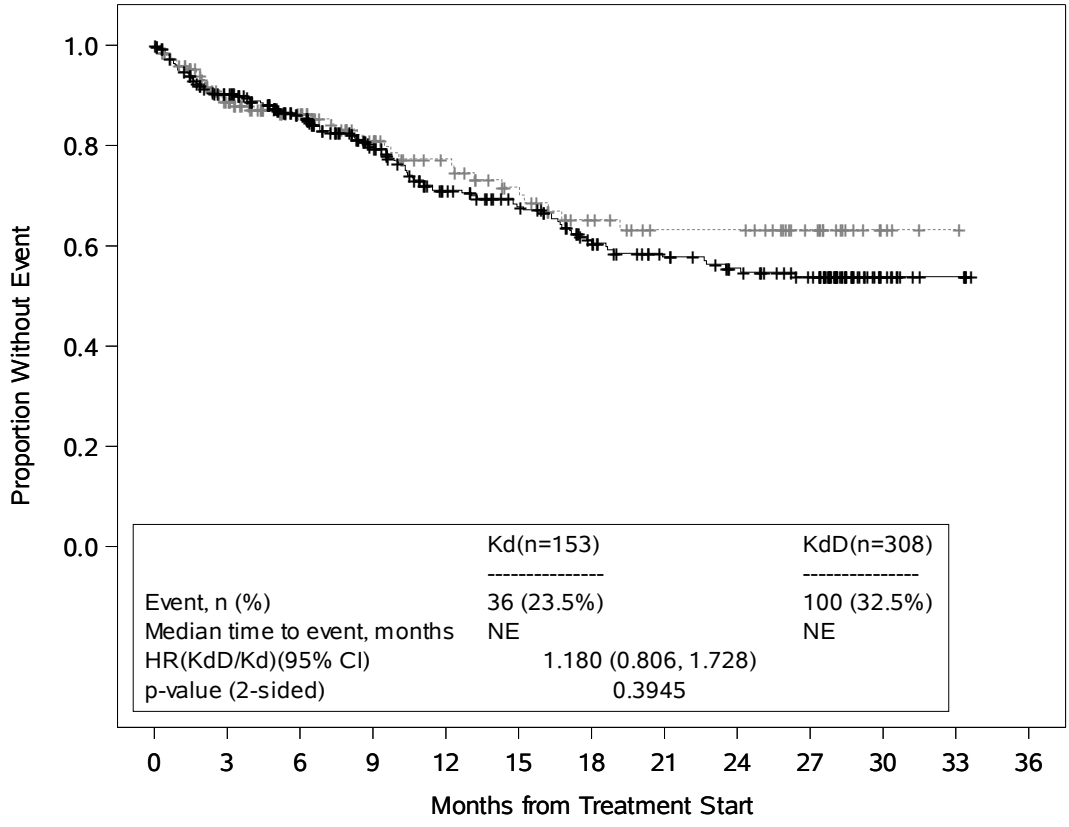


Number of Subjects at Risk:

Kd	153	129	105	85	66	58	44	36	34	25	5	2	0
KdD	308	286	248	205	182	167	150	135	123	103	34	10	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-538-ae-km-soc-infec-pt-sinus-ge10.rtf (Date Generated: 16SEP20:20:37:31).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.539. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Infections and Infestations) and PT (Upper Respiratory Tract Infection) <Safety Population>

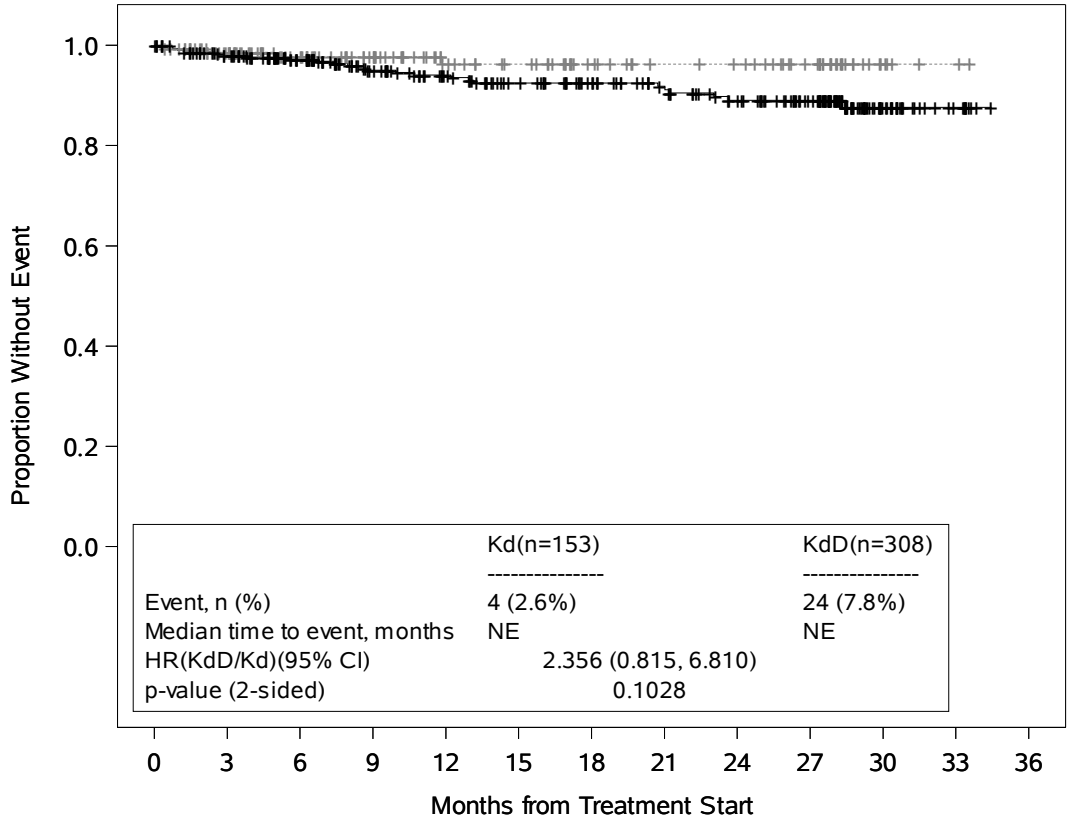


Number of Subjects at Risk:

Kd	153	117	94	70	57	46	34	27	27	17	4	1	0
KdD	308	260	217	172	136	119	95	80	70	59	13	5	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-539-ae-km-soc-infec-pt-upper-ge10.rtf (Date Generated: 16SEP20:20:37:33).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.540. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Infections and Infestations) and PT (Urinary Tract Infection) <Safety Population>

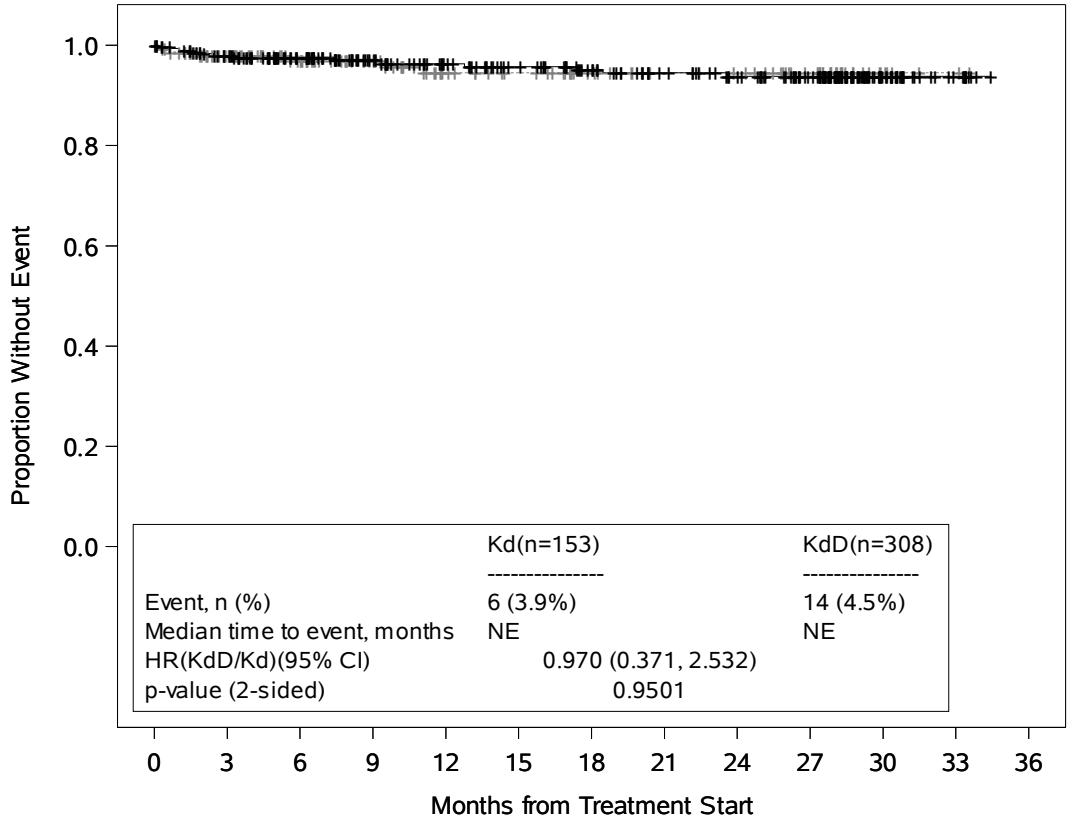


Number of Subjects at Risk:

Kd	153	130	106	86	65	58	45	38	36	27	6	2	0
KdD	308	283	246	205	184	166	151	136	121	100	32	10	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-540-ae-km-soc-infec-pt-urina-ge10.rtf (Date Generated: 16SEP20:20:37:34).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.541. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Infections and Infestations) and PT (Viral Infection) <Safety Population>

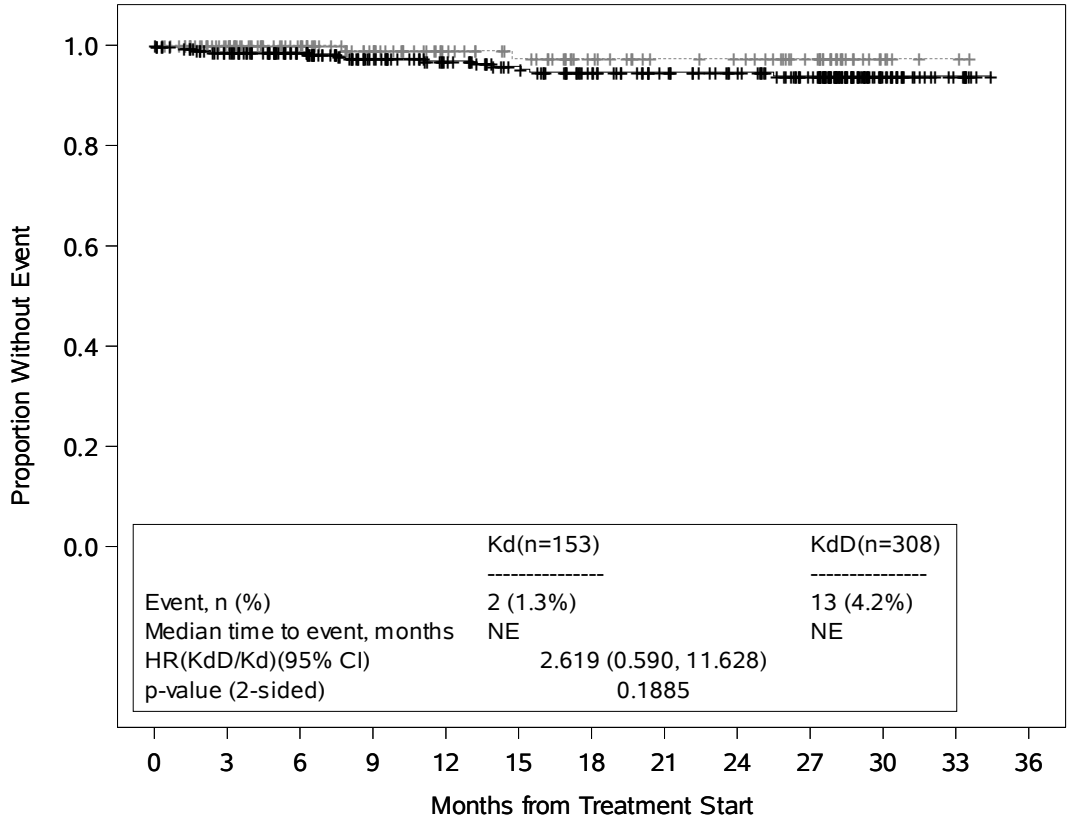


Number of Subjects at Risk:

Kd	153	130	105	85	63	56	46	39	37	27	6	2	0
KdD	308	284	248	209	188	172	155	139	128	108	35	10	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-541-ae-km-soc-infec-pt-viral-ge10.rtf (Date Generated: 16SEP20:20:37:36).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.542. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Injury, Poisoning and Procedural Complications) and PT (Contusion) <Safety Population>

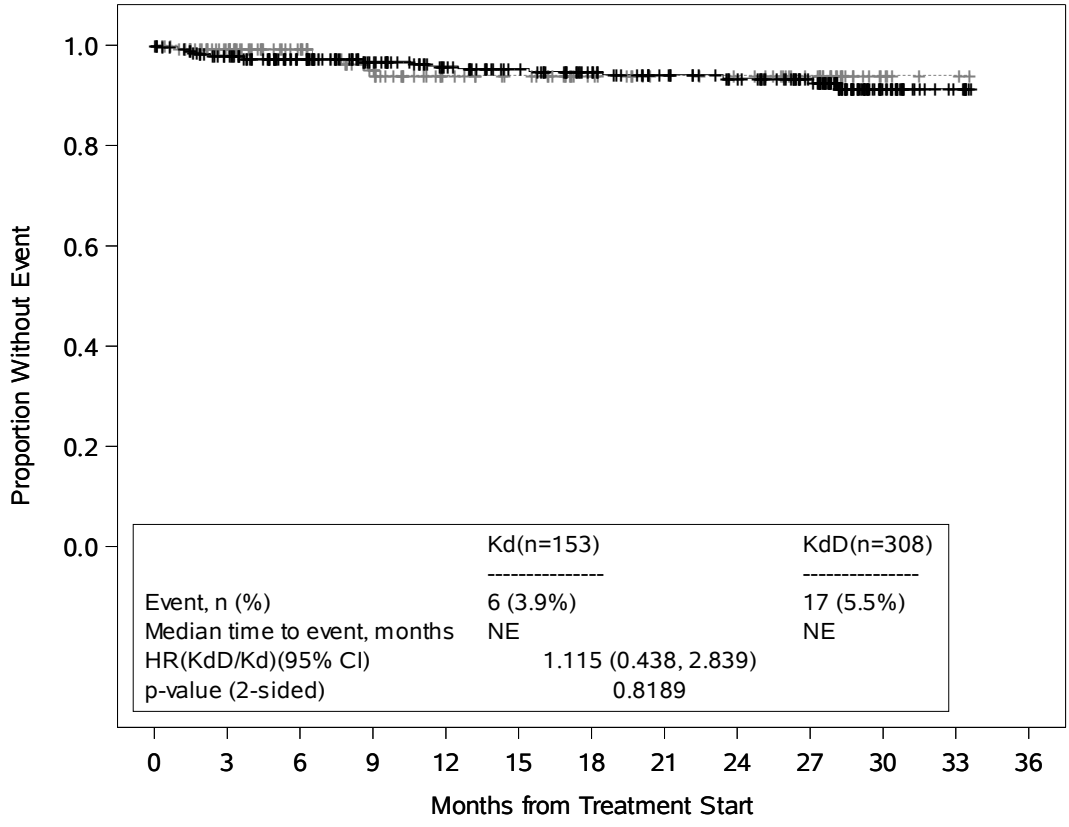


Number of Subjects at Risk:

Kd	153	132	108	87	67	59	47	39	37	27	6	2	0
KdD	308	285	250	209	187	170	152	137	126	106	33	10	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-542-ae-km-soc-injur-pt-contu-ge10.rtf (Date Generated: 16SEP20:20:37:37).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.543. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Injury, Poisoning and Procedural Complications) and PT (Fall) <Safety Population>

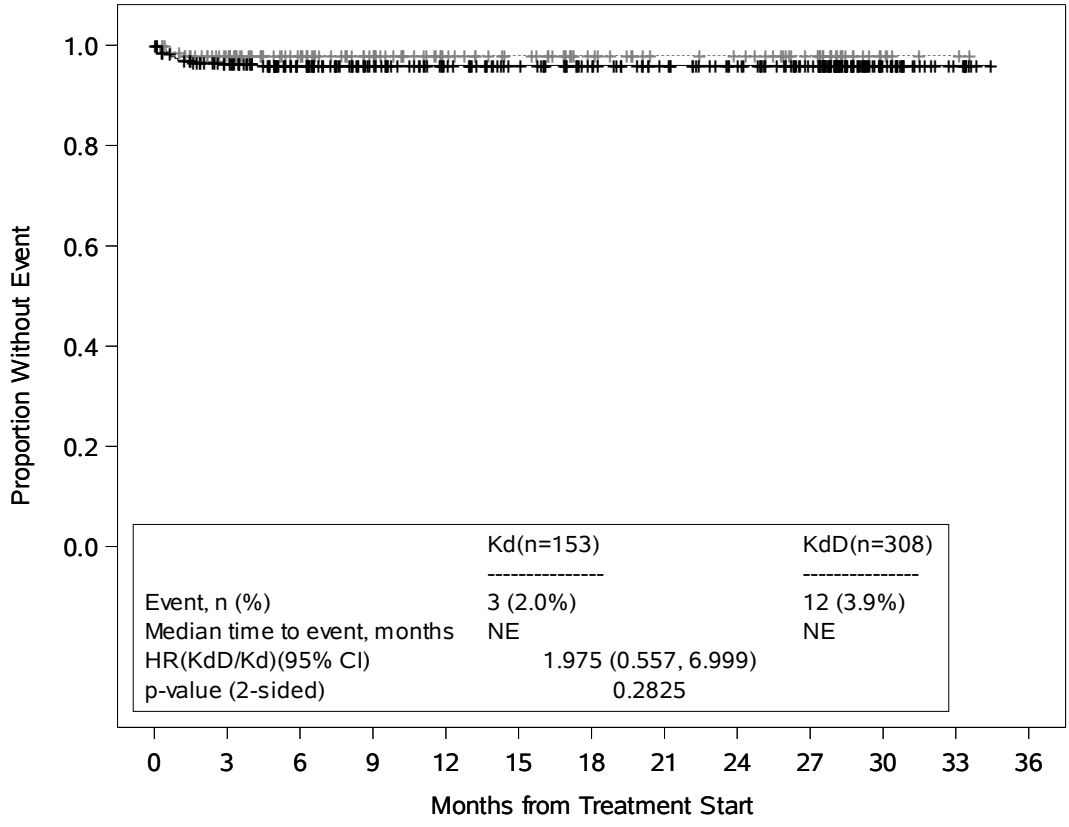


Number of Subjects at Risk:

Kd	153	131	107	84	64	58	45	38	36	27	6	2	0
KdD	308	284	247	210	187	171	154	139	128	107	33	8	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-543-ae-km-soc-injur-pt-fall-ge10.rtf (Date Generated: 16SEP20:20:37:39).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.545. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Investigations) and PT (Alanine Aminotransferase Increased) <Safety Population>

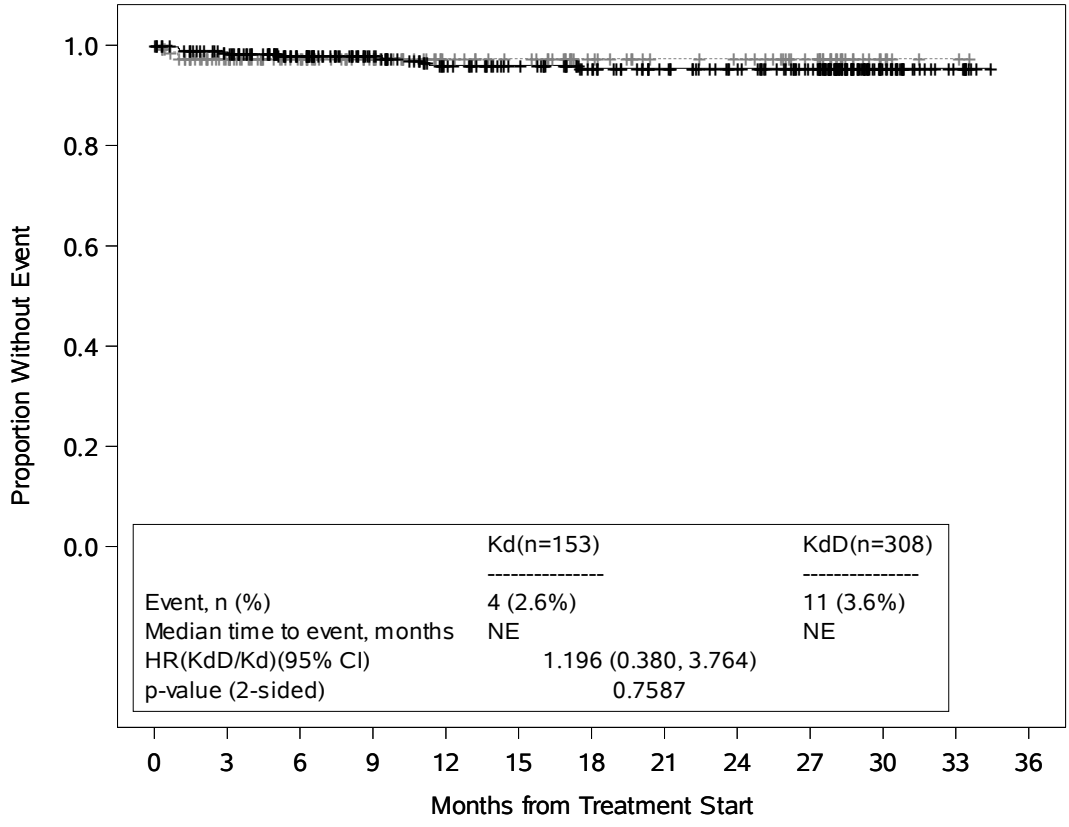


Number of Subjects at Risk:

Kd	153	131	108	88	68	60	47	39	37	27	6	2	0
KdD	308	278	242	204	183	167	152	139	127	106	35	10	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-545-ae-km-soc-inves-pt-alani-ge10.rtf (Date Generated: 16SEP20:20:37:42).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.546. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Investigations) and PT (Weight Decreased) <Safety Population>

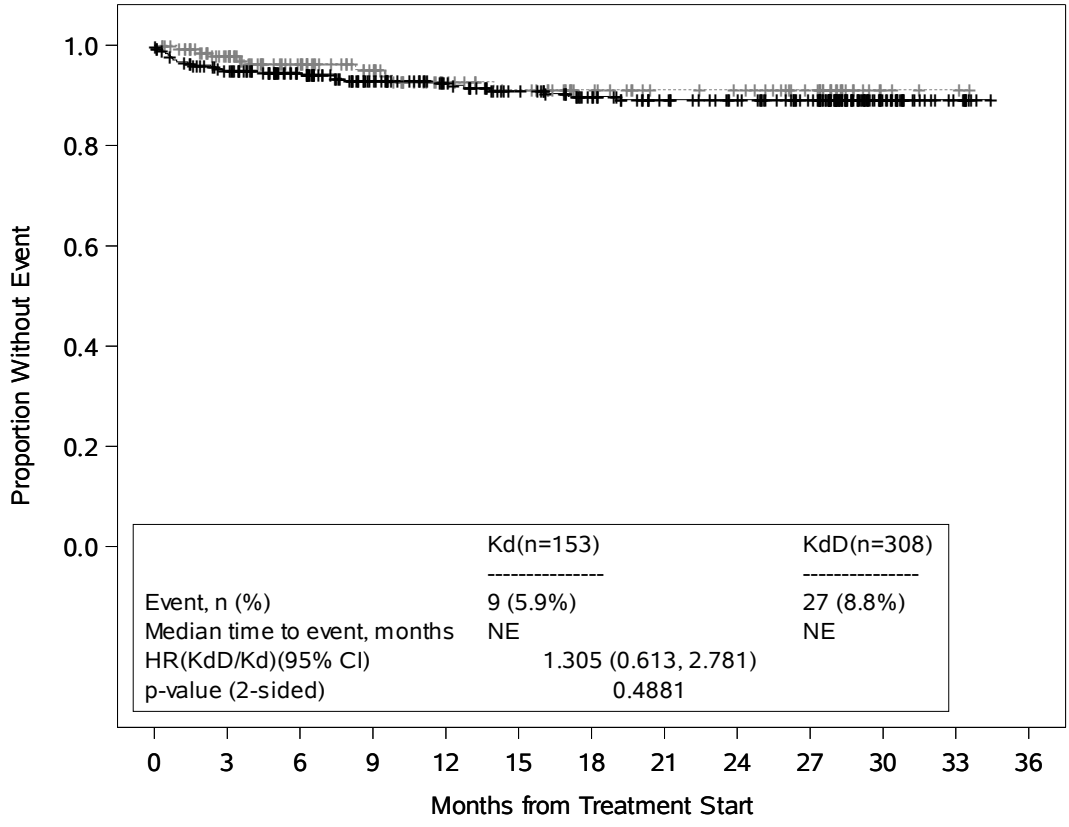


Number of Subjects at Risk:

Kd	153	128	106	86	66	60	47	39	37	27	6	2	0
KdD	308	286	249	212	187	172	155	140	128	109	35	10	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-546-ae-km-soc-inves-pt-weigh-ge10.rtf (Date Generated: 16SEP20:20:37:43).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.547. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Metabolism and Nutrition Disorders) and PT (Decreased Appetite) <Safety Population>

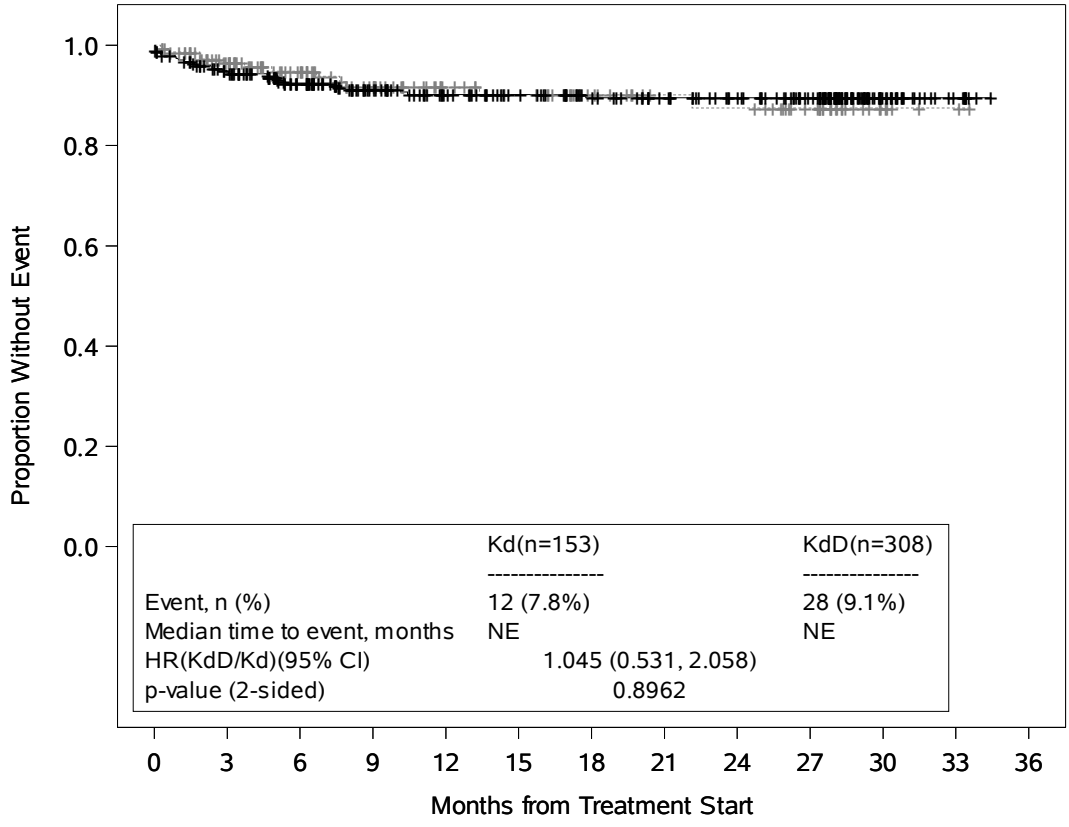


Number of Subjects at Risk:

Kd	153	129	104	84	63	56	44	36	34	25	4	2	0
KdD	308	277	242	205	183	165	148	132	122	105	35	10	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-547-ae-km-soc-metab-pt-decrea-ge10.rtf (Date Generated: 16SEP20:20:37:45).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.548. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Metabolism and Nutrition Disorders) and PT (Hyperglycaemia) <Safety Population>

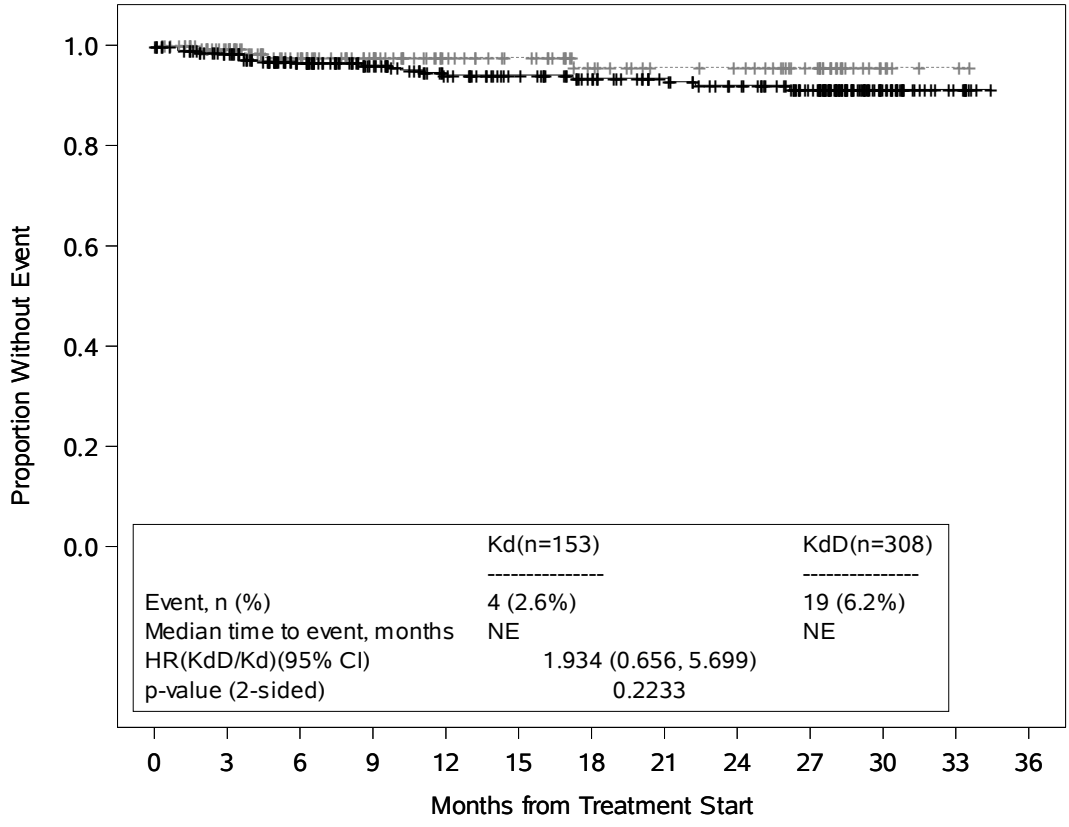


Number of Subjects at Risk:

Kd	153	127	102	81	62	55	43	35	34	25	6	2	0
KdD	308	274	235	194	173	159	144	132	120	101	31	9	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-548-ae-km-soc-metab-pt-hyper-ge10.rtf (Date Generated: 16SEP20:20:37:46).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.549. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Metabolism and Nutrition Disorders) and PT (Hypocalcaemia) <Safety Population>

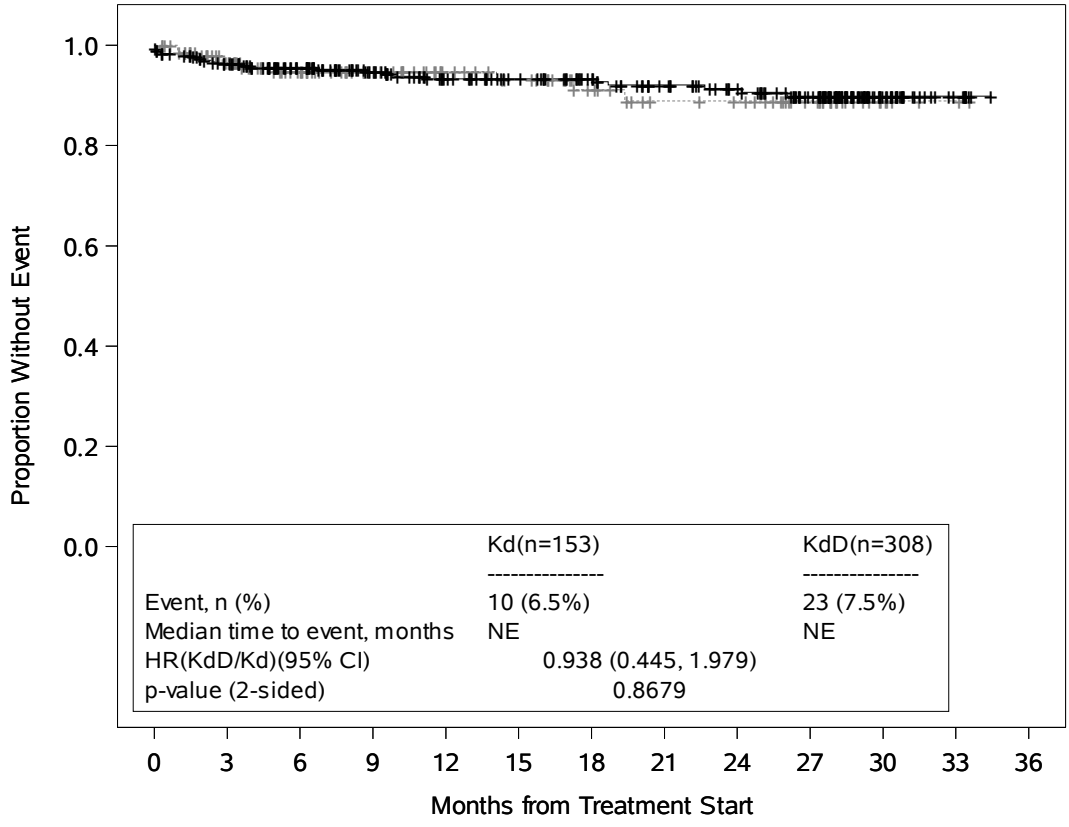


Number of Subjects at Risk:

Kd	153	132	106	86	66	58	45	38	36	26	6	2	0
KdD	308	284	243	204	179	164	149	135	124	103	35	10	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-549-ae-km-soc-metab-pt-hypoc-ge10.rtf (Date Generated: 16SEP20:20:37:48).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.550. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Metabolism and Nutrition Disorders) and PT (Hypokalaemia) <Safety Population>

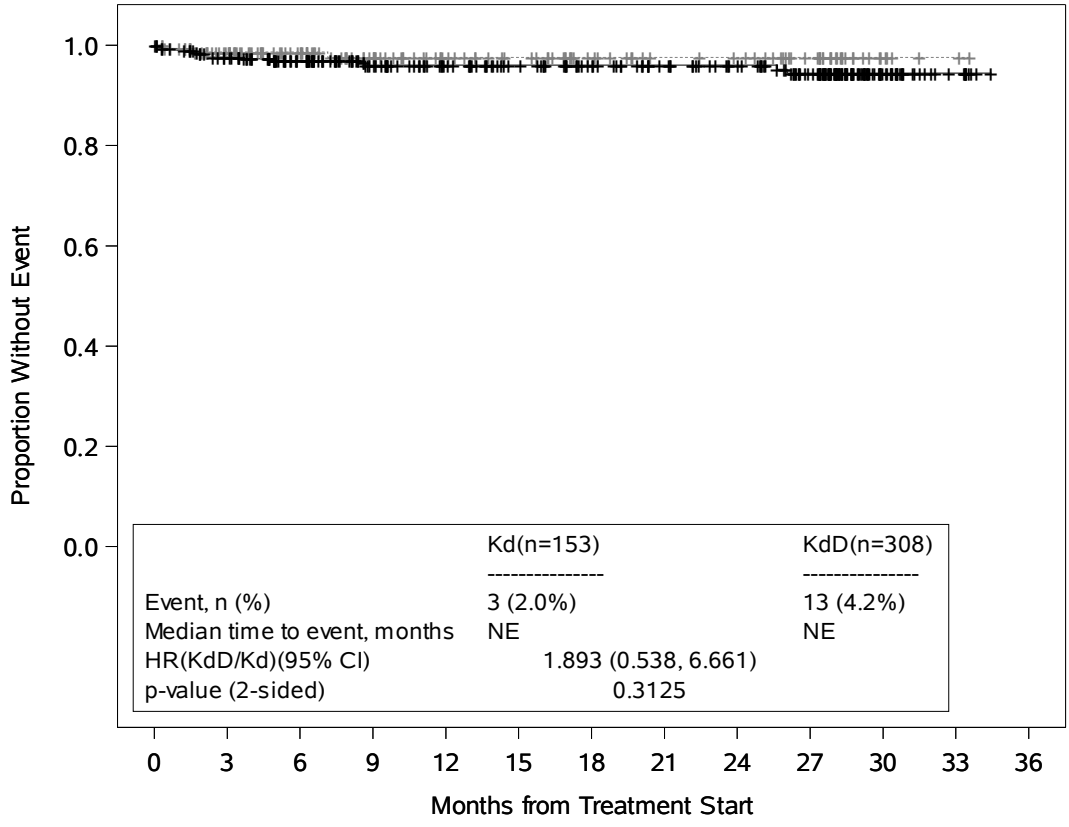


Number of Subjects at Risk:

Kd	153	128	102	83	63	56	43	35	33	23	6	2	0
KdD	308	279	244	207	183	169	154	138	125	103	35	9	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-550-ae-km-soc-metab-pt-hypok-ge10.rtf (Date Generated: 16SEP20:20:37:49).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.551. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Metabolism and Nutrition Disorders) and PT (Hypomagnesaemia) <Safety Population>

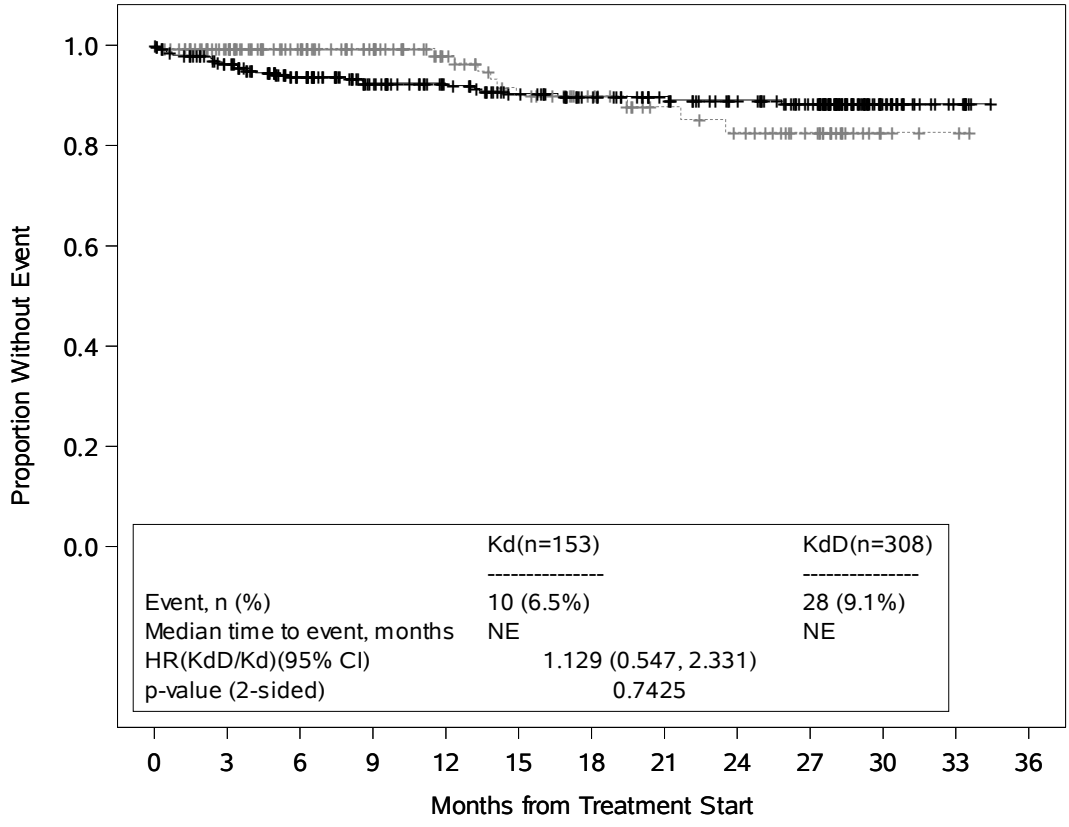


Number of Subjects at Risk:

Kd	153	131	107	86	68	60	47	39	37	27	6	2	0
KdD	308	283	249	208	187	171	156	142	130	107	33	9	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-551-ae-km-soc-metab-pt-hypom-ge10.rtf (Date Generated: 16SEP20:20:37:51).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.552. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Musculoskeletal and Connective Tissue Disorders) and PT (Arthralgia) <Safety Population>

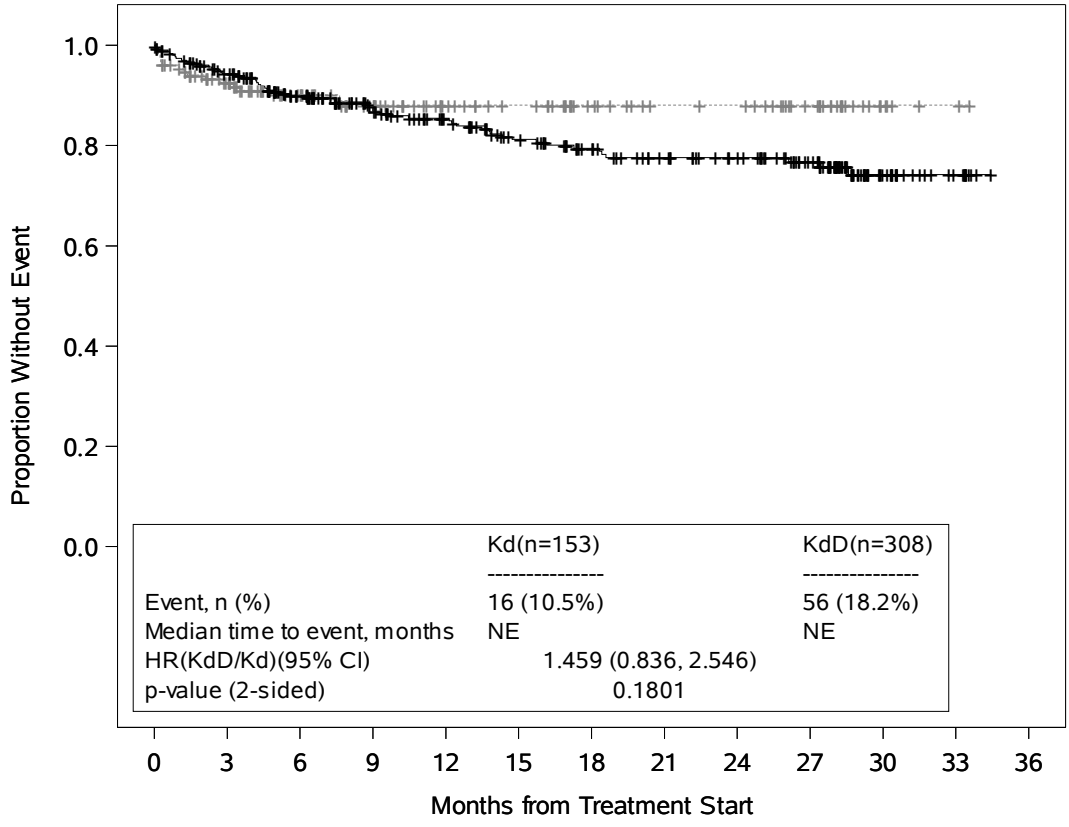


Number of Subjects at Risk:

Kd	153	131	107	87	66	54	44	35	31	22	4	2	0
KdD	308	278	238	201	180	163	148	134	121	104	31	9	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-552-ae-km-soc-muscu-pt-arthr-ge10.rtf (Date Generated: 16SEP20:20:37:52).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.553. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Musculoskeletal and Connective Tissue Disorders) and PT (Back Pain) <Safety Population>

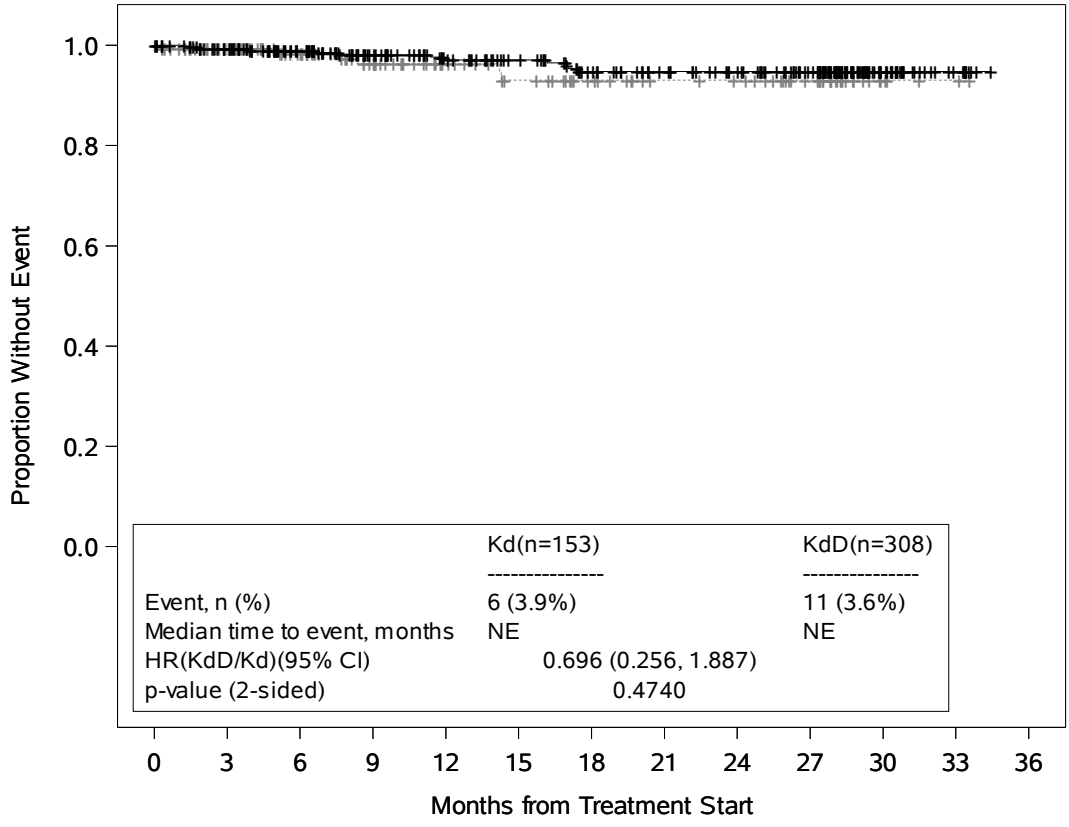


Number of Subjects at Risk:

Kd	153	123	97	78	60	53	41	34	33	23	6	2	0
KdD	308	273	231	189	168	146	129	115	105	85	27	10	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-553-ae-km-soc-muscu-pt-back-ge10.rtf (Date Generated: 16SEP20:20:37:54).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.554. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Musculoskeletal and Connective Tissue Disorders) and PT (Bone Pain) <Safety Population>

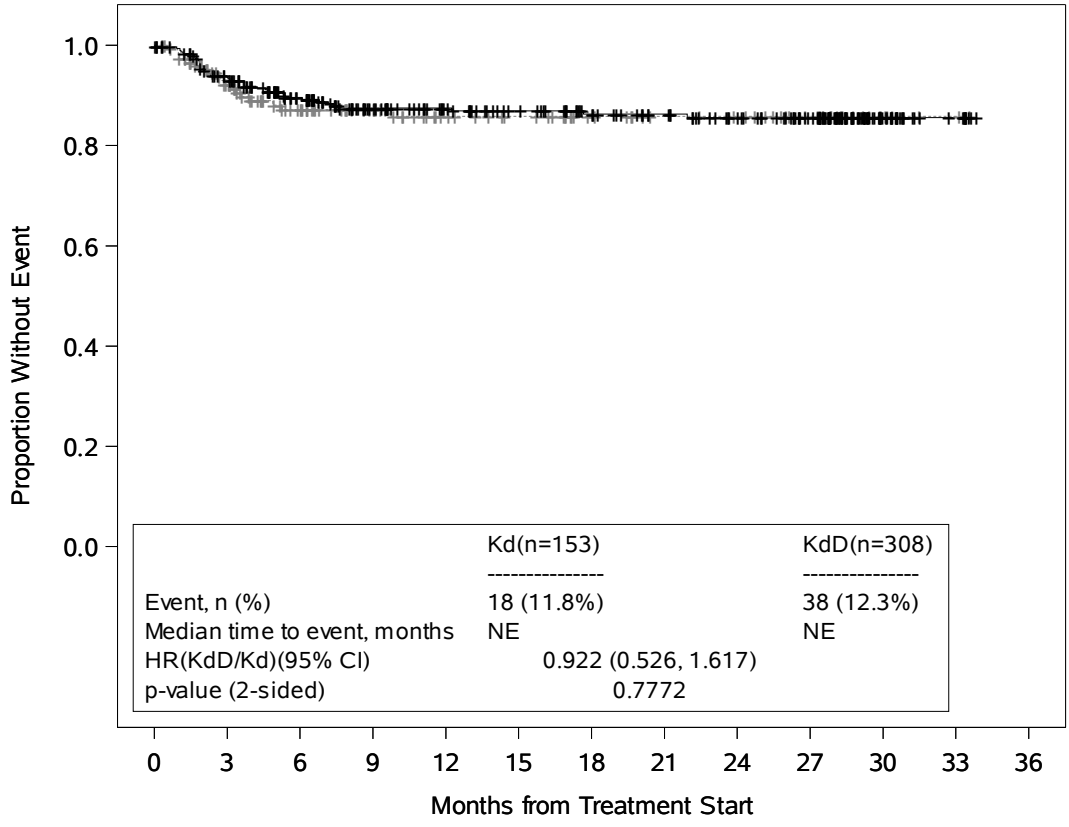


Number of Subjects at Risk:

Kd	153	131	106	84	64	55	46	38	36	26	5	2	0
KdD	308	287	252	212	190	174	155	141	130	109	35	10	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-554-ae-km-soc-muscu-pt-bone-ge10.rtf (Date Generated: 16SEP20:20:37:55).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.555. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Musculoskeletal and Connective Tissue Disorders) and PT (Muscle Spasms) <Safety Population>

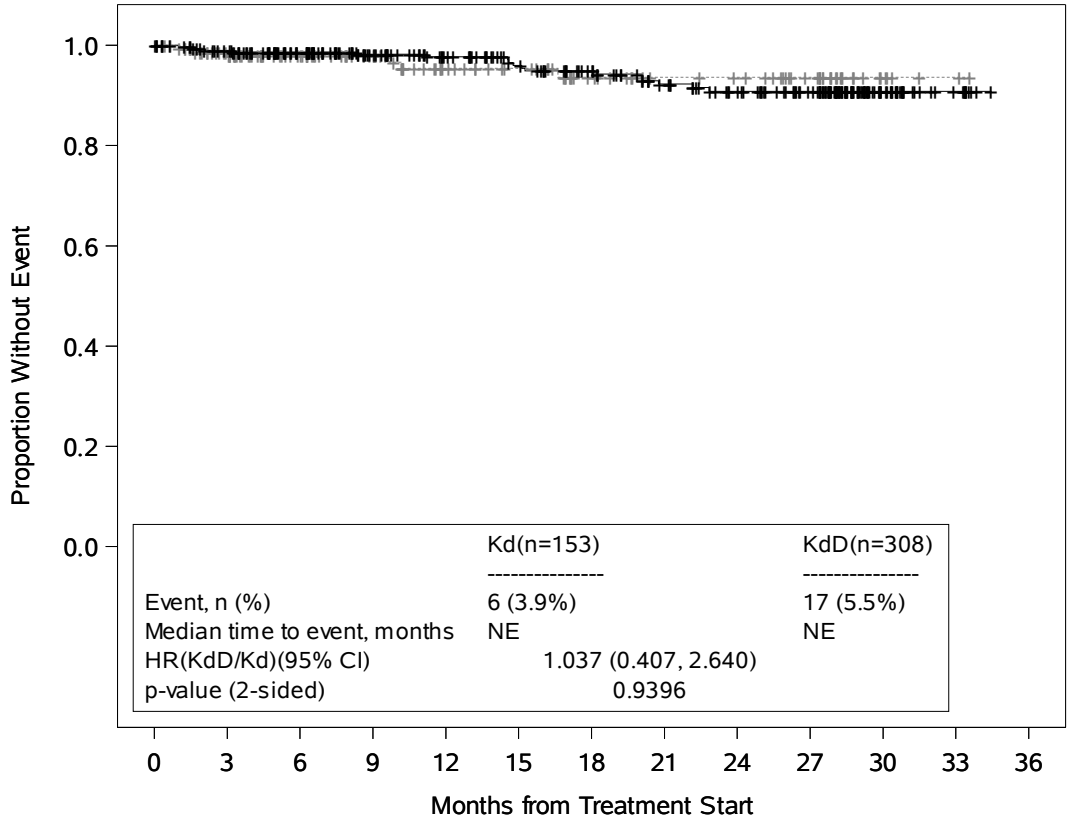


Number of Subjects at Risk:

Kd	153	121	91	71	55	49	39	33	31	23	6	2	0
KdD	308	271	226	184	164	150	135	124	111	93	29	9	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-555-ae-km-soc-muscu-pt-muscl-ge10.rtf (Date Generated: 16SEP20:20:37:57).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.556. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Musculoskeletal and Connective Tissue Disorders) and PT (Muscular Weakness) <Safety Population>

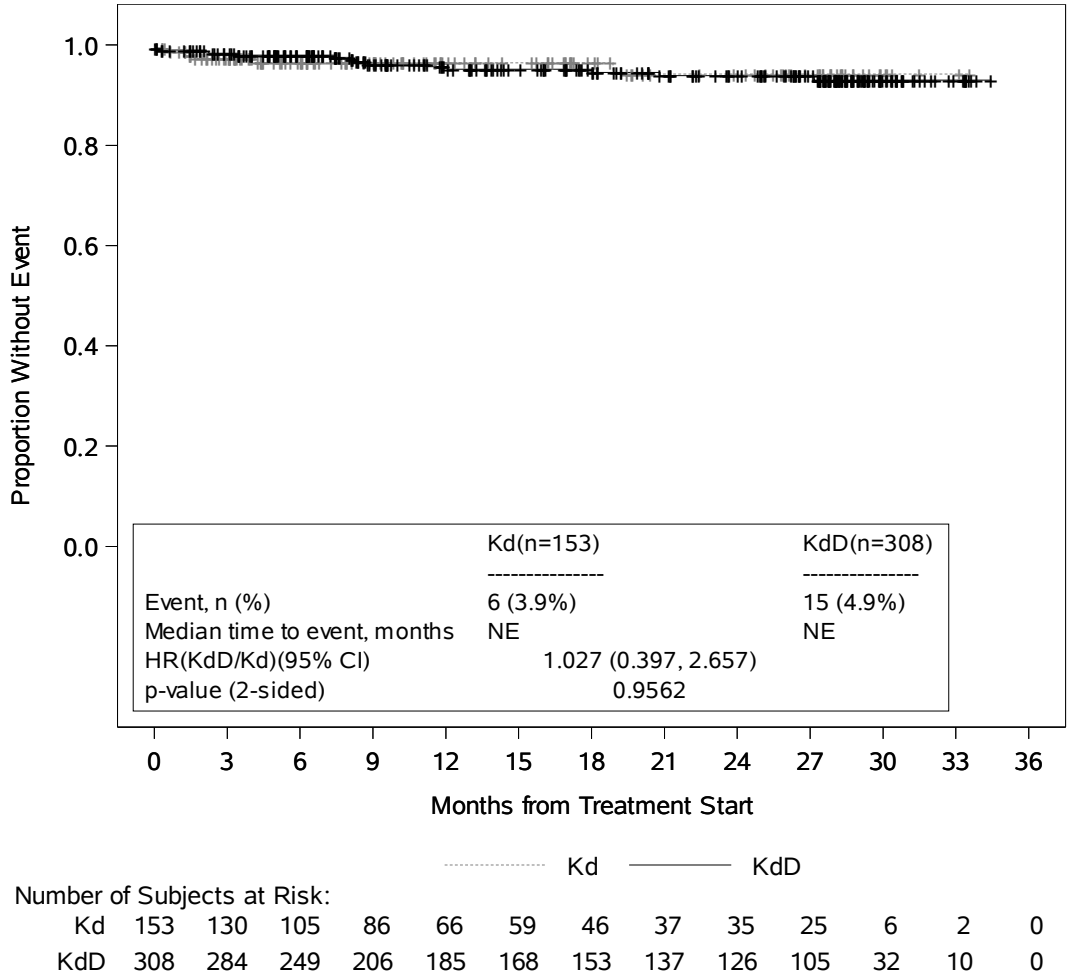


Number of Subjects at Risk:

Kd	153	131	106	87	66	58	44	36	34	25	6	2	0
KdD	308	288	251	211	189	170	154	135	121	102	33	10	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-556-ae-km-soc-muscu-pt-muscu-ge10.rtf (Date Generated: 16SEP20: 20:37:58).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.557. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Musculoskeletal and Connective Tissue Disorders) and PT (Musculoskeletal Chest Pain)
<Safety Population>

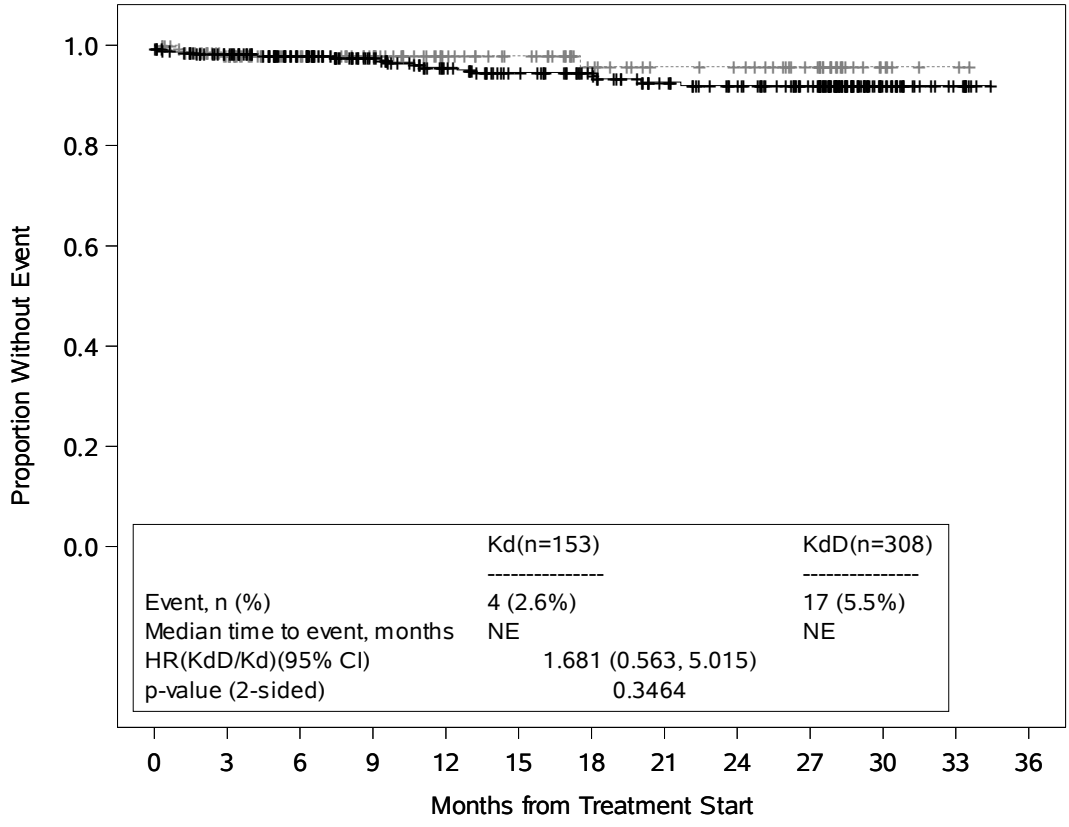


Number of Subjects at Risk:

Kd	153	130	105	86	66	59	46	37	35	25	6	2	0
KdD	308	284	249	206	185	168	153	137	126	105	32	10	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-557-ae-km-soc-muscu-pt-musche-ge10.rtf (Date Generated: 16SEP20: 20:38:00).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.558. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Musculoskeletal and Connective Tissue Disorders) and PT (Myalgia) <Safety Population>

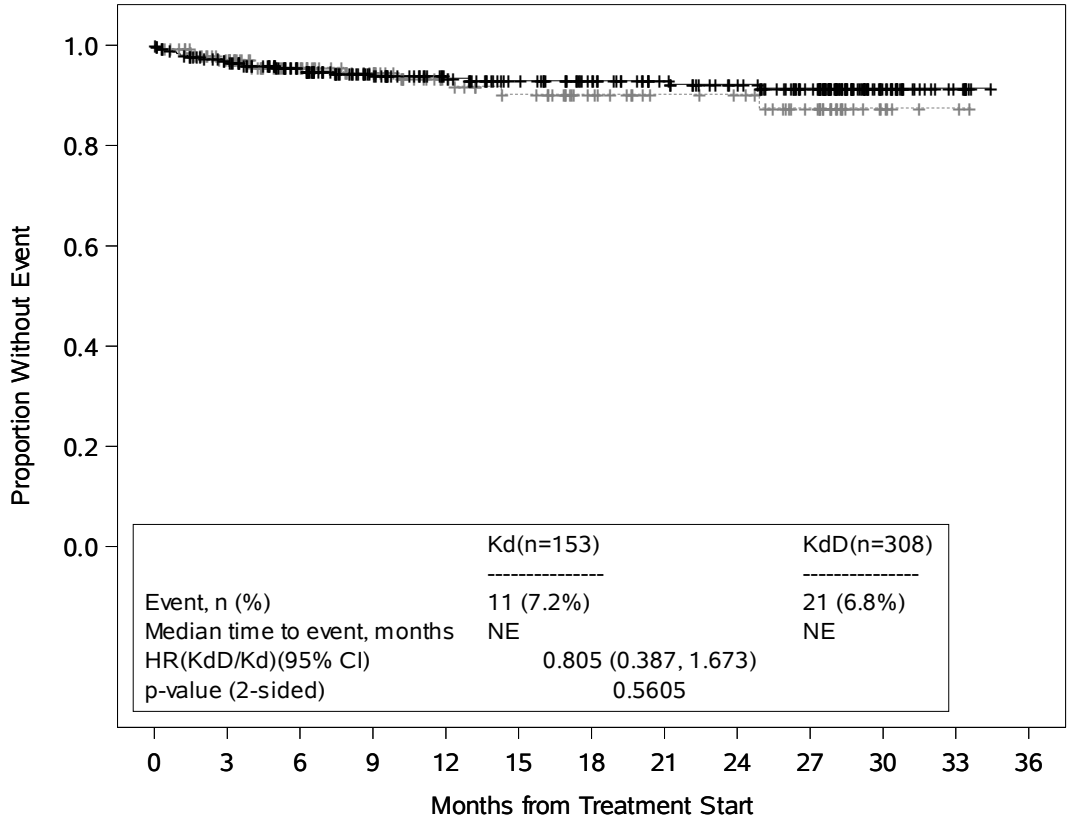


Number of Subjects at Risk:

Kd	153	129	105	85	65	57	43	36	34	25	6	2	0
KdD	308	284	248	210	185	167	152	134	122	102	32	10	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-558-ae-km-soc-muscu-pt-myalg-ge10.rtf (Date Generated: 16SEP20:20:38:01).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.559. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Musculoskeletal and Connective Tissue Disorders) and PT (Pain in Extremity) <Safety Population>

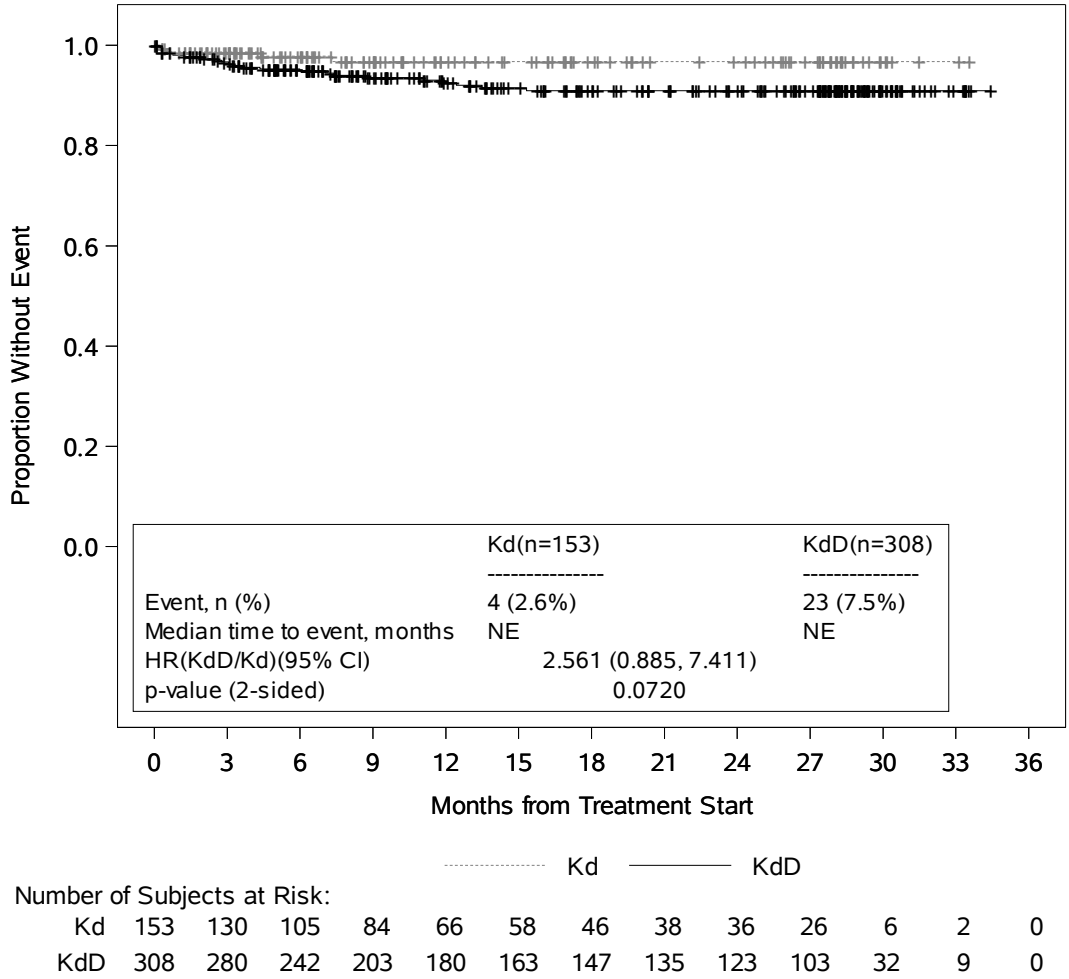


Number of Subjects at Risk:

Kd	153	130	105	84	64	56	45	37	35	25	6	2	0
KdD	308	282	246	206	185	167	152	137	125	104	34	9	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-559-ae-km-soc-muscu-pt-pain-ge10.rtf (Date Generated: 16SEP20:20:38:03).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.560. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Nervous System Disorders) and PT (Dizziness) <Safety Population>

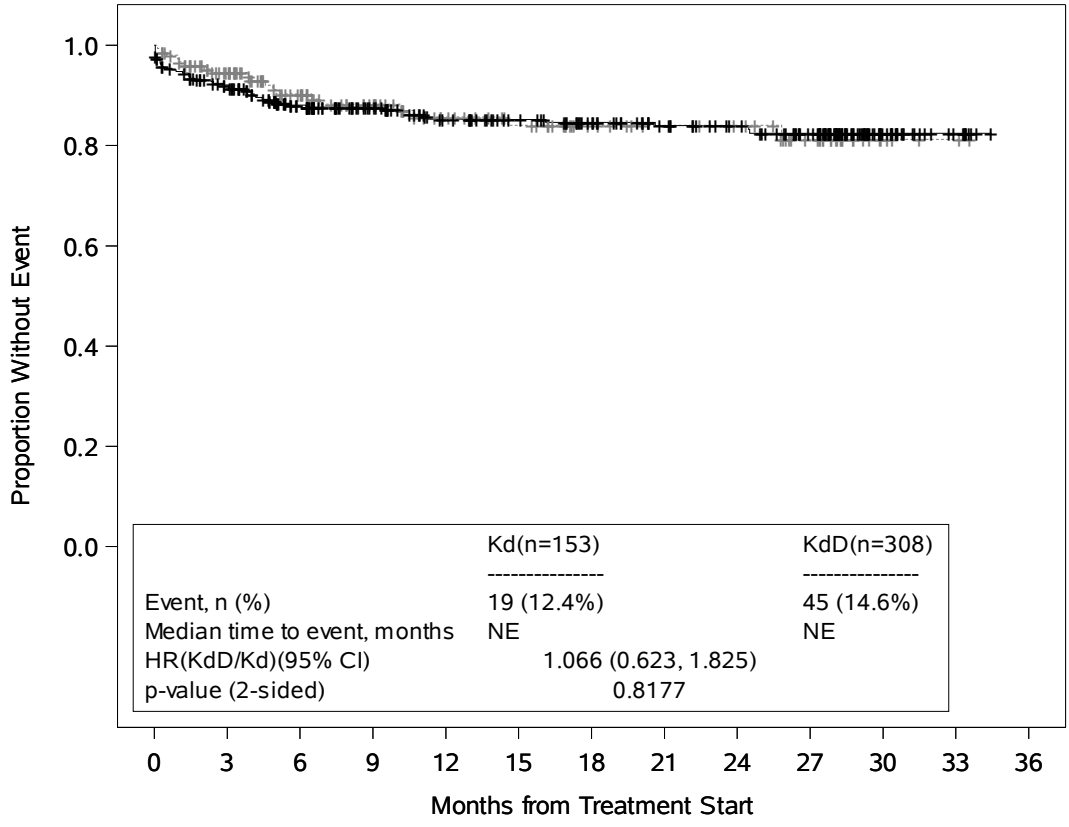


Number of Subjects at Risk:

Kd	153	130	105	84	66	58	46	38	36	26	6	2	0
KdD	308	280	242	203	180	163	147	135	123	103	32	9	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-560-ae-km-soc-nervo-pt-dizzi-ge10.rtf (Date Generated: 16SEP20:20:38:05).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.561. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Nervous System Disorders) and PT (Headache)
<Safety Population>

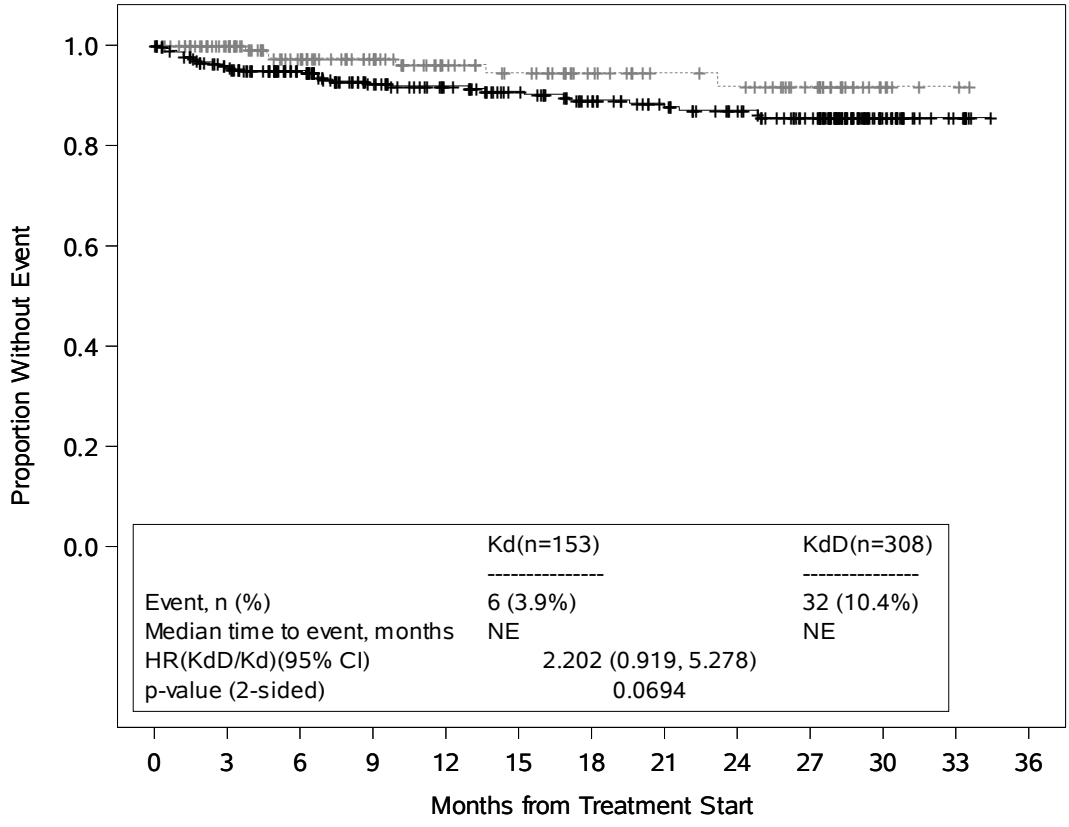


Number of Subjects at Risk:

Kd	153	125	97	78	60	52	40	35	33	23	5	2	0
KdD	308	266	223	189	165	152	138	122	112	95	30	9	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-561-ae-km-soc-nervo-pt-heada-ge10.rtf (Date Generated: 16SEP20:20:38:06).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.5.562. KM Curves of Most Frequent Adverse Events by MedDRA SOC (Nervous System Disorders) and PT (Neuropathy Peripheral) <Safety Population>

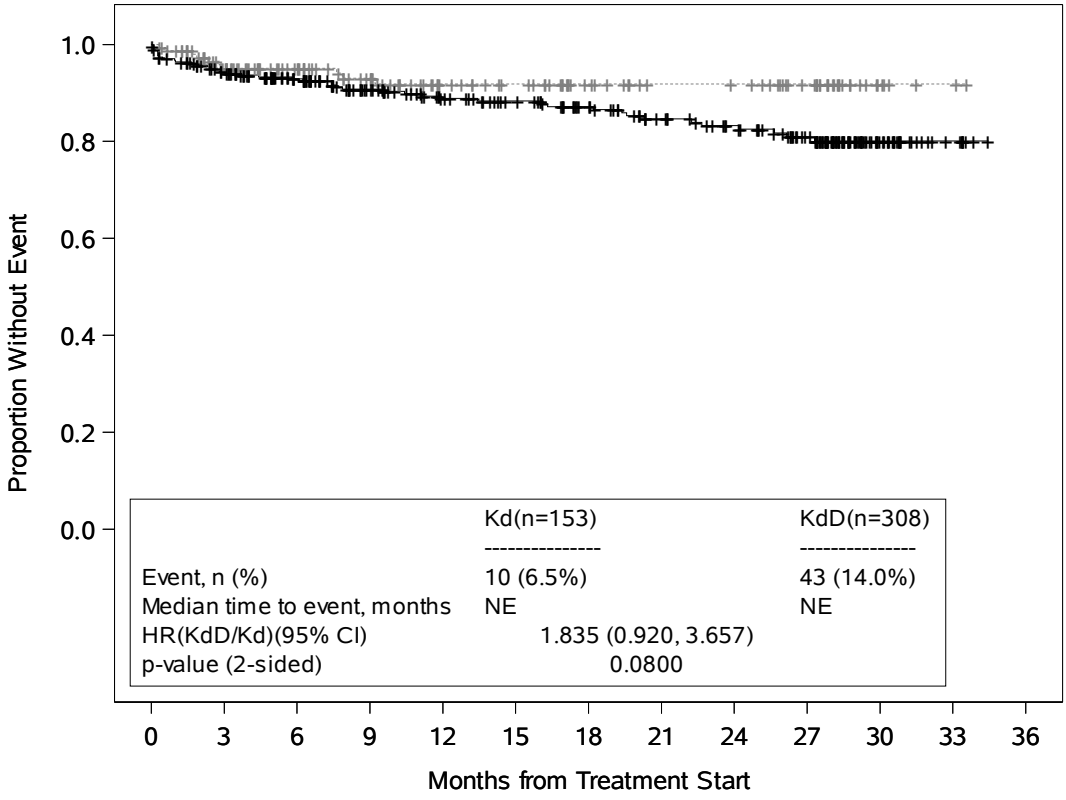


Number of Subjects at Risk:

Kd	153	132	105	85	64	56	44	36	34	24	6	2	0
KdD	308	277	239	197	178	161	144	130	119	101	32	9	0

Includes PT where at least 10 subjects with at least one adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-005-562-ae-km-soc-nervo-pt-neuro-ge10.rtf (Date Generated: 16SEP20:20:38:08).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.6.508. KM Curves of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC (Metabolism and Nutrition Disorders)
<Safety Population>

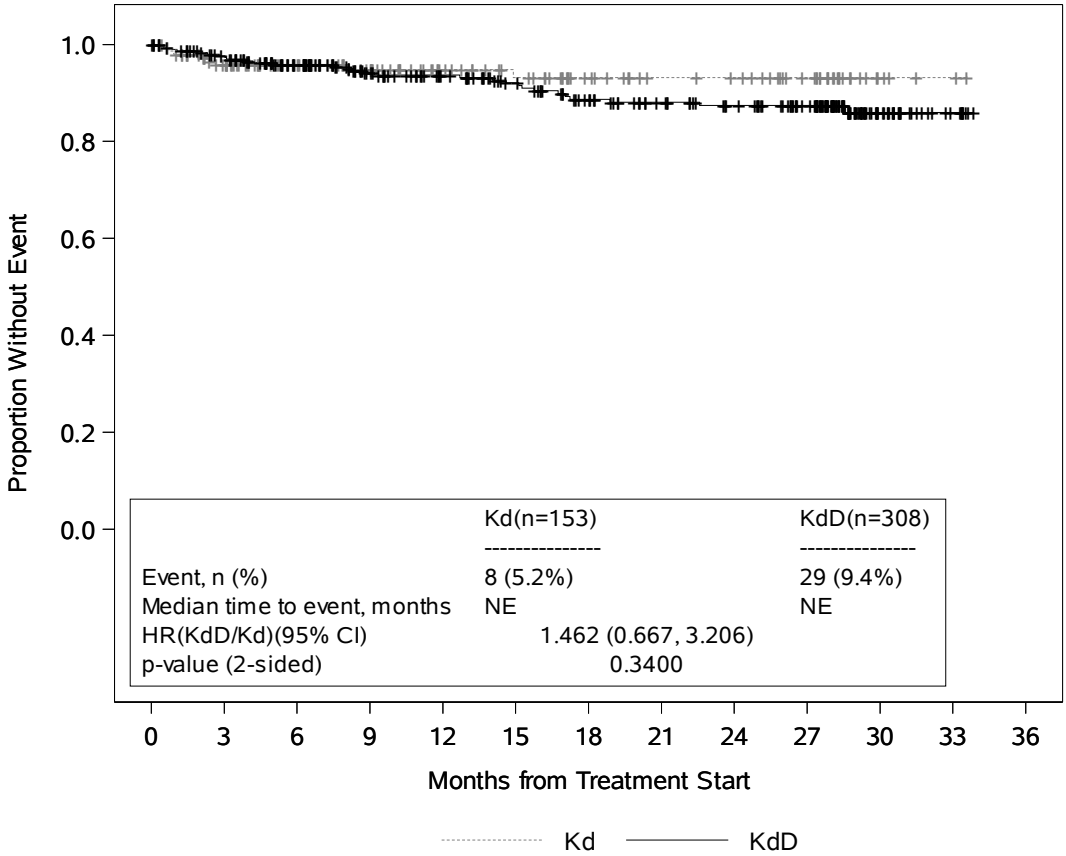


Number of Subjects at Risk:

Kd	153	127	104	85	65	58	45	37	36	27	6	2	0
KdD	308	273	236	198	174	161	144	126	114	94	31	8	0

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-sub.sas.
Output: f14-06-006-508-ae-km-soc-metab-grd345-ge5pct.rtf (Date Generated: 16SEP20:01:22:24).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.6.509. KM Curves of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC (Musculoskeletal and Connective Tissue Disorders) <Safety Population>

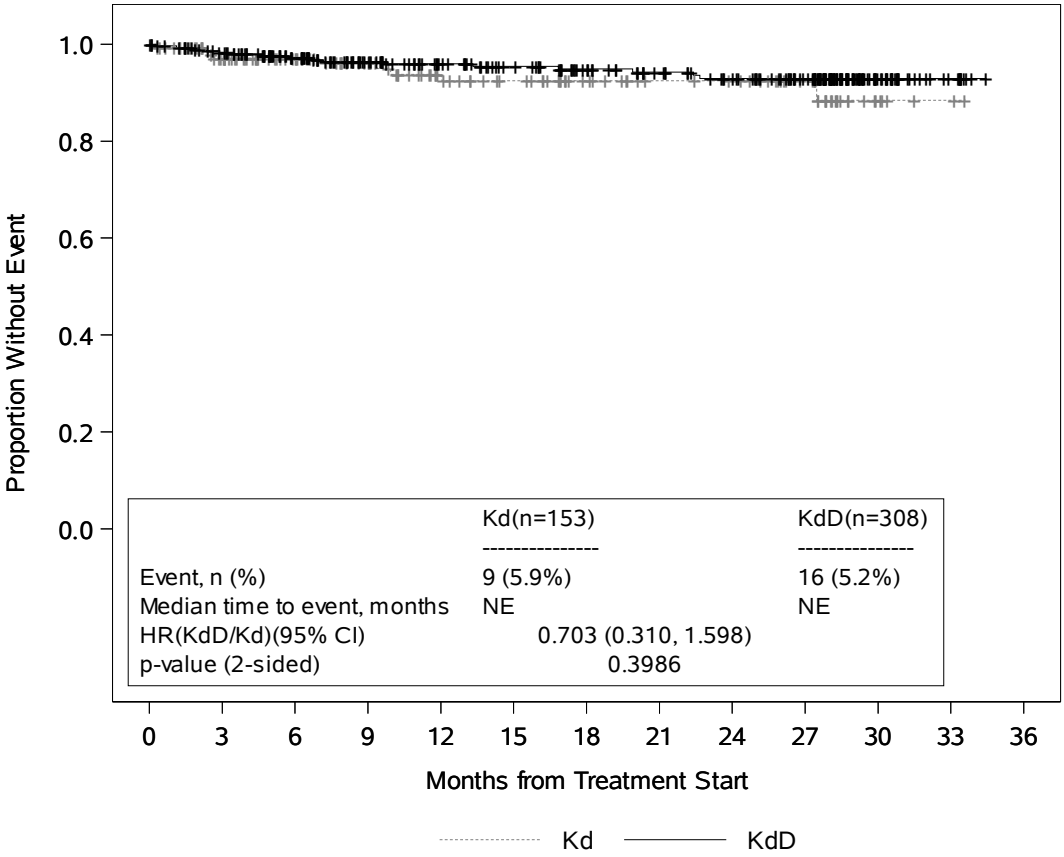


Number of Subjects at Risk:

Kd	153	130	107	86	66	57	44	36	34	25	5	2	0
KdD	308	284	247	206	186	168	149	134	123	105	31	9	0

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-sub.sas.
Output: f14-06-006-509-ae-km-soc-muscu-grd345-ge5pct.rtf (Date Generated: 16SEP20:01:22:26).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.6.510. KM Curves of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC (Neoplasms Benign, Malignant and Unspecified (Incl Cysts and Polyps))
<Safety Population>

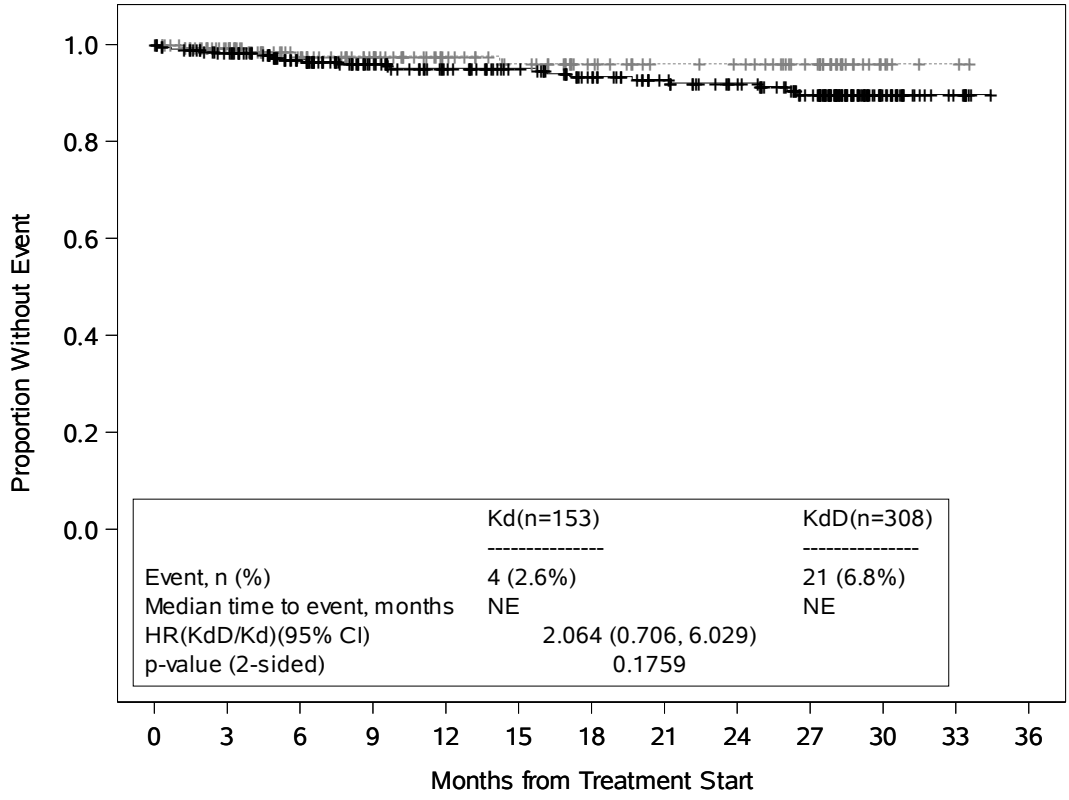


Number of Subjects at Risk:

Kd	153	130	108	88	68	59	47	39	37	27	6	2	0
KdD	308	288	252	214	192	176	159	145	133	111	36	10	0

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-sub.sas.
Output: f14-06-006-510-ae-km-soc-neopl-grd345-ge5pct.rtf (Date Generated: 16SEP20:01:22:28).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.6.511. KM Curves of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC (Nervous System Disorders)
<Safety Population>

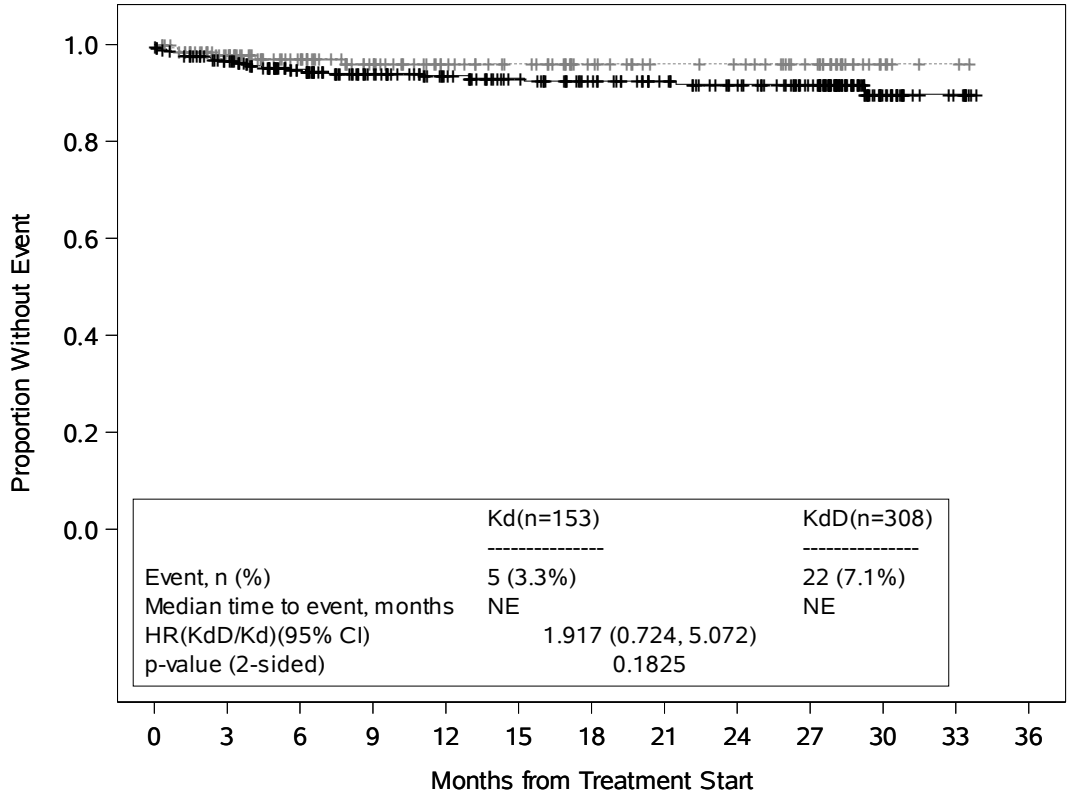


Number of Subjects at Risk:

Kd	153	132	106	88	68	59	47	39	37	27	6	2	0
KdD	308	286	250	210	188	172	154	138	126	105	33	9	0

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-sub.sas.
Output: f14-06-006-511-ae-km-soc-nervo-grd345-ge5pct.rtf (Date Generated: 16SEP20:01:22:29).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.6.512. KM Curves of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC (Psychiatric Disorders)
<Safety Population>

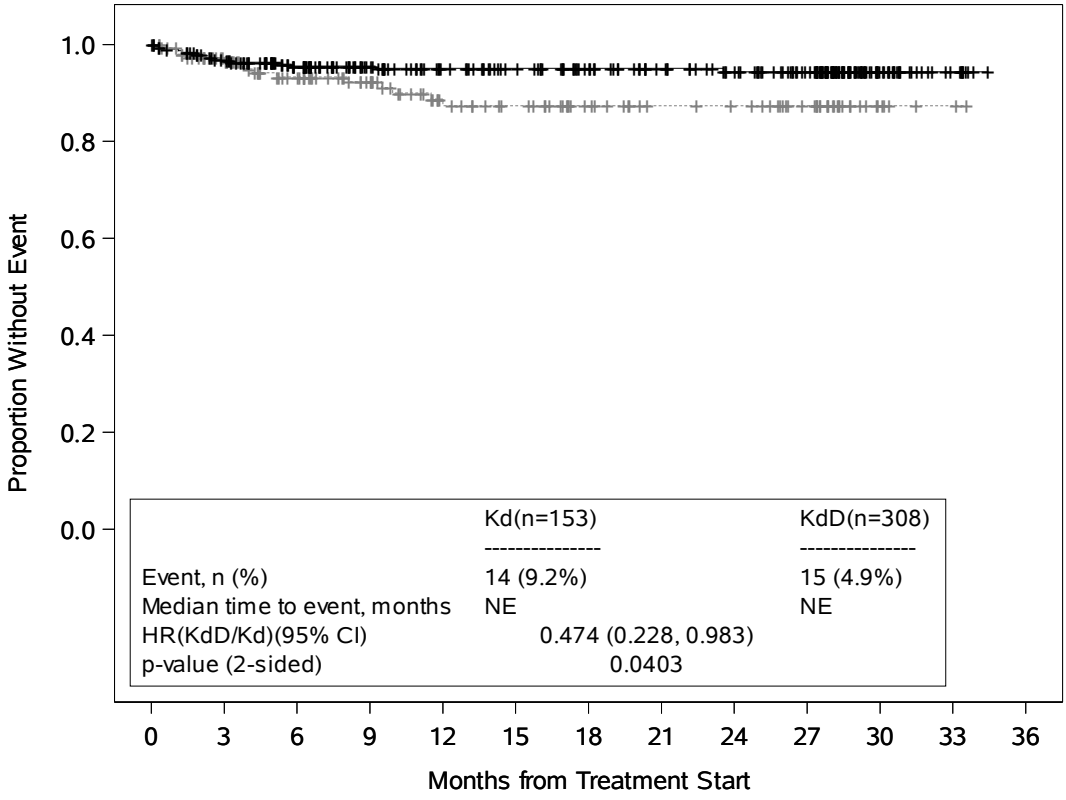


Number of Subjects at Risk:

Kd	153	129	104	83	66	58	45	37	35	26	6	2	0
KdD	308	280	241	204	183	166	150	136	123	103	30	9	0

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-sub.sas.
Output: f14-06-006-512-ae-km-soc-psych-grd345-ge5pct.rtf (Date Generated: 16SEP20:01:22:31).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.6.513. KM Curves of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC (Renal and Urinary Disorders)
<Safety Population>

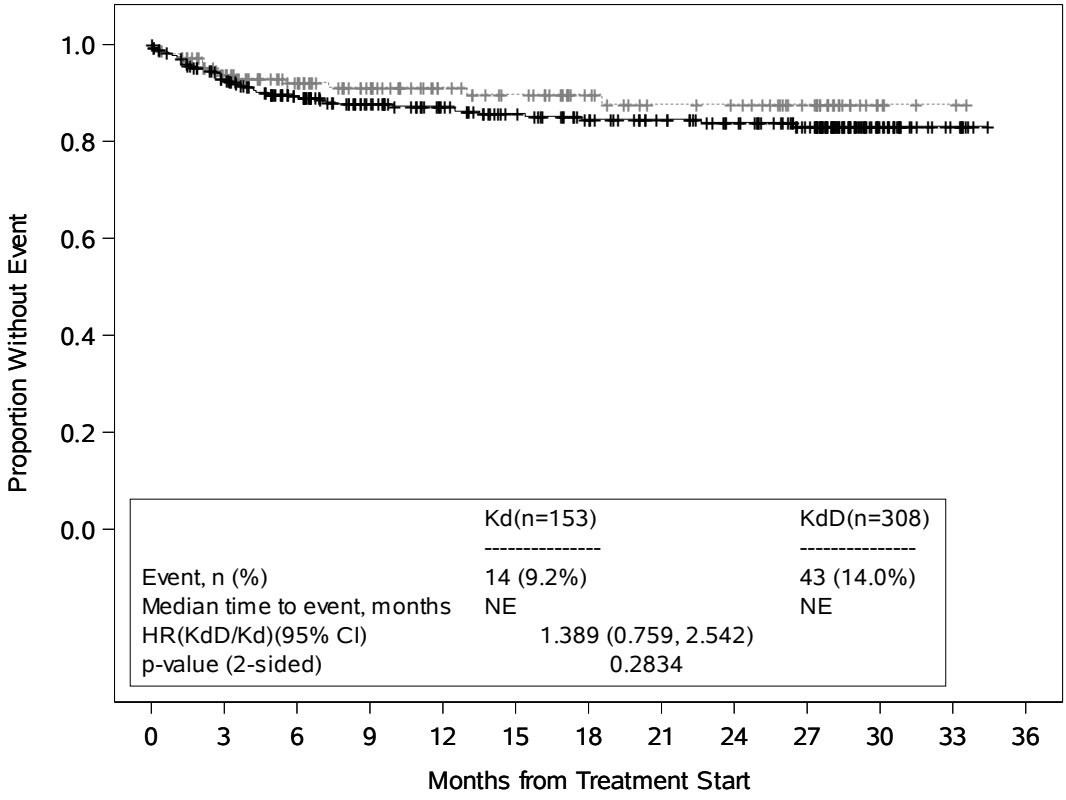


Number of Subjects at Risk:

Kd	153	130	106	87	66	58	46	38	36	27	6	2	0
KdD	308	282	246	208	186	172	156	141	129	109	33	10	0

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-sub.sas.
Output: f14-06-006-513-ae-km-soc-renal-grd345-ge5pct.rtf (Date Generated: 16SEP20:01:22:33).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.6.514. KM Curves of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC (Respiratory, Thoracic and Mediastinal Disorders) <Safety Population>

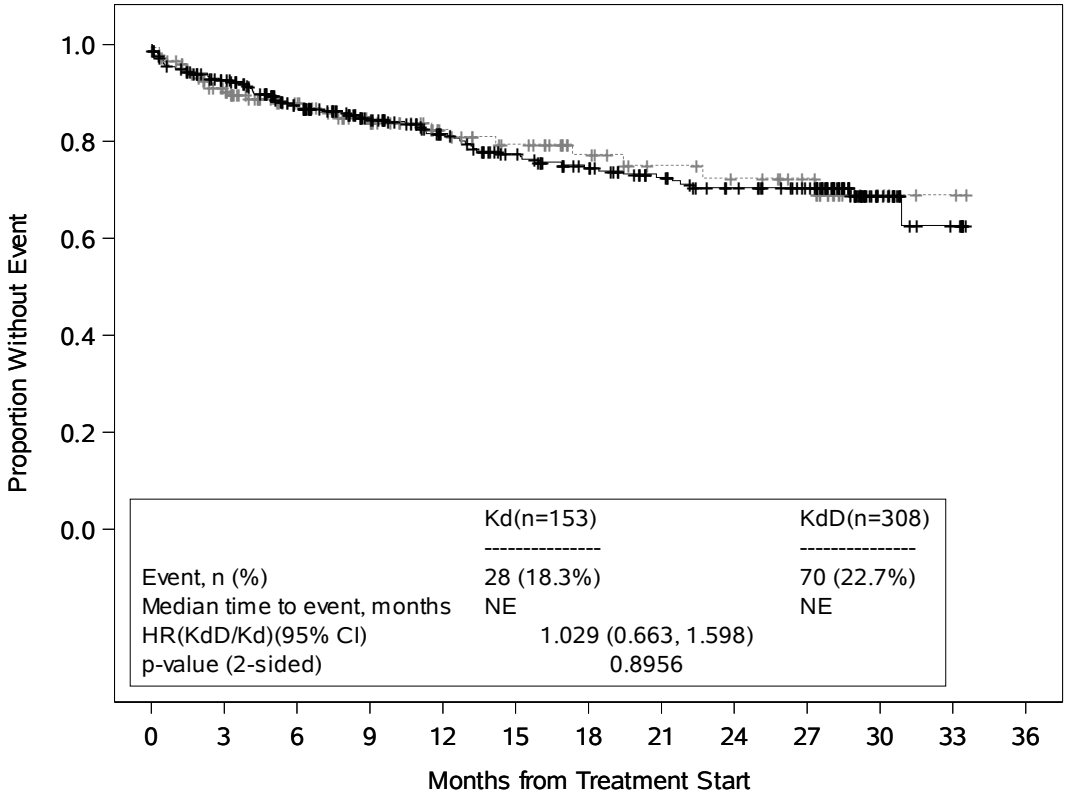


Number of Subjects at Risk:

Kd	153	127	104	84	66	58	45	37	35	25	5	2	0
KdD	308	268	232	195	174	157	143	131	119	100	32	9	0

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-sub.sas.
Output: f14-06-006-514-ae-km-soc-respi-grd345-ge5pct.rtf (Date Generated: 16SEP20:01:22:34).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.6.515. KM Curves of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC (Vascular Disorders)
<Safety Population>

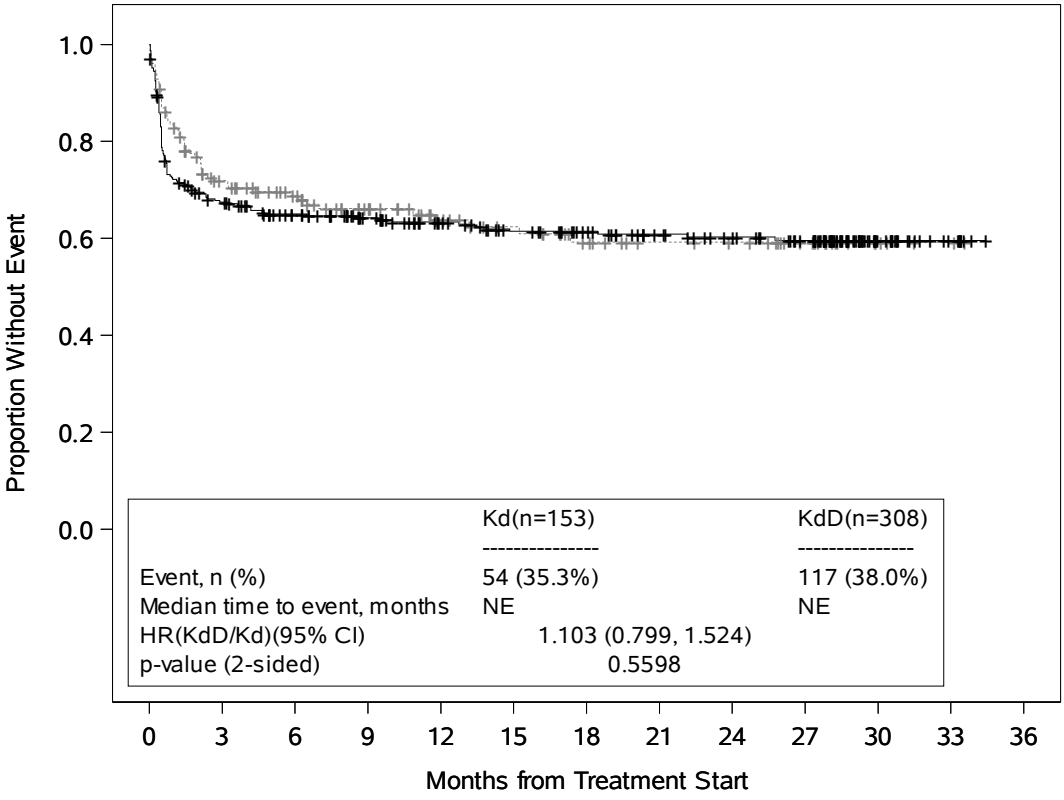


Number of Subjects at Risk:

Kd	153	122	96	75	56	48	37	30	27	22	5	2	0
KdD	308	267	224	186	158	138	122	106	94	83	23	7	0

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-sub.sas.
Output: f14-06-006-515-ae-km-soc-vascu-grd345-ge5pct.rtf (Date Generated: 16SEP20:01:22:36).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.6.501. KM Curves of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC (Blood and Lymphatic System Disorders)
<Safety Population>

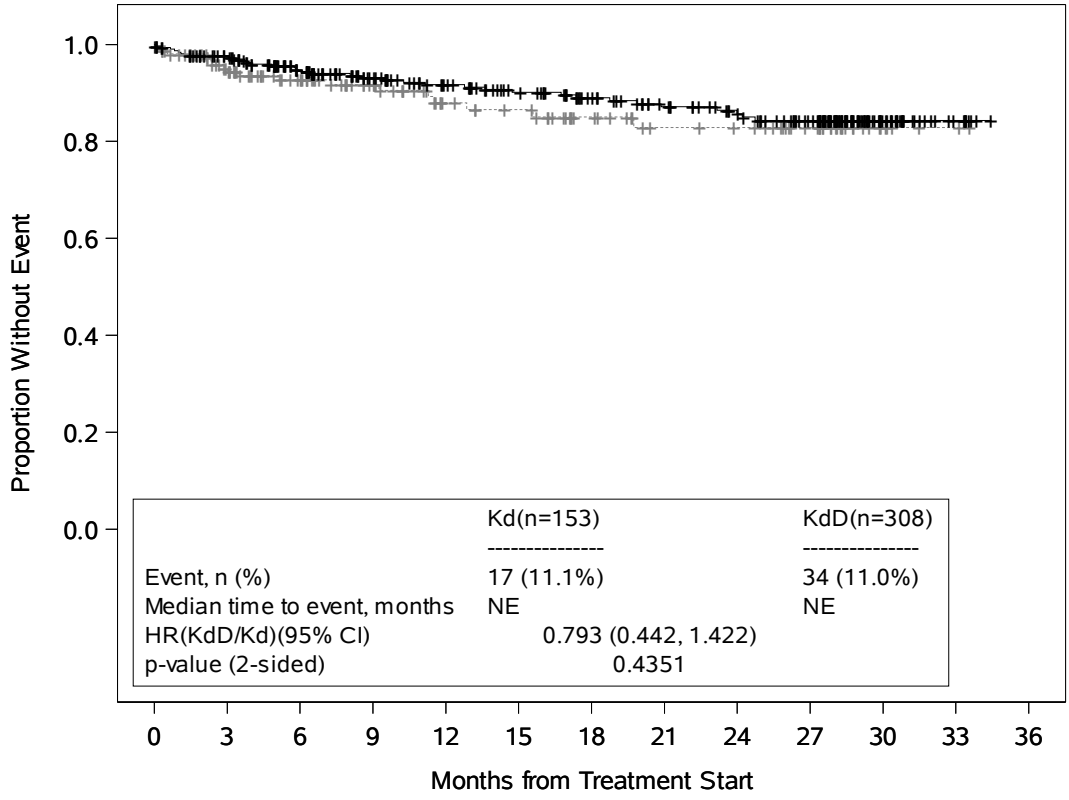


Number of Subjects at Risk:

Kd	153	98	82	65	49	42	33	27	25	18	5	2	0
KdD	308	198	174	154	136	122	112	99	91	80	27	9	0

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-sub.sas.
Output: f14-06-006-501-ae-km-soc-blood-grd345-ge5pct.rtf (Date Generated: 16SEP20:01:22:12).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.6.502. KM Curves of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC (Cardiac Disorders)
<Safety Population>

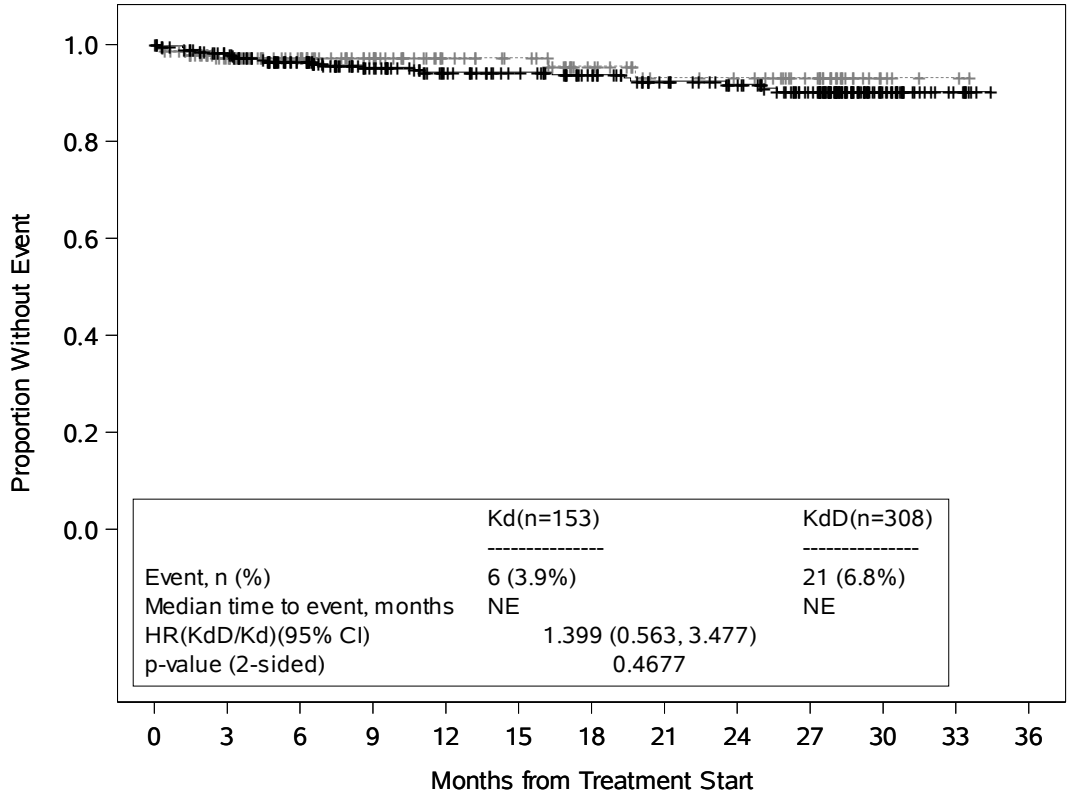


Number of Subjects at Risk:

Kd	153	126	103	83	63	58	46	37	35	26	6	2	0
KdD	308	284	243	205	184	167	149	134	121	103	33	9	0

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-sub.sas.
Output: f14-06-006-502-ae-km-soc-cardi-grd345-ge5pct.rtf (Date Generated: 16SEP20:01:22:14).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.6.503. KM Curves of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC (Gastrointestinal Disorders)
<Safety Population>

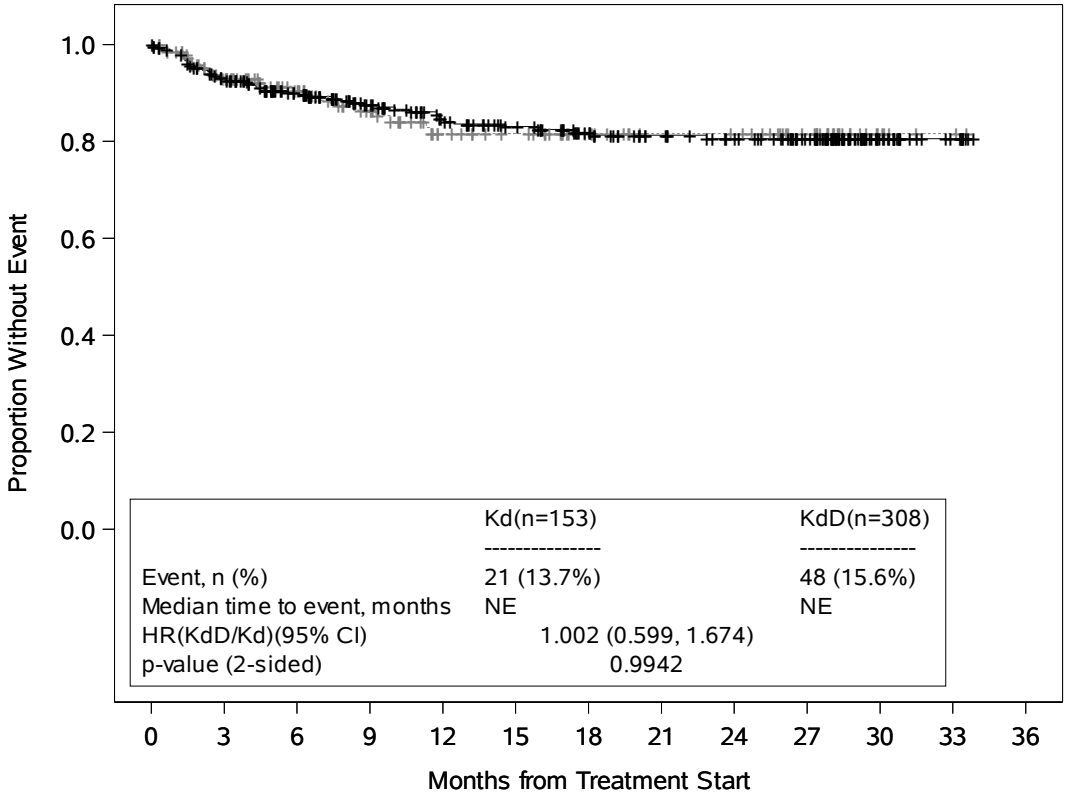


Number of Subjects at Risk:

Kd	153	128	106	86	66	60	46	37	35	26	5	2	0
KdD	308	285	246	207	184	172	156	139	128	106	34	9	0

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-sub.sas.
Output: f14-06-006-503-ae-km-soc-gastr-grd345-ge5pct.rtf (Date Generated: 16SEP20:01:22:16).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.6.504. KM Curves of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC (General Disorders and Administration Site Conditions) <Safety Population>

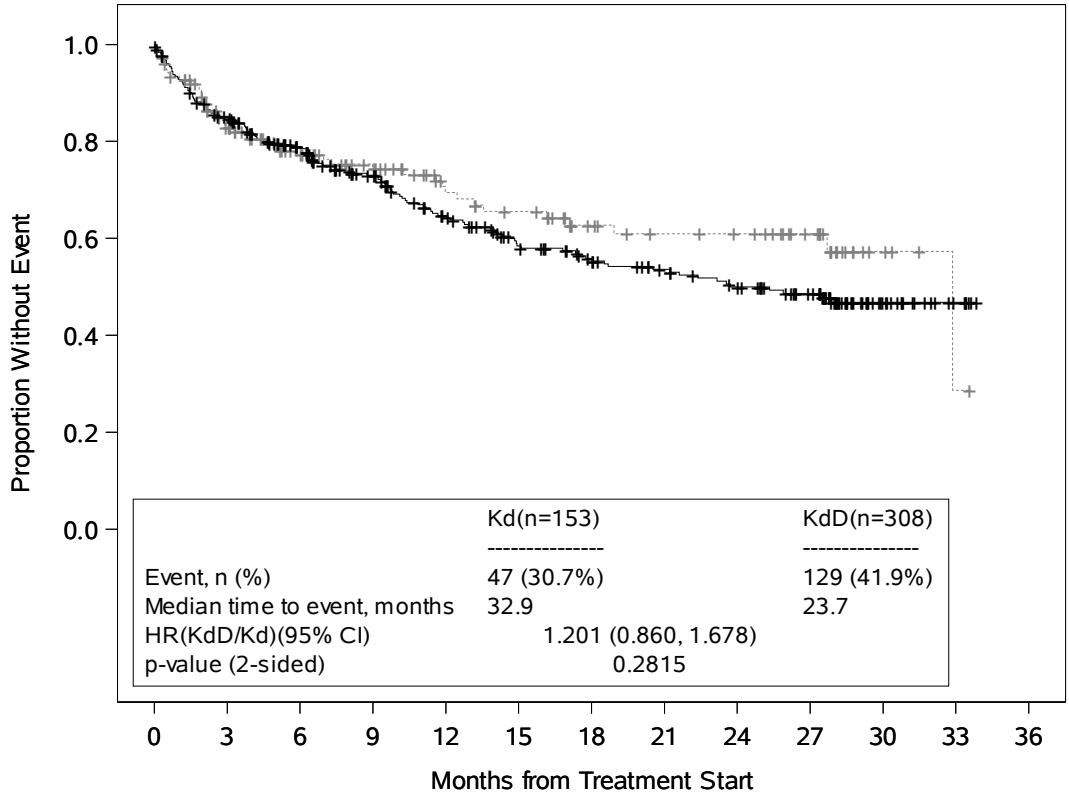


Number of Subjects at Risk:

Kd	153	125	100	80	61	55	44	37	36	26	6	2	0
KdD	308	270	231	191	167	151	133	119	110	92	28	9	0

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-sub.sas.
Output: f14-06-006-504-ae-km-soc-gener-grd345-ge5pct.rtf (Date Generated: 16SEP20:01:22:17).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.6.505. KM Curves of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC (Infections and Infestations)
<Safety Population>

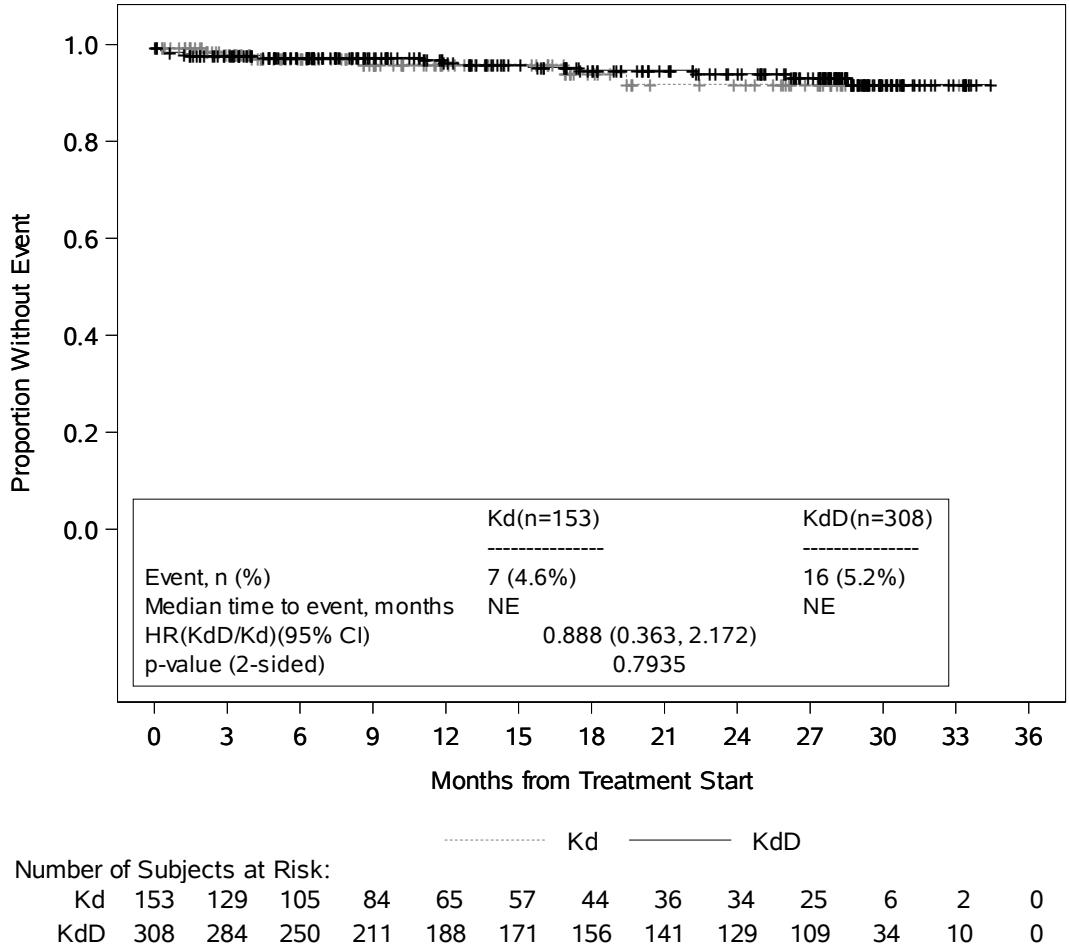


Number of Subjects at Risk:

Kd	153	113	90	72	55	49	37	32	30	22	5	1	0
KdD	308	253	211	173	142	117	103	91	81	66	22	7	0

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-sub.sas.
Output: f14-06-006-505-ae-km-soc-infec-grd345-ge5pct.rtf (Date Generated: 16SEP20:01:22:19).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.6.506. KM Curves of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC (Injury, Poisoning and Procedural Complications) <Safety Population>

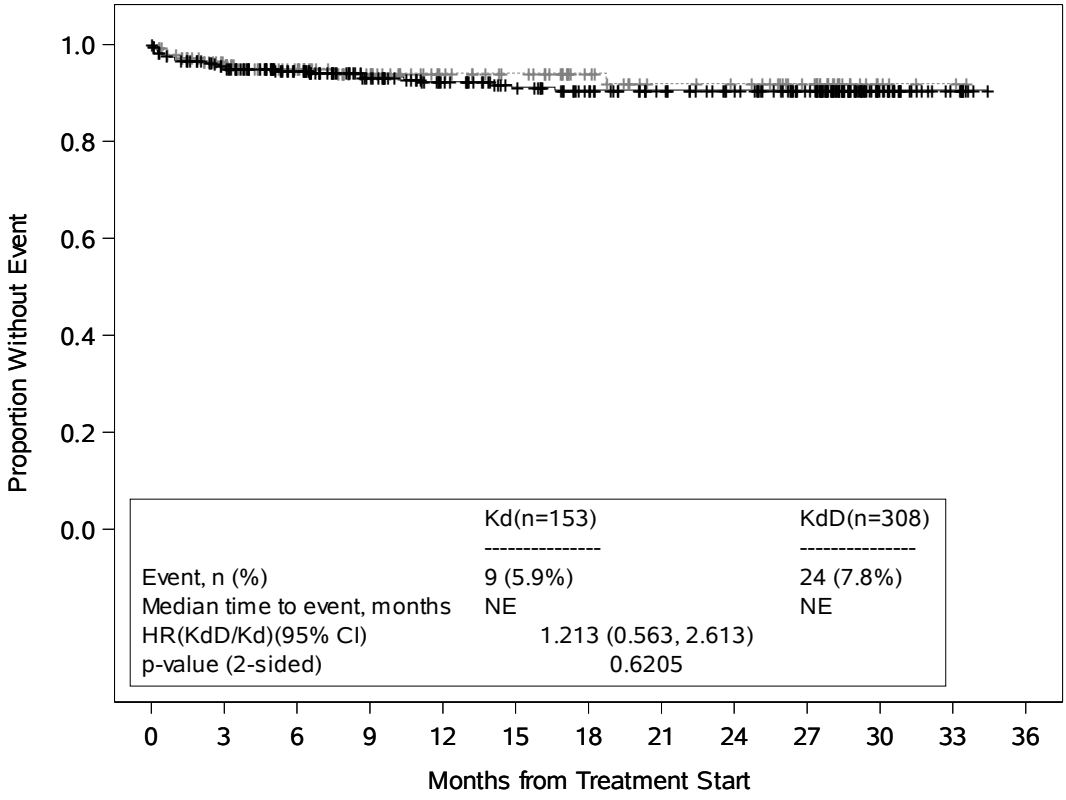


Number of Subjects at Risk:

Kd	153	129	105	84	65	57	44	36	34	25	6	2	0
KdD	308	284	250	211	188	171	156	141	129	109	34	10	0

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-sub.sas.
Output: f14-06-006-506-ae-km-soc-injur-grd345-ge5pct.rtf (Date Generated: 16SEP20:01:22:21).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.6.507. KM Curves of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC (Investigations)
<Safety Population>

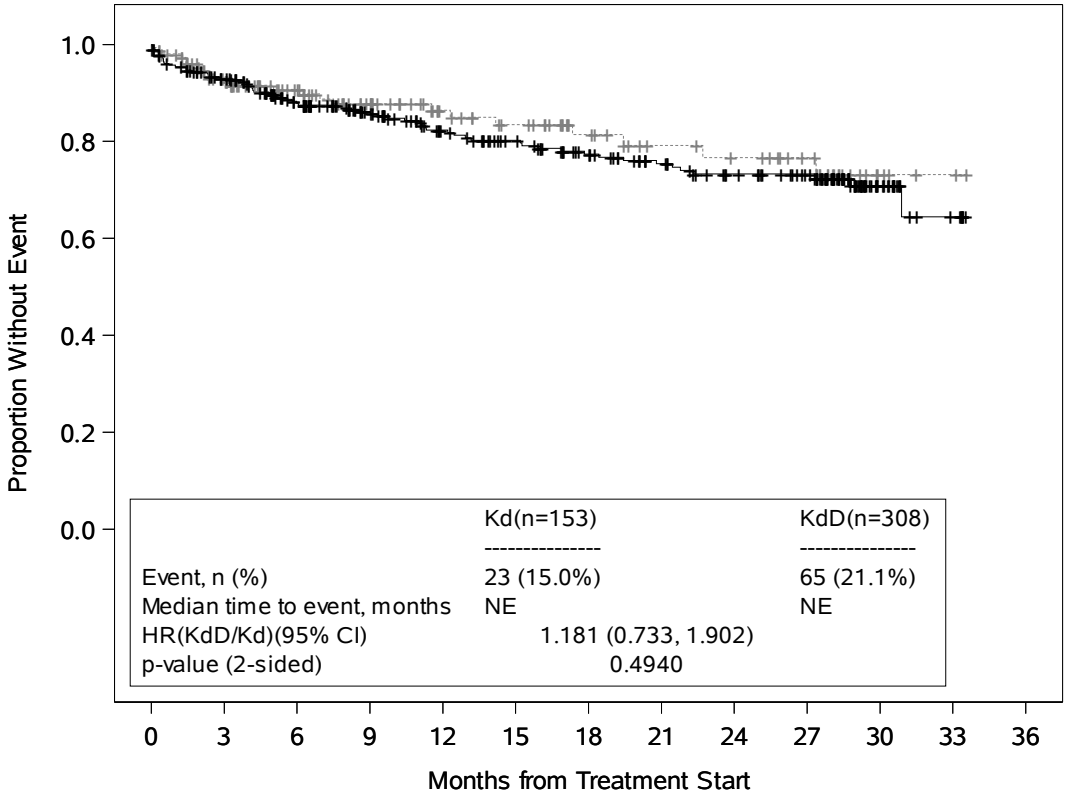


Number of Subjects at Risk:

Kd	153	128	106	85	66	59	46	37	35	26	5	2	0
KdD	308	277	239	200	177	160	145	131	120	100	34	10	0

Includes SOC where at least 5% subjects with at least one Grade ≥3 adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-sub.sas.
Output: f14-06-006-507-ae-km-soc-inves-grd345-ge5pct.rtf (Date Generated: 16SEP20:01:22:23).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.7.507. KM Curves of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC (Vascular Disorders) and PT (Hypertension) <Safety Population>

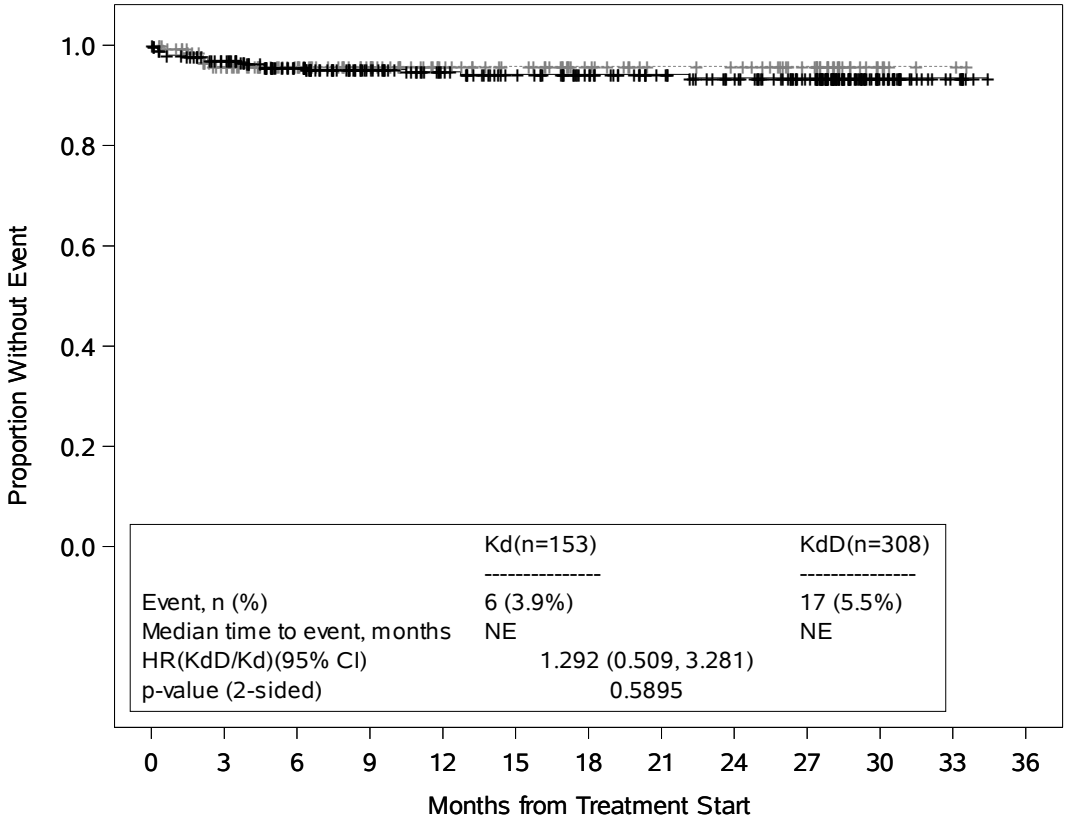


Number of Subjects at Risk:

Kd	153	124	99	78	60	52	40	32	29	23	5	2	0
KdD	308	268	226	189	160	144	126	110	97	86	24	7	0

Includes PT where at least 5% subjects with at least one Grade ≥ 3 adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-007-507-ae-km-soc-vascu-pt-hyper-grd345-ge5pct.rtf (Date Generated: 16SEP20:20:38:43).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.8.501. KM Curves of Most Frequent Serious Adverse Events by MedDRA SOC (Blood and Lymphatic System Disorders)
<Safety Population>

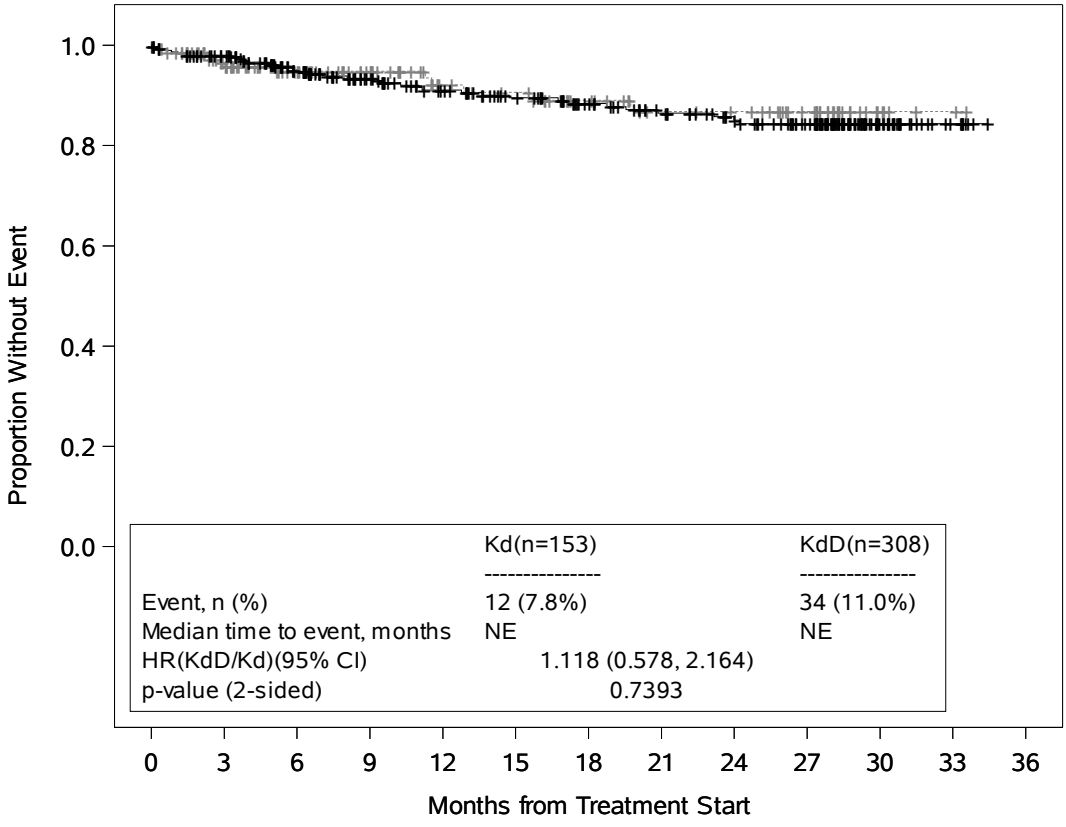


Number of Subjects at Risk:

Kd	153	128	108	88	68	60	47	39	37	27	6	2	0
KdD	308	281	244	207	186	171	156	141	129	107	34	9	0

Includes SOC where at least 5% subjects with at least one serious adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-sub.sas.
Output: f14-06-008-501-sae-km-soc-blood-ge5pct.rtf (Date Generated: 16SEP20:01:21:58).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.8.502. KM Curves of Most Frequent Serious Adverse Events by MedDRA SOC (Cardiac Disorders)
<Safety Population>

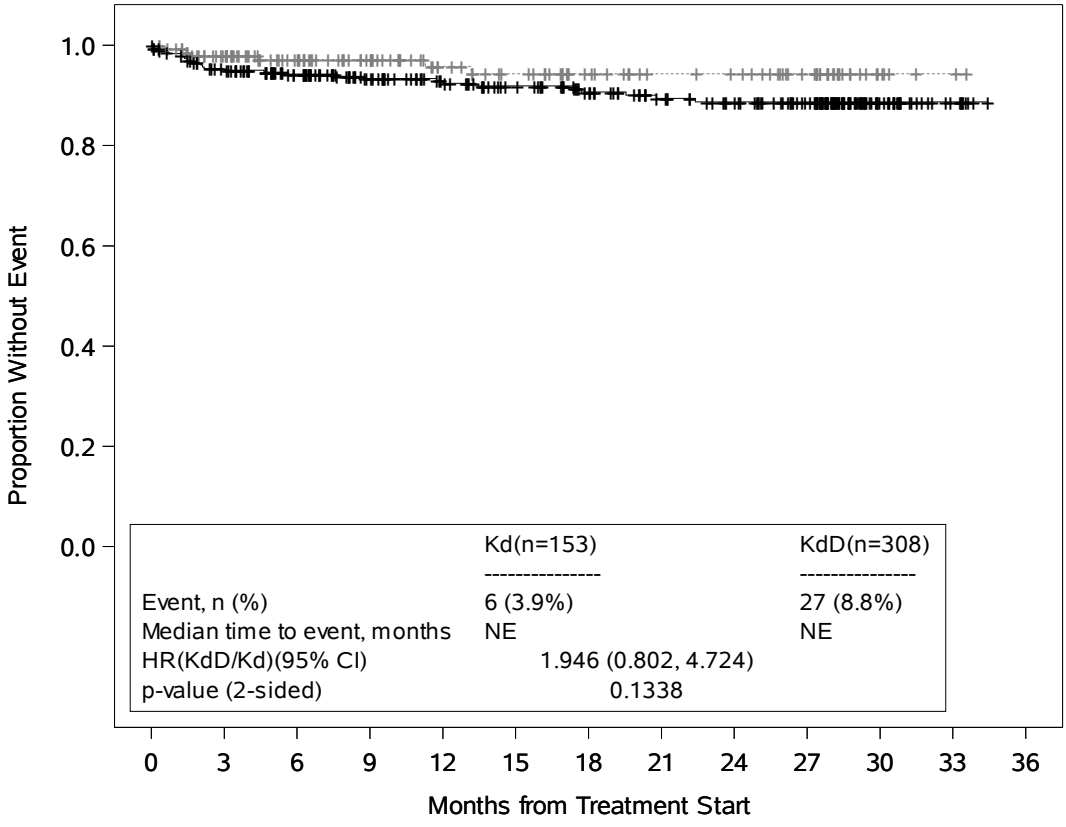


Number of Subjects at Risk:

Kd	153	127	103	84	63	58	46	37	35	26	6	2	0
KdD	308	285	244	205	183	166	148	133	120	102	34	9	0

Includes SOC where at least 5% subjects with at least one serious adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-sub.sas.
Output: f14-06-008-502-sae-km-soc-cardi-ge5pct.rtf (Date Generated: 16SEP20:01:22:01).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.8.503. KM Curves of Most Frequent Serious Adverse Events by MedDRA SOC (General Disorders and Administration Site Conditions) <Safety Population>

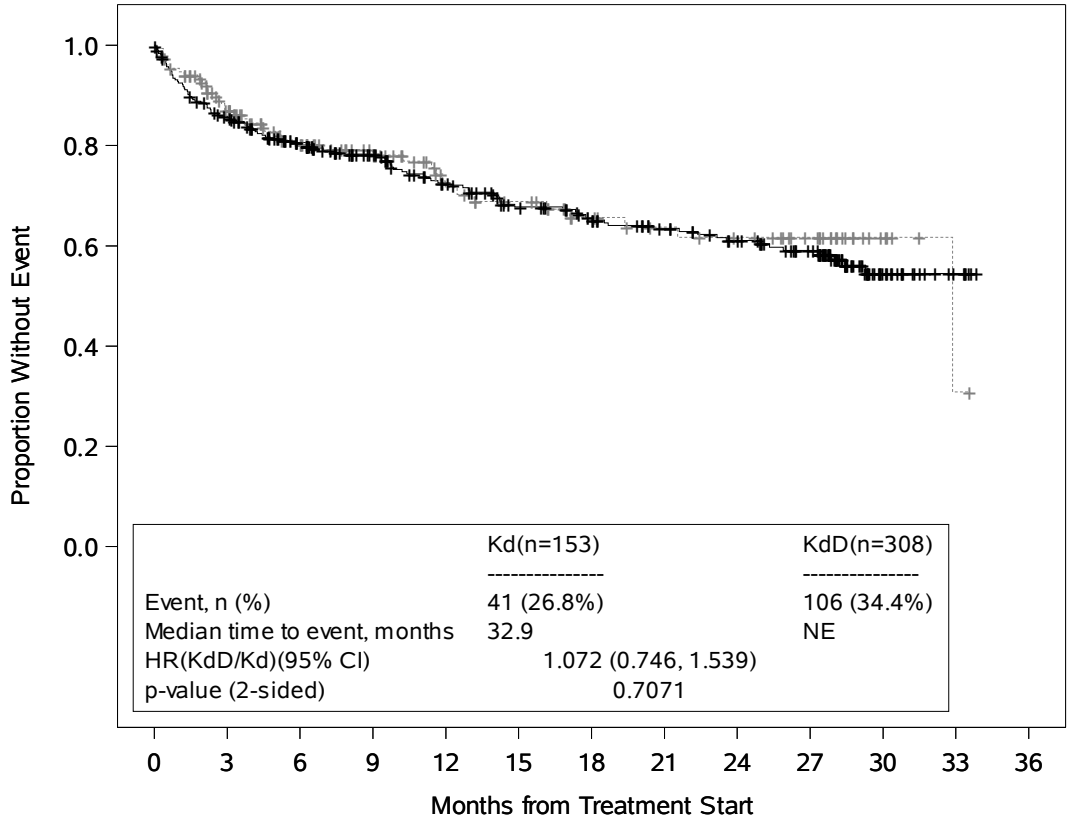


Number of Subjects at Risk:

Kd	153	132	107	87	67	59	47	39	37	27	6	2	0
KdD	308	277	245	207	186	170	152	135	124	104	32	9	0

Includes SOC where at least 5% subjects with at least one serious adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-sub.sas.
Output: f14-06-008-503-sae-km-soc-gener-ge5pct.rtf (Date Generated: 16SEP20:01:22:02).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.8.504. KM Curves of Most Frequent Serious Adverse Events by MedDRA SOC (Infections and Infestations)
<Safety Population>

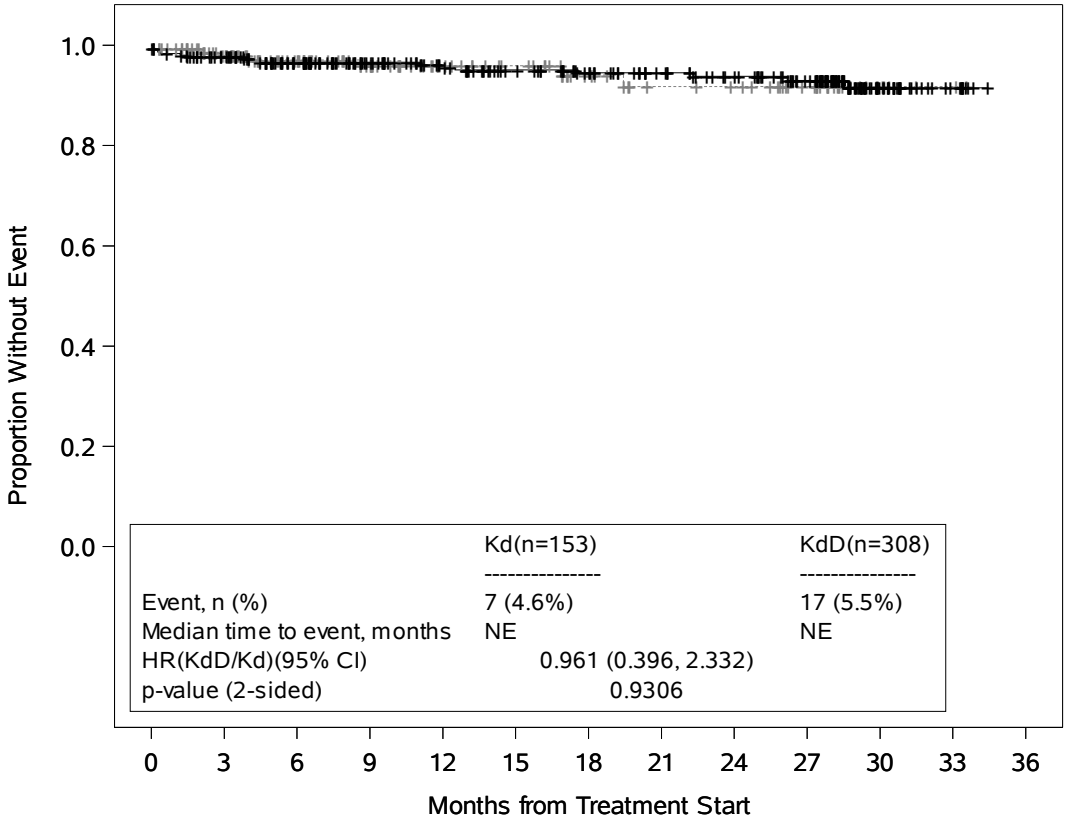


Number of Subjects at Risk:

Kd	153	117	90	71	53	47	36	31	28	21	6	1	0
KdD	308	255	217	185	158	136	123	109	98	82	22	6	0

Includes SOC where at least 5% subjects with at least one serious adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-sub.sas.
Output: f14-06-008-504-sae-km-soc-infec-ge5pct.rtf (Date Generated: 16SEP20:01:22:05).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.8.505. KM Curves of Most Frequent Serious Adverse Events by MedDRA SOC (Injury, Poisoning and Procedural Complications) <Safety Population>

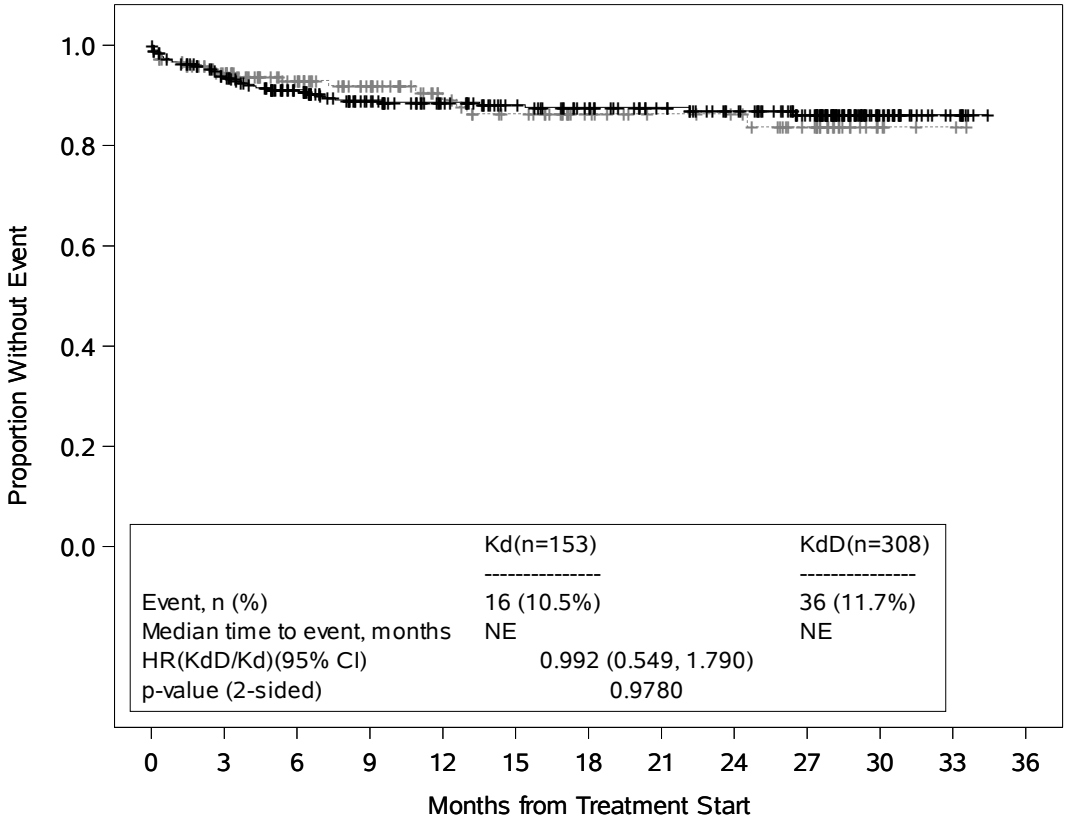


Number of Subjects at Risk:

Kd	153	129	105	84	65	57	44	36	34	25	6	2	0
KdD	308	284	248	209	187	170	155	140	128	108	34	10	0

Includes SOC where at least 5% subjects with at least one serious adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-sub.sas.
Output: f14-06-008-505-sae-km-soc-injur-ge5pct.rtf (Date Generated: 16SEP20:01:22:07).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.8.507. KM Curves of Most Frequent Serious Adverse Events by MedDRA SOC (Respiratory, Thoracic and Mediastinal Disorders) <Safety Population>

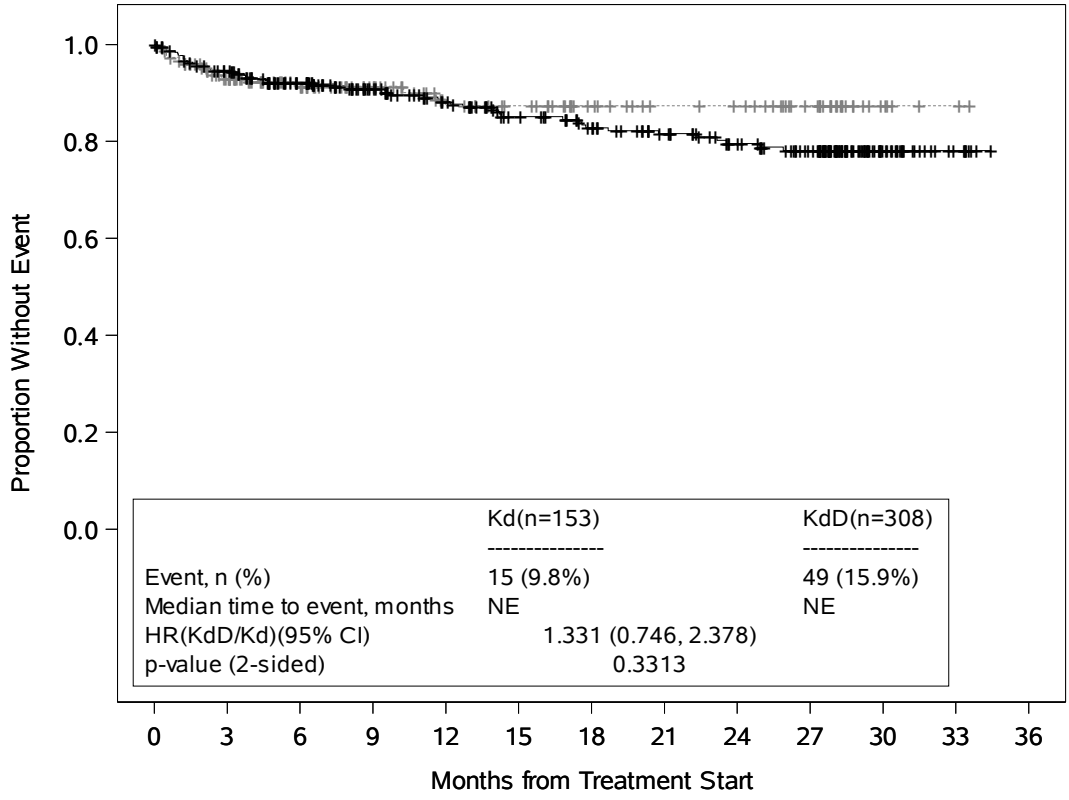


Number of Subjects at Risk:

Kd	153	129	103	83	63	55	42	36	34	25	5	2	0
KdD	308	271	236	200	179	162	149	136	124	103	33	9	0

Includes SOC where at least 5% subjects with at least one serious adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-sub.sas.
Output: f14-06-008-507-sae-km-soc-respi-ge5pct.rtf (Date Generated: 16SEP20:01:22:10).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.9.501. KM Curves of Most Frequent Serious Adverse Events by MedDRA SOC (Infections and Infestations) and PT (Pneumonia) <Safety Population>

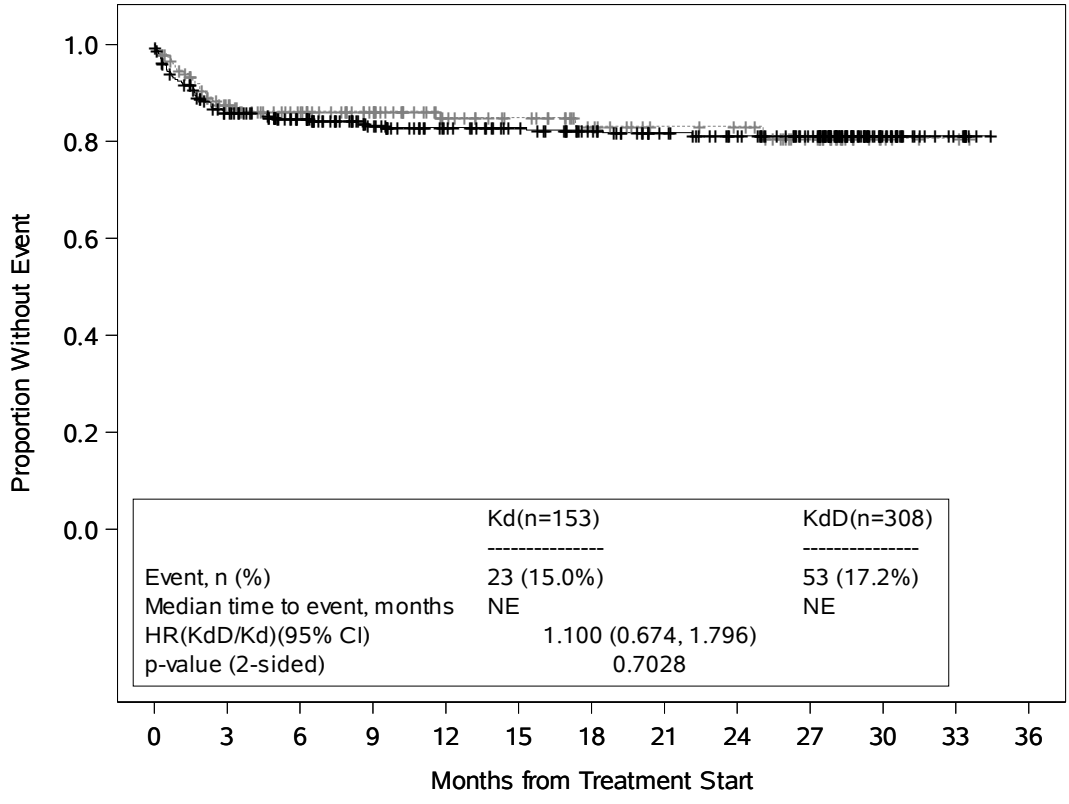


Number of Subjects at Risk:

Kd	153	123	99	80	62	56	44	37	35	25	6	2	0
KdD	308	278	242	204	180	158	143	128	113	96	29	8	0

Includes PT where at least 5% subjects with at least one serious adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-009-501-sae-km-soc-infec-pt-pneum-ge5pct.rtf (Date Generated: 16SEP20: 20:38:46).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.7.501. KM Curves of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC (Blood and Lymphatic System Disorders) and PT (Anaemia) <Safety Population>

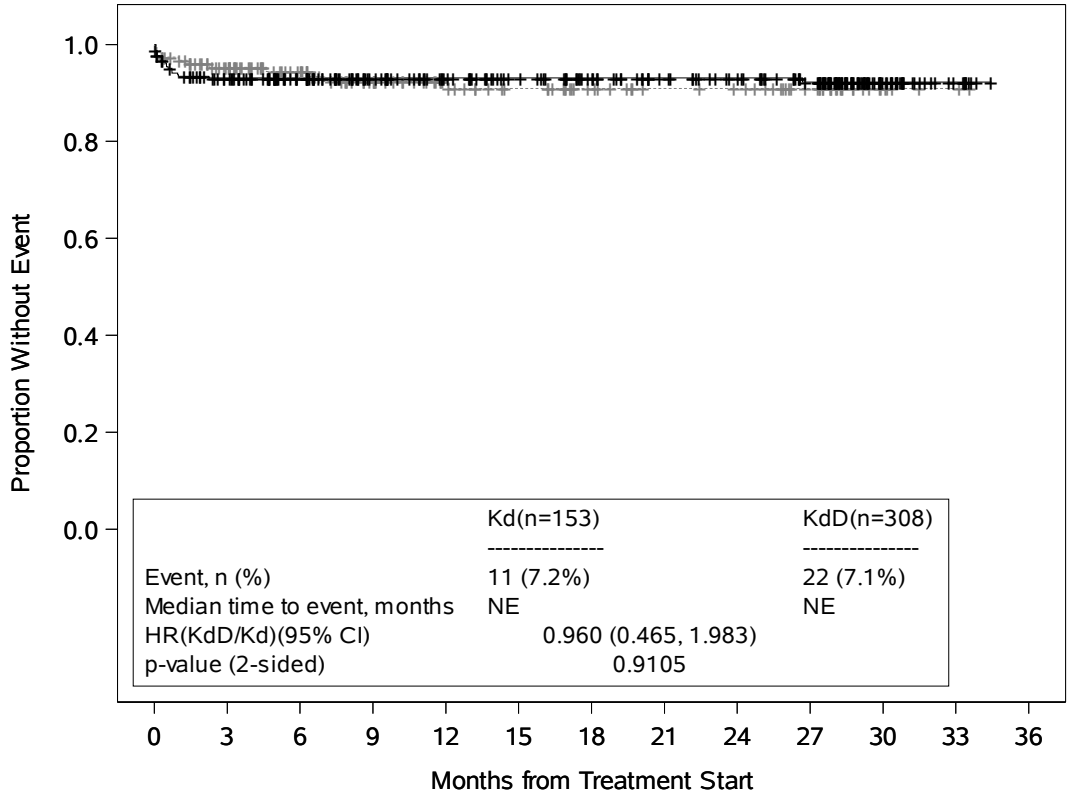


Number of Subjects at Risk:

Kd	153	119	102	85	64	56	45	38	36	25	5	2	0
KdD	308	249	220	189	169	157	143	128	117	99	31	9	0

Includes PT where at least 5% subjects with at least one Grade ≥ 3 adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-007-501-ae-km-soc-blood-pt-anaem-grd345-ge5pct.rtf (Date Generated: 16SEP20:20:38:34).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.7.502. KM Curves of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC (Blood and Lymphatic System Disorders) and PT (Lymphopenia) <Safety Population>

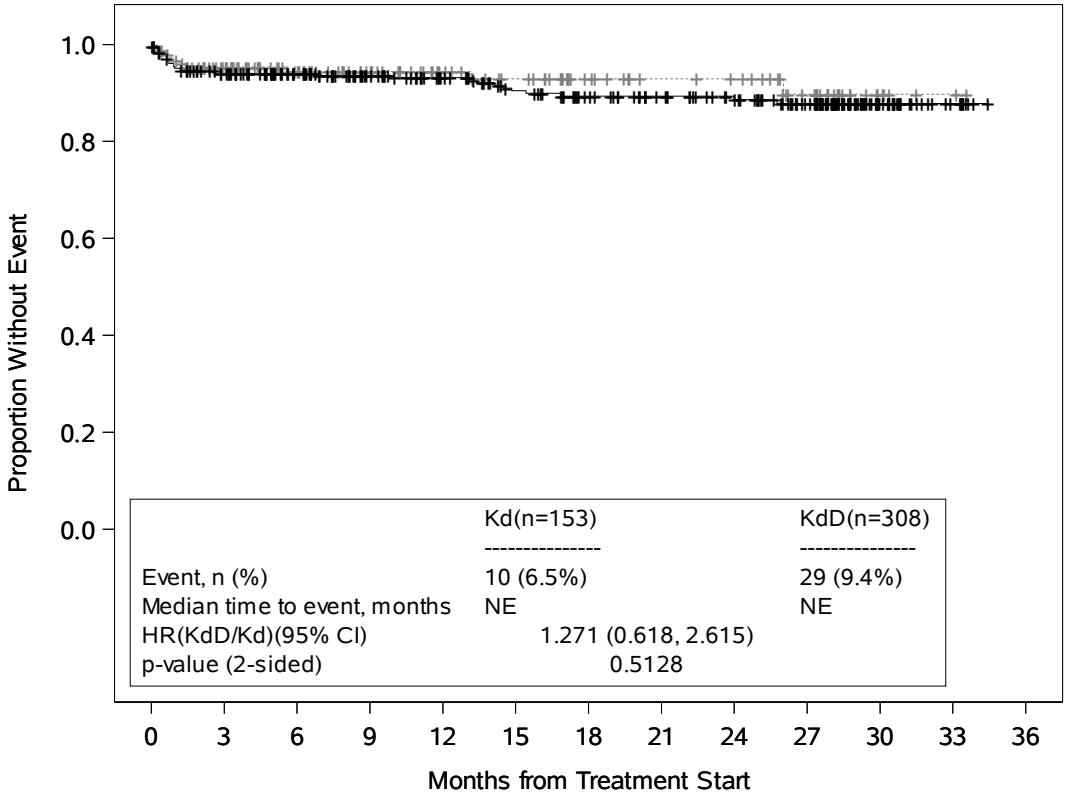


Number of Subjects at Risk:

Kd	153	127	102	80	63	54	44	37	35	25	6	2	0
KdD	308	268	235	201	181	165	150	135	125	108	36	10	0

Includes PT where at least 5% subjects with at least one Grade ≥ 3 adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-007-502-ae-km-soc-blood-pt-lymph-grd345-ge5pct.rtf (Date Generated: 16SEP20:20:38:36).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.7.503. KM Curves of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC (Blood and Lymphatic System Disorders) and PT (Neutropenia) <Safety Population>

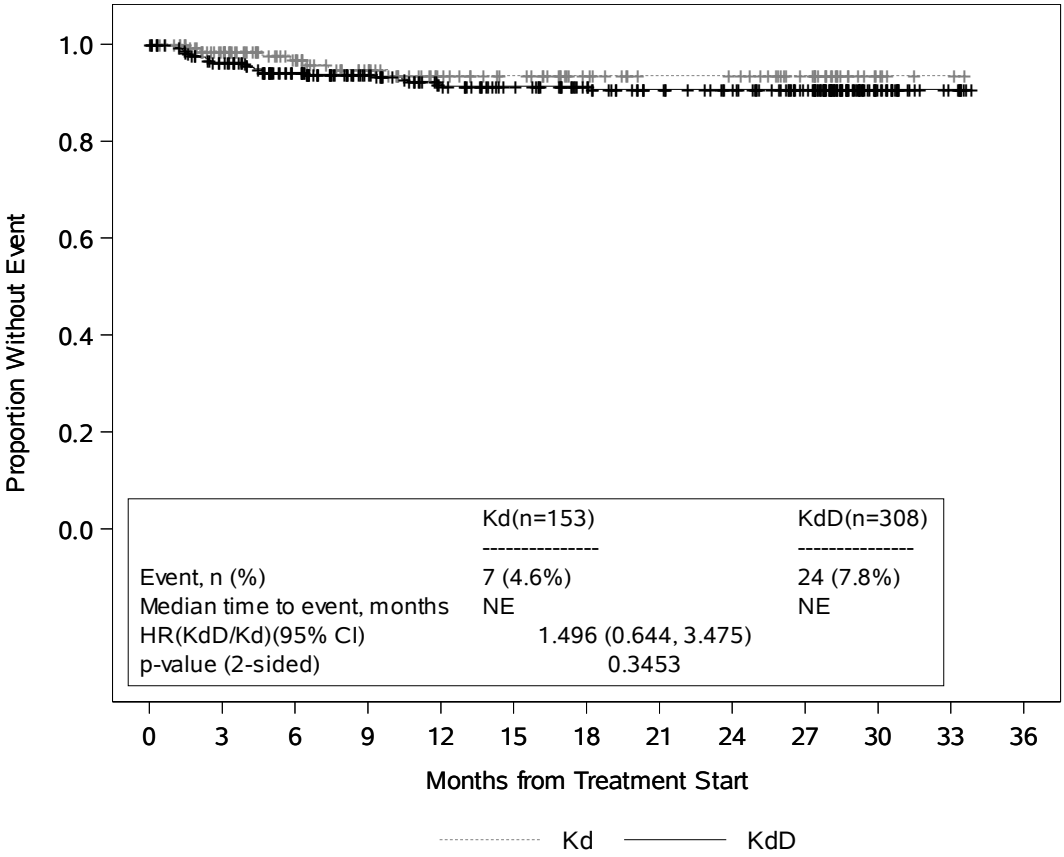


Number of Subjects at Risk:

Kd	153	127	103	83	66	57	44	37	35	24	6	2	0
KdD	308	272	239	205	184	164	149	136	124	102	35	10	0

Includes PT where at least 5% subjects with at least one Grade ≥ 3 adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-007-503-ae-km-soc-blood-pt-neutr-grd345-ge5pct.rtf (Date Generated: 16SEP20:20:38:37).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.7.505. KM Curves of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC (General Disorders and Administration Site Conditions) and PT (Fatigue)
<Safety Population>

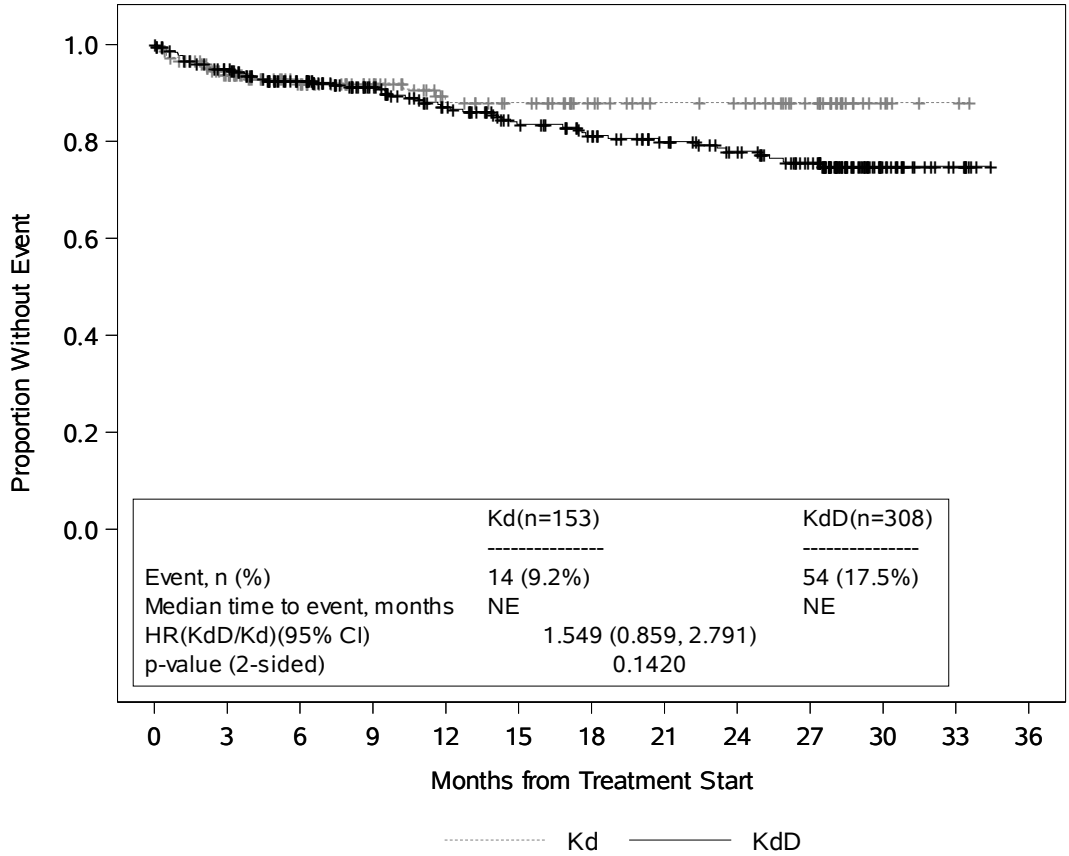


Number of Subjects at Risk:

Kd	153	130	104	84	64	56	44	37	36	26	6	2	0
KdD	308	279	240	203	180	164	148	133	124	103	31	9	0

Includes PT where at least 5% subjects with at least one Grade ≥ 3 adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-007-505-ae-km-soc-gener-pt-fatig-grd345-ge5pct.rtf (Date Generated: 16SEP20:20:38:40).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.7.506. KM Curves of Most Frequent Grade ≥3 Adverse Events by MedDRA SOC (Infections and Infestations) and PT (Pneumonia) <Safety Population>

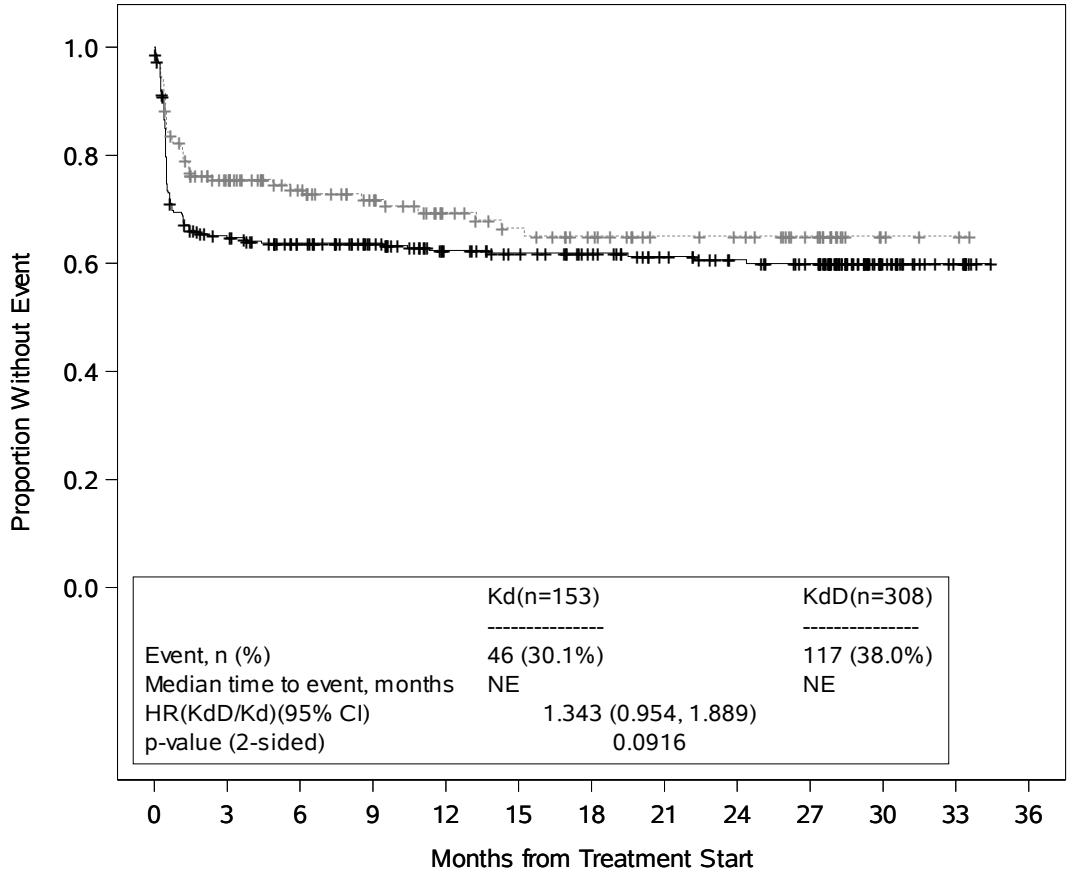


Number of Subjects at Risk:

Kd	153	124	99	80	62	56	44	37	35	25	6	2	0
KdD	308	279	243	205	178	155	140	125	112	94	27	9	0

Includes PT where at least 5% subjects with at least one Grade ≥ 3 adverse event in one treatment arm.
Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-soc-pt-ge10.sas.
Output: f14-06-007-506-ae-km-soc-infec-pt-pneum-grd345-ge5pct.rtf (Date Generated: 16SEP20:20:38:42).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.10.509. KM Curves of Adverse Events of Interest for Carfilzomib - Haematopoietic Thrombocytopenia (SMQ) - Narrow
<Safety Population>

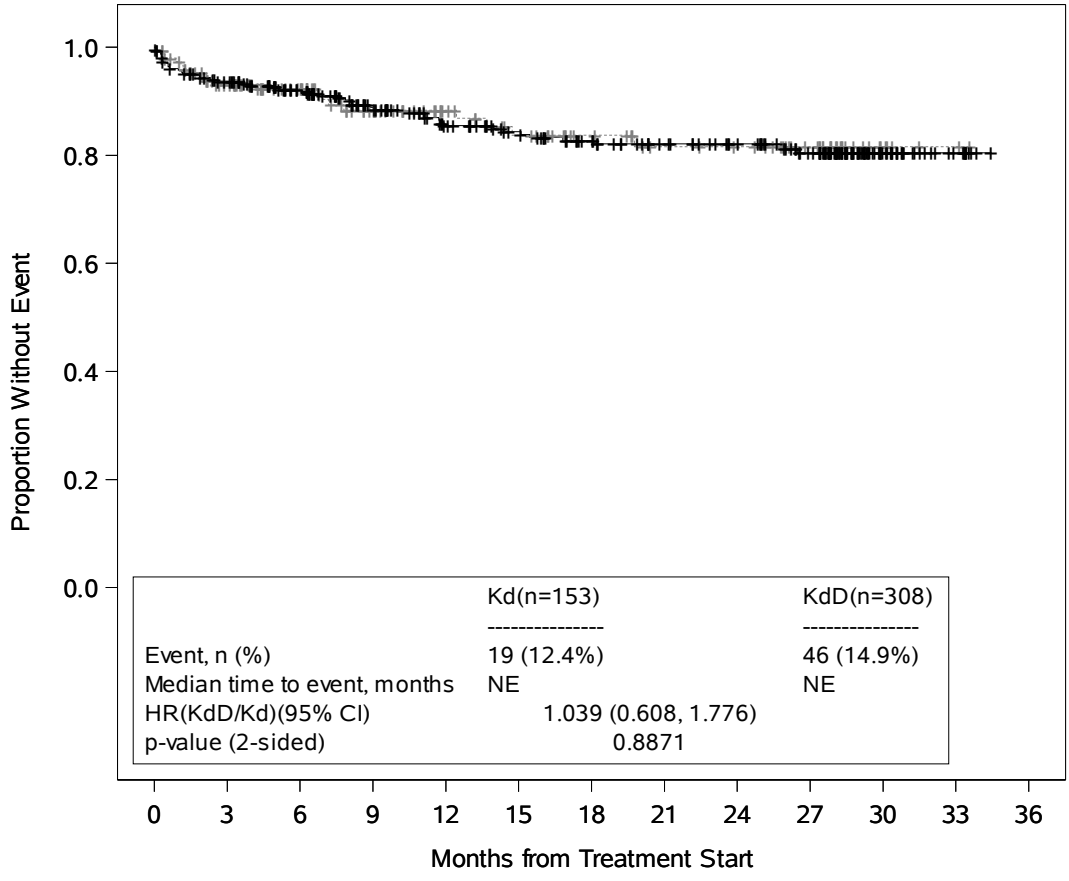


Number of Subjects at Risk:

Kd	153	101	81	66	51	44	37	29	27	19	4	2	0
KdD	308	189	170	151	129	120	110	98	89	81	28	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-010-509-ae-km-eoi-haethr-cfz.rtf (Date Generated: 16SEP20:19:38:10).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.10.510. KM Curves of Adverse Events of Interest for Carfilzomib - Haemorrhage Terms (Excl Laboratory Terms) (SMQ) - Narrow <Safety Population>

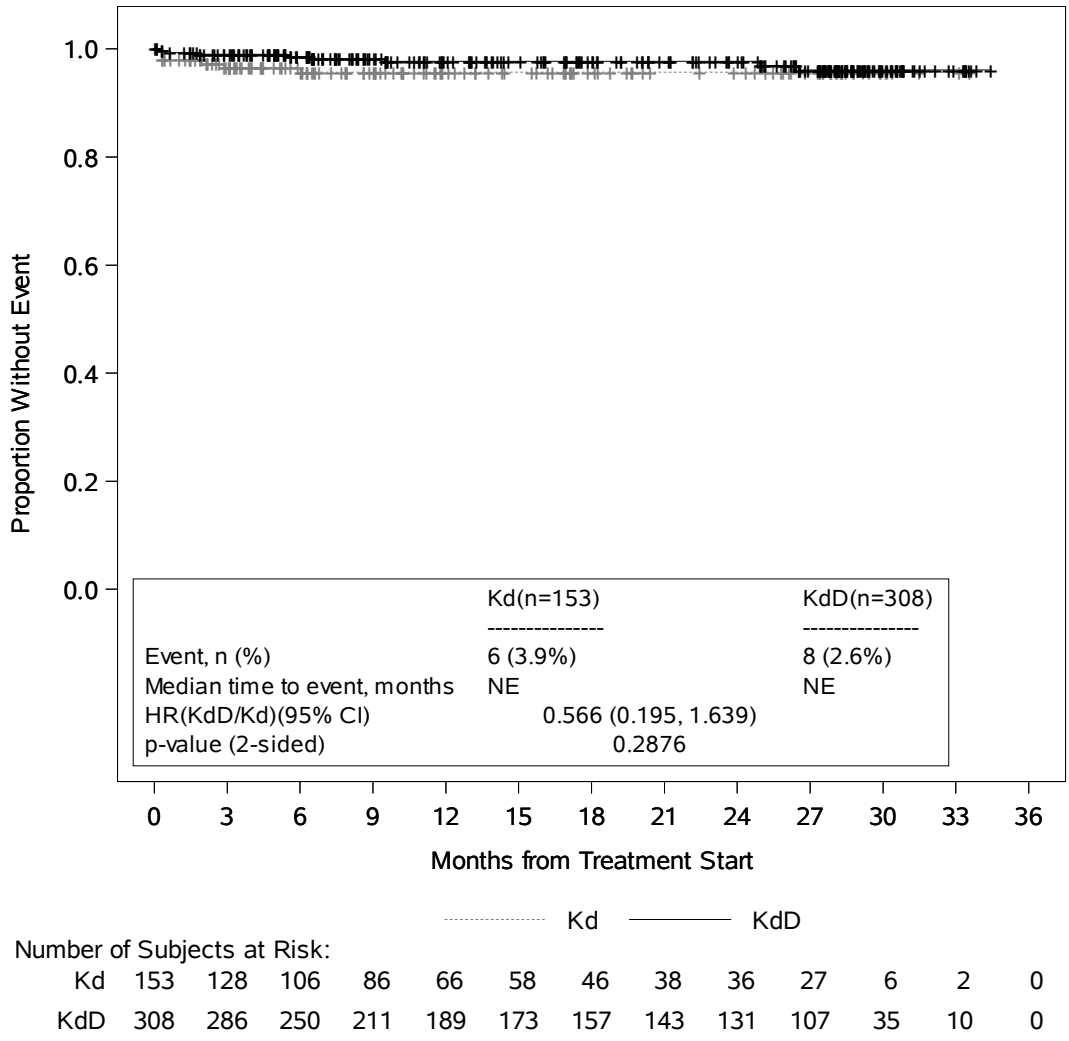


Number of Subjects at Risk:

Kd	153	124	103	80	62	53	43	36	34	25	6	2	0
KdD	308	273	239	196	168	152	137	123	113	95	32	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-010-510-ae-km-eoi-haeter-cfz.rtf (Date Generated: 16SEP20:19:38:11).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.10.511. KM Curves of Adverse Events of Interest for Carfilzomib - Hepatic Failure, Fibrosis and Cirrhosis and Other Liver Damage-related Conditions (SMQ) - Narrow
<Safety Population>

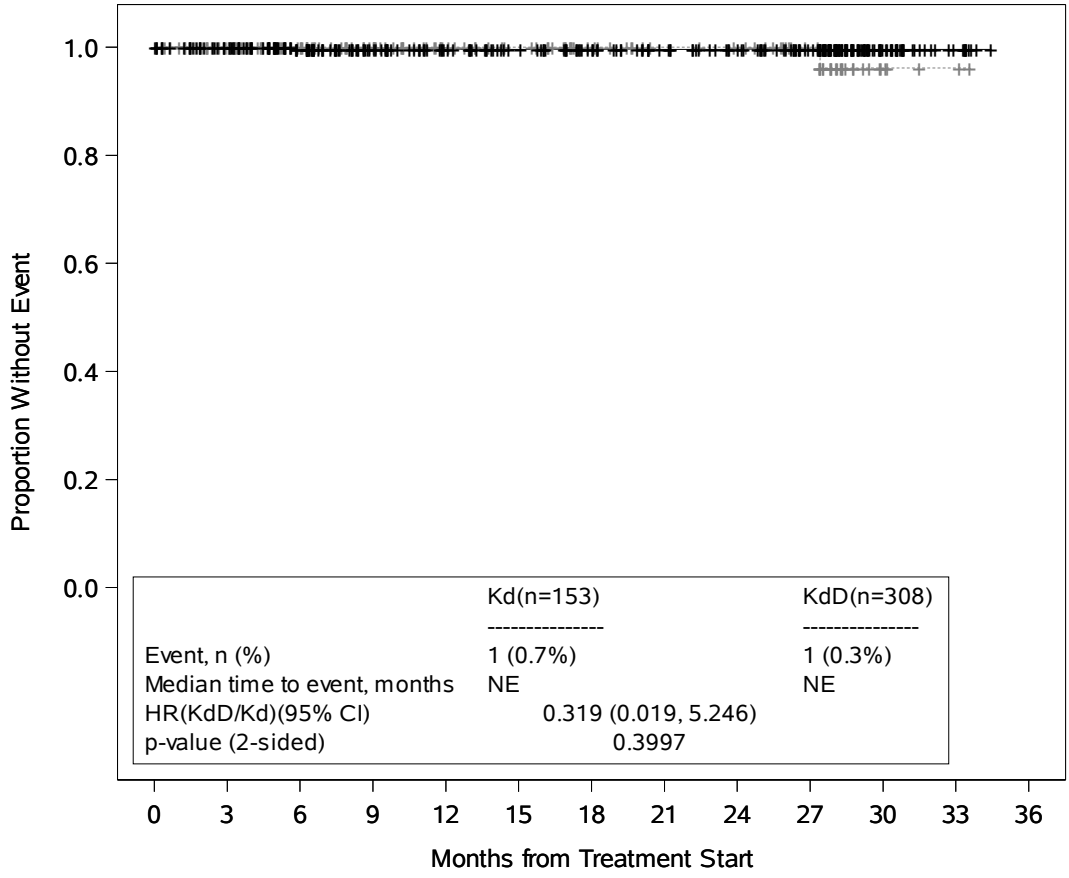


Number of Subjects at Risk:

Kd	153	128	106	86	66	58	46	38	36	27	6	2	0
KdD	308	286	250	211	189	173	157	143	131	107	35	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-010-511-ae-km-eoi-hepac-cfz.rtf (Date Generated: 16SEP20:19:38:13).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.10.512. KM Curves of Adverse Events of Interest for Carfilzomib - Hepatitis B Virus Reactivation (AMQ) - Broad
<Safety Population>

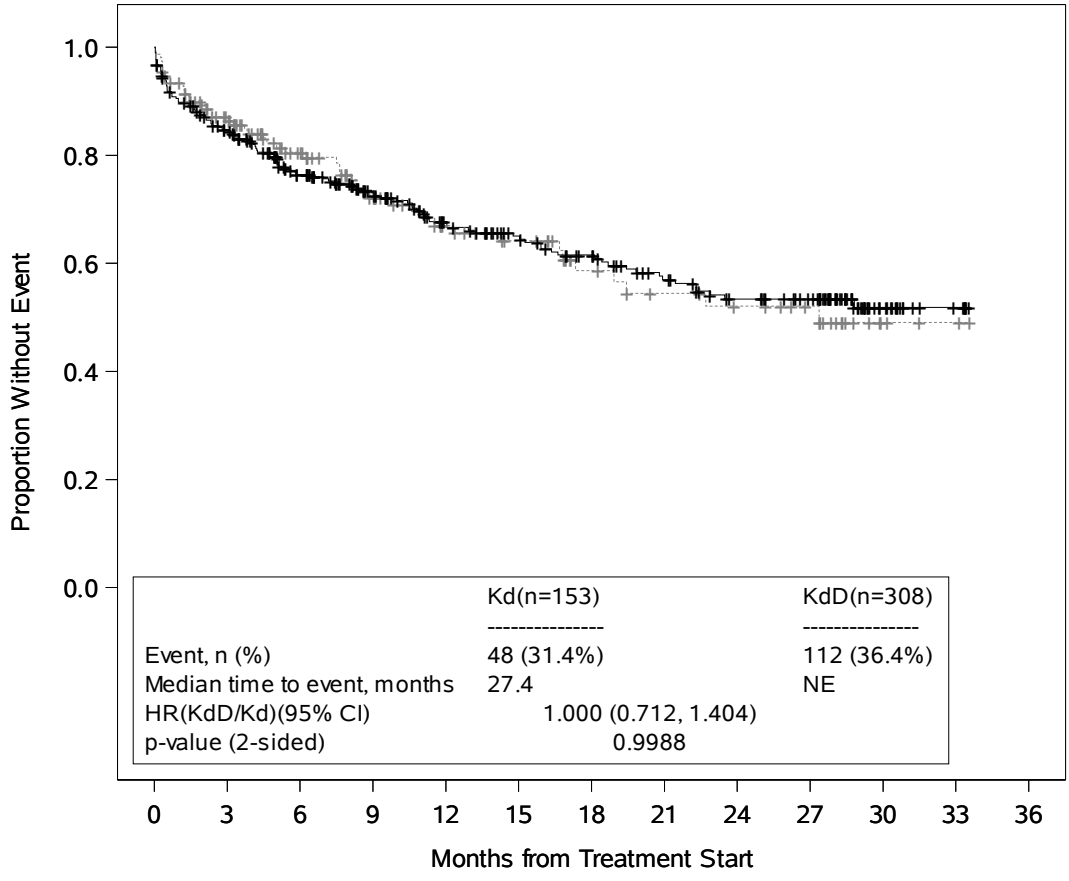


Number of Subjects at Risk:

Kd	153	132	108	88	68	60	47	39	37	27	5	2	0
KdD	308	289	252	214	193	177	161	146	134	112	36	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-010-512-ae-km-eoi-hepat-cfz.rtf (Date Generated: 16SEP20:19:38:14).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.10.513. KM Curves of Adverse Events of Interest for Carfilzomib - Hypertension (SMQ) - Narrow
<Safety Population>

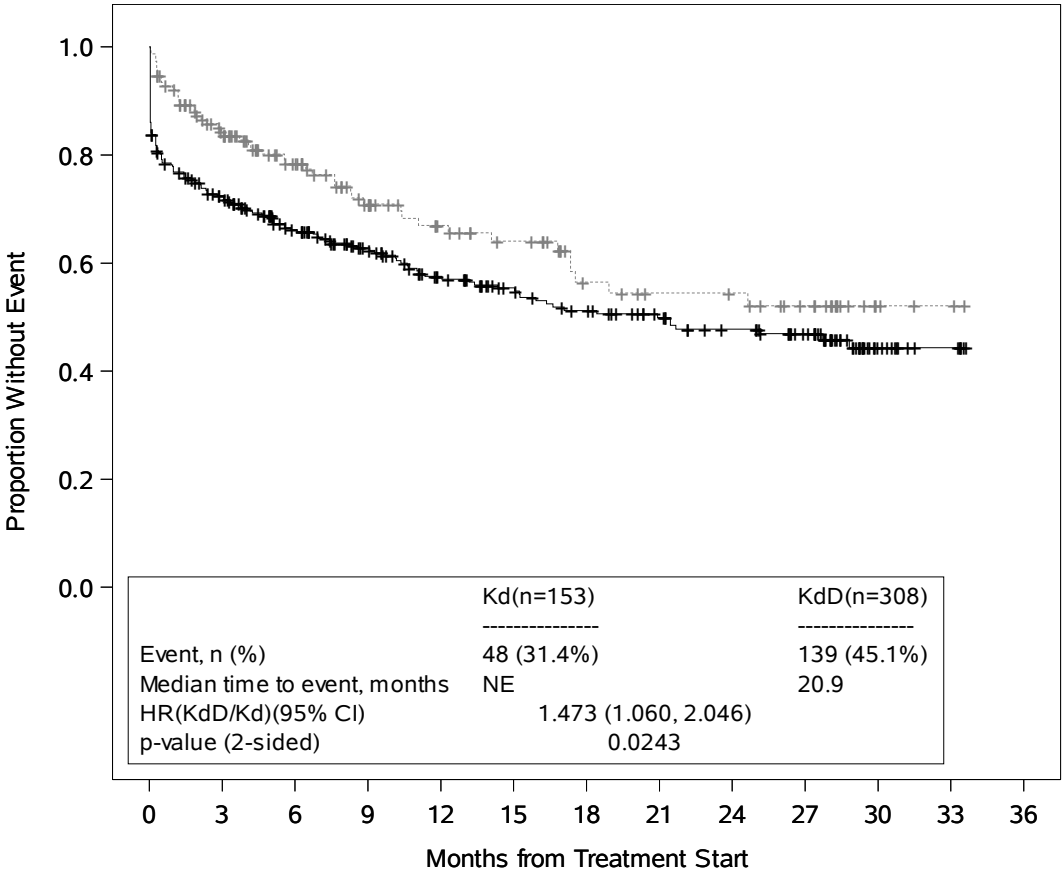


Number of Subjects at Risk:

Kd	153	116	87	63	48	41	29	24	21	17	4	2	0
KdD	308	247	197	161	130	113	100	84	71	62	19	6	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-010-513-ae-km-eoi-hyper-cfz.rtf (Date Generated: 16SEP20:19:38:16).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.10.514. KM Curves of Adverse Events of Interest for Carfilzomib - Infusion Reaction (AMQ) - Narrow (Event on Same Date of Any Carfilzomib Dosing)
<Safety Population>

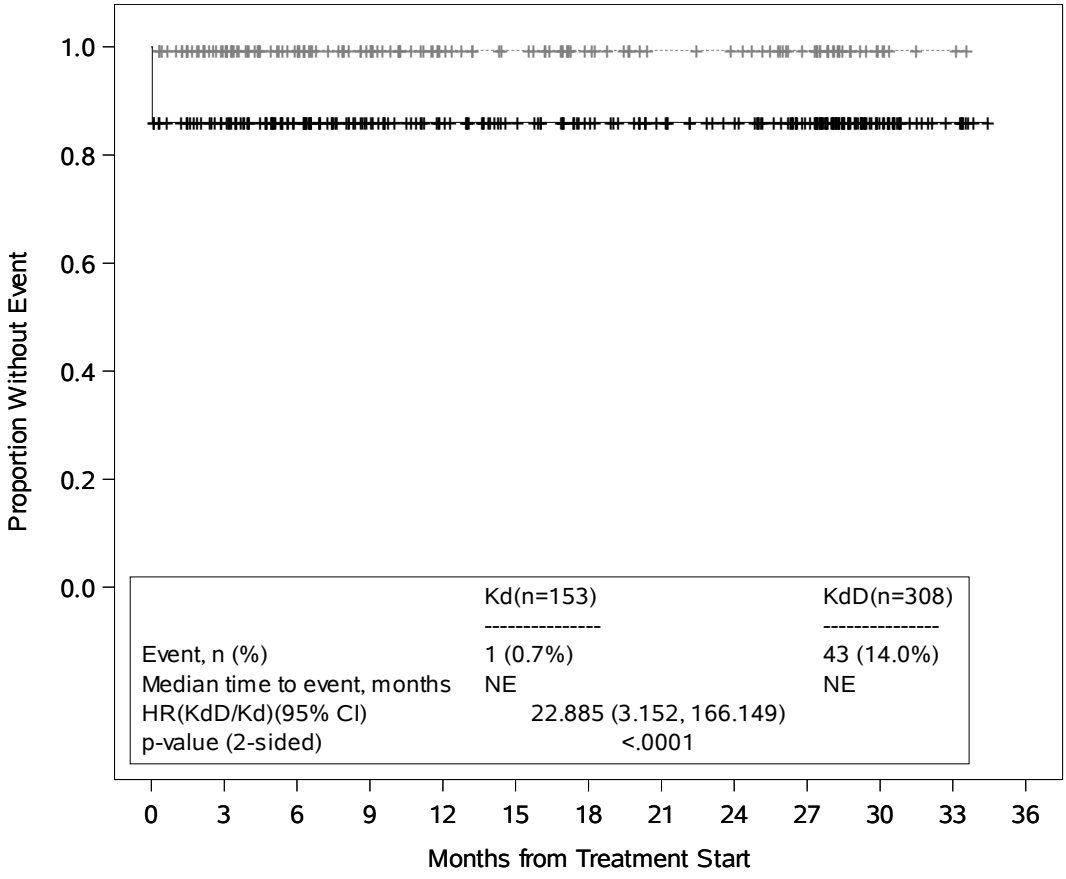


Number of Subjects at Risk:

Kd	153	112	84	62	48	41	28	24	23	17	4	2	0
KdD	308	209	168	138	112	95	84	72	62	51	15	6	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-010-514-ae-km-eoi-infany-cfz.rtf (Date Generated: 16SEP20:19:38:18).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.10.515. KM Curves of Adverse Events of Interest for Carfilzomib - Infusion Reaction (AMQ) - Narrow (Event on Same Date of First Carfilzomib Dosing)
<Safety Population>

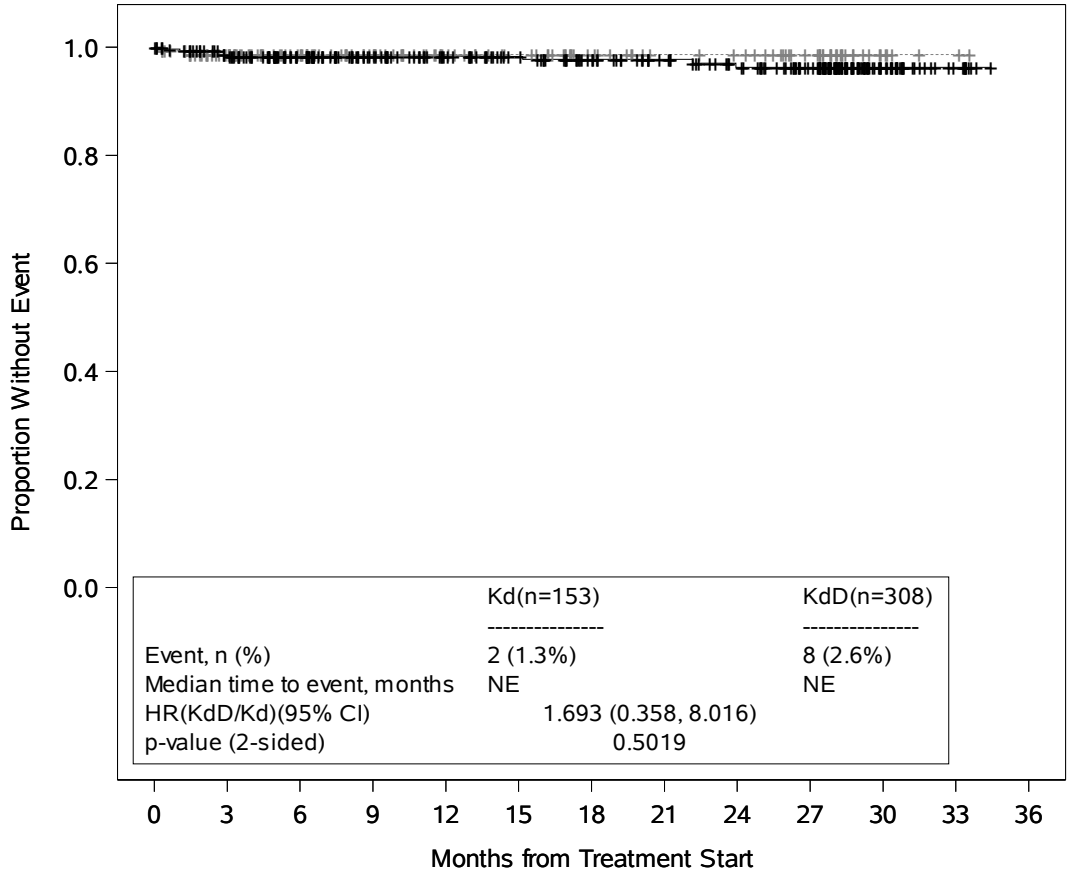


Number of Subjects at Risk:

Kd	153	131	107	87	67	60	47	39	37	27	6	2	0
KdD	308	248	215	184	167	152	138	126	118	98	32	9	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-010-515-ae-km-eoi-inffir-cfz.rtf (Date Generated: 16SEP20:19:38:19).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.10.516. KM Curves of Adverse Events of Interest for Carfilzomib - Interstitial Lung Disease (SMQ) - Narrow
<Safety Population>

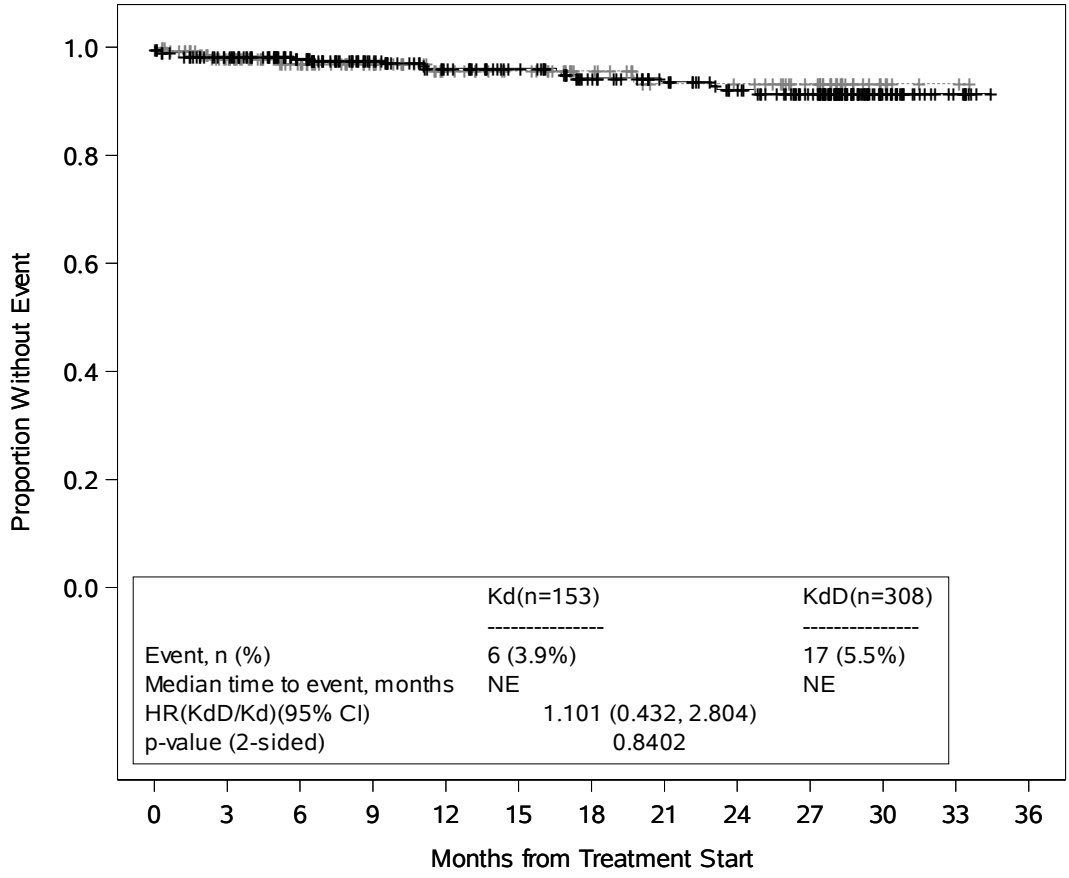


Number of Subjects at Risk:

Kd	153	131	107	87	68	60	47	39	37	27	6	2	0
KdD	308	284	249	212	191	175	158	143	130	109	35	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-010-516-ae-km-eoi-inter-cfz.rtf (Date Generated: 16SEP20:19:38:21).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.10.517. KM Curves of Adverse Events of Interest for Carfilzomib - Ischaemic Heart Disease (SMQ) - Narrow
<Safety Population>

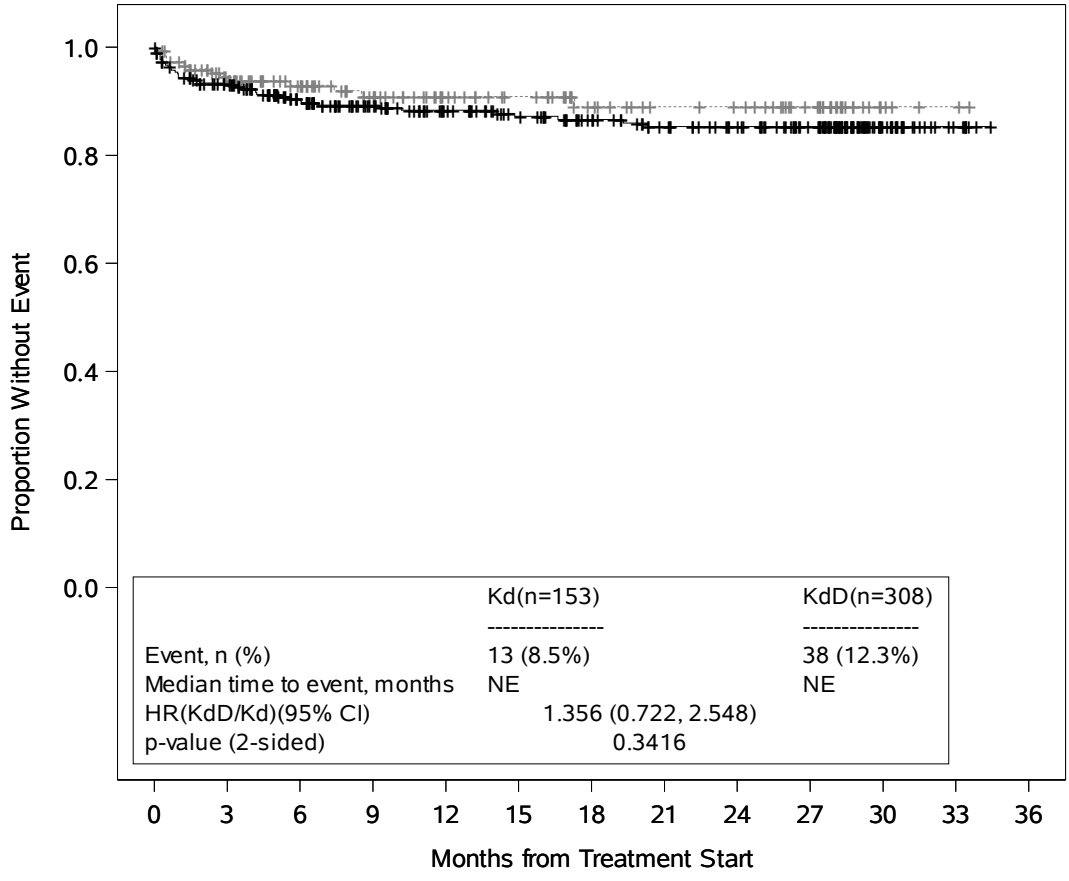


Number of Subjects at Risk:

Kd	153	129	104	85	65	58	46	37	36	27	6	2	0
KdD	308	284	248	209	186	171	152	138	124	103	32	9	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-010-517-ae-km-eoi-ischa-cfz.rtf (Date Generated: 16SEP20:19:38:22).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.10.518. KM Curves of Adverse Events of Interest for Carfilzomib - Liver Related Investigations, Signs and Symptoms (SMQ) - Narrow <Safety Population>

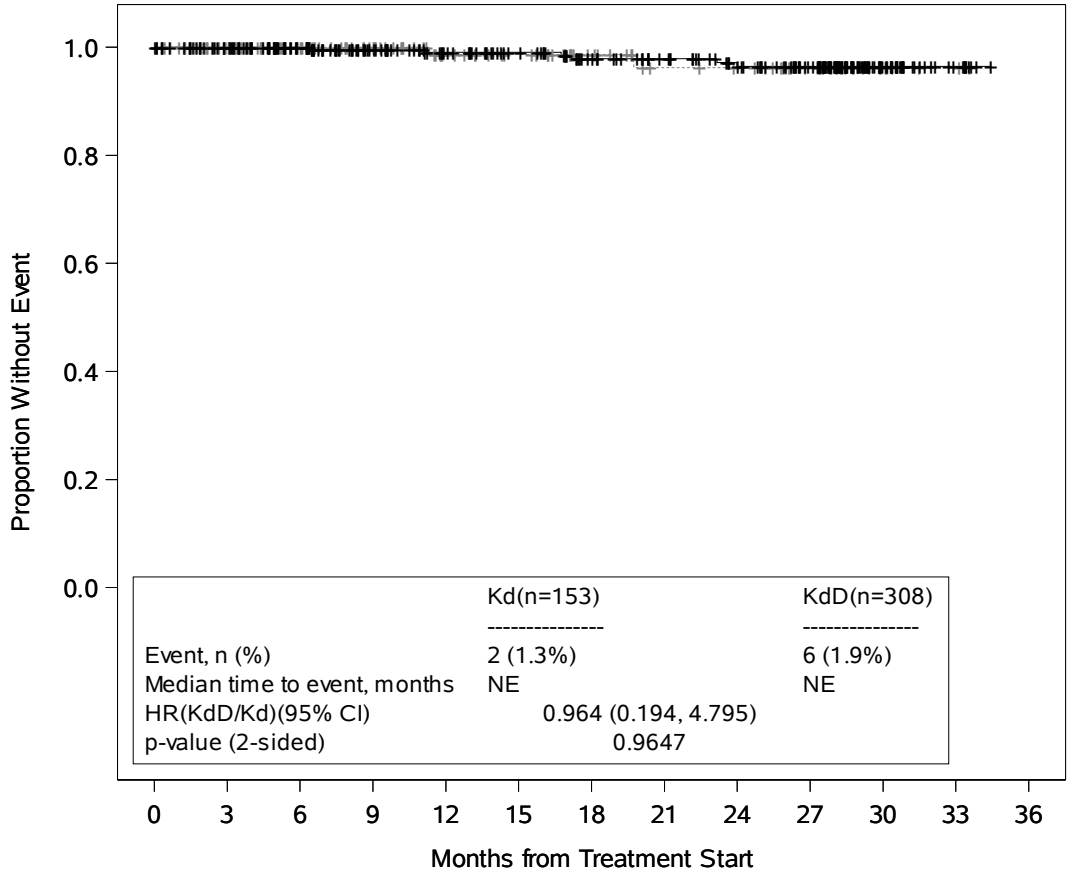


Number of Subjects at Risk:

Kd	153	126	104	83	66	58	45	38	36	26	5	2	0
KdD	308	269	228	194	172	155	139	125	114	95	31	8	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-010-518-ae-km-eoi-liver-cfz.rtf (Date Generated: 16SEP20:19:38:24).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.10.519. KM Curves of Adverse Events of Interest for Carfilzomib - Myocardial Infarction (SMQ) - Narrow
<Safety Population>

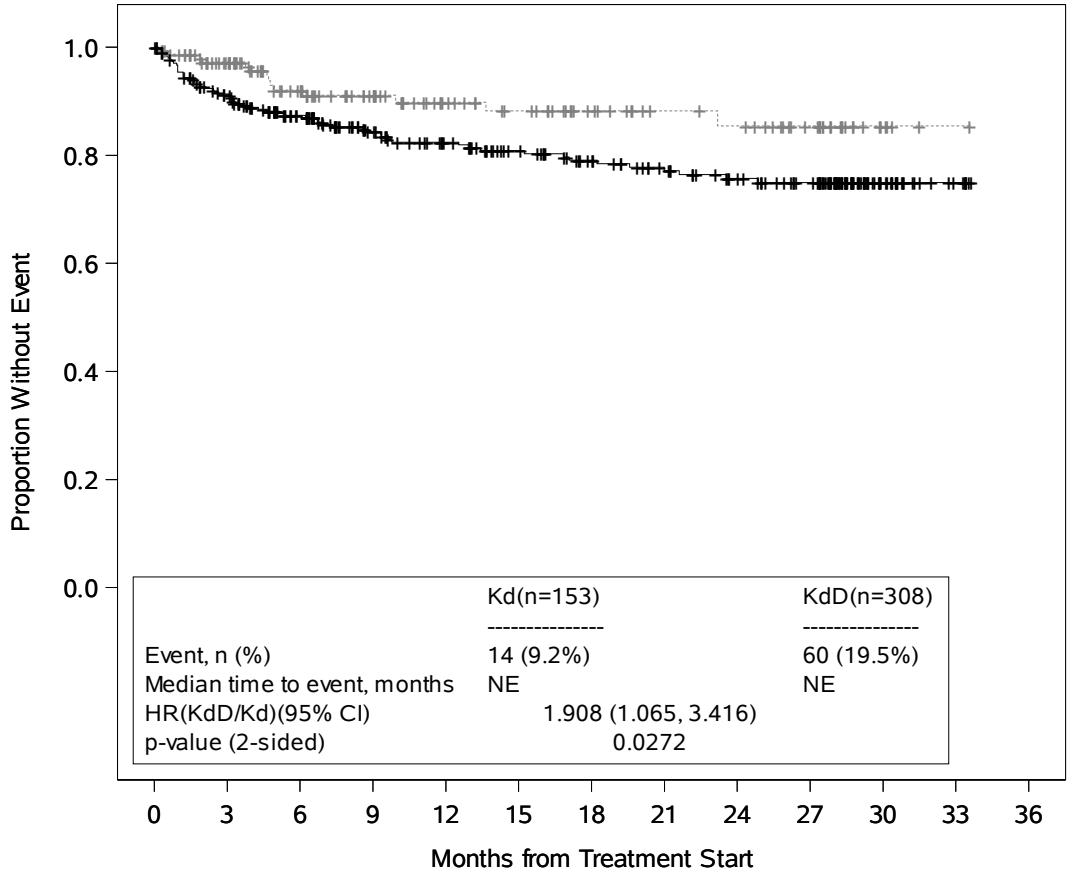


Number of Subjects at Risk:

Kd	153	132	108	88	67	60	47	38	36	27	6	2	0
KdD	308	289	253	214	192	176	158	145	131	110	36	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-010-519-ae-km-eoi-myoca-cfz.rtf (Date Generated: 16SEP20:19:38:25).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.10.520. KM Curves of Adverse Events of Interest for Carfilzomib - Peripheral Neuropathy (SMQ) - Narrow
<Safety Population>

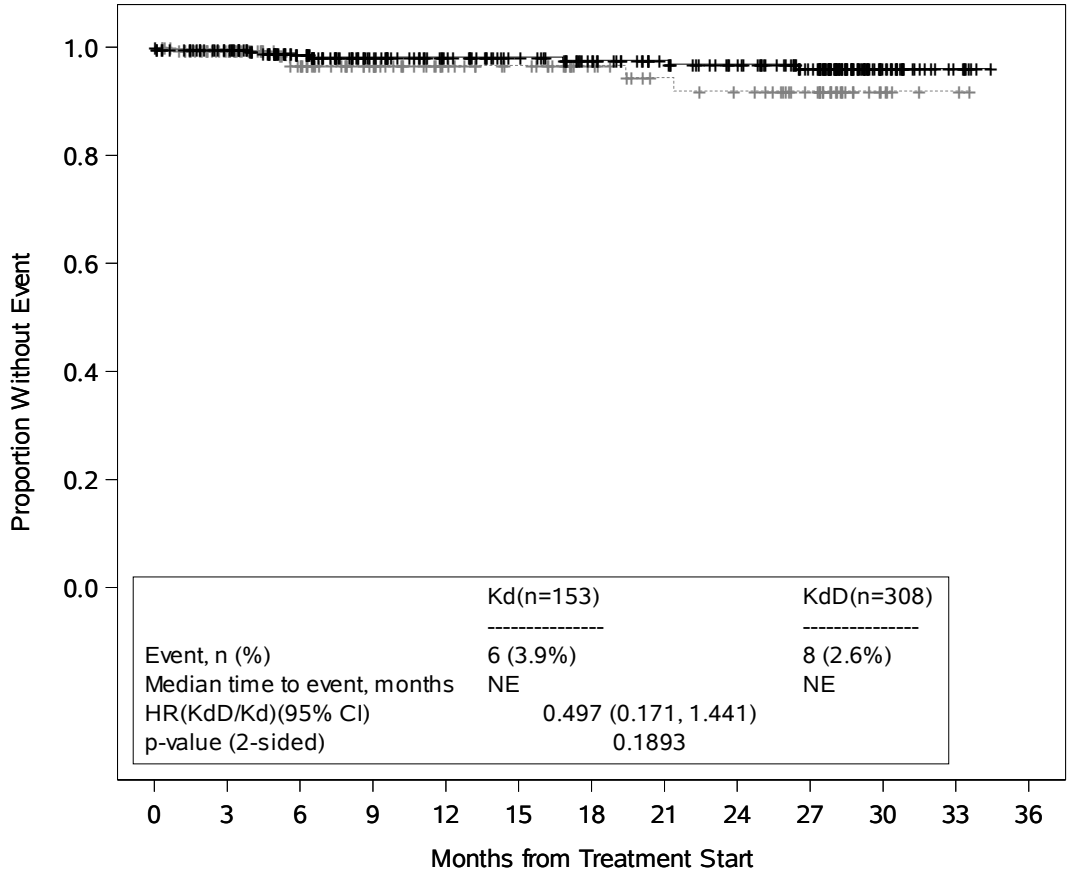


Number of Subjects at Risk:

Kd	153	128	99	79	60	52	41	33	31	22	5	1	0
KdD	308	264	221	180	160	142	127	114	102	89	26	7	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-010-520-ae-km-eoi-perip-cfz.rtf (Date Generated: 16SEP20:19:38:27).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.10.521. KM Curves of Adverse Events of Interest for Carfilzomib - Pulmonary Hypertension (SMQ) - Narrow
<Safety Population>

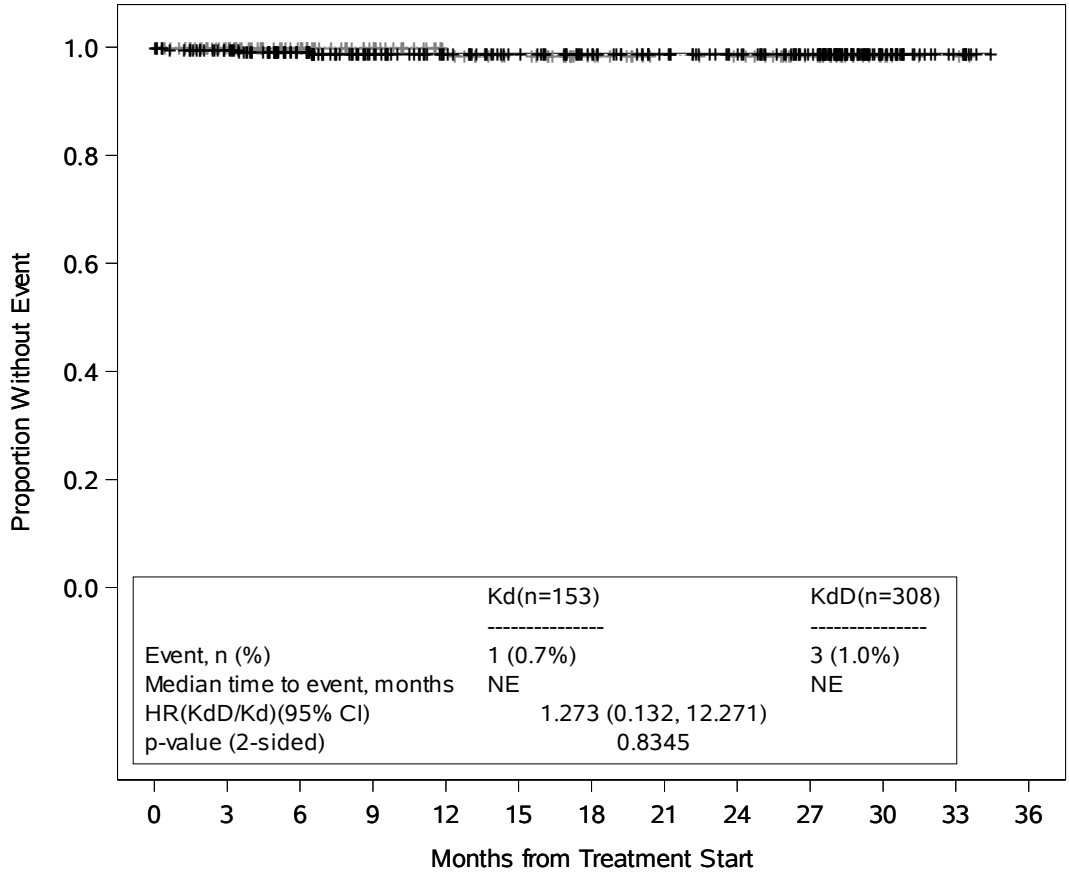


Number of Subjects at Risk:

Kd	153	131	105	85	66	59	46	38	35	26	6	2	0
KdD	308	288	250	210	189	173	157	142	130	107	32	8	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-010-521-ae-km-eoi-pulmo-cfz.rtf (Date Generated: 16SEP20:19:38:28).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.10.522. KM Curves of Adverse Events of Interest for Carfilzomib - Respiratory Failure (SMQ) - Narrow
<Safety Population>

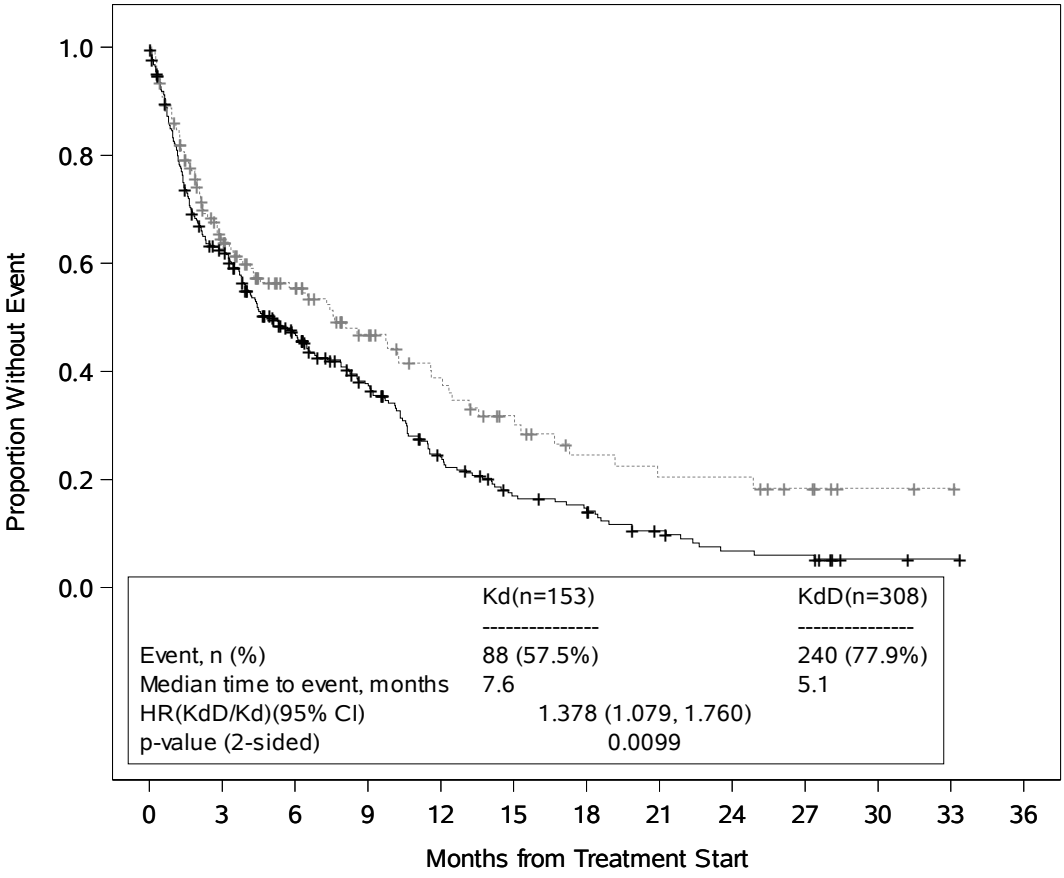


Number of Subjects at Risk:

Kd	153	132	108	88	67	60	47	39	37	27	6	2	0
KdD	308	288	252	214	193	177	161	146	134	112	36	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-010-522-ae-km-eoi-respi-cfz.rtf (Date Generated: 16SEP20:19:38:30).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.10.523. KM Curves of Adverse Events of Interest for Carfilzomib - Respiratory Tract Infections (AMQ) - Broad
<Safety Population>

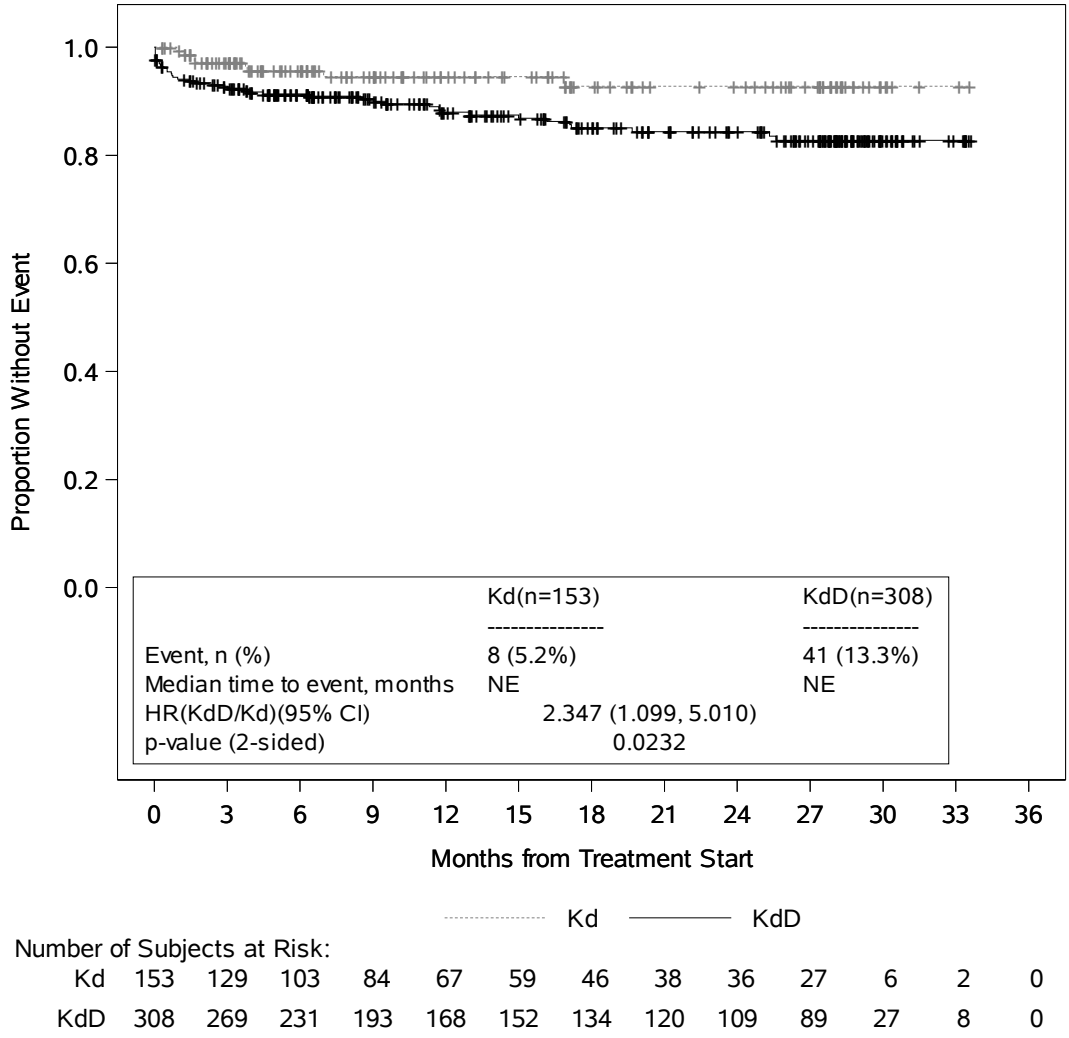


Number of Subjects at Risk:

Kd	153	84	58	39	28	19	12	10	10	6	2	1	0
KdD	308	184	121	85	49	31	25	15	9	8	2	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-010-523-ae-km-eoi-restra-cfz.rtf (Date Generated: 16SEP20:19:38:31).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.10.524. KM Curves of Adverse Events of Interest for Carfilzomib - Reversible Posterior Leukoencephalopathy Syndrome (AMQ) - Narrow <Safety Population>

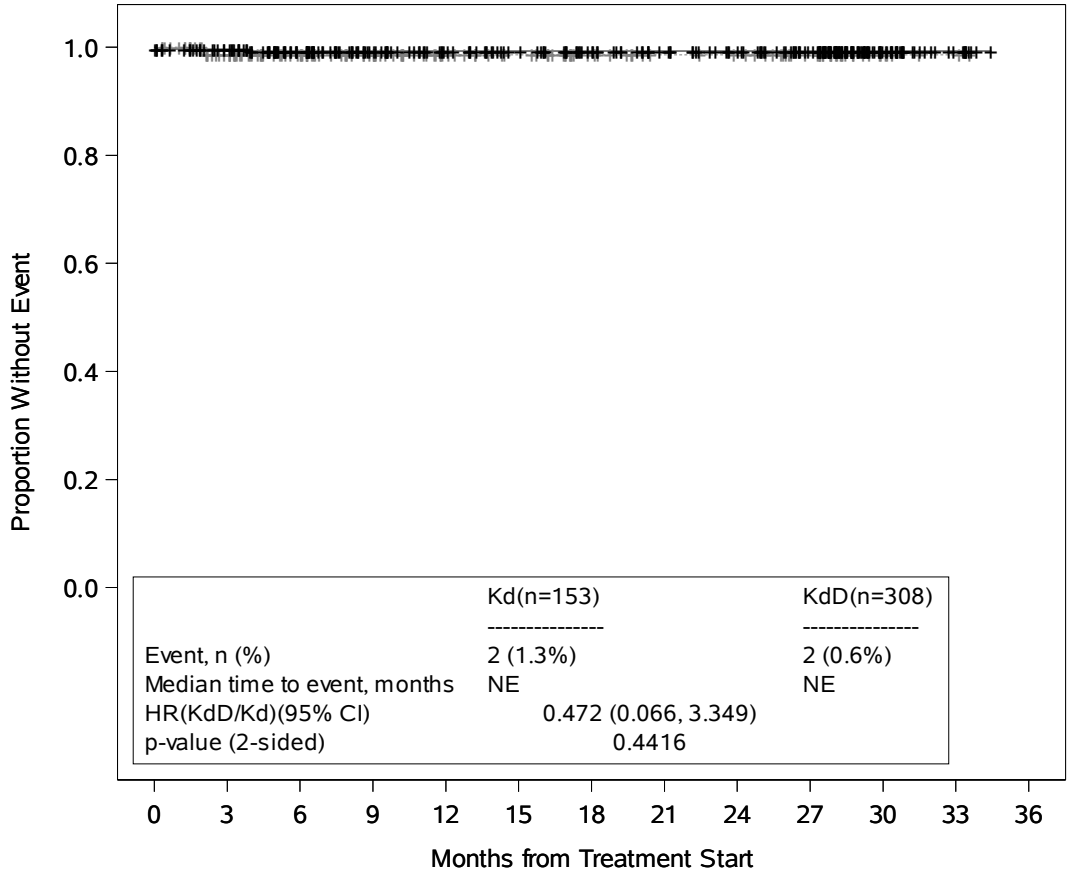


Number of Subjects at Risk:

Kd	153	129	103	84	67	59	46	38	36	27	6	2	0
KdD	308	269	231	193	168	152	134	120	109	89	27	8	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-010-524-ae-km-eoi-rever-cfz.rtf (Date Generated: 16SEP20:19:38:33).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.10.525. KM Curves of Adverse Events of Interest for Carfilzomib - Thrombotic Microangiopathy (Carfilzomib) (AMQ) - Narrow
<Safety Population>

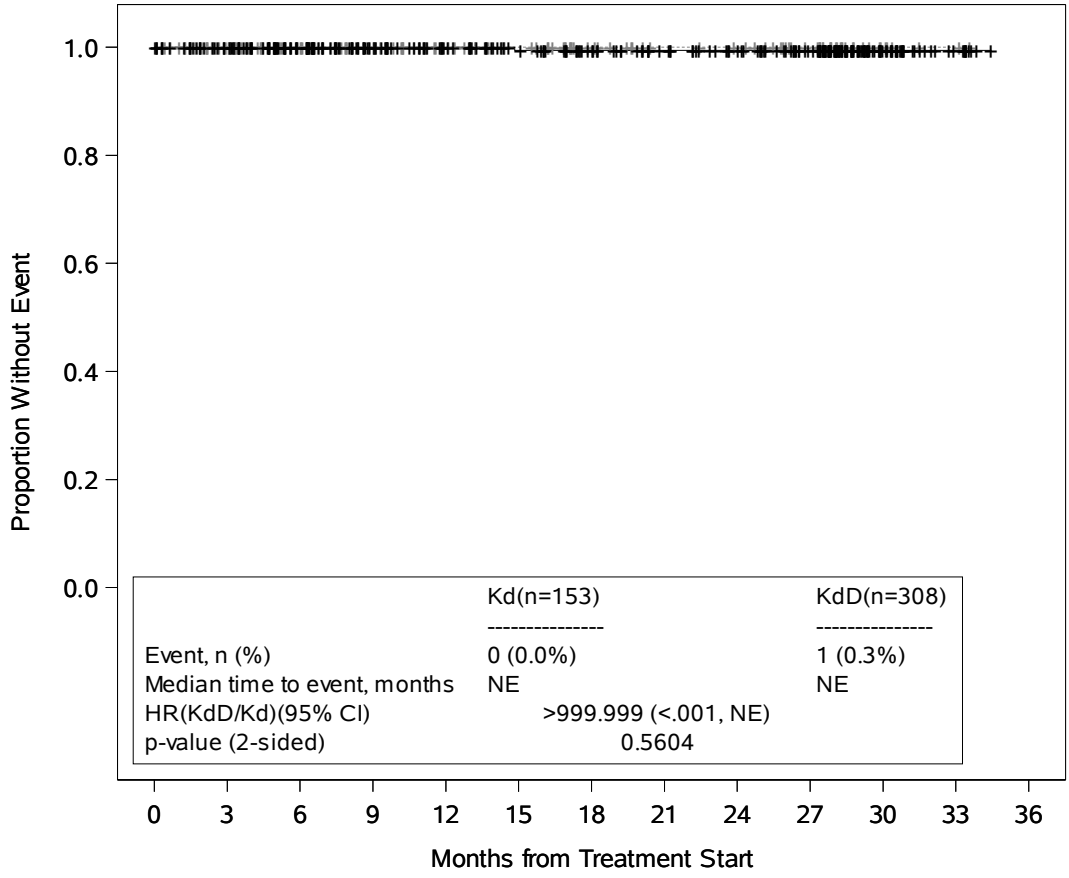


Number of Subjects at Risk:

Kd	153	131	108	88	68	60	47	39	37	27	6	2	0
KdD	308	288	251	213	192	177	161	146	134	112	36	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-010-525-ae-km-eoi-throm-cfz.rtf (Date Generated: 16SEP20:19:38:34).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.10.526. KM Curves of Adverse Events of Interest for Carfilzomib - Torsade de Pointes/QT Prolongation (SMQ) - Narrow
<Safety Population>

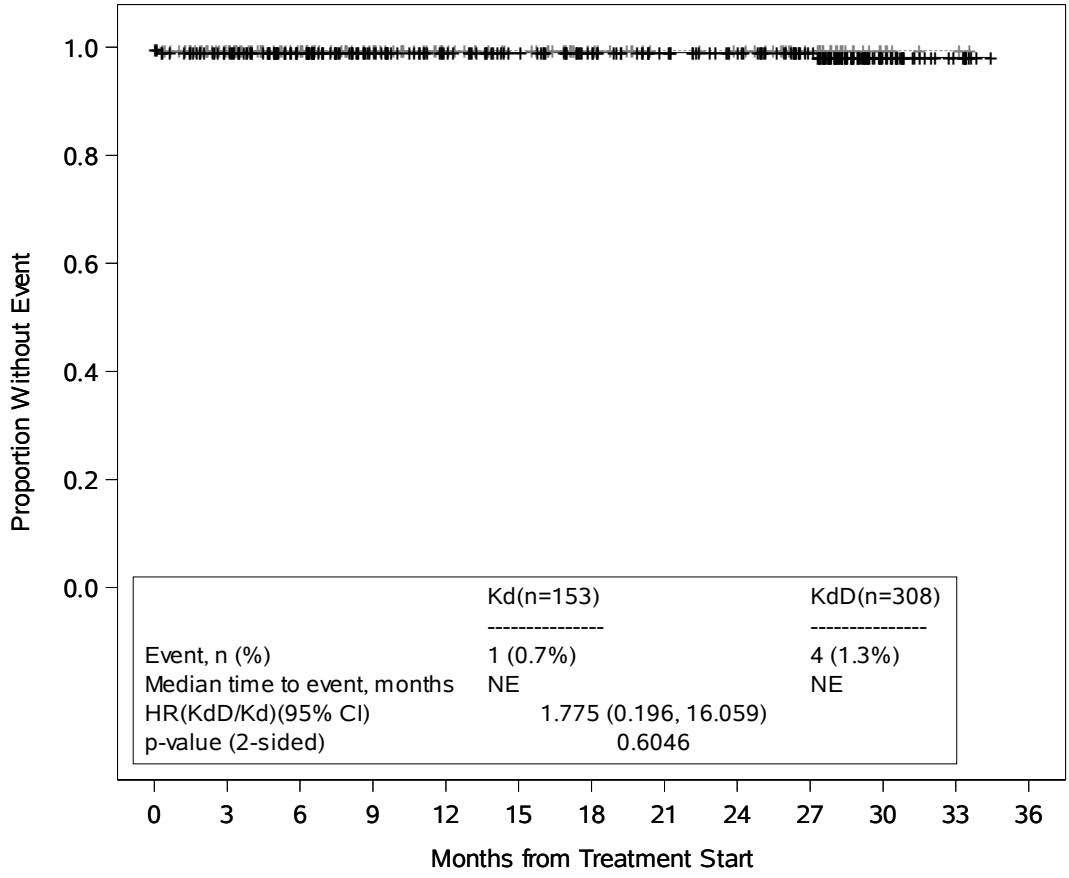


Number of Subjects at Risk:

Kd	153	132	108	88	68	60	47	39	37	27	6	2	0
KdD	308	289	253	214	193	176	160	145	133	112	36	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-010-526-ae-km-eoi-torsa-cfz.rtf (Date Generated: 16SEP20:19:38:36).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.10.527. KM Curves of Adverse Events of Interest for Carfilzomib - Tumour Lysis Syndrome (SMQ) - Narrow
<Safety Population>

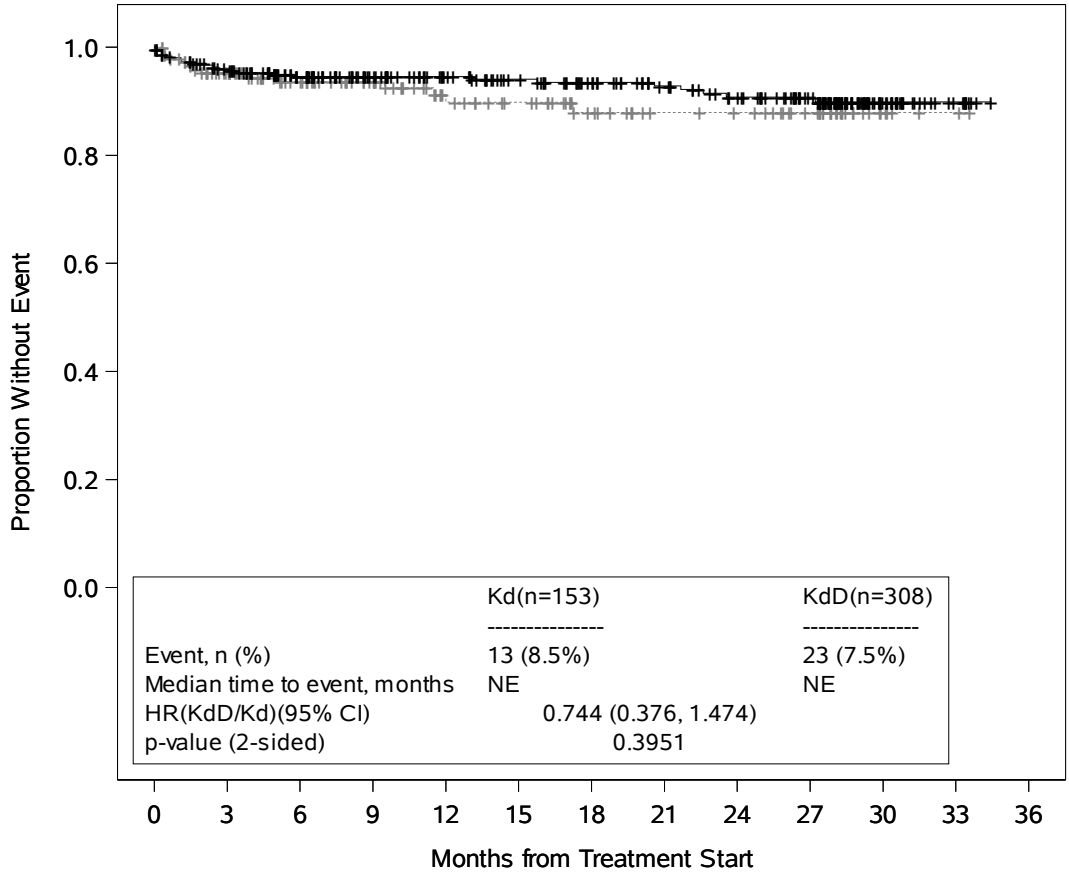


Number of Subjects at Risk:

Kd	153	132	108	88	68	60	47	39	37	27	6	2	0
KdD	308	287	252	213	192	177	161	146	134	112	36	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-010-527-ae-km-eoi-tumou-cfz.rtf (Date Generated: 16SEP20:19:38:37).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.10.501. KM Curves of Adverse Events of Interest for Carfilzomib - Acute Renal Failure (SMQ) - Narrow
<Safety Population>

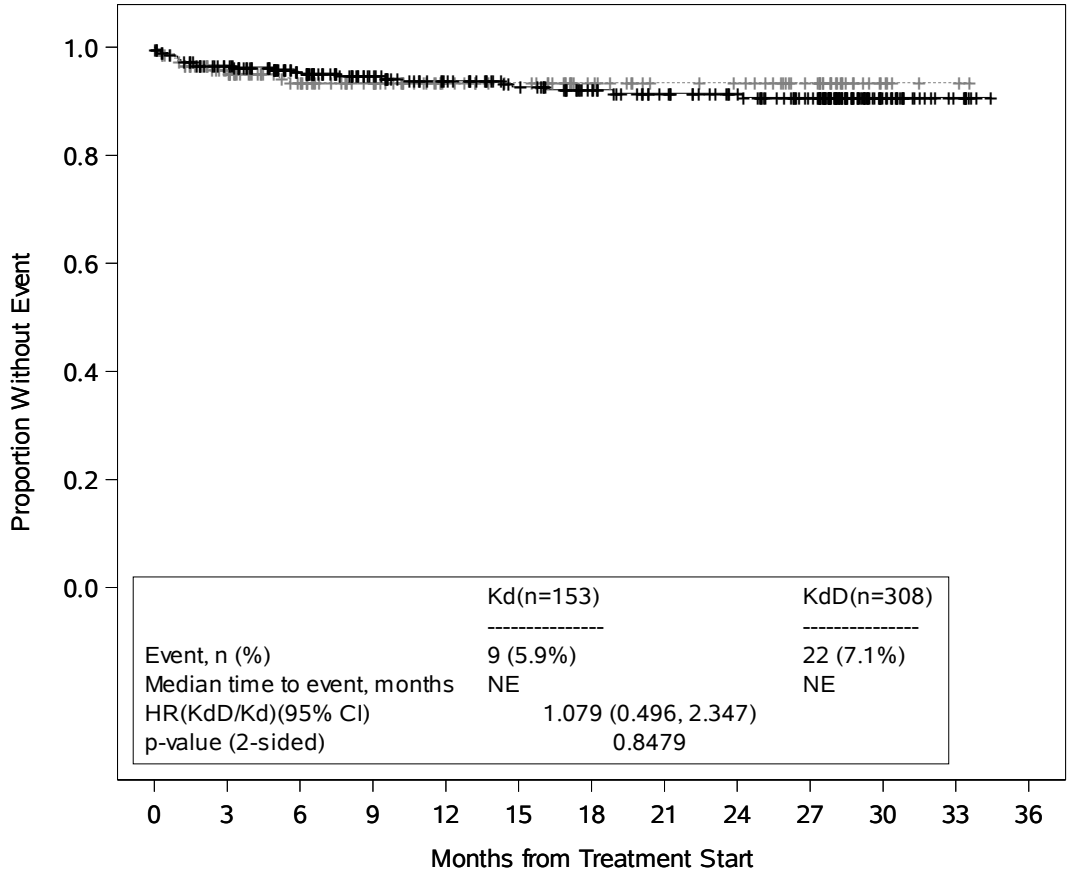


Number of Subjects at Risk:

Kd	153	128	106	87	66	58	45	37	35	27	6	2	0
KdD	308	280	245	209	188	171	155	139	126	105	33	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-010-501-ae-km-eoi-acute-cfz.rtf (Date Generated: 16SEP20:19:37:55).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.10.502. KM Curves of Adverse Events of Interest for Carfilzomib - Cardiac Arrhythmias (SMQ) - Narrow
<Safety Population>

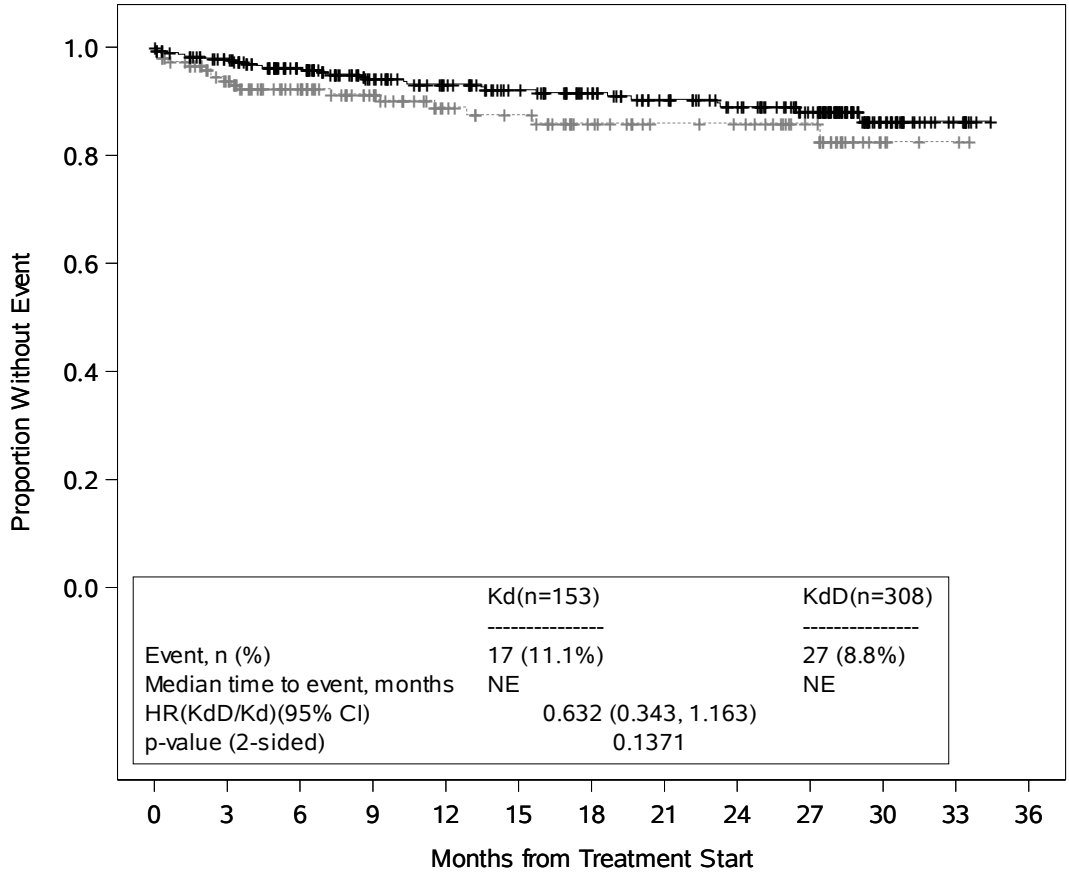


Number of Subjects at Risk:

Kd	153	126	103	86	66	60	47	39	37	27	6	2	0
KdD	308	279	241	203	183	167	150	136	125	106	32	9	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-010-502-ae-km-eoi-cardi-cfz.rtf (Date Generated: 16SEP20:19:37:57).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.10.503. KM Curves of Adverse Events of Interest for Carfilzomib - Cardiac Failure (SMQ) - Narrow
<Safety Population>

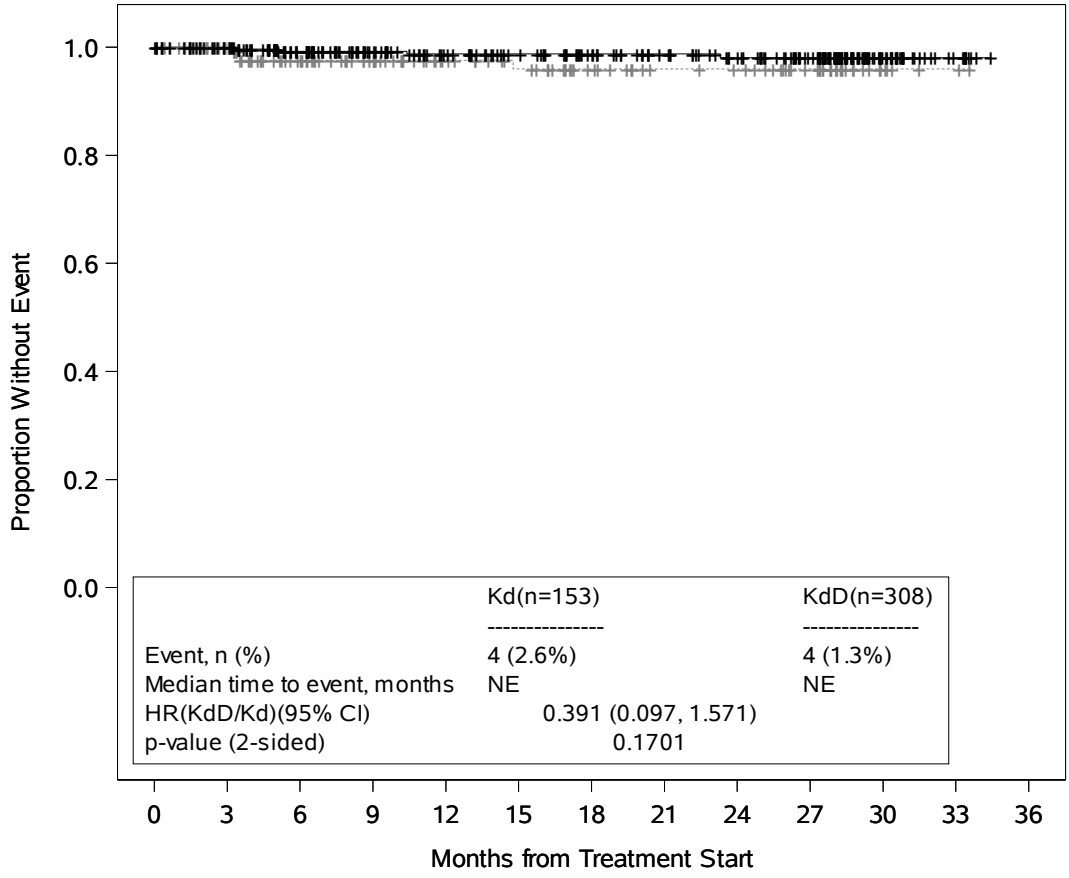


Number of Subjects at Risk:

Kd	153	128	105	84	65	59	46	38	36	26	5	2	0
KdD	308	285	248	207	188	171	154	138	125	104	33	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-010-503-ae-km-eoi-carfai-cfz.rtf (Date Generated: 16SEP20:19:37:59).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.10.504. KM Curves of Adverse Events of Interest for Carfilzomib - Cardiomyopathy (SMQ) - Narrow
<Safety Population>

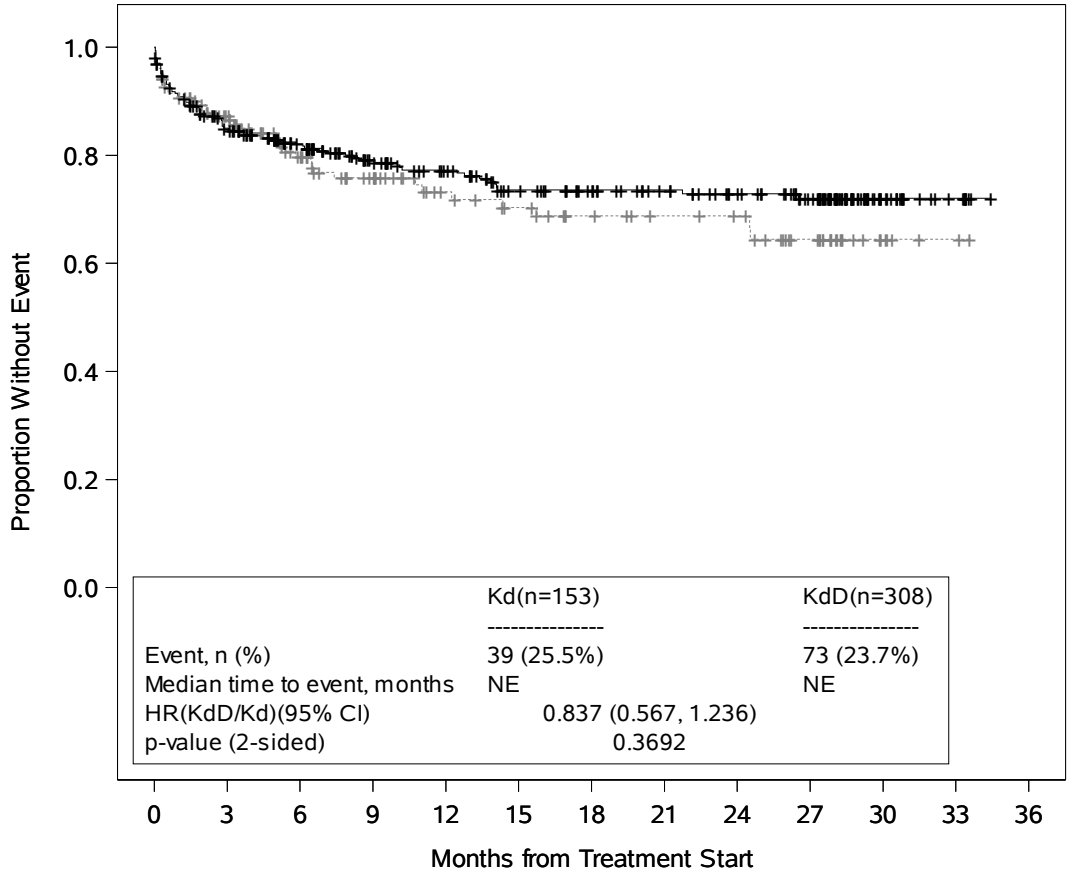


Number of Subjects at Risk:

Kd	153	132	106	86	67	59	47	39	37	27	6	2	0
KdD	308	289	251	212	191	176	160	145	132	110	36	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-010-504-ae-km-eoi-cardio-cfz.rtf (Date Generated: 16SEP20:19:38:01).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.10.505. KM Curves of Adverse Events of Interest for Carfilzomib - Dyspnoeas (HLT)
<Safety Population>

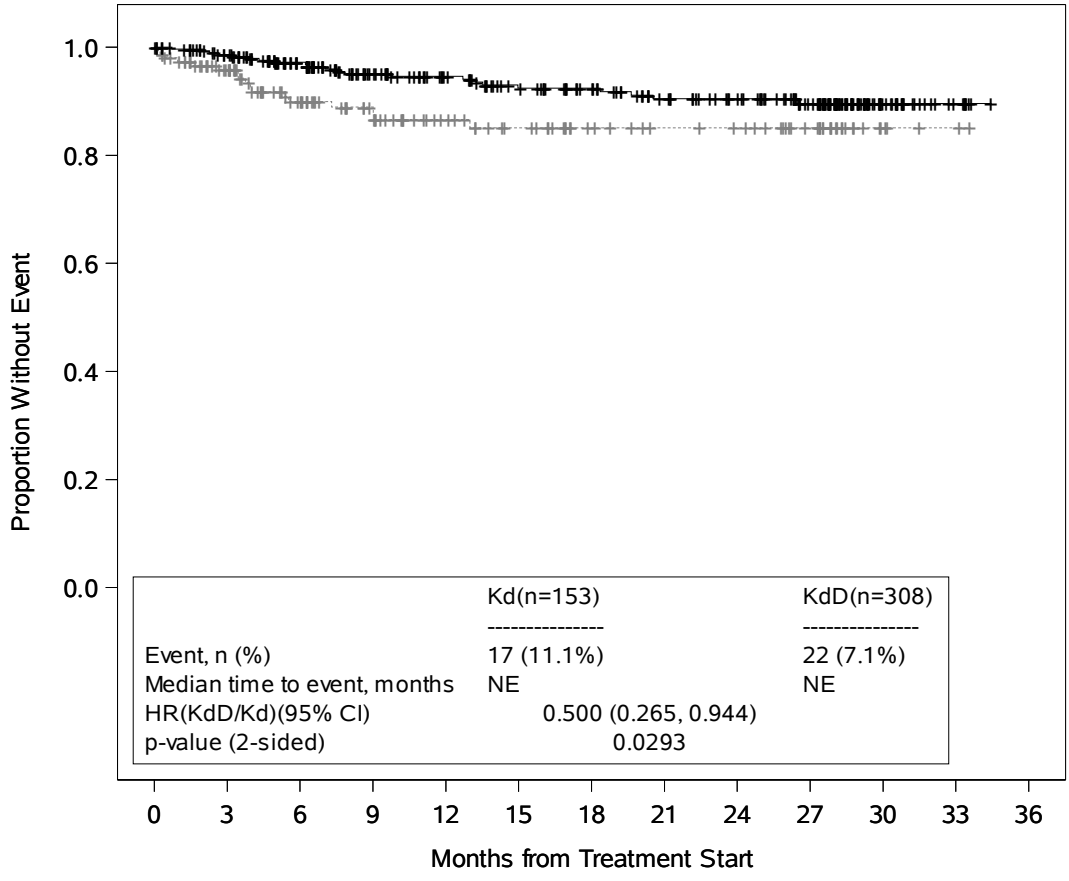


Number of Subjects at Risk:

Kd	153	118	88	68	52	46	39	35	33	23	6	2	0
KdD	308	245	209	173	154	133	121	110	99	83	24	9	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-010-505-ae-km-eoi-dyspn-cfz.rtf (Date Generated: 16SEP20:19:38:03).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.10.506. KM Curves of Adverse Events of Interest for Carfilzomib - Embolic and Thrombotic Events, Venous (SMQ) - Narrow
<Safety Population>

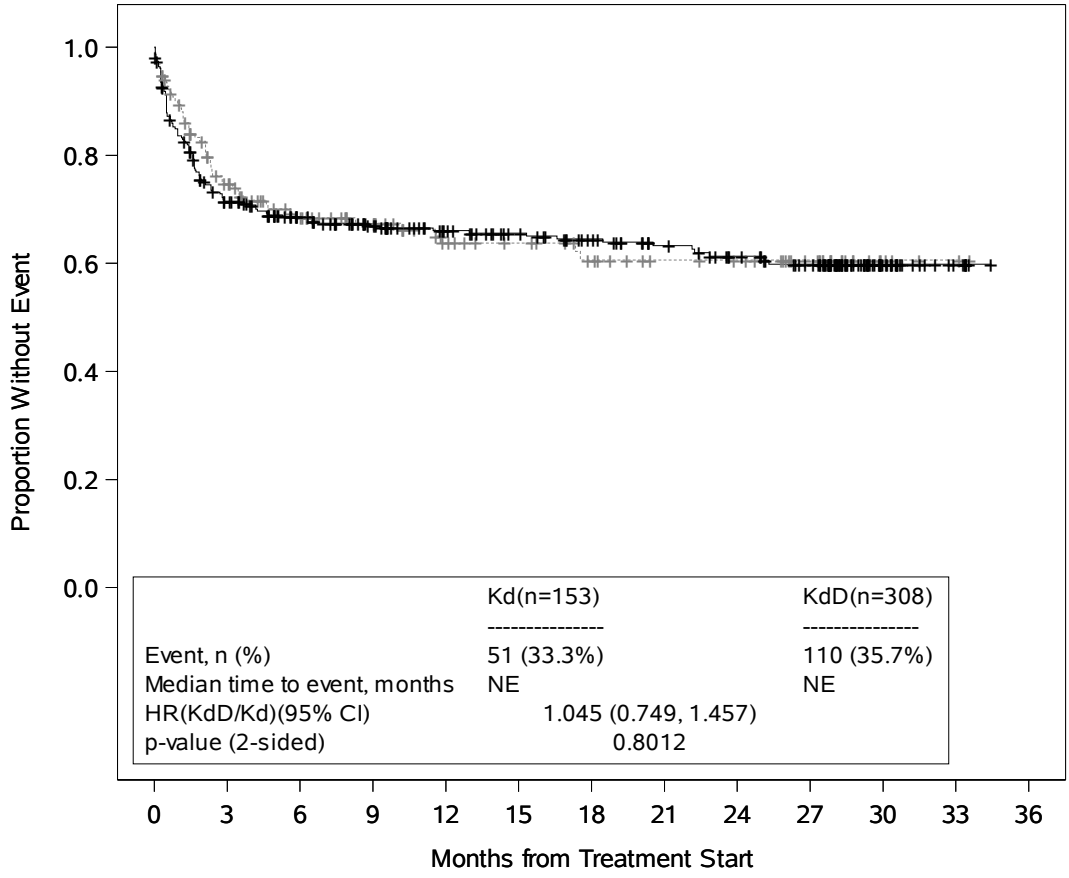


Number of Subjects at Risk:

Kd	153	126	96	77	60	51	40	35	33	24	5	2	0
KdD	308	285	245	203	181	163	150	132	120	97	30	8	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-010-506-ae-km-eoi-embol-cfz.rtf (Date Generated: 16SEP20:19:38:05).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.10.507. KM Curves of Adverse Events of Interest for Carfilzomib - Haematopoietic Erythropenia (SMQ) - Broad
<Safety Population>

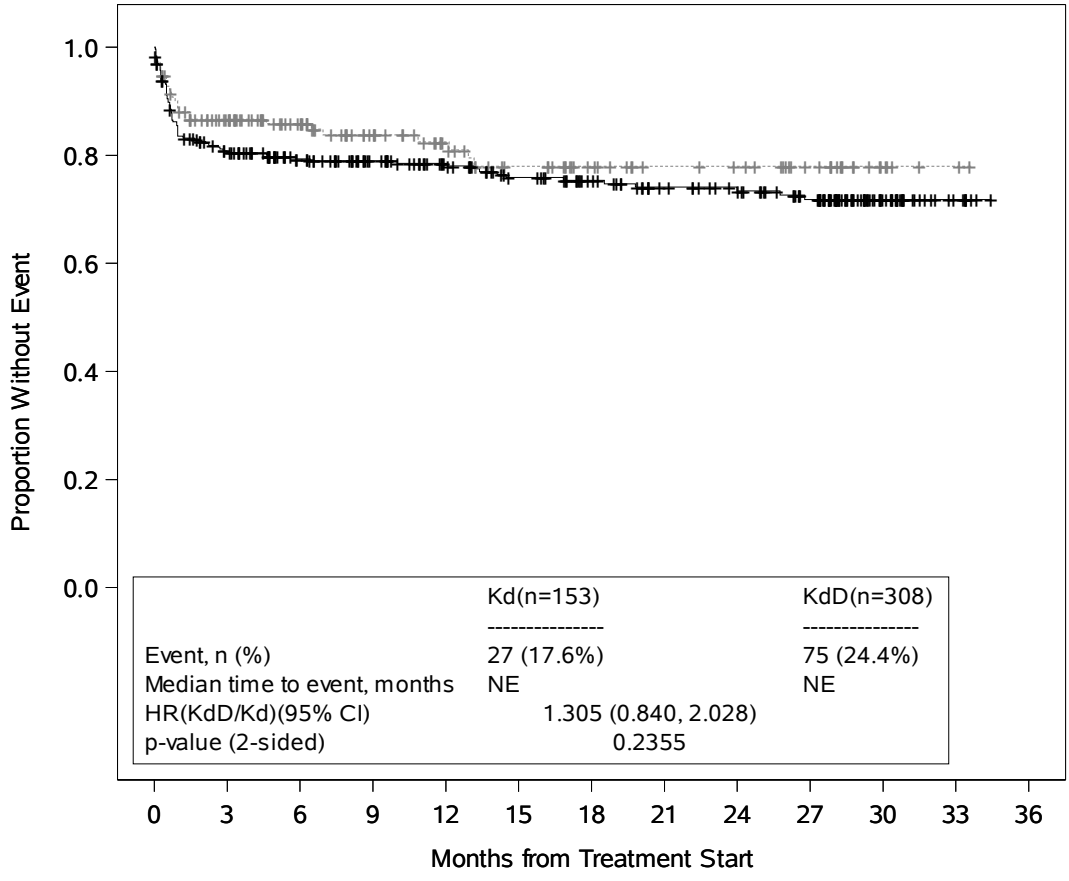


Number of Subjects at Risk:

Kd	153	102	82	66	49	44	37	31	29	21	5	2	0
KdD	308	207	177	155	135	123	111	98	88	77	25	7	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-010-507-ae-km-eoi-haema-cfz.rtf (Date Generated: 16SEP20:19:38:07).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.10.508. KM Curves of Adverse Events of Interest for Carfilzomib - Haematopoietic Leukopenia (SMQ) - Narrow
<Safety Population>

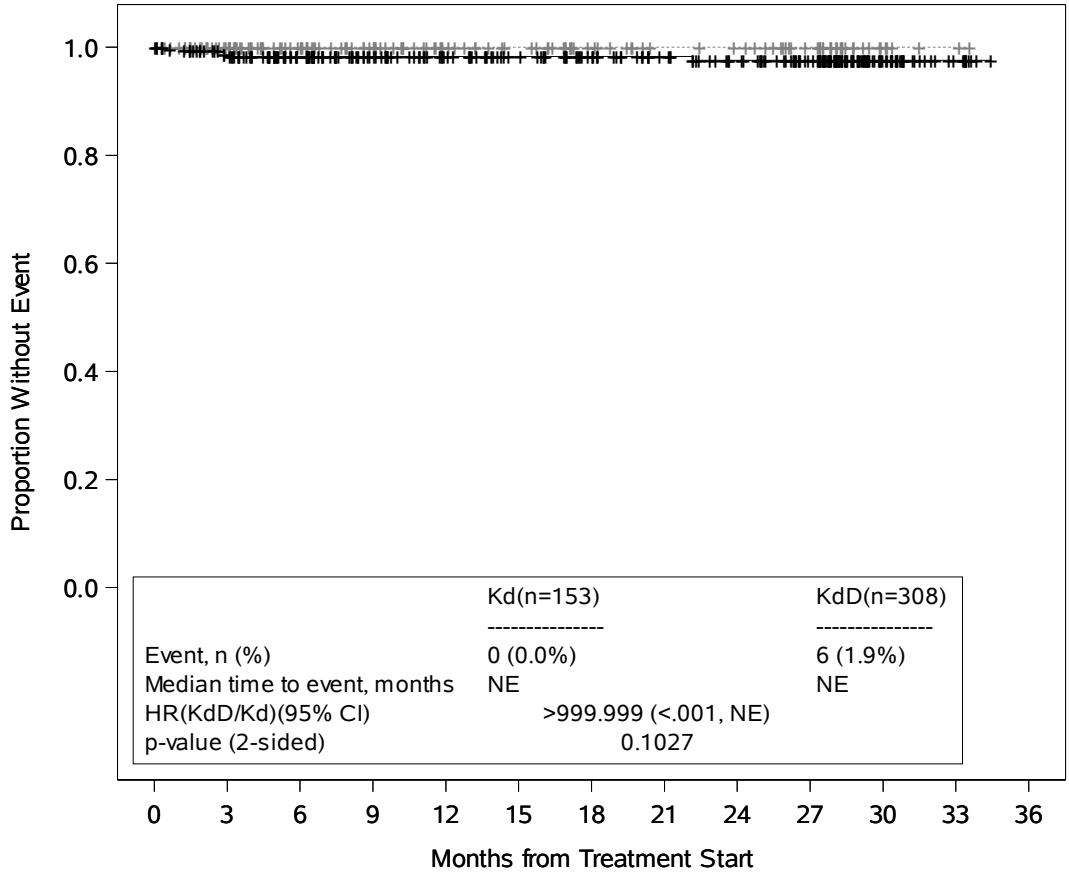


Number of Subjects at Risk:

Kd	153	115	92	71	57	46	36	29	27	19	6	2	0
KdD	308	233	202	178	158	140	126	111	103	87	33	8	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-010-508-ae-km-eoi-haeleu-cfz.rtf (Date Generated: 16SEP20:19:38:08).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.11.515. KM Curves of Grade ≥3 Adverse Events of Interest for Carfilzomib - Interstitial Lung Disease (SMQ) - Narrow
<Safety Population>

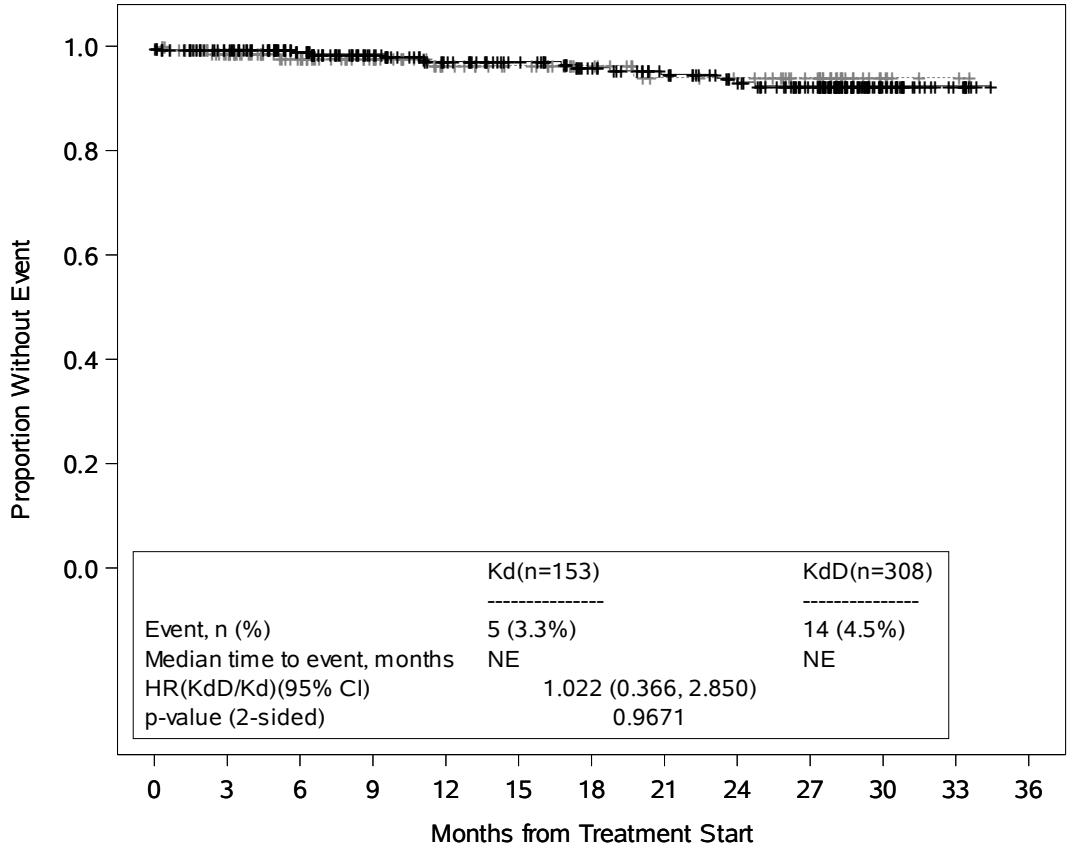


Number of Subjects at Risk:

Kd	153	132	108	88	68	60	47	39	37	27	6	2	0
KdD	308	284	249	212	191	175	159	144	131	110	36	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-011-515-ae-km-eoi-inter-cfz-grd345.rtf (Date Generated: 16SEP20:19:39:01).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.11.516. KM Curves of Grade ≥3 Adverse Events of Interest for Carfilzomib - Ischaemic Heart Disease (SMQ) - Narrow <Safety Population>

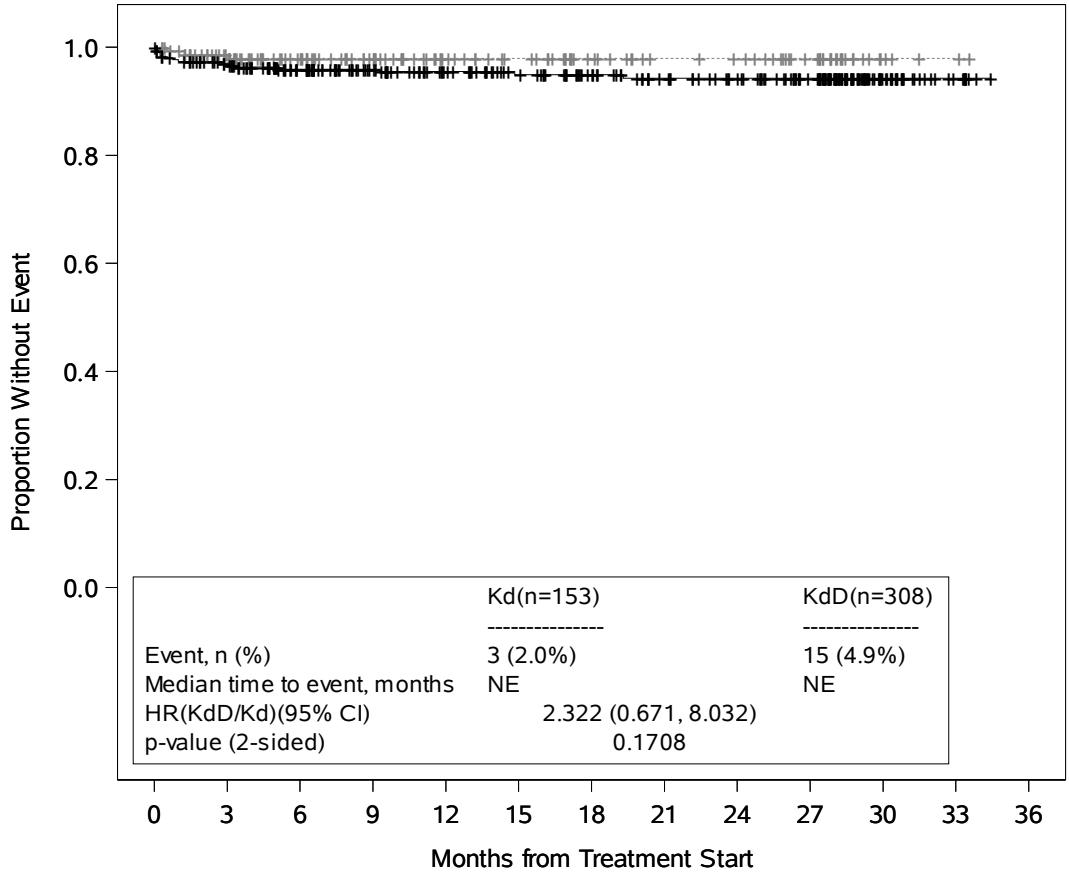


Number of Subjects at Risk:

Kd	153	130	105	86	66	59	47	38	36	27	6	2	0
KdD	308	287	251	212	189	174	156	141	127	106	35	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-011-516-ae-km-eoi-ischa-cfz-grd345.rtf (Date Generated: 16SEP20:19:39:02).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.11.517. KM Curves of Grade ≥3 Adverse Events of Interest for Carfilzomib - Liver Related Investigations, Signs and Symptoms (SMQ) - Narrow <Safety Population>

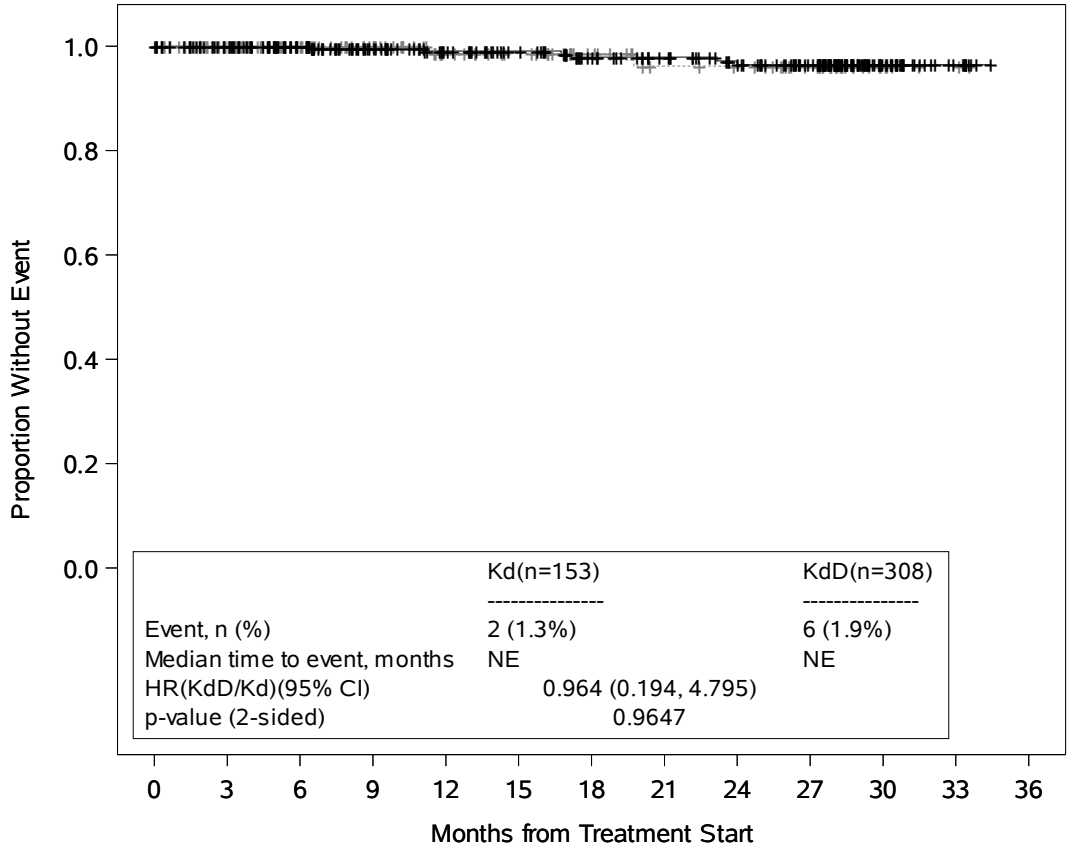


Number of Subjects at Risk:

Kd	153	131	107	87	67	59	46	38	36	26	5	2	0
KdD	308	280	243	207	185	168	152	136	125	104	33	9	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-011-517-ae-km-eoi-liver-cfz-grd345.rtf (Date Generated: 16SEP20:19:39:04).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.11.518. KM Curves of Grade ≥3 Adverse Events of Interest for Carfilzomib - Myocardial Infarction (SMQ) - Narrow
<Safety Population>

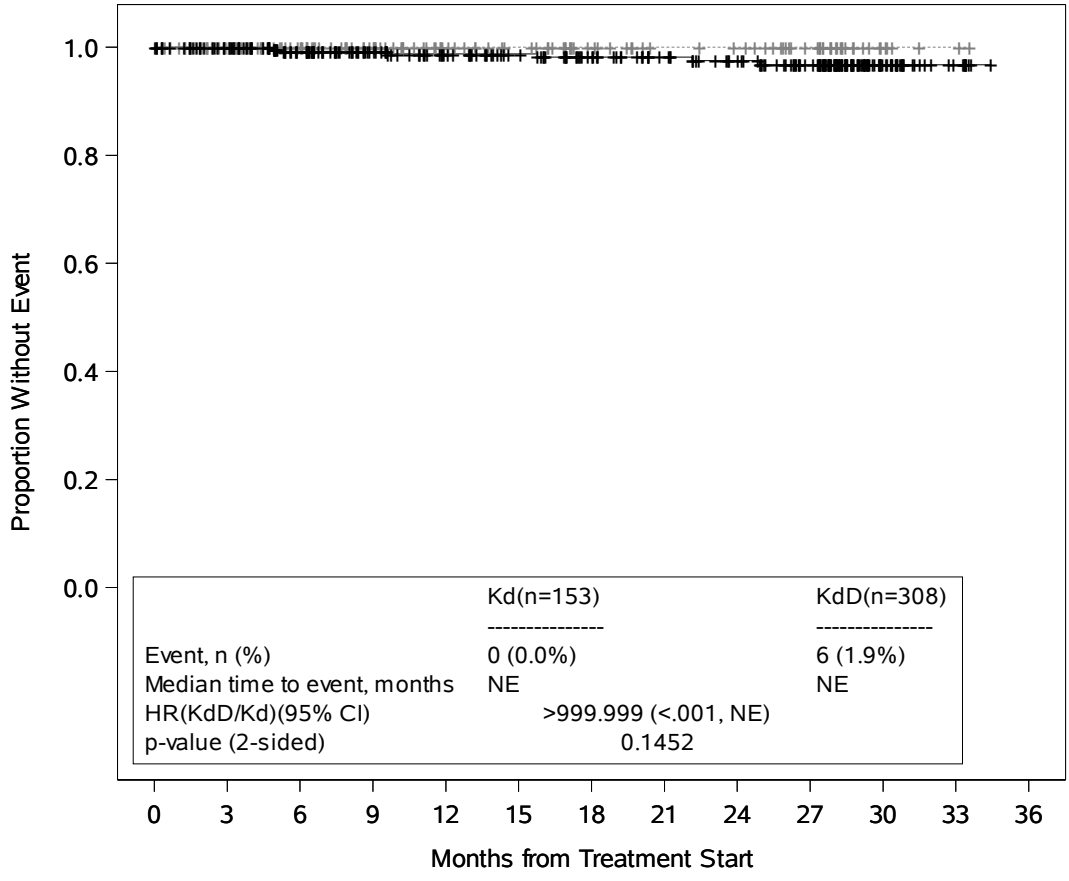


Number of Subjects at Risk:

Kd	153	132	108	88	67	60	47	38	36	27	6	2	0
KdD	308	289	253	214	192	176	158	145	131	110	36	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-011-518-ae-km-eoi-myoca-cfz-grd345.rtf (Date Generated: 16SEP20:19:39:06).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.11.519. KM Curves of Grade ≥3 Adverse Events of Interest for Carfilzomib - Peripheral Neuropathy (SMQ) - Narrow <Safety Population>

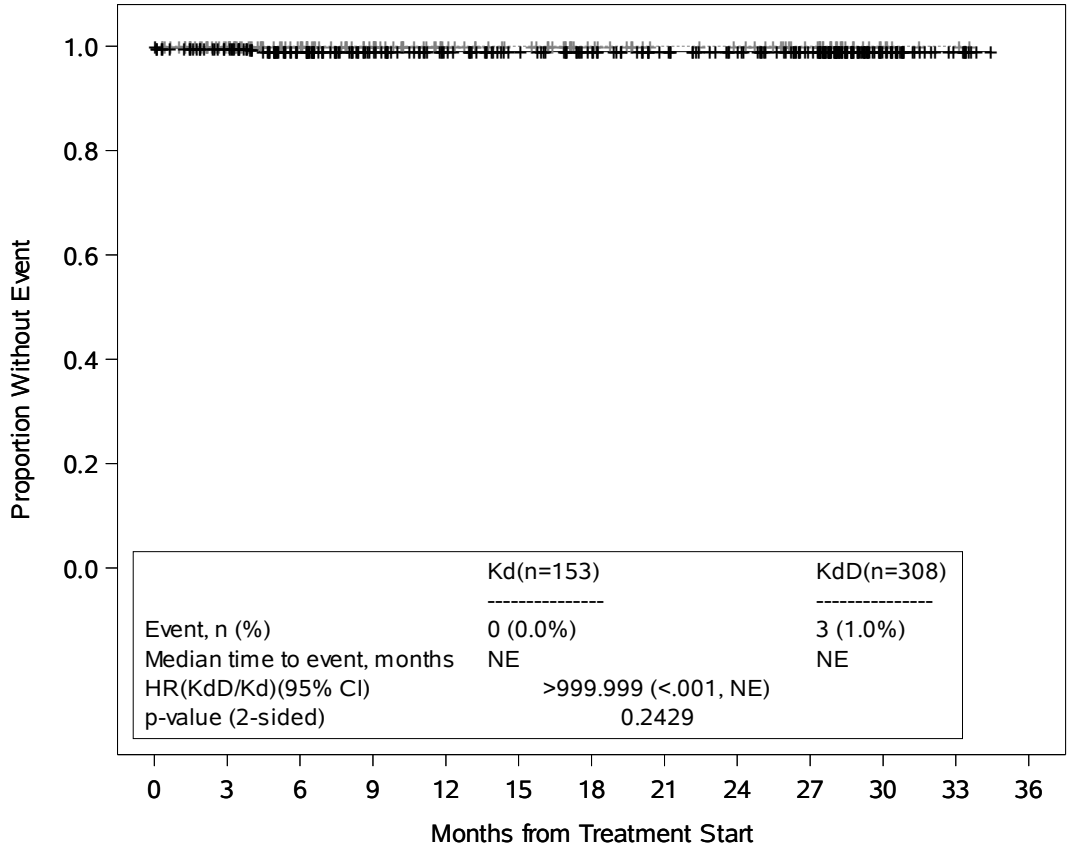


Number of Subjects at Risk:

Kd	153	132	108	88	68	60	47	39	37	27	6	2	0
KdD	308	289	252	213	192	176	159	144	132	110	34	9	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-011-519-ae-km-eoi-perip-cfz-grd345.rtf (Date Generated: 16SEP20:19:39:07).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.11.520. KM Curves of Grade ≥3 Adverse Events of Interest for Carfilzomib - Pulmonary Hypertension (SMQ) - Narrow
<Safety Population>

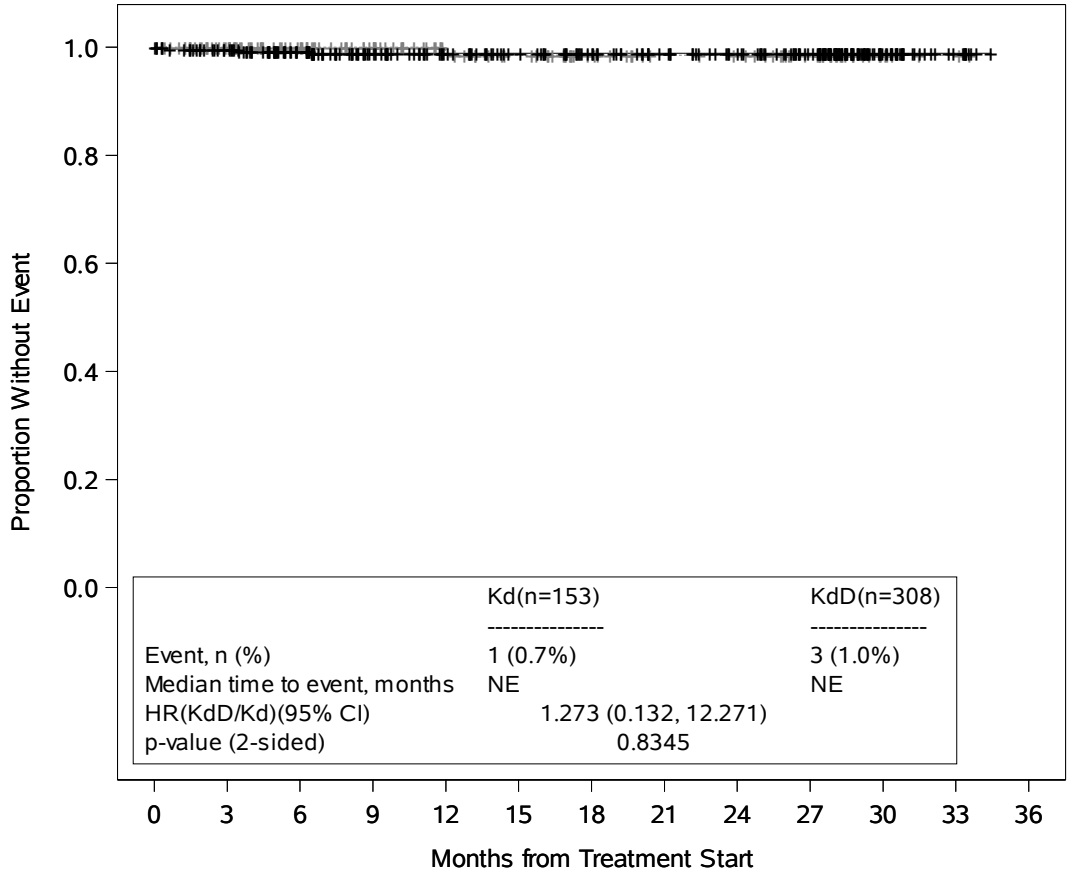


Number of Subjects at Risk:

Kd	153	132	108	88	68	60	47	39	37	27	6	2	0
KdD	308	288	251	212	191	175	160	145	133	111	35	9	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-011-520-ae-km-eoi-pulmo-cfz-grd345.rtf (Date Generated: 16SEP20:19:39:09).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.11.521. KM Curves of Grade ≥3 Adverse Events of Interest for Carfilzomib - Respiratory Failure (SMQ) - Narrow
<Safety Population>

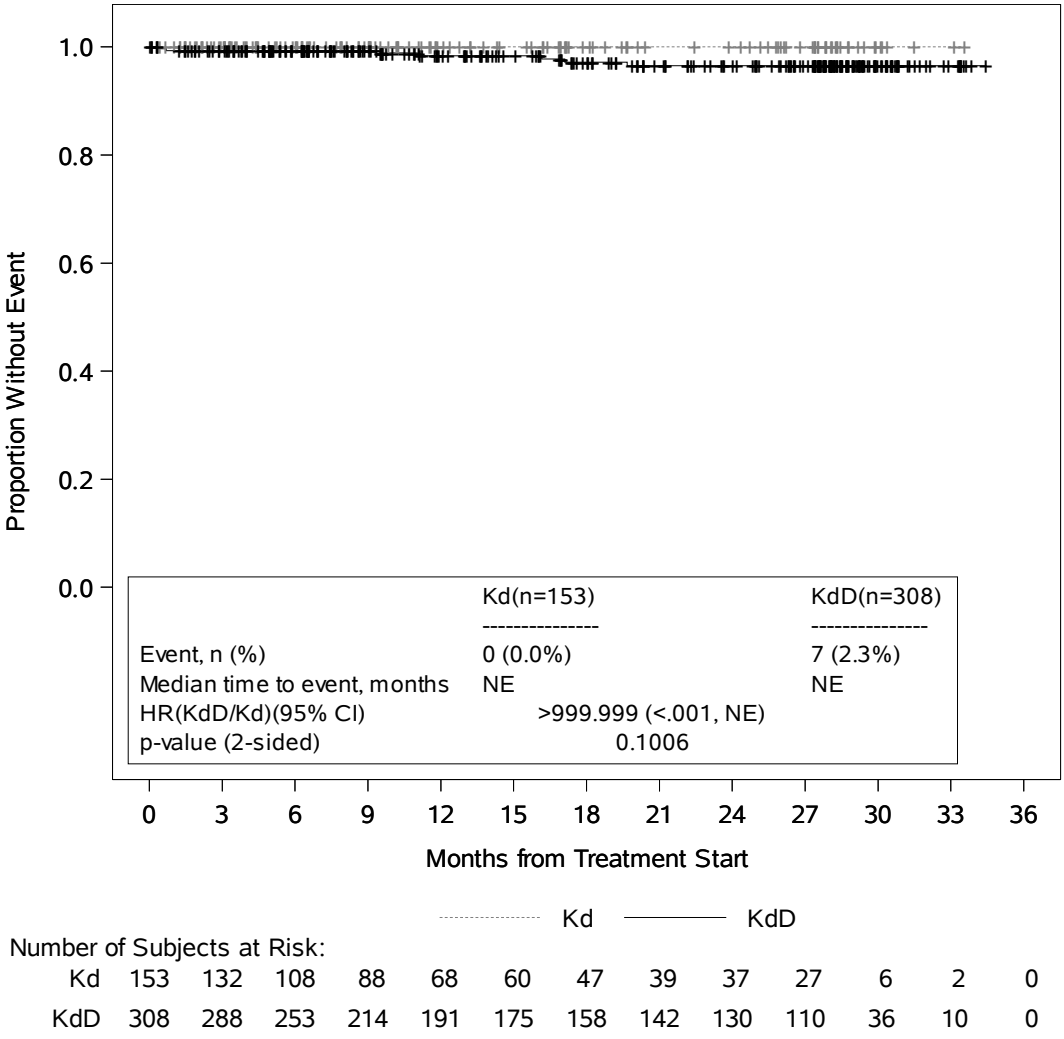


Number of Subjects at Risk:

Kd	153	132	108	88	67	60	47	39	37	27	6	2	0
KdD	308	288	252	214	193	177	161	146	134	112	36	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-011-521-ae-km-eoi-respi-cfz-grd345.rtf (Date Generated: 16SEP20:19:39:10).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.11.523. KM Curves of Grade ≥3 Adverse Events of Interest for Carfilzomib - Reversible Posterior Leukoencephalopathy Syndrome (AMQ) - Narrow
<Safety Population>

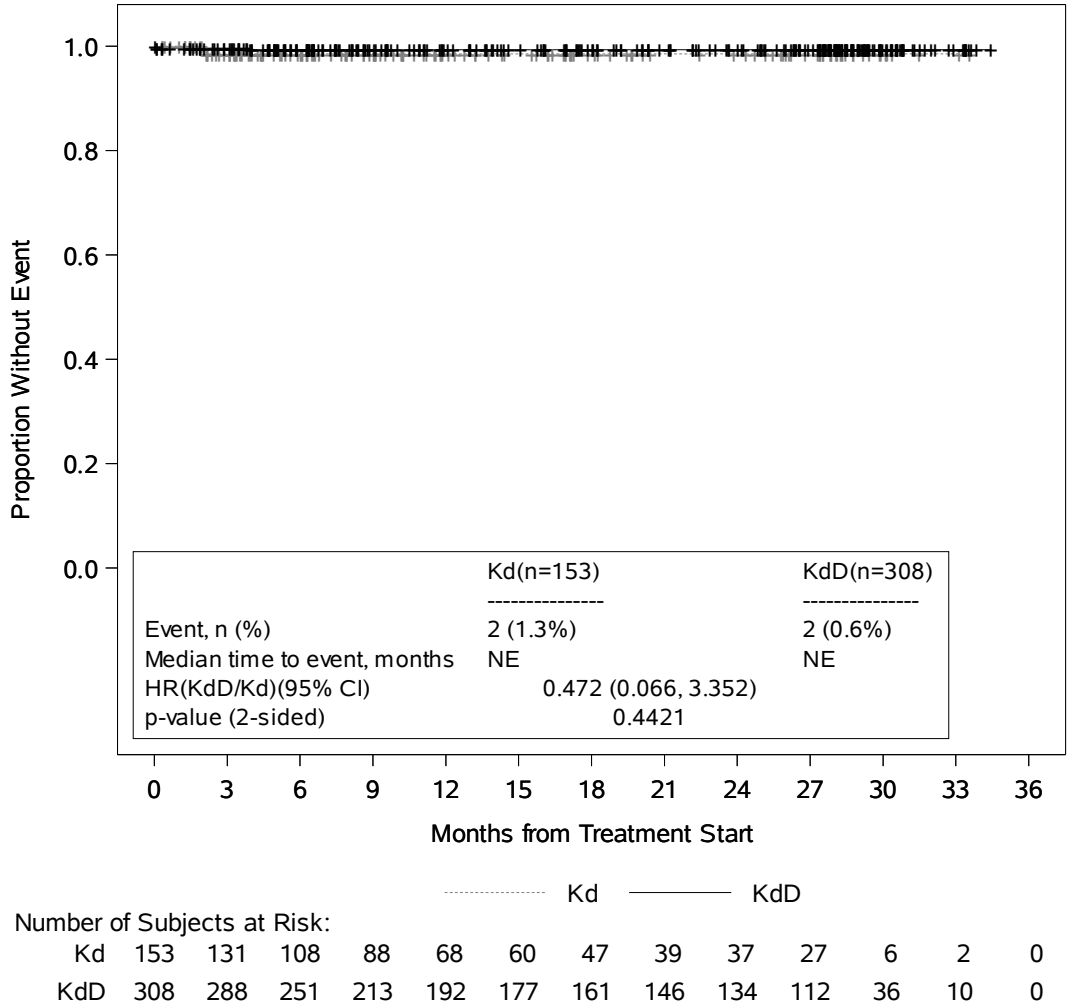


Number of Subjects at Risk:

Kd	153	132	108	88	68	60	47	39	37	27	6	2	0
KdD	308	288	253	214	191	175	158	142	130	110	36	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-011-523-ae-km-eoi-rever-cfz-grd345.rtf (Date Generated: 16SEP20:19:39:13).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.11.524. KM Curves of Grade ≥3 Adverse Events of Interest for Carfilzomib - Thrombotic Microangiopathy (Carfilzomib) (AMQ) - Narrow <Safety Population>

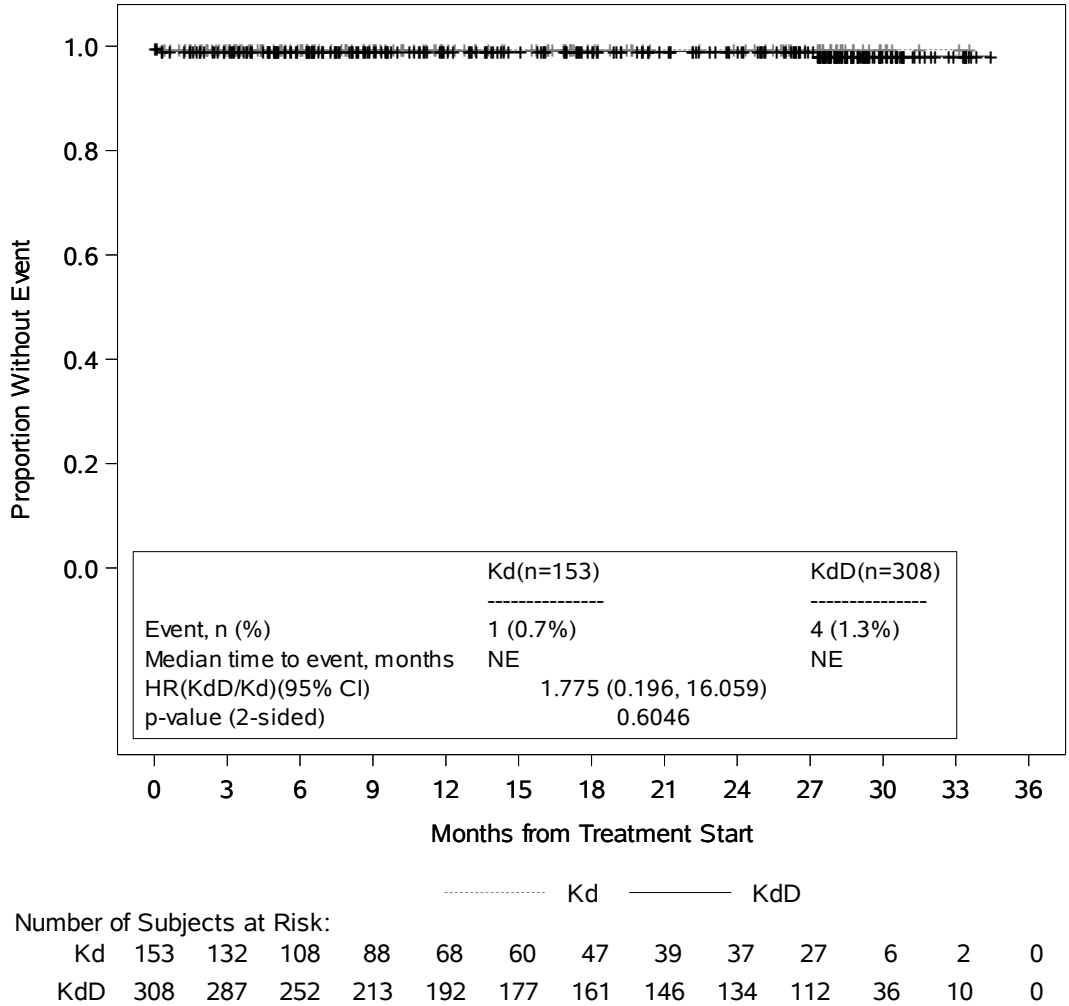


Number of Subjects at Risk:

Kd	153	131	108	88	68	60	47	39	37	27	6	2	0
KdD	308	288	251	213	192	177	161	146	134	112	36	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-011-524-ae-km-eoi-throm-cfz-grd345.rtf (Date Generated: 16SEP20:19:39:15).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.11.525. KM Curves of Grade ≥3 Adverse Events of Interest for Carfilzomib - Tumour Lysis Syndrome (SMQ) - Narrow
<Safety Population>

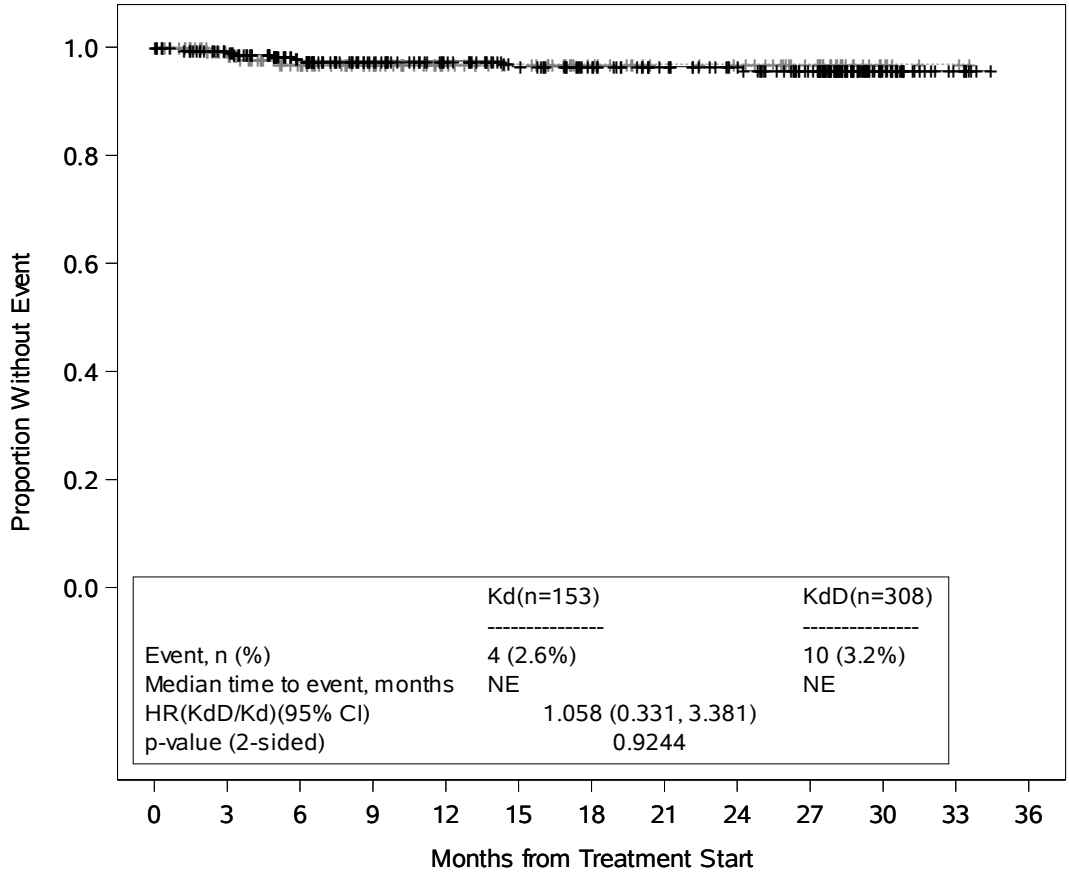


Number of Subjects at Risk:

Kd	153	132	108	88	68	60	47	39	37	27	6	2	0
KdD	308	287	252	213	192	177	161	146	134	112	36	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-011-525-ae-km-eoi-tumou-cfz-grd345.rtf (Date Generated: 16SEP20:19:39:16).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.11.502. KM Curves of Grade ≥3 Adverse Events of Interest for Carfilzomib - Cardiac Arrhythmias (SMQ) - Narrow
<Safety Population>

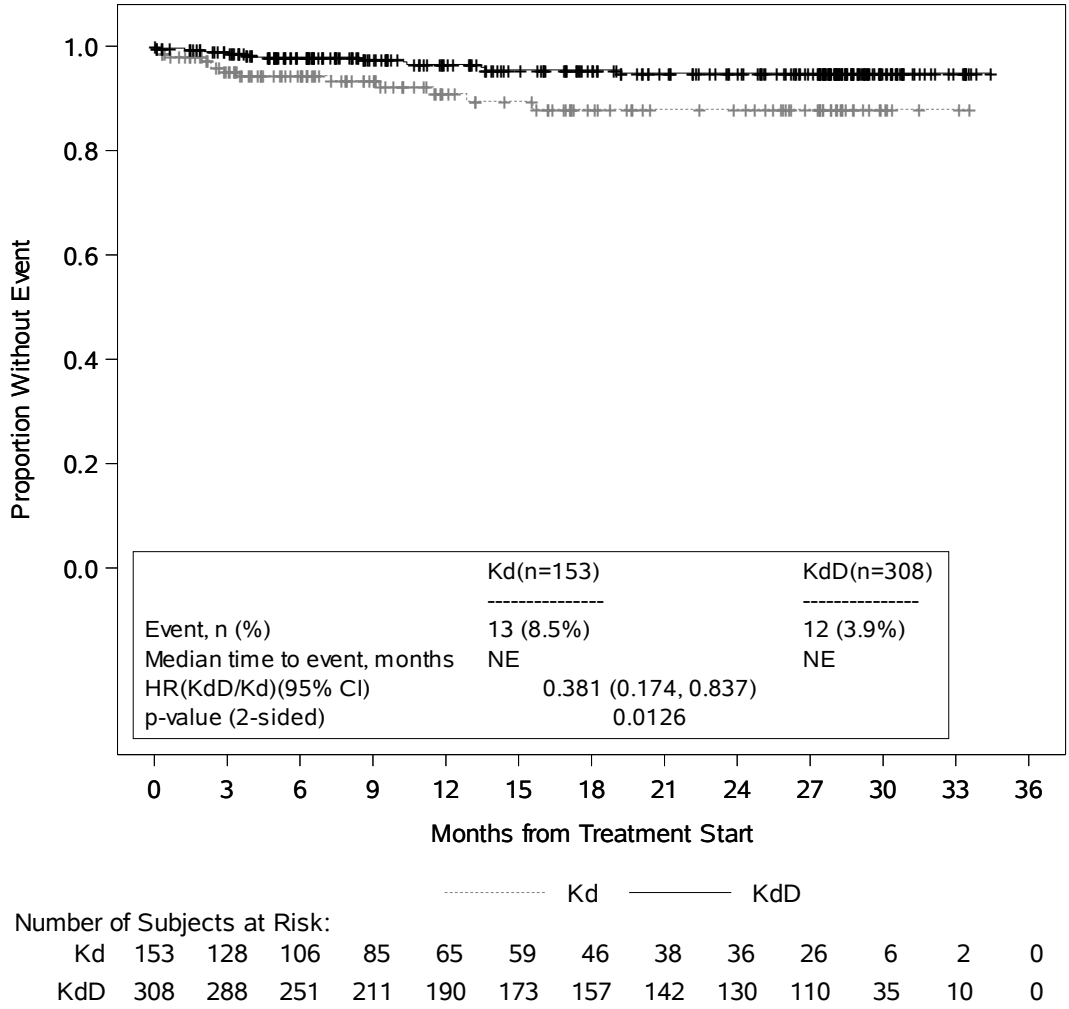


Number of Subjects at Risk:

Kd	153	131	107	88	68	60	47	39	37	27	6	2	0
KdD	308	287	247	210	190	172	156	141	130	110	34	9	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-011-502-ae-km-eoi-cardi-cfz-grd345.rtf (Date Generated: 16SEP20:19:38:41).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.11.503. KM Curves of Grade ≥3 Adverse Events of Interest for Carfilzomib - Cardiac Failure (SMQ) - Narrow
<Safety Population>

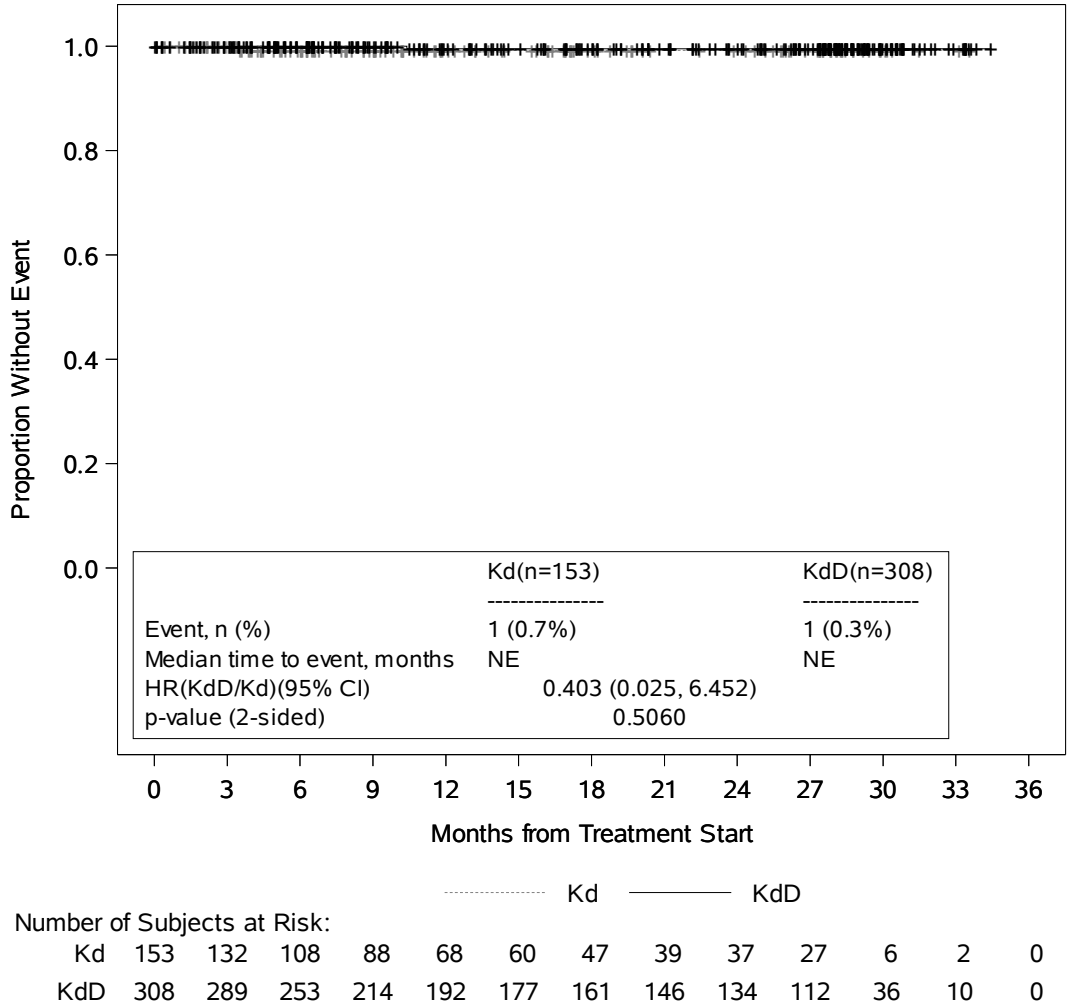


Number of Subjects at Risk:

Kd	153	128	106	85	65	59	46	38	36	26	6	2	0
KdD	308	288	251	211	190	173	157	142	130	110	35	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-011-503-ae-km-eoi-carfai-cfz-grd345.rtf (Date Generated: 16SEP20:19:38:42).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.11.504. KM Curves of Grade ≥3 Adverse Events of Interest for Carfilzomib - Cardiomyopathy (SMQ) - Narrow
<Safety Population>

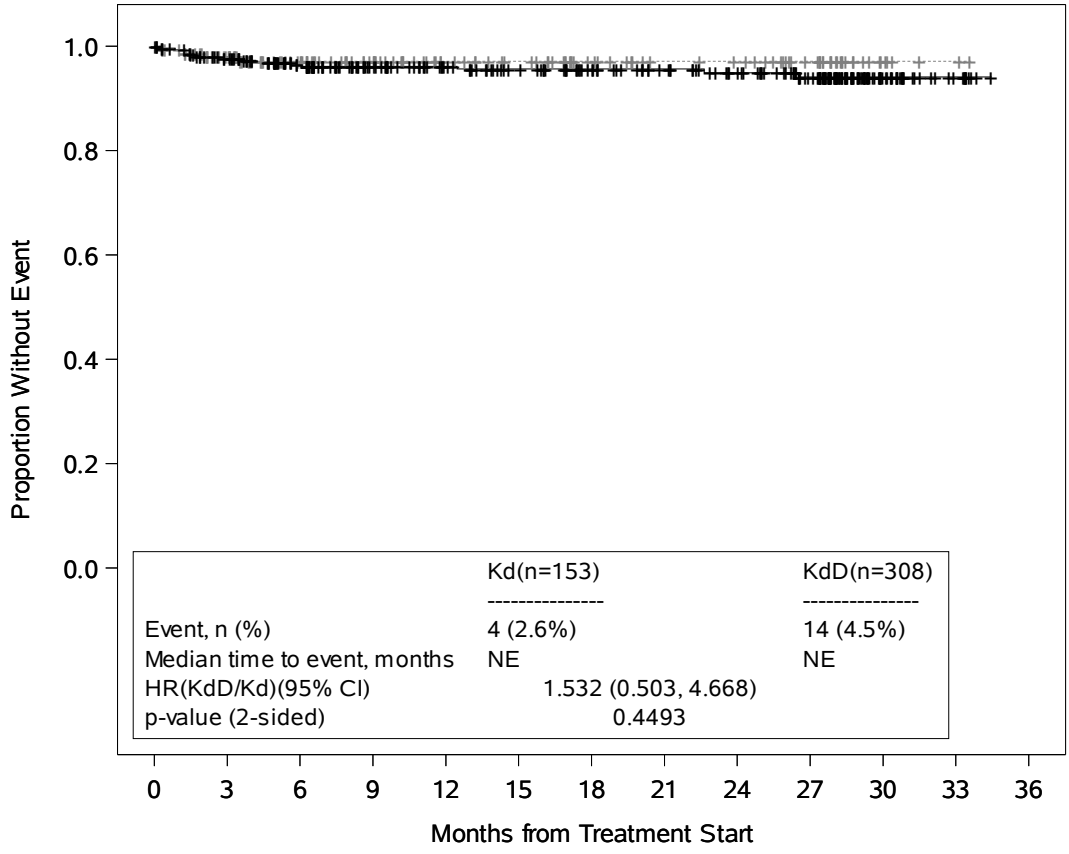


Number of Subjects at Risk:

Kd	153	132	108	88	68	60	47	39	37	27	6	2	0
KdD	308	289	253	214	192	177	161	146	134	112	36	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-011-504-ae-km-eoi-cardio-cfz-grd345.rtf (Date Generated: 16SEP20:19:38:44).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.11.505. KM Curves of Grade ≥3 Adverse Events of Interest for Carfilzomib - Dyspnoeas (HLT)
<Safety Population>

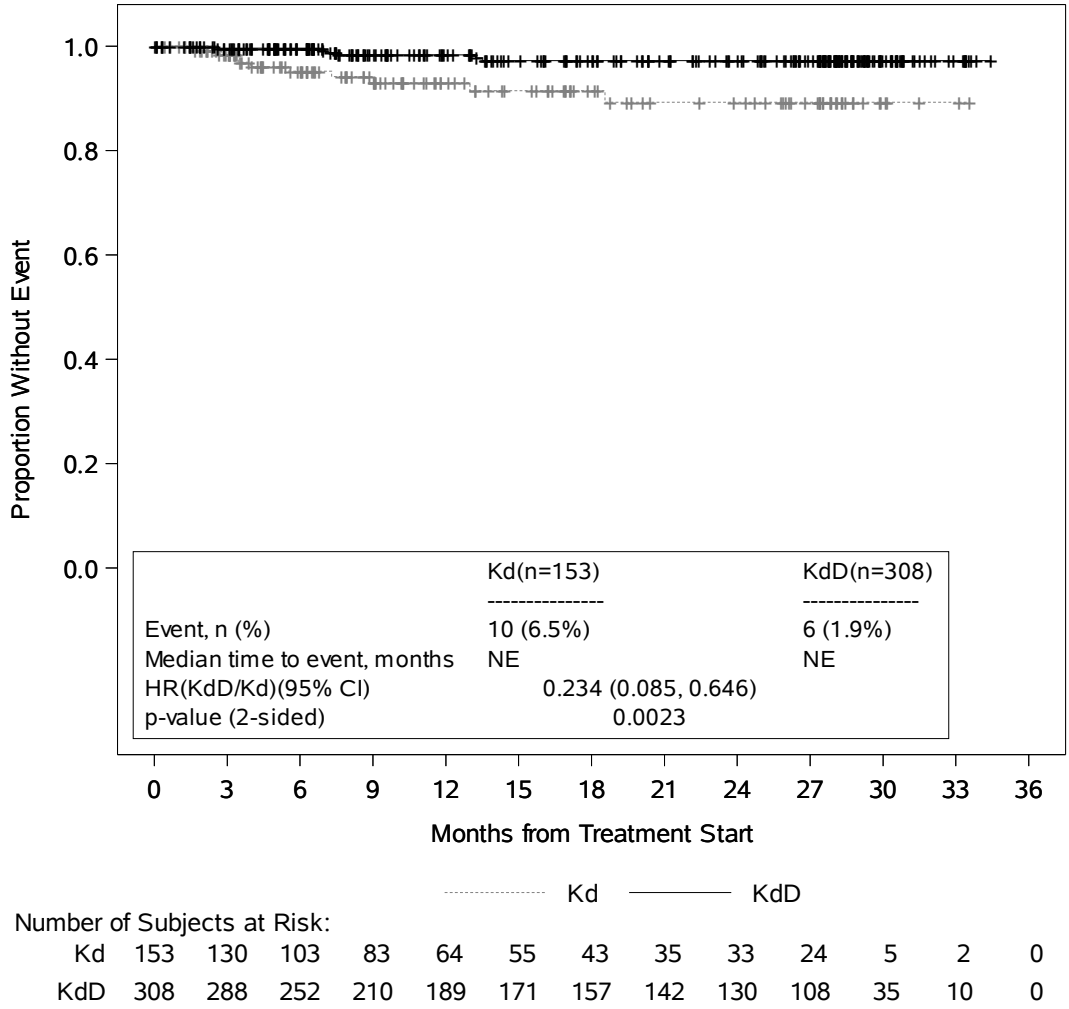


Number of Subjects at Risk:

Kd	153	130	106	86	67	60	47	39	37	27	6	2	0
KdD	308	282	247	208	187	172	156	143	130	108	33	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-011-505-ae-km-eoi-dyspn-cfz-grd345.rtf (Date Generated: 16SEP20:19:38:45).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.11.506. KM Curves of Grade ≥3 Adverse Events of Interest for Carfilzomib - Embolic and Thrombotic Events, Venous (SMQ) - Narrow <Safety Population>

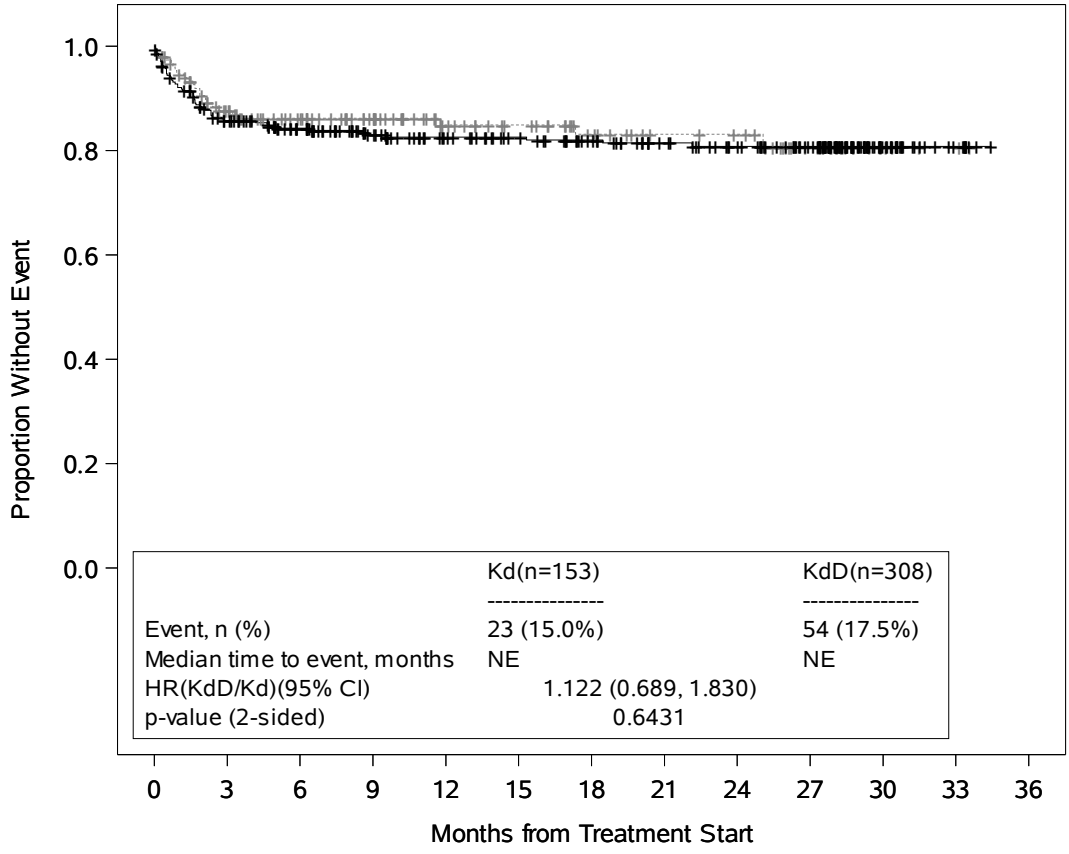


Number of Subjects at Risk:

Kd	153	130	103	83	64	55	43	35	33	24	5	2	0
KdD	308	288	252	210	189	171	157	142	130	108	35	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-011-506-ae-km-eoi-embol-cfz-grd345.rtf (Date Generated: 16SEP20:19:38:47).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.11.507. KM Curves of Grade ≥3 Adverse Events of Interest for Carfilzomib - Haematopoietic Erythropenia (SMQ) - Broad
<Safety Population>

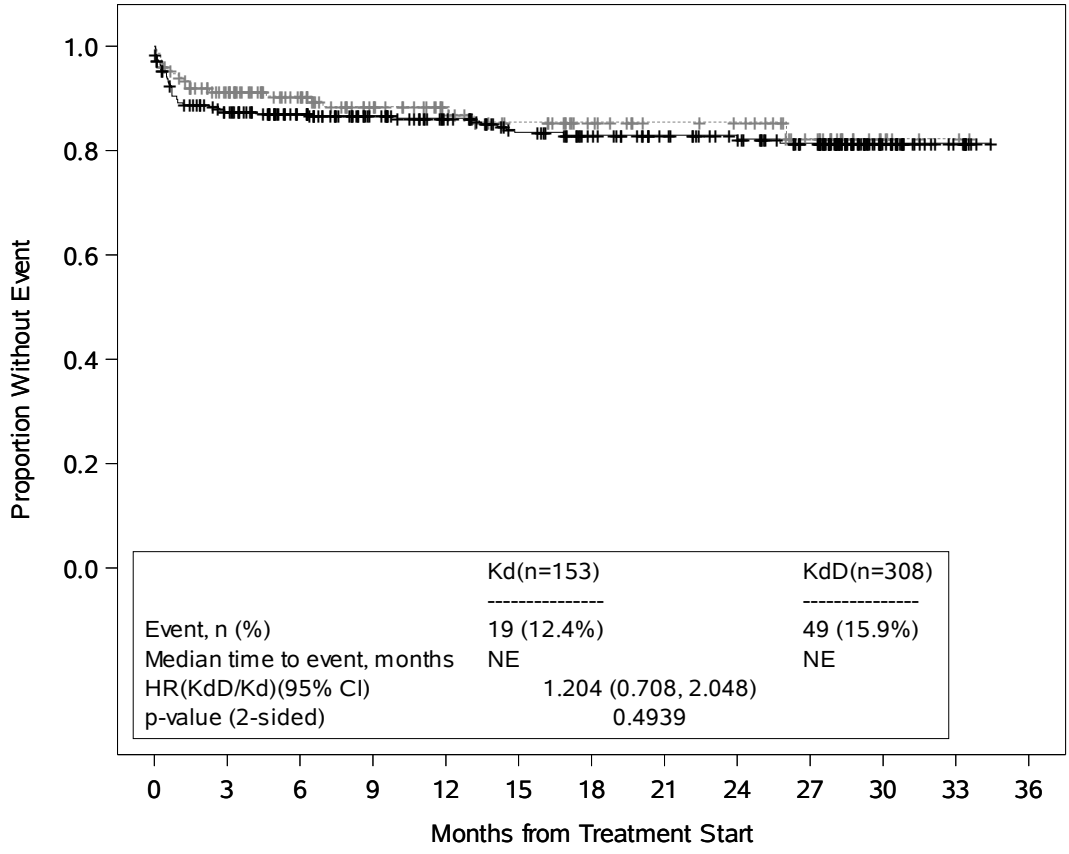


Number of Subjects at Risk:

Kd	153	119	102	85	64	56	45	38	36	25	5	2	0
KdD	308	249	220	189	169	157	143	128	117	99	31	9	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-011-507-ae-km-eoi-haema-cfz-grd345.rtf (Date Generated: 16SEP20:19:38:48).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.11.508. KM Curves of Grade ≥3 Adverse Events of Interest for Carfilzomib - Haematopoietic Leukopenia (SMQ) - Narrow <Safety Population>

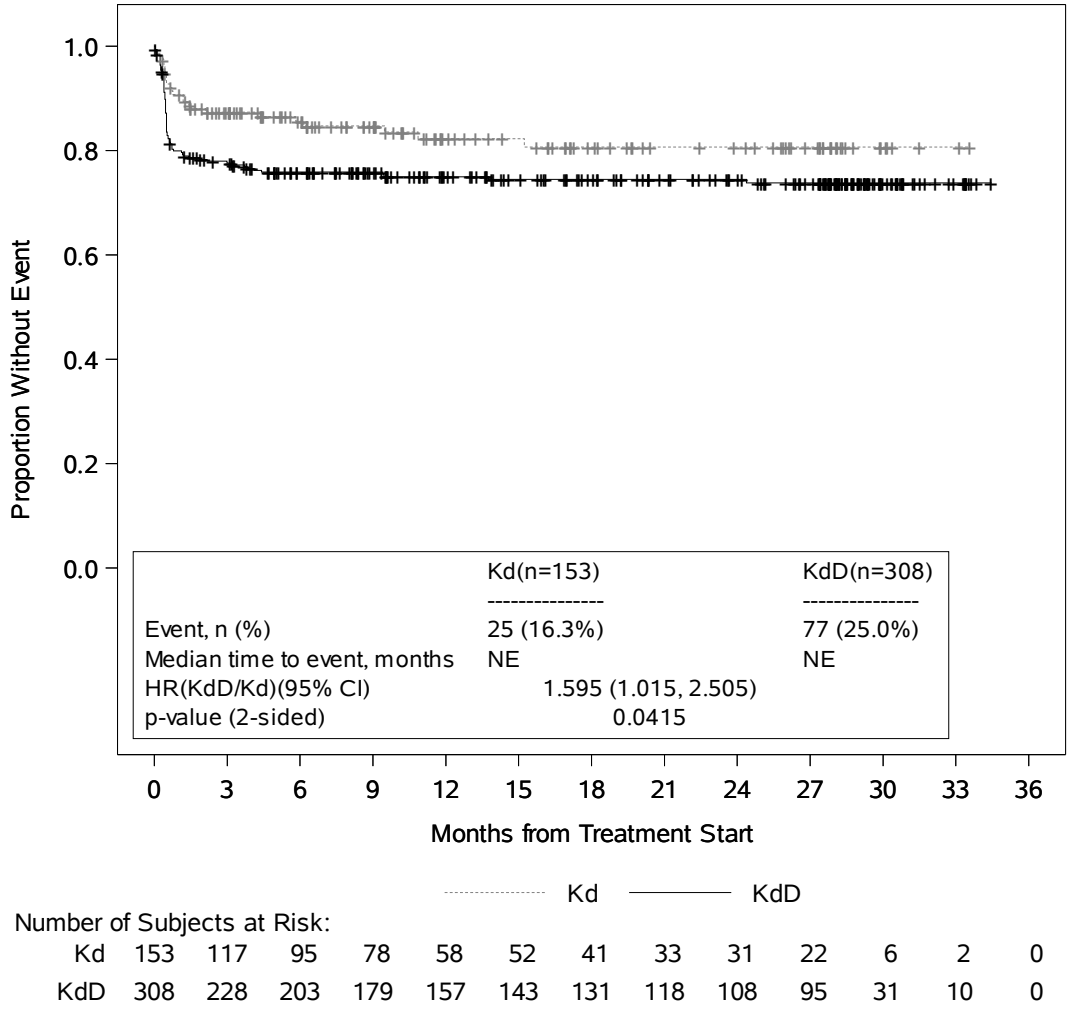


Number of Subjects at Risk:

Kd	153	122	98	76	62	52	42	35	33	22	6	2	0
KdD	308	253	221	191	171	151	137	124	114	98	35	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-011-508-ae-km-eoi-haeleu-cfz-grd345.rtf (Date Generated: 16SEP20:19:38:50).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.11.509. KM Curves of Grade ≥3 Adverse Events of Interest for Carfilzomib - Haematopoietic Thrombocytopenia (SMQ) - Narrow <Safety Population>

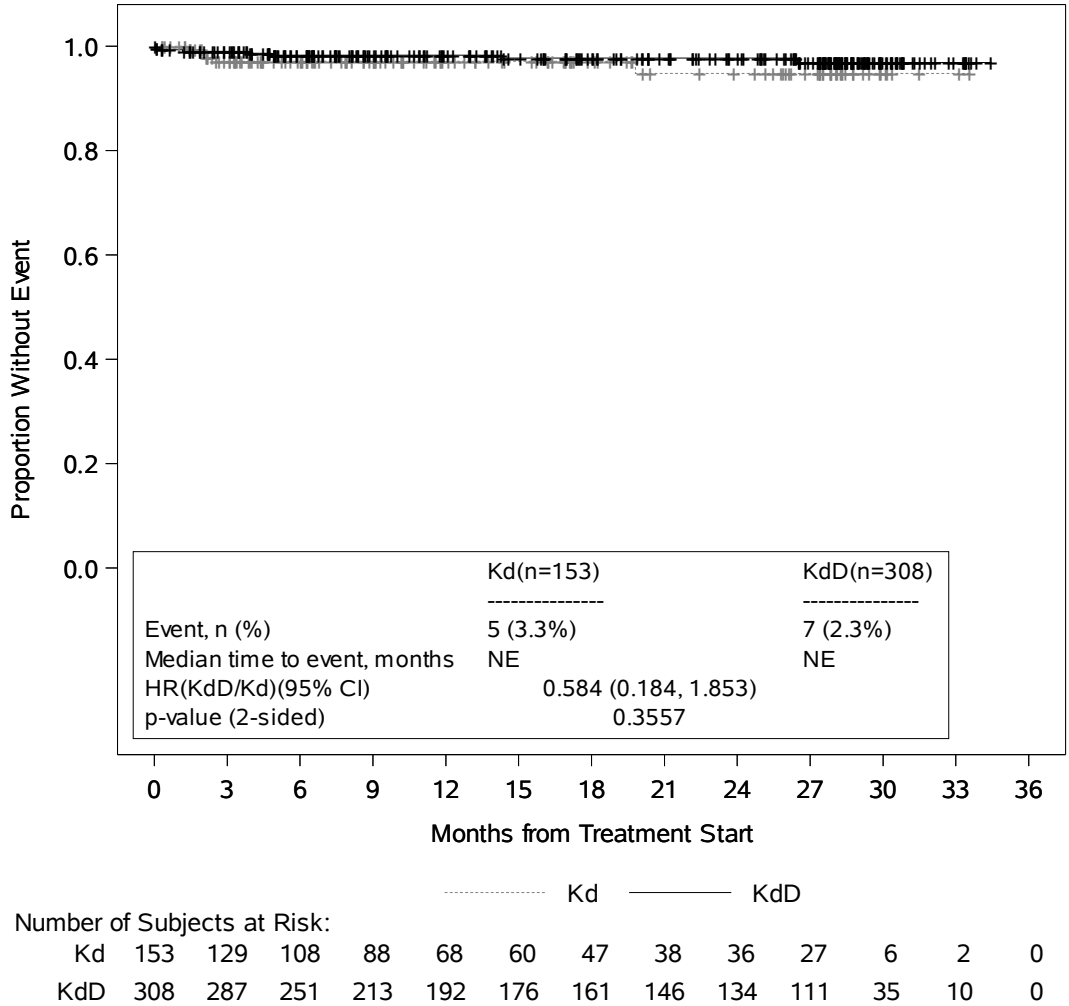


Number of Subjects at Risk:

Kd	153	117	95	78	58	52	41	33	31	22	6	2	0
KdD	308	228	203	179	157	143	131	118	108	95	31	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-011-509-ae-km-eoi-haethr-cfz-grd345.rtf (Date Generated: 16SEP20:19:38:52).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.11.510. KM Curves of Grade ≥3 Adverse Events of Interest for Carfilzomib - Haemorrhage Terms (Excl Laboratory Terms) (SMQ) - Narrow <Safety Population>

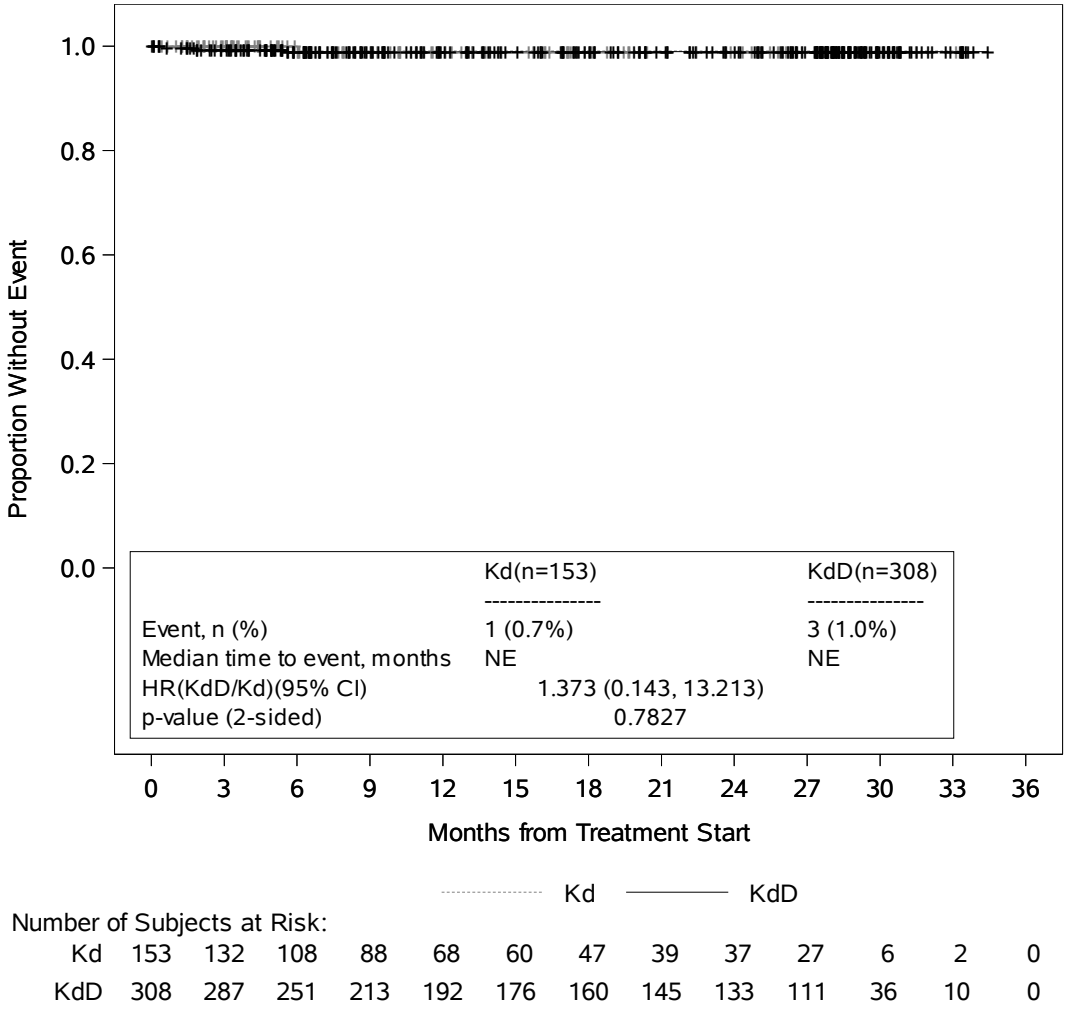


Number of Subjects at Risk:

Kd	153	129	108	88	68	60	47	38	36	27	6	2	0
KdD	308	287	251	213	192	176	161	146	134	111	35	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-011-510-ae-km-eoi-haeter-cfz-grd345.rtf (Date Generated: 16SEP20:19:38:53).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.11.511. KM Curves of Grade ≥3 Adverse Events of Interest for Carfilzomib - Hepatic Failure, Fibrosis and Cirrhosis and Other Liver Damage-related Conditions (SMQ) - Narrow
<Safety Population>

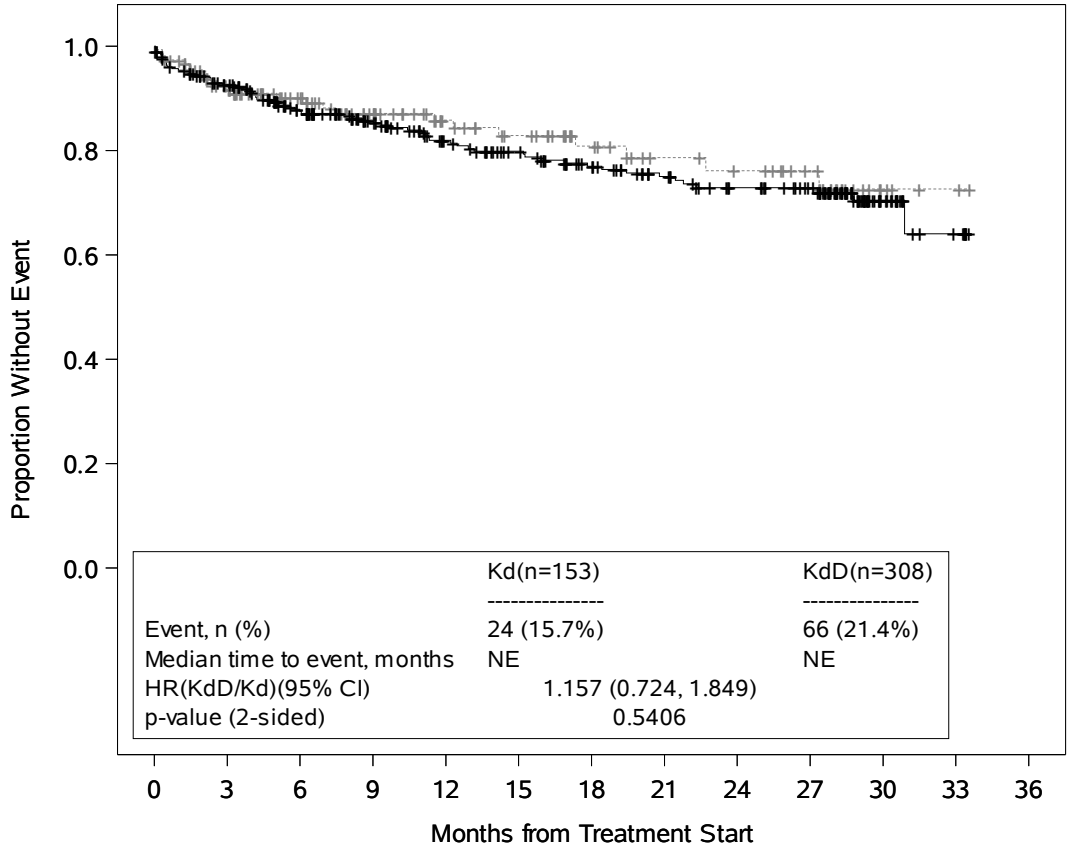


Number of Subjects at Risk:

Kd	153	132	108	88	68	60	47	39	37	27	6	2	0
KdD	308	287	251	213	192	176	160	145	133	111	36	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-011-511-ae-km-eoi-hepac-cfz-grd345.rtf (Date Generated: 16SEP20:19:38:55).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.11.512. KM Curves of Grade ≥3 Adverse Events of Interest for Carfilzomib - Hypertension (SMQ) - Narrow
<Safety Population>

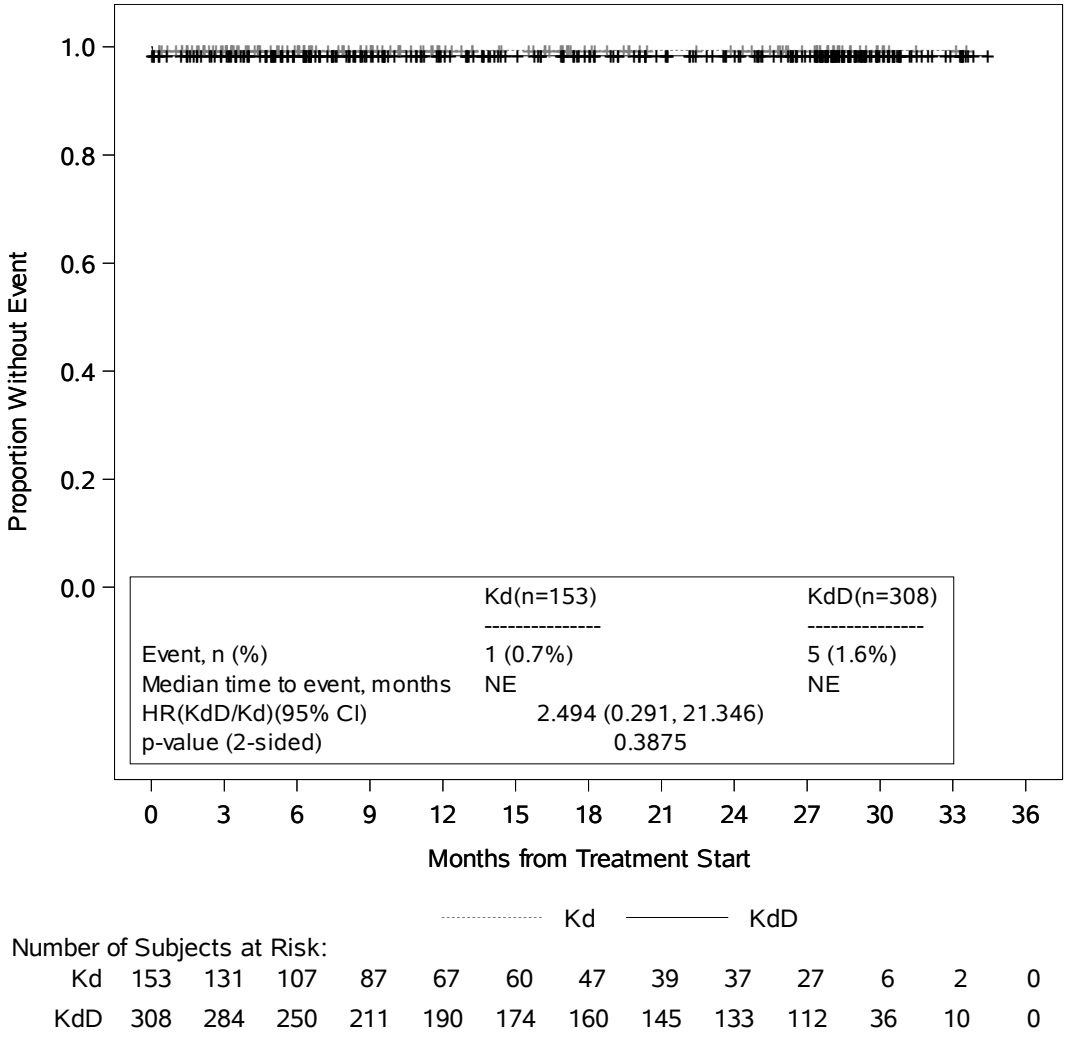


Number of Subjects at Risk:

Kd	153	124	99	78	60	52	40	32	29	23	5	2	0
KdD	308	267	225	188	159	143	125	109	96	86	24	7	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-011-512-ae-km-eoi-hyper-cfz-grd345.rtf (Date Generated: 16SEP20:19:38:56).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.11.514. KM Curves of Grade ≥3 Adverse Events of Interest for Carfilzomib - Infusion Reaction (AMQ) - Narrow (Event on Same Date of First Carfilzomib Dosing)
<Safety Population>

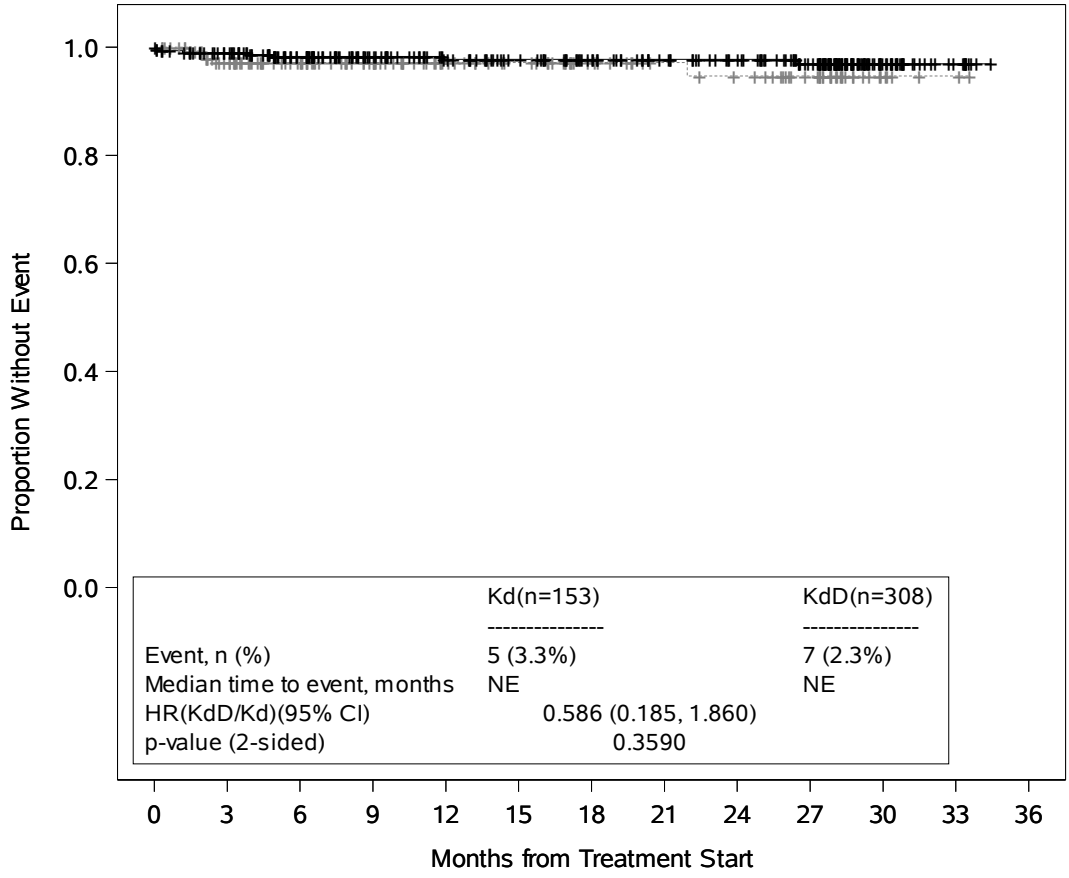


Number of Subjects at Risk:

Kd	153	131	107	87	67	60	47	39	37	27	6	2	0
KdD	308	284	250	211	190	174	160	145	133	112	36	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-011-514-ae-km-eoi-inffir-cfz-grd345.rtf (Date Generated: 16SEP20:19:38:59).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.12.510. KM Curves of Serious Adverse Events of Interest for Carfilzomib - Haemorrhage Terms (Excl Laboratory Terms) (SMQ) - Narrow <Safety Population>

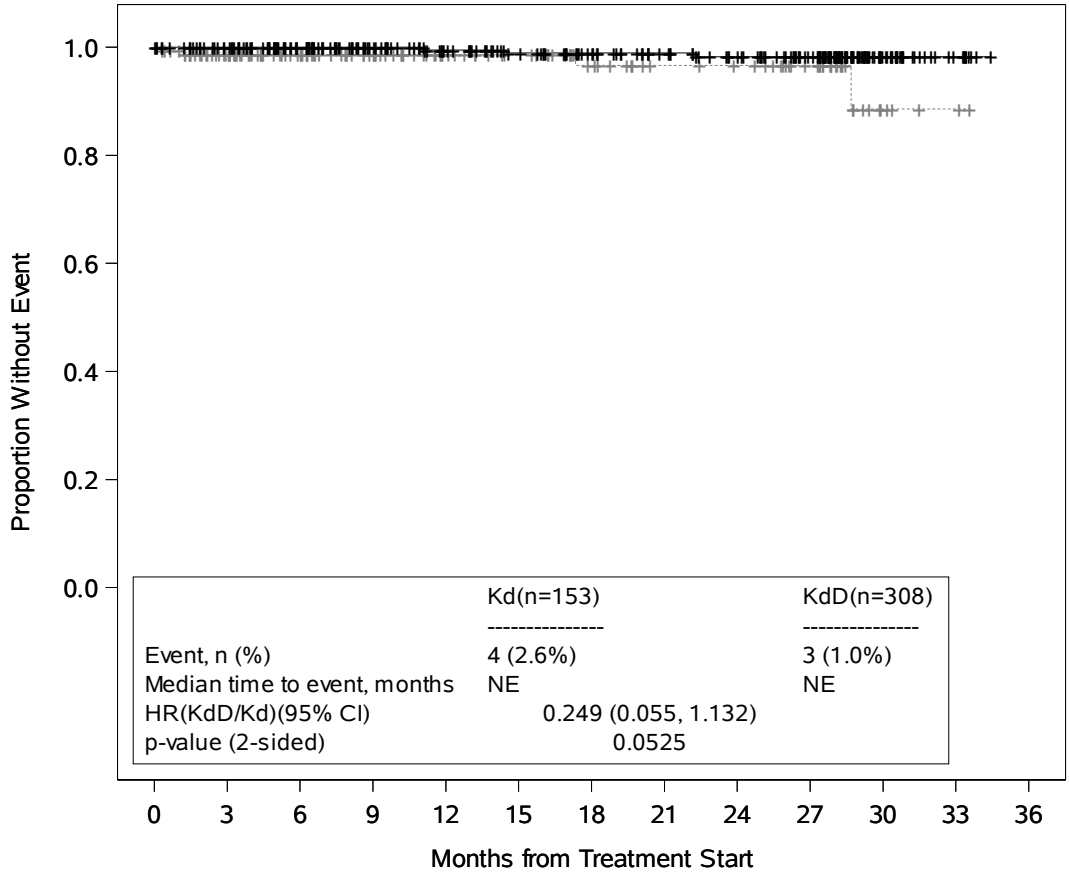


Number of Subjects at Risk:

Kd	153	129	108	88	68	60	47	39	36	27	6	2	0
KdD	308	287	251	213	191	176	160	145	133	110	35	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-012-510-sae-km-eoi-haeter-cfz.rtf (Date Generated: 16SEP20:19:39:32).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.12.511. KM Curves of Serious Adverse Events of Interest for Carfilzomib - Hypertension (SMQ) - Narrow
<Safety Population>

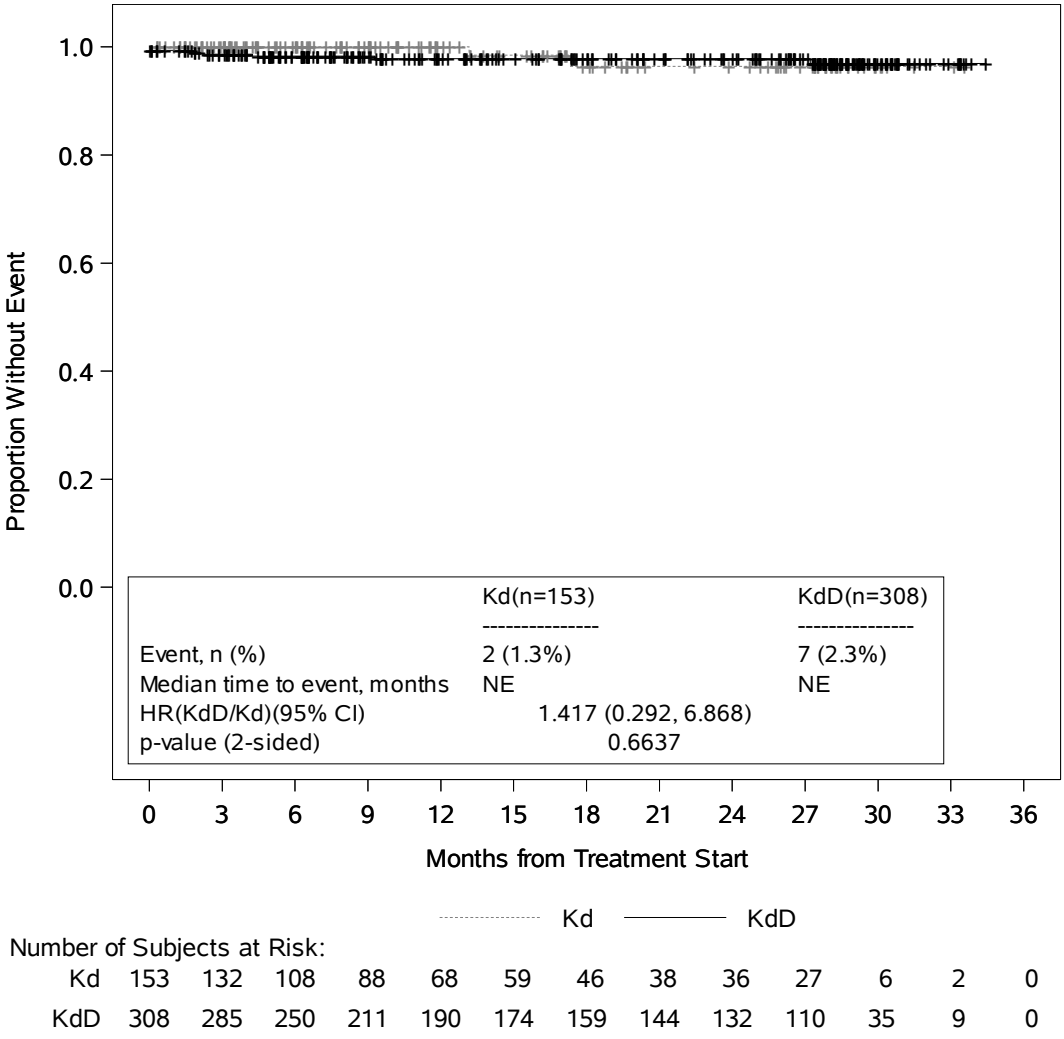


Number of Subjects at Risk:

Kd	153	132	108	88	68	60	46	38	36	27	5	2	0
KdD	308	289	253	214	192	175	160	145	133	111	35	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-012-511-sae-km-eoi-hyper-cfz.rtf (Date Generated: 16SEP20:19:39:33).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.12.512. KM Curves of Serious Adverse Events of Interest for Carfilzomib - Infusion Reaction (AMQ) - Narrow (Event on Same Date of Any Carfilzomib Dosing)
<Safety Population>

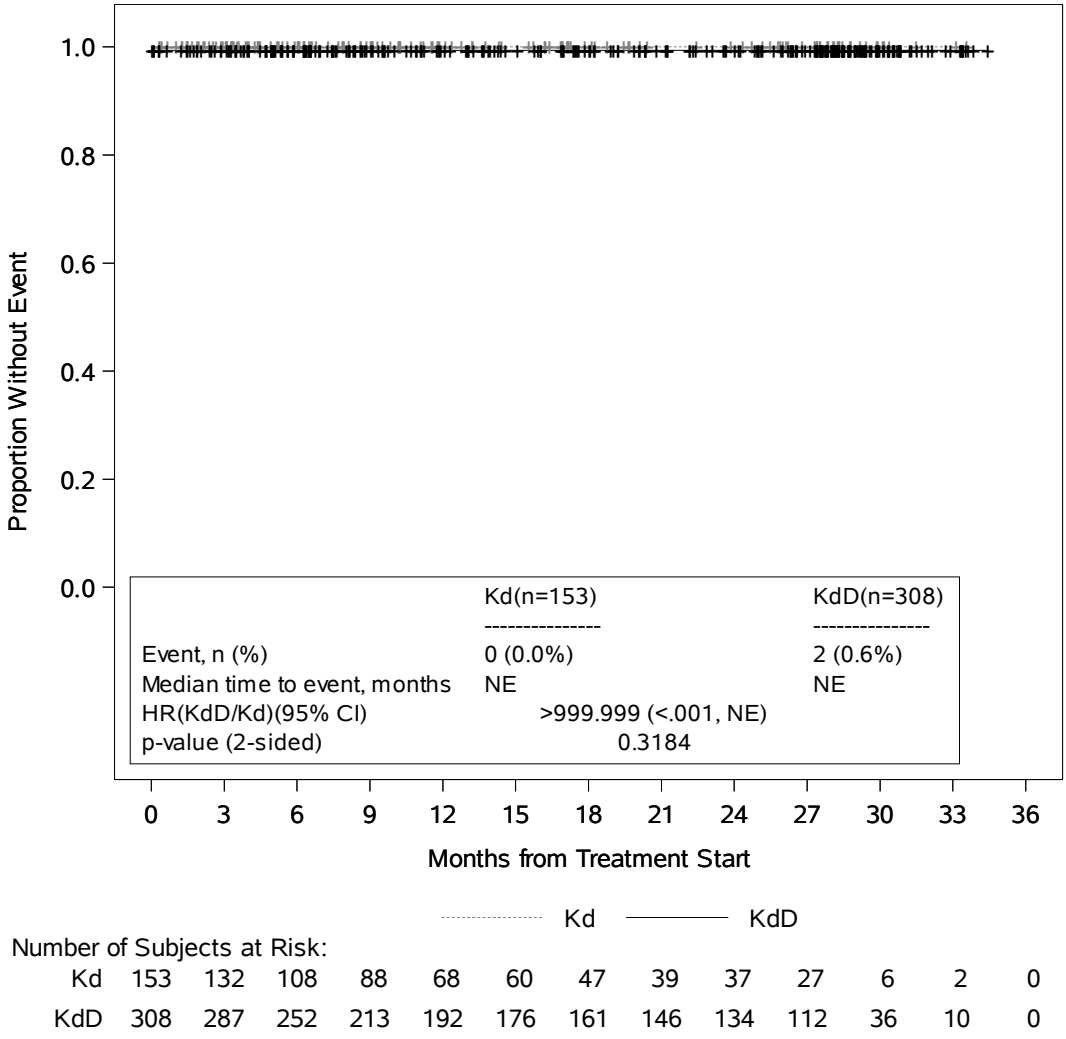


Number of Subjects at Risk:

Kd	153	132	108	88	68	59	46	38	36	27	6	2	0
KdD	308	285	250	211	190	174	159	144	132	110	35	9	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-012-512-sae-km-eoi-infany-cfz.rtf (Date Generated: 16SEP20:19:39:35).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.12.513. KM Curves of Serious Adverse Events of Interest for Carfilzomib - Infusion Reaction (AMQ) - Narrow (Event on Same Date of First Carfilzomib Dosing)
<Safety Population>

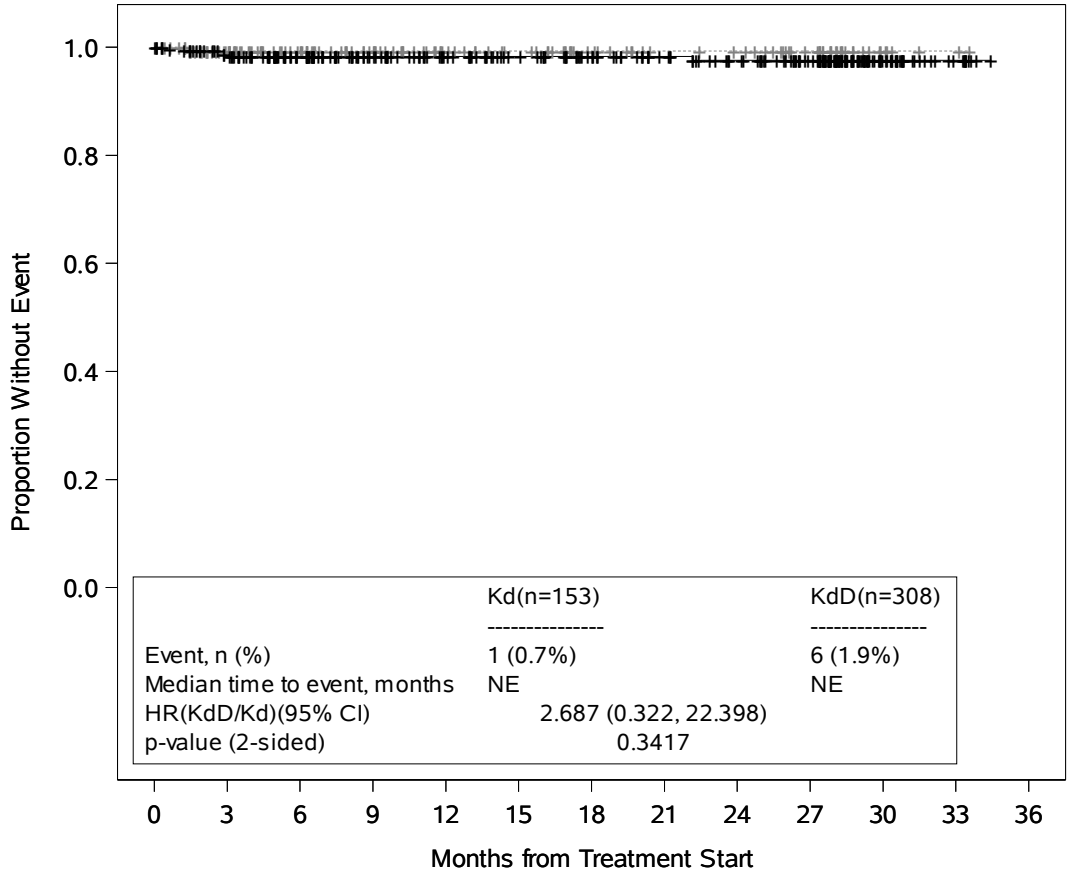


Number of Subjects at Risk:

Kd	153	132	108	88	68	60	47	39	37	27	6	2	0
KdD	308	287	252	213	192	176	161	146	134	112	36	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-012-513-sae-km-eoi-inffir-cfz.rtf (Date Generated: 16SEP20:19:39:36).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.12.514. KM Curves of Serious Adverse Events of Interest for Carfilzomib - Interstitial Lung Disease (SMQ) - Narrow
<Safety Population>

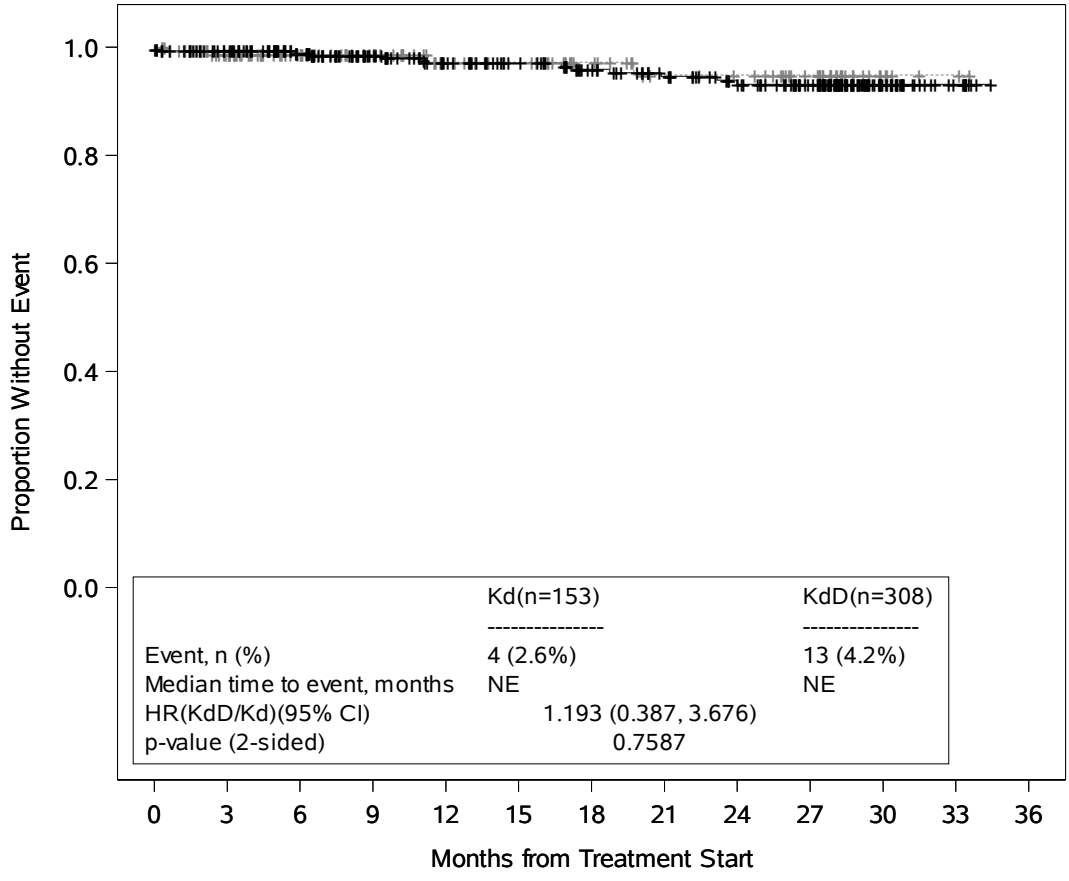


Number of Subjects at Risk:

Kd	153	131	107	87	68	60	47	39	37	27	6	2	0
KdD	308	284	249	212	191	175	159	144	131	110	36	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-012-514-sae-km-eoi-inter-cfz.rtf (Date Generated: 16SEP20:19:39:38).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.12.515. KM Curves of Serious Adverse Events of Interest for Carfilzomib - Ischaemic Heart Disease (SMQ) - Narrow <Safety Population>

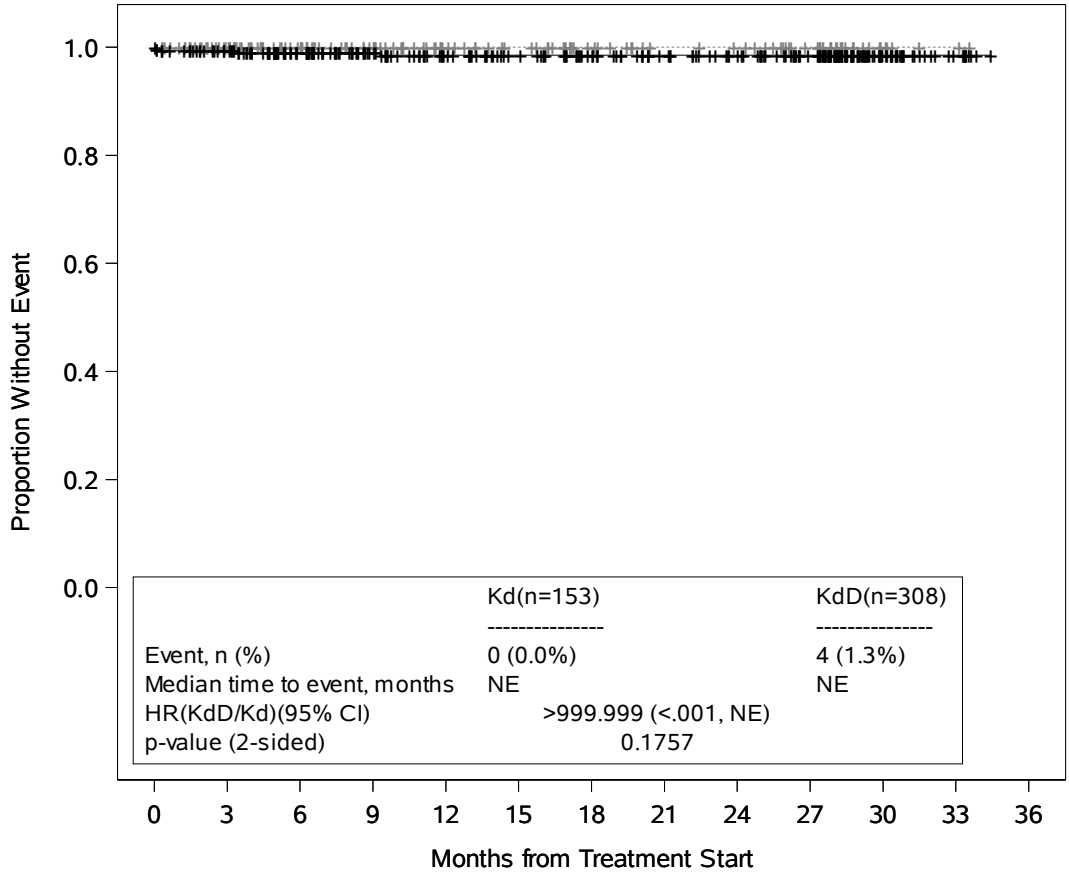


Number of Subjects at Risk:

Kd	153	130	106	86	66	59	47	38	36	27	6	2	0
KdD	308	287	251	212	189	174	156	141	127	107	36	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-012-515-sae-km-eoi-ischa-cfz.rtf (Date Generated: 16SEP20:19:39:39).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.12.516. KM Curves of Serious Adverse Events of Interest for Carfilzomib - Liver Related Investigations, Signs and Symptoms (SMQ) - Narrow <Safety Population>

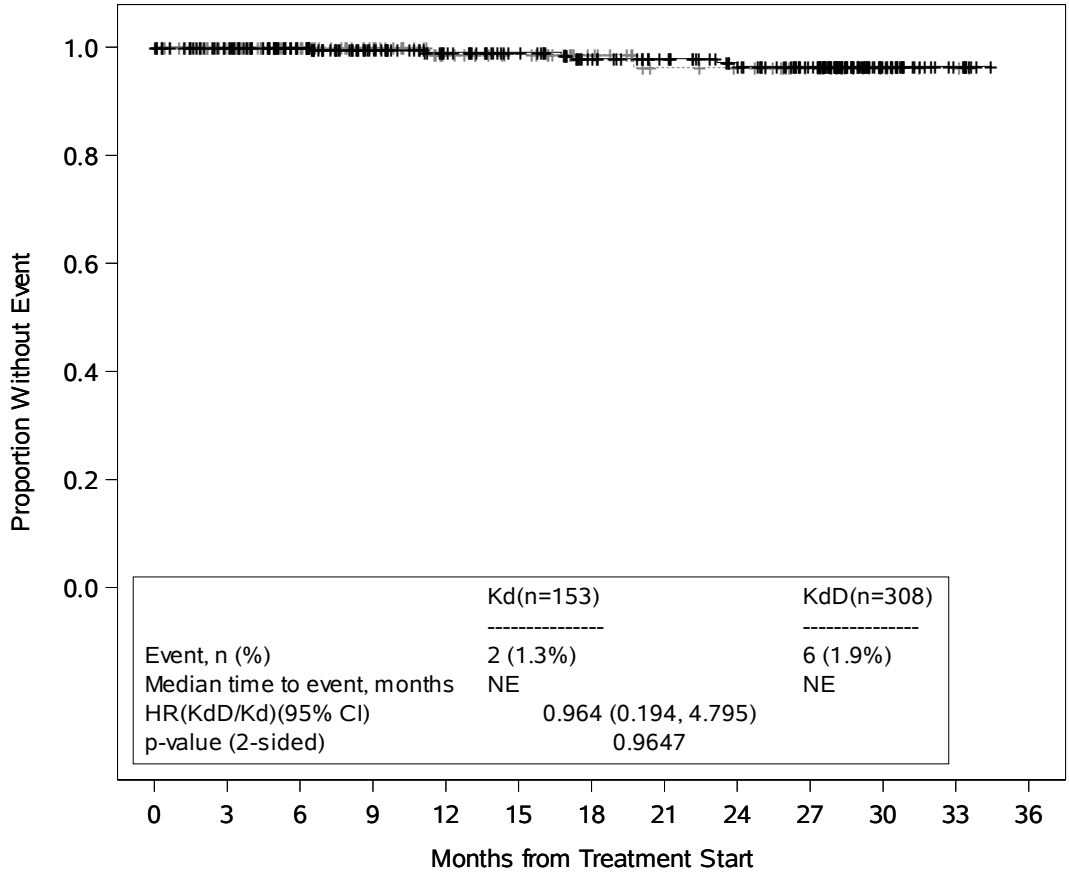


Number of Subjects at Risk:

Kd	153	132	108	88	68	60	47	39	37	27	6	2	0
KdD	308	287	251	212	190	174	158	143	131	110	36	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-012-516-sae-km-eoi-liver-cfz.rtf (Date Generated: 16SEP20:19:39:41).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.12.517. KM Curves of Serious Adverse Events of Interest for Carfilzomib - Myocardial Infarction (SMQ) - Narrow
<Safety Population>

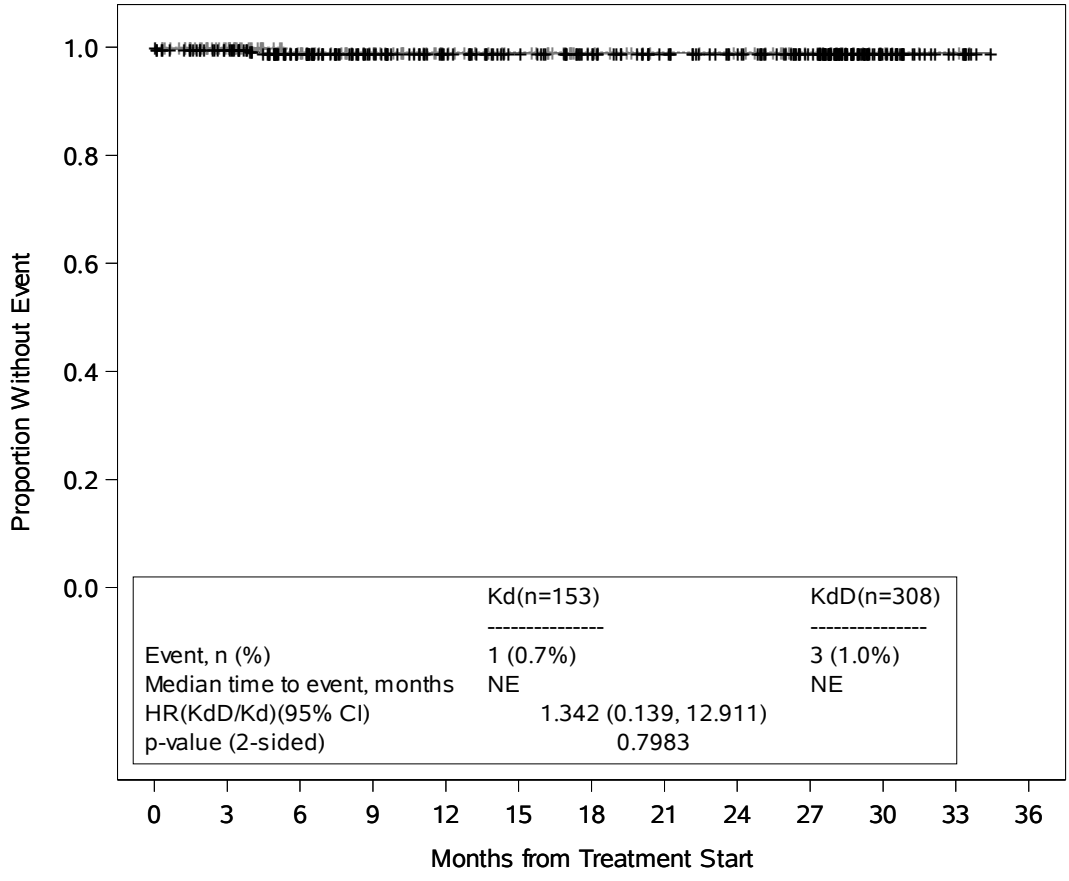


Number of Subjects at Risk:

Kd	153	132	108	88	67	60	47	38	36	27	6	2	0
KdD	308	289	253	214	192	176	158	145	131	110	36	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-012-517-sae-km-eoi-myoca-cfz.rtf (Date Generated: 16SEP20:19:39:42).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.12.518. KM Curves of Serious Adverse Events of Interest for Carfilzomib - Pulmonary Hypertension (SMQ) - Narrow <Safety Population>

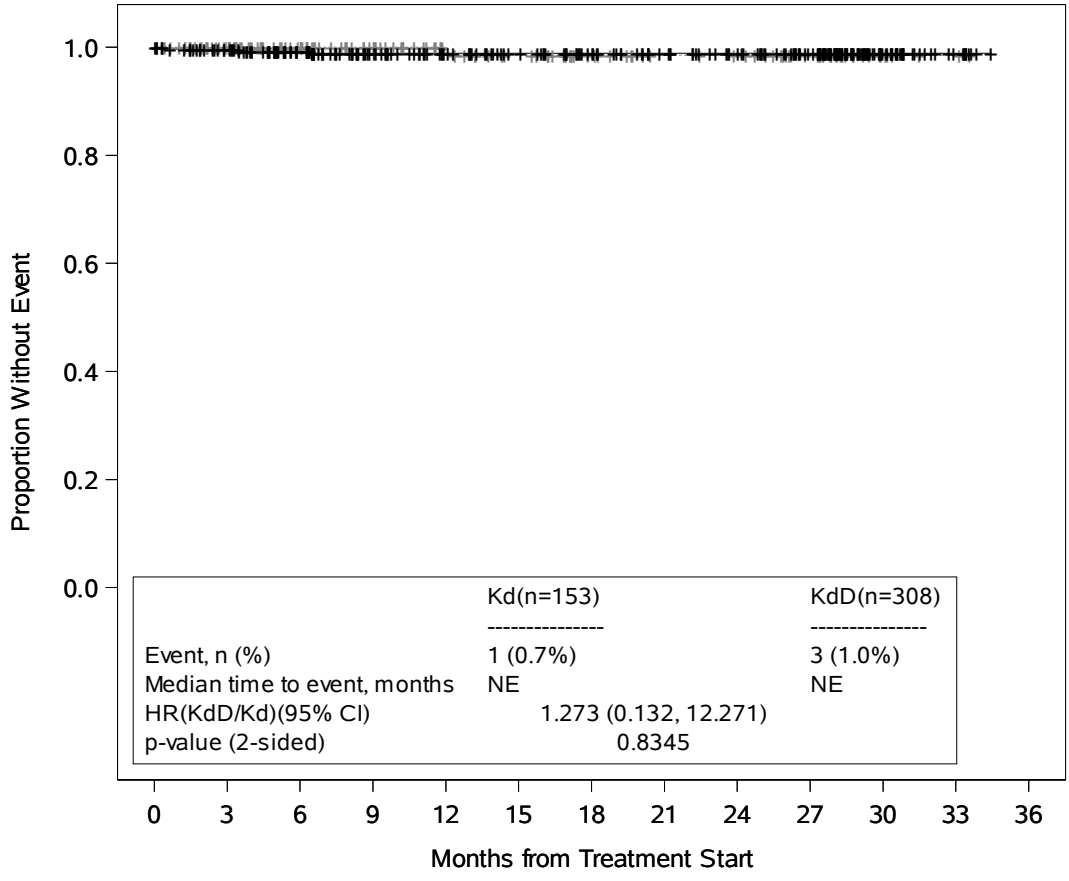


Number of Subjects at Risk:

Kd	153	132	107	87	67	59	46	39	37	27	6	2	0
KdD	308	288	251	212	191	175	160	145	133	111	35	9	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-012-518-sae-km-eoi-pulmo-cfz.rtf (Date Generated: 16SEP20:19:39:44).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.12.519. KM Curves of Serious Adverse Events of Interest for Carfilzomib - Respiratory Failure (SMQ) - Narrow
<Safety Population>

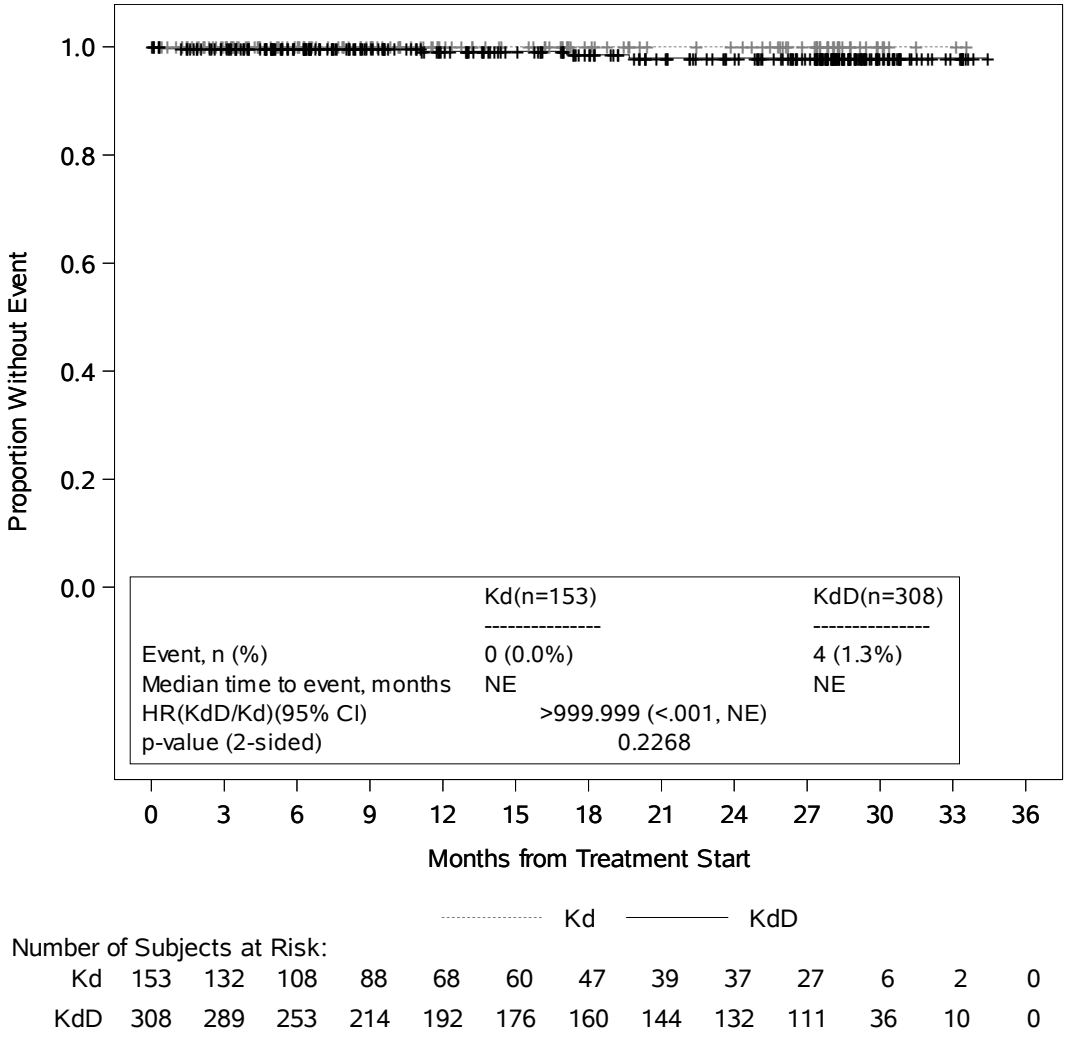


Number of Subjects at Risk:

Kd	153	132	108	88	67	60	47	39	37	27	6	2	0
KdD	308	288	252	214	193	177	161	146	134	112	36	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-012-519-sae-km-eoi-respi-cfz.rtf (Date Generated: 16SEP20:19:39:45).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.12.521. KM Curves of Serious Adverse Events of Interest for Carfilzomib - Reversible Posterior Leukoencephalopathy Syndrome (AMQ) - Narrow
<Safety Population>

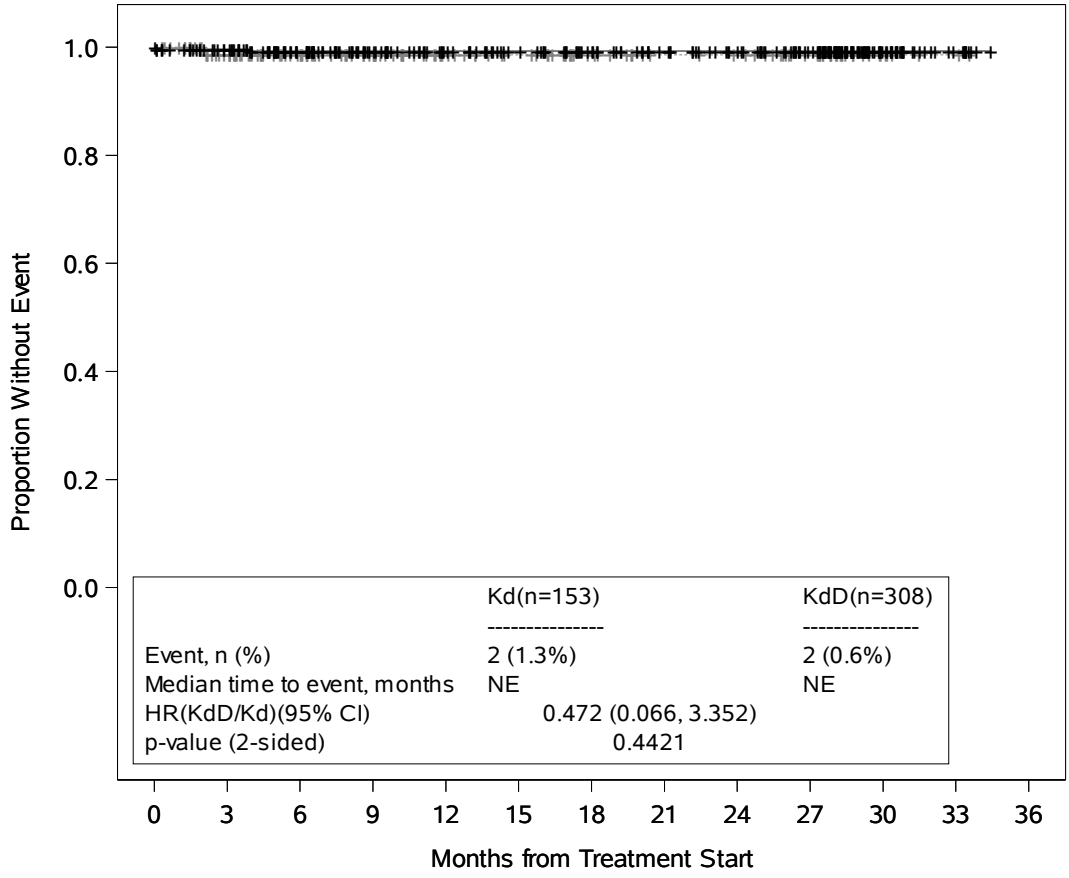


Number of Subjects at Risk:

Kd	153	132	108	88	68	60	47	39	37	27	6	2	0
KdD	308	289	253	214	192	176	160	144	132	111	36	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-012-521-sae-km-eoi-rever-cfz.rtf (Date Generated: 16SEP20:19:39:48).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.12.522. KM Curves of Serious Adverse Events of Interest for Carfilzomib - Thrombotic Microangiopathy (Carfilzomib) (AMQ) - Narrow <Safety Population>

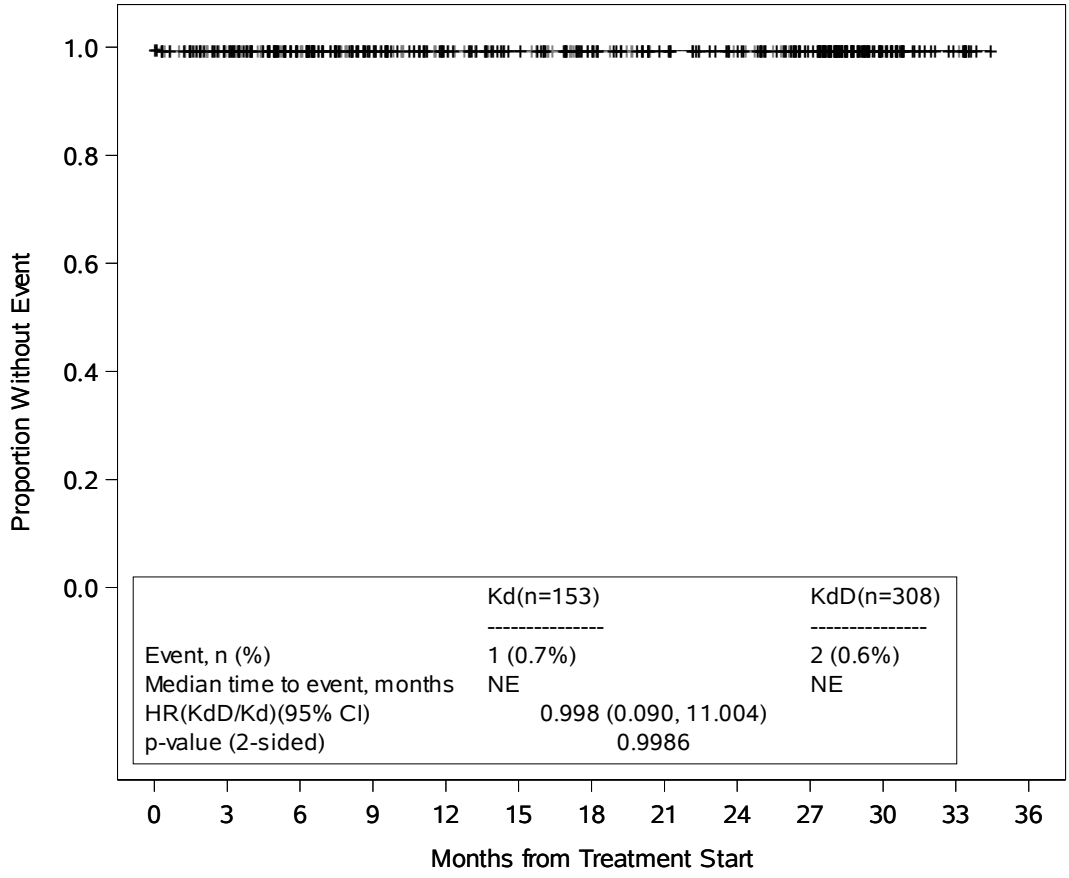


Number of Subjects at Risk:

Kd	153	131	108	88	68	60	47	39	37	27	6	2	0
KdD	308	288	251	213	192	177	161	146	134	112	36	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-012-522-sae-km-eoi-throm-cfz.rtf (Date Generated: 16SEP20:19:39:50).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.12.523. KM Curves of Serious Adverse Events of Interest for Carfilzomib - Tumour Lysis Syndrome (SMQ) - Narrow <Safety Population>

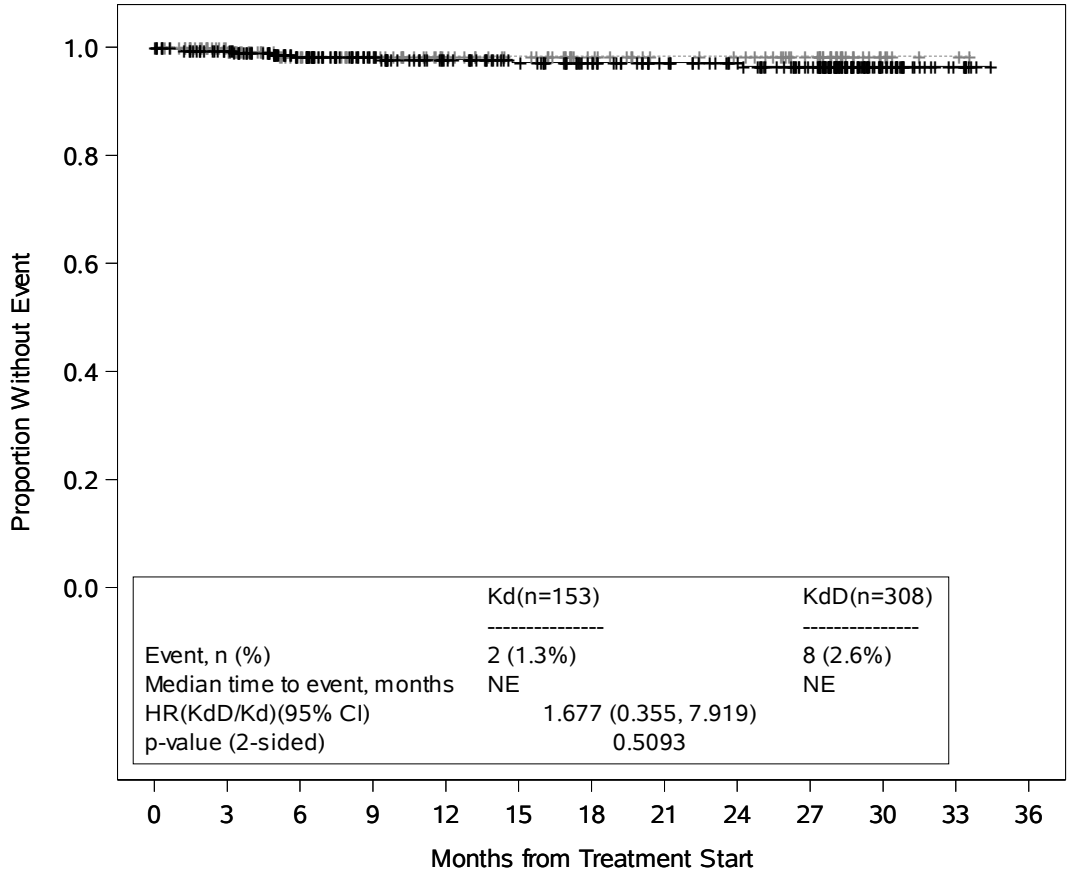


Number of Subjects at Risk:

Kd	153	132	108	88	68	60	47	39	37	27	6	2	0
KdD	308	288	252	213	192	177	161	146	134	112	36	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-012-523-sae-km-eoi-tumou-cfz.rtf (Date Generated: 16SEP20:19:39:51).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.12.502. KM Curves of Serious Adverse Events of Interest for Carfilzomib - Cardiac Arrhythmias (SMQ) - Narrow <Safety Population>

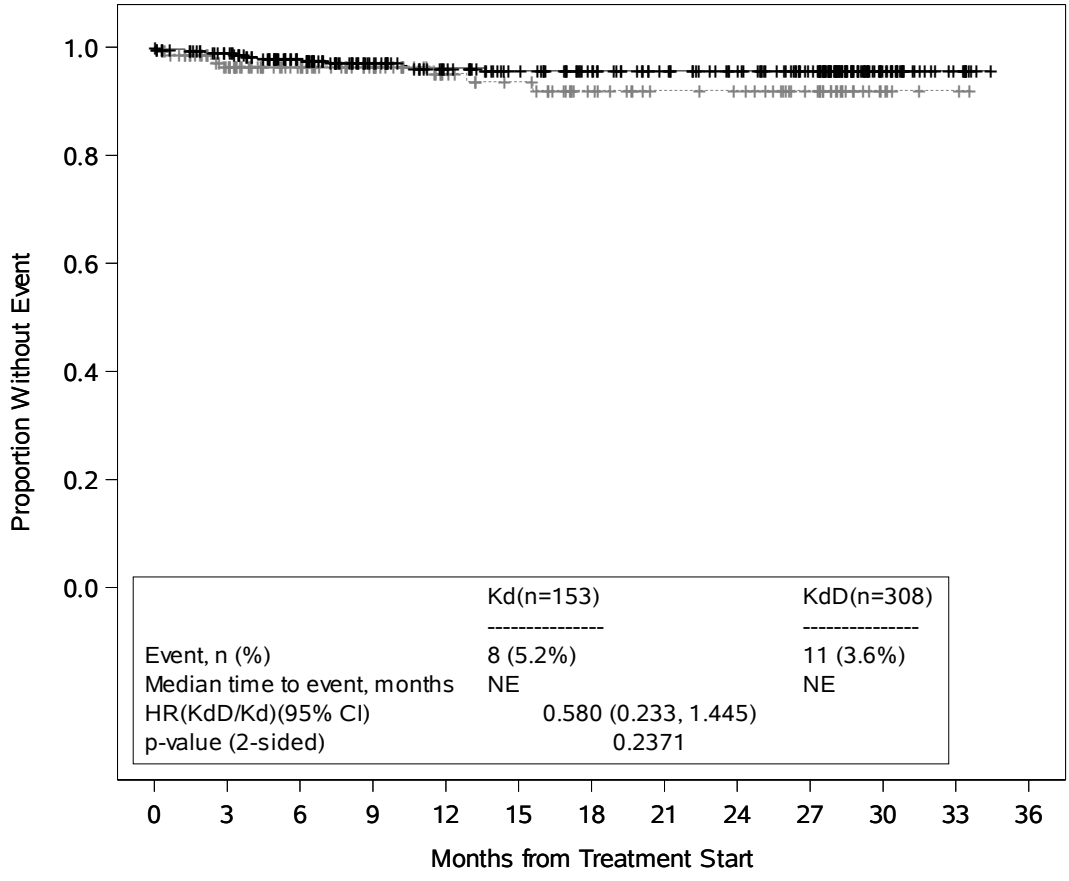


Number of Subjects at Risk:

Kd	153	132	107	88	68	60	47	39	37	27	6	2	0
KdD	308	287	248	211	190	173	157	142	131	111	35	9	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-012-502-sae-km-eoi-cardi-cfz.rtf (Date Generated: 16SEP20:19:39:20).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.12.503. KM Curves of Serious Adverse Events of Interest for Carfilzomib - Cardiac Failure (SMQ) - Narrow
<Safety Population>

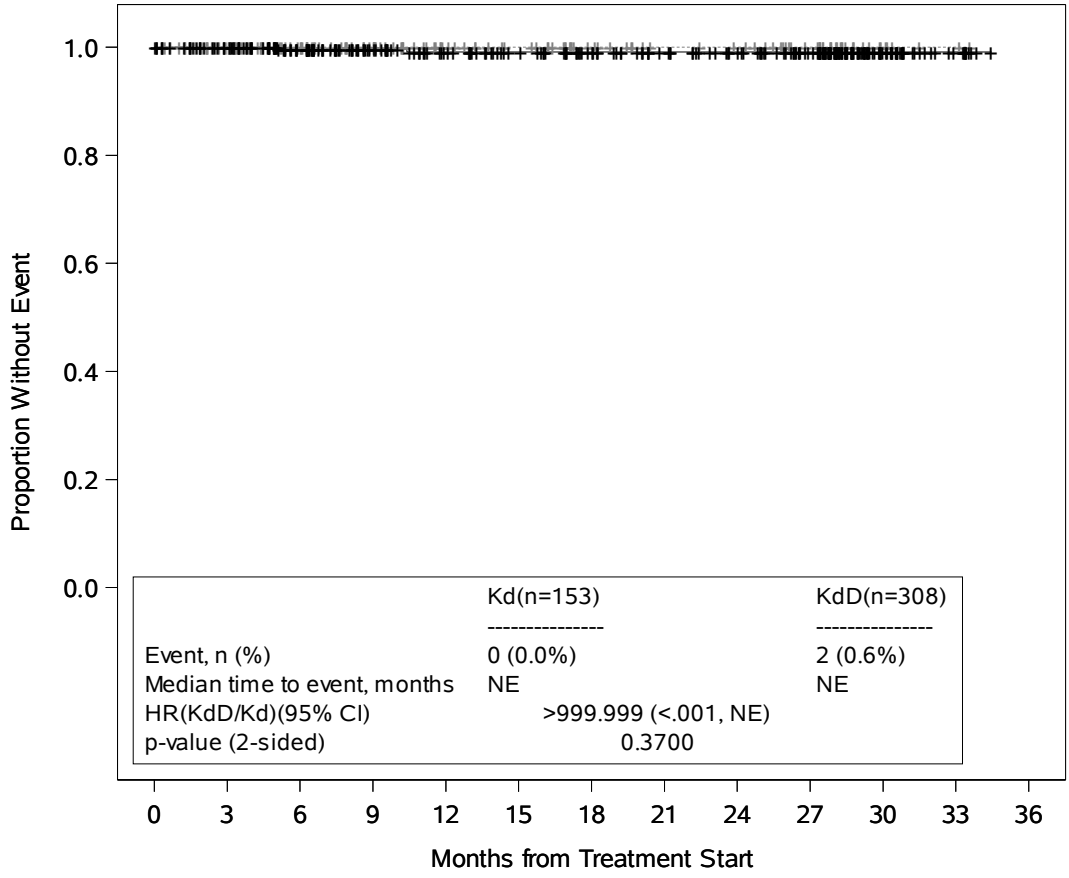


Number of Subjects at Risk:

Kd	153	129	106	86	65	59	46	38	36	26	6	2	0
KdD	308	288	251	210	189	173	157	143	131	110	35	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-012-503-sae-km-eoi-carfai-cfz.rtf (Date Generated: 16SEP20:19:39:21).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.12.504. KM Curves of Serious Adverse Events of Interest for Carfilzomib - Cardiomyopathy (SMQ) - Narrow
<Safety Population>

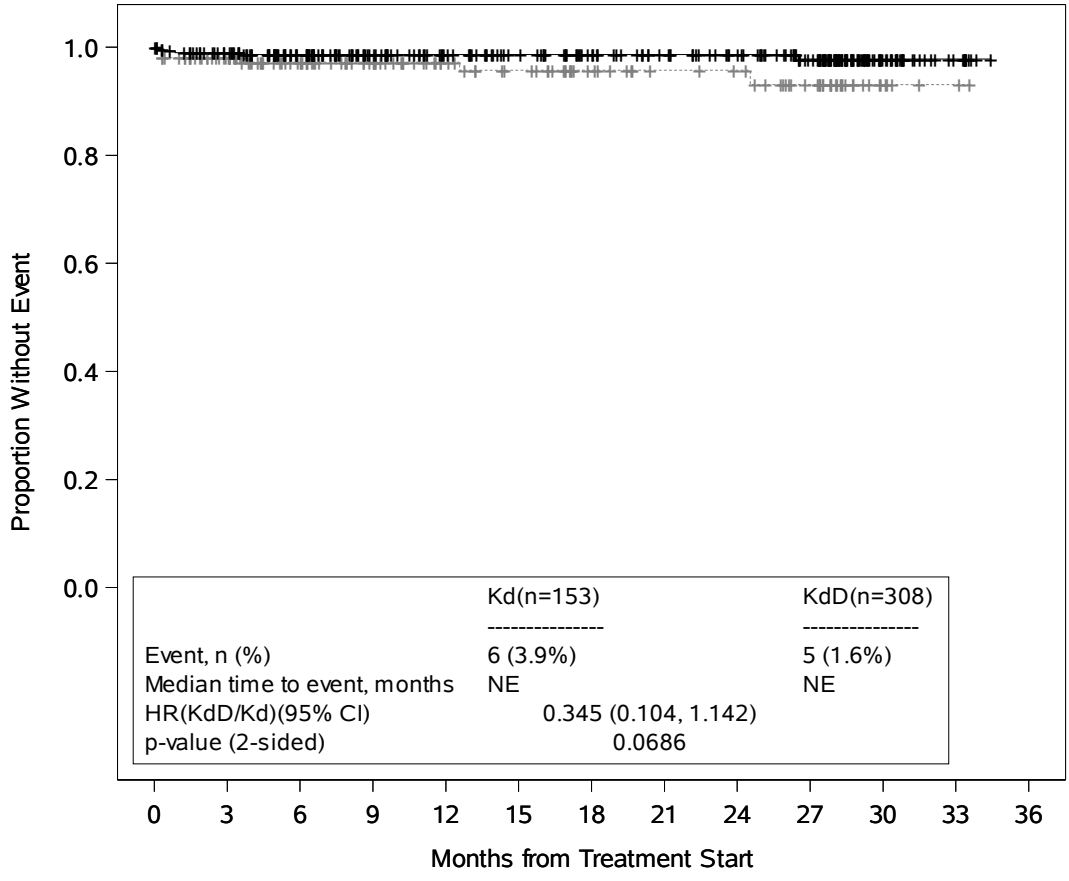


Number of Subjects at Risk:

Kd	153	132	108	88	68	60	47	39	37	27	6	2	0
KdD	308	289	252	213	192	177	161	146	134	112	36	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-012-504-sae-km-eoi-cardio-cfz.rtf (Date Generated: 16SEP20:19:39:23).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.12.505. KM Curves of Serious Adverse Events of Interest for Carfilzomib - Dyspnoeas (HLT)
<Safety Population>

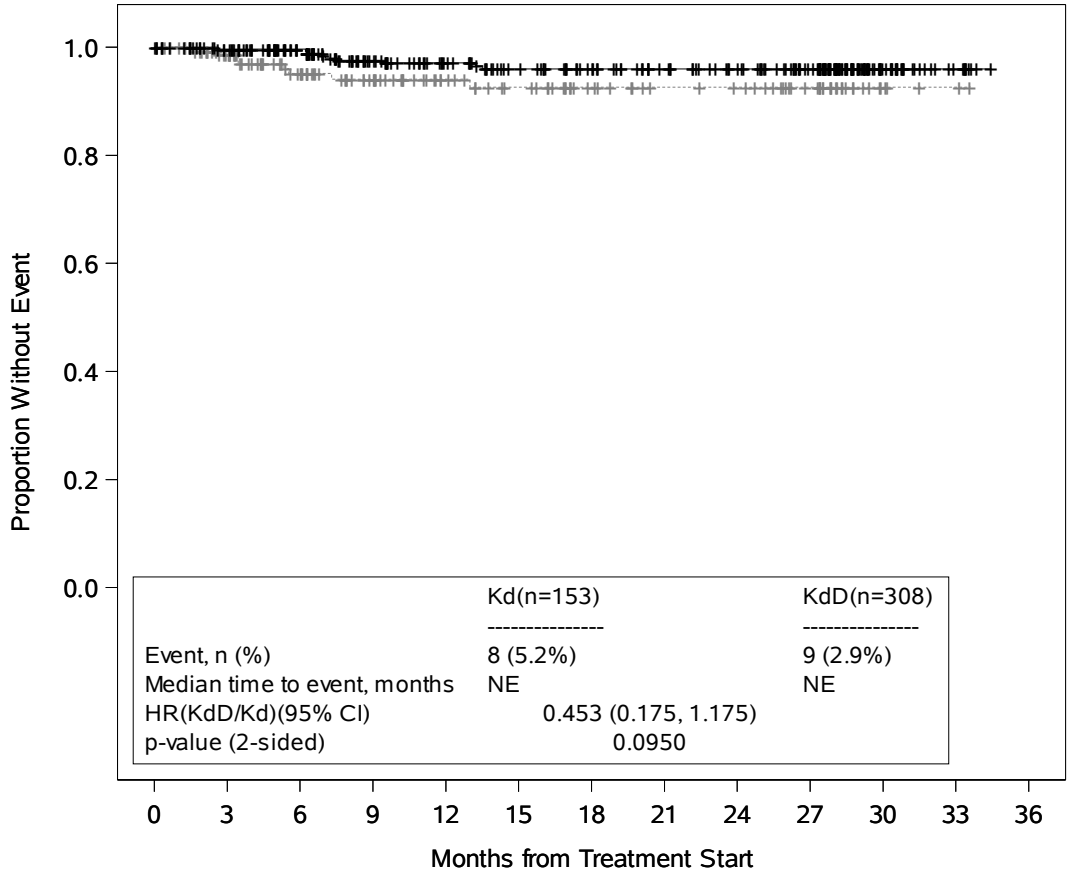


Number of Subjects at Risk:

Kd	153	131	106	86	67	59	46	39	37	27	6	2	0
KdD	308	286	251	212	191	175	159	146	134	111	35	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-012-505-sae-km-eoi-dyspn-cfz.rtf (Date Generated: 16SEP20:19:39:24).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.12.506. KM Curves of Serious Adverse Events of Interest for Carfilzomib - Embolic and Thrombotic Events, Venous (SMQ) - Narrow <Safety Population>

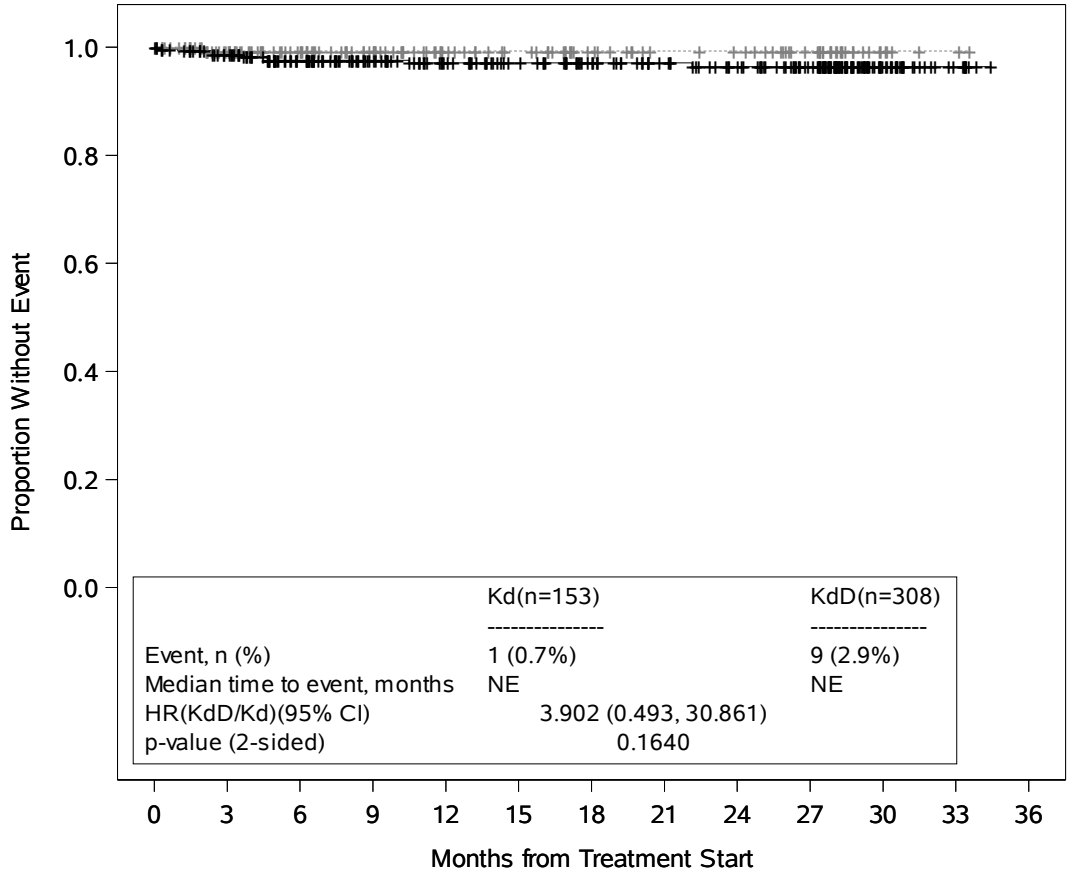


Number of Subjects at Risk:

Kd	153	130	103	83	65	56	44	37	35	25	5	2	0
KdD	308	288	252	208	186	168	154	139	127	105	33	9	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-012-506-sae-km-eoi-embol-cfz.rtf (Date Generated: 16SEP20:19:39:26).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.12.507. KM Curves of Serious Adverse Events of Interest for Carfilzomib - Haematopoietic Erythropenia (SMQ) - Broad <Safety Population>

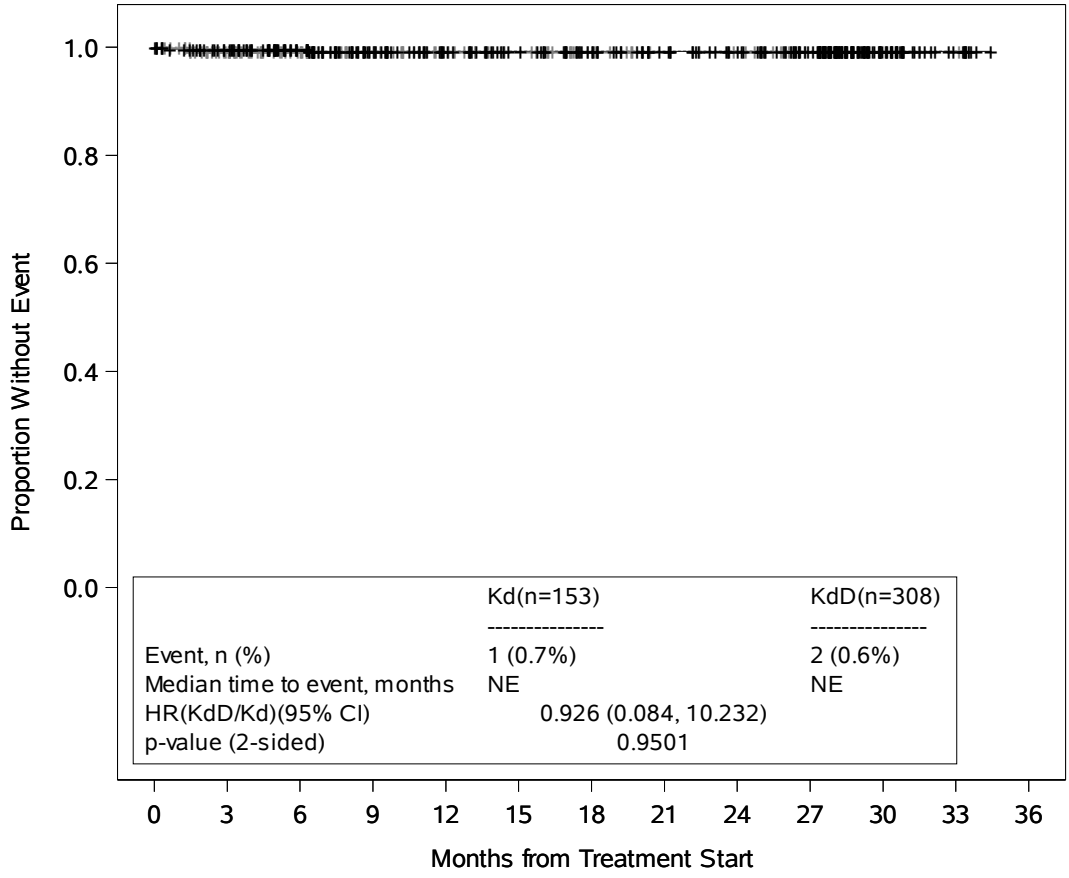


Number of Subjects at Risk:

Kd	153	131	108	88	68	60	47	39	37	27	6	2	0
KdD	308	286	250	211	189	173	158	143	131	109	34	9	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-012-507-sae-km-eoi-haema-cfz.rtf (Date Generated: 16SEP20:19:39:27).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.12.508. KM Curves of Serious Adverse Events of Interest for Carfilzomib - Haematopoietic Leukopenia (SMQ) - Narrow <Safety Population>

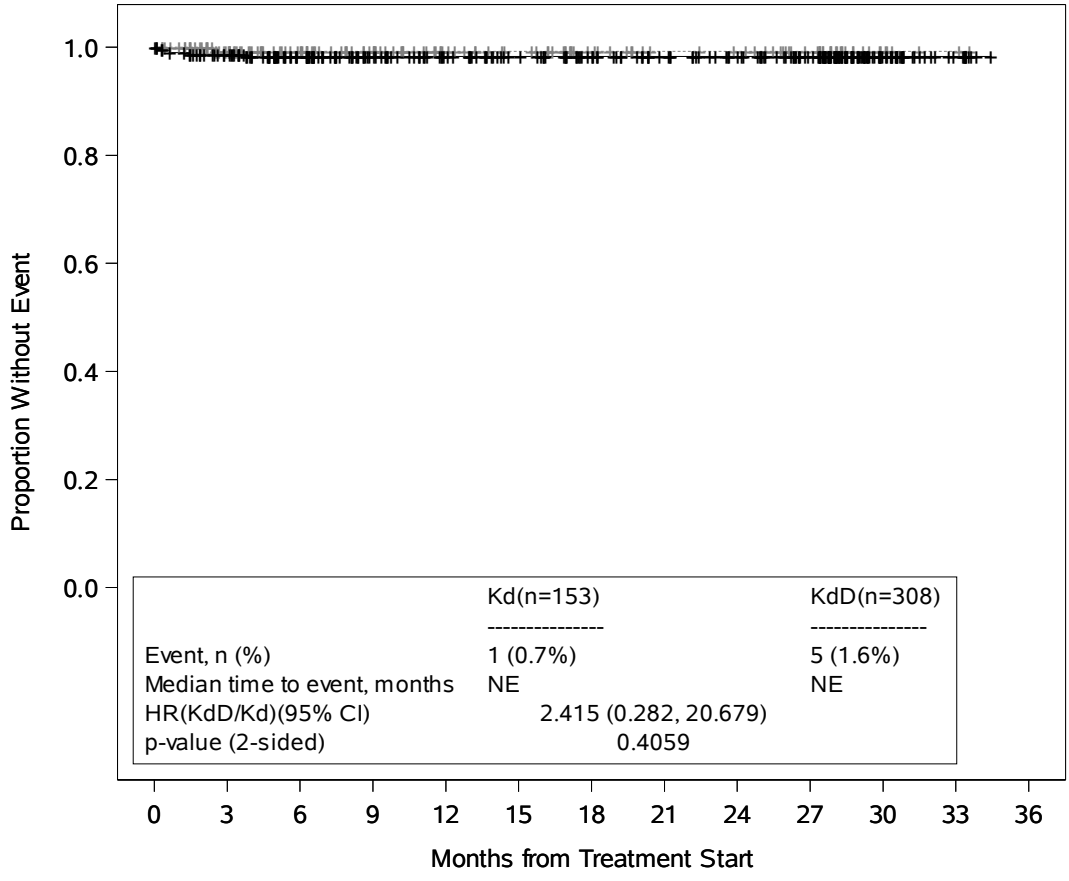


Number of Subjects at Risk:

Kd	153	132	108	88	68	60	47	39	37	27	6	2	0
KdD	308	289	253	214	193	177	161	146	134	112	36	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-012-508-sae-km-eoi-haeleu-cfz.rtf (Date Generated: 16SEP20:19:39:29).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.12.509. KM Curves of Serious Adverse Events of Interest for Carfilzomib - Haematopoietic Thrombocytopenia (SMQ) - Narrow <Safety Population>

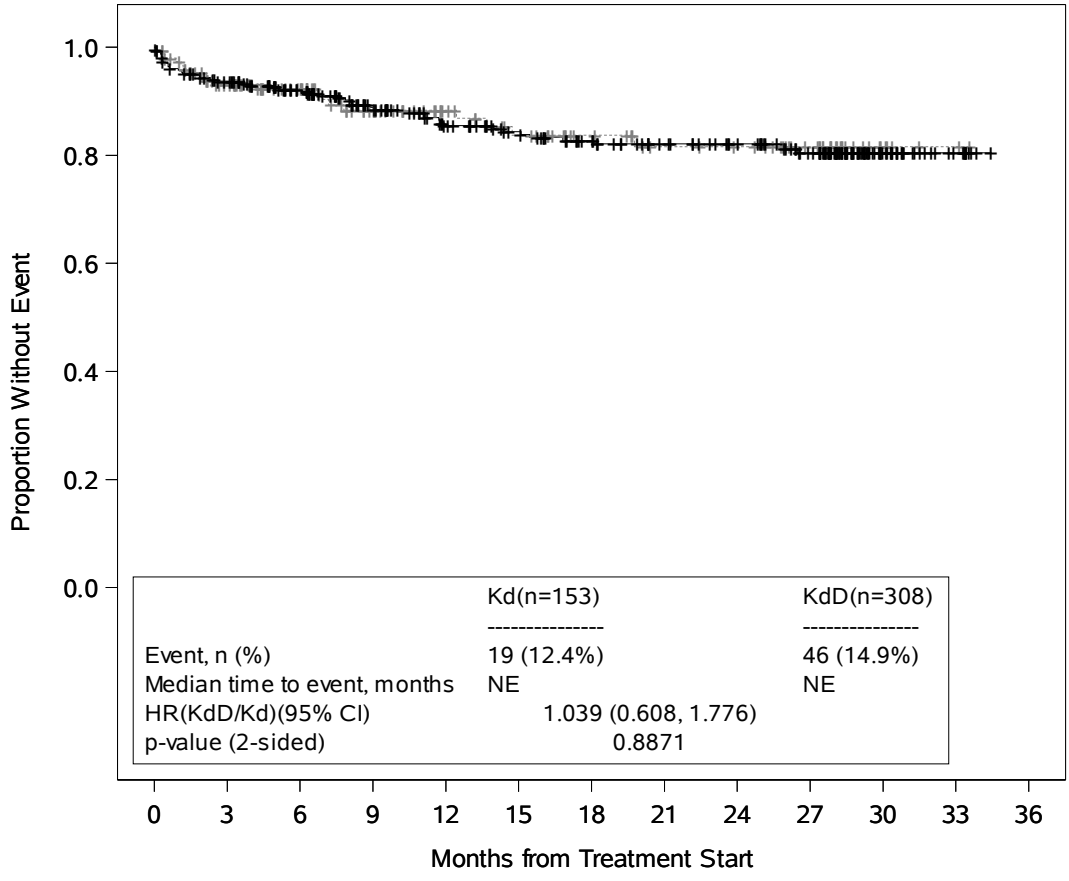


Number of Subjects at Risk:

Kd	153	131	108	88	68	60	47	39	37	27	6	2	0
KdD	308	285	249	211	191	175	159	144	132	110	36	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-012-509-sae-km-eoi-haethr-cfz.rtf (Date Generated: 16SEP20:19:39:30).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.13.503. KM Curves of Adverse Events of Interest for Daratumumab - Haemorrhage Terms (Excl Laboratory Terms) (SMQ) - Narrow <Safety Population>

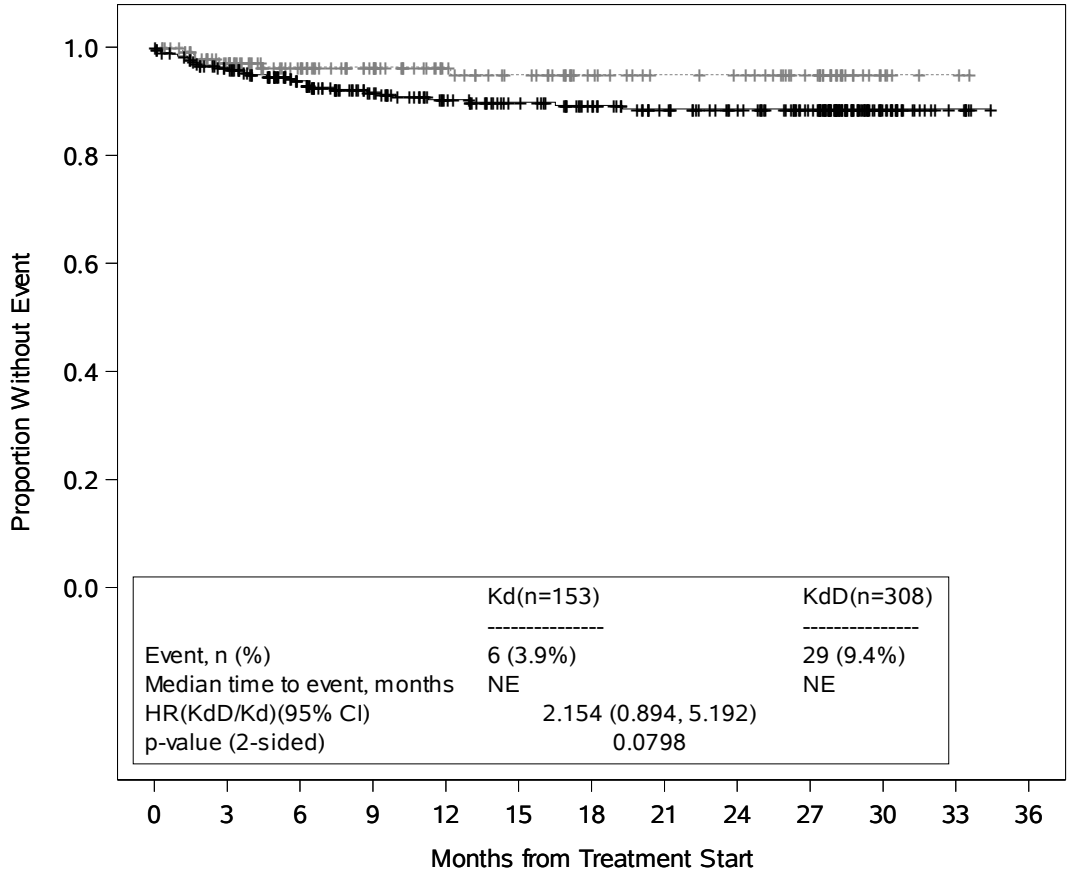


Number of Subjects at Risk:

Kd	153	124	103	80	62	53	43	36	34	25	6	2	0
KdD	308	273	239	196	168	152	137	123	113	95	32	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-013-503-ae-km-eoi-haemo-dar.rtf (Date Generated: 16SEP20:19:39:56).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.13.505. KM Curves of Adverse Events of Interest for Daratumumab - Opportunistic Infections (JMQ)
<Safety Population>

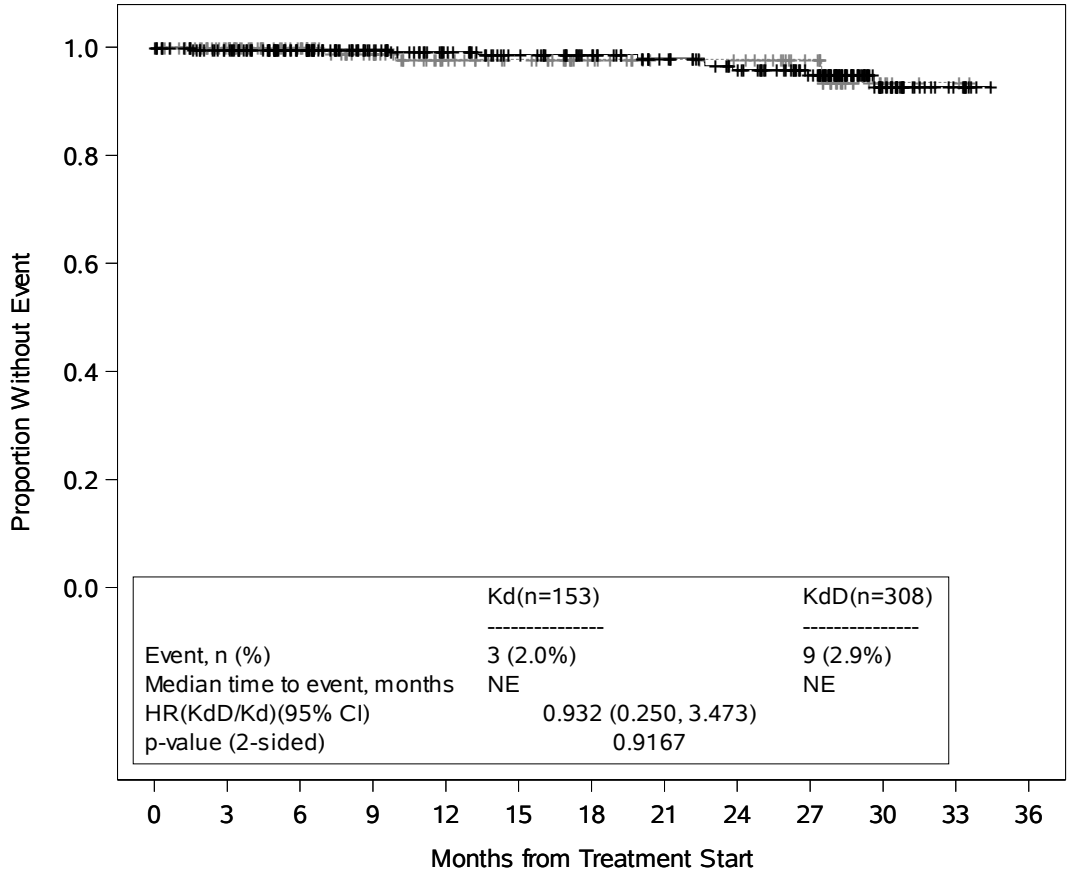


Number of Subjects at Risk:

Kd	153	129	105	87	68	59	46	39	37	27	6	2	0
KdD	308	279	239	202	179	162	147	131	119	100	29	7	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-013-505-ae-km-eoi-oppor-dar.rtf (Date Generated: 16SEP20:19:39:59).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.13.506. KM Curves of Adverse Events of Interest for Daratumumab - Second Primary Malignancies: Malignant Tumours (SMQ) - Narrow <Safety Population>

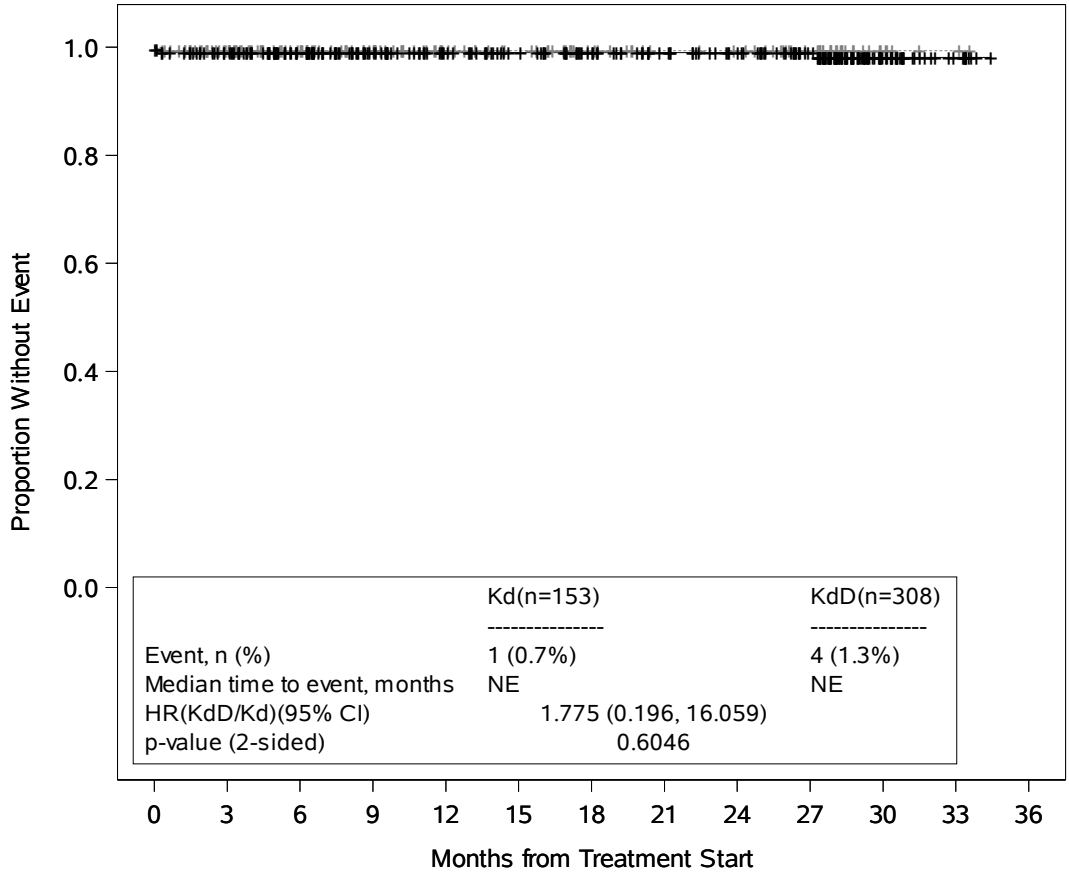


Number of Subjects at Risk:

Kd	153	132	108	88	68	60	47	39	37	27	6	2	0
KdD	308	288	252	213	191	175	160	145	131	109	35	9	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-013-506-ae-km-eoi-secon-dar.rtf (Date Generated: 16SEP20:19:40:01).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.13.507. KM Curves of Adverse Events of Interest for Daratumumab - Tumour Lysis Syndrome (SMQ) - Narrow
<Safety Population>

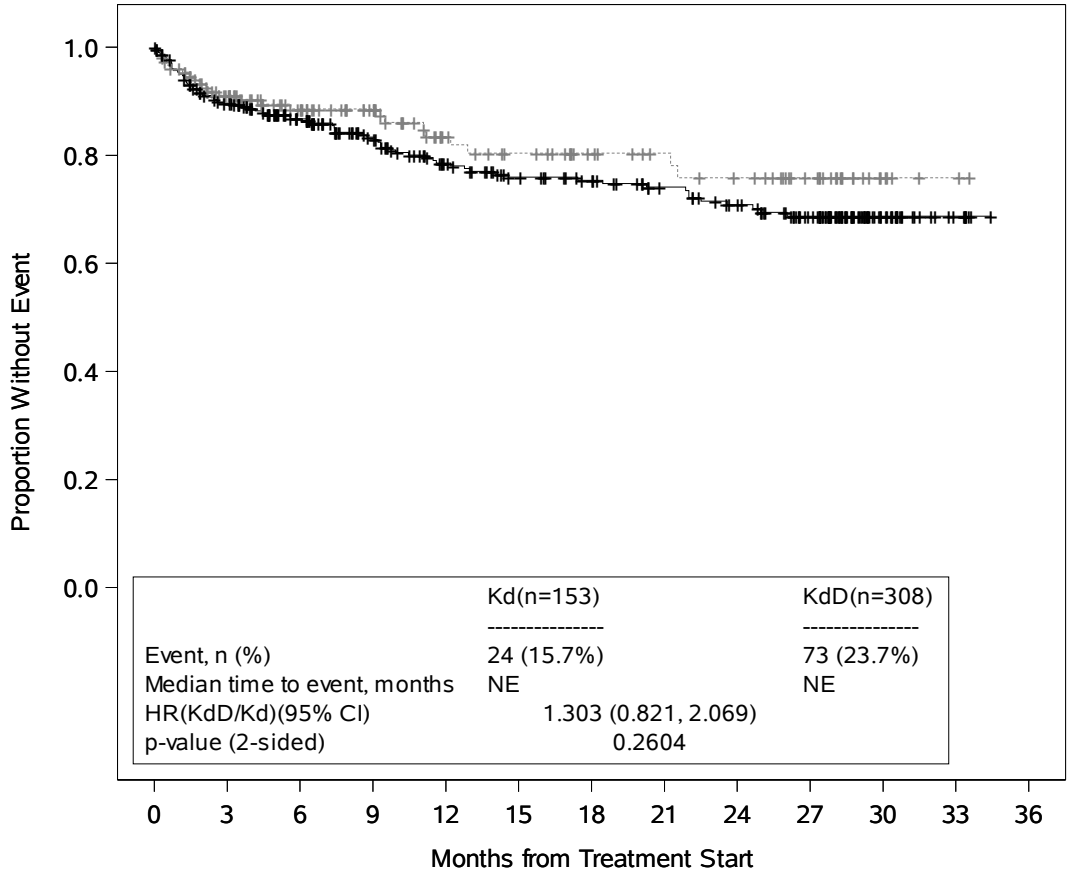


Number of Subjects at Risk:

Kd	153	132	108	88	68	60	47	39	37	27	6	2	0
KdD	308	287	252	213	192	177	161	146	134	112	36	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-013-507-ae-km-eoi-tumou-dar.rtf (Date Generated: 16SEP20:19:40:02).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.13.508. KM Curves of Adverse Events of Interest for Daratumumab - Viral Infection (JMQ)
<Safety Population>

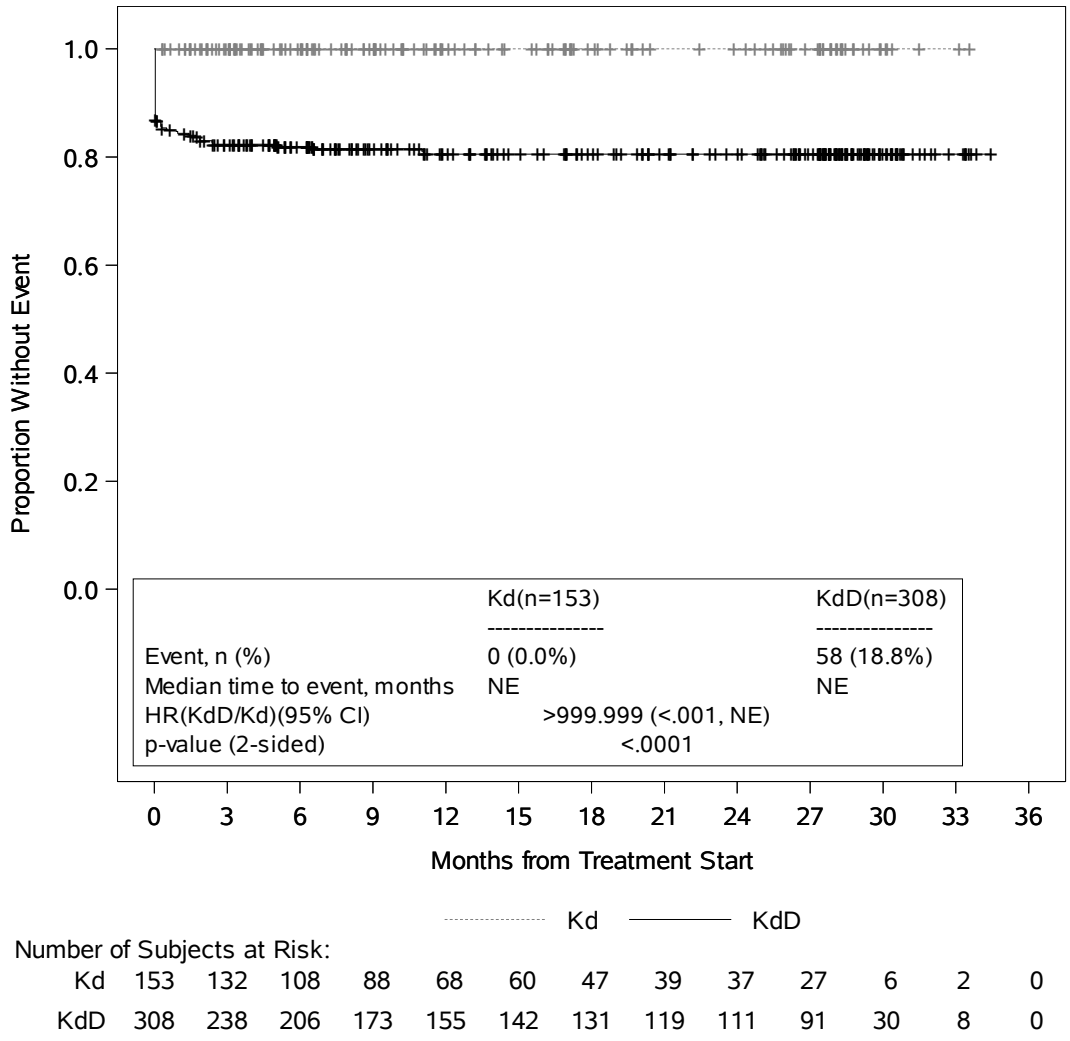


Number of Subjects at Risk:

Kd	153	120	95	78	56	49	40	35	31	22	6	2	0
KdD	308	260	221	182	154	137	128	115	104	83	28	8	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-013-508-ae-km-eoi-viral-dar.rtf (Date Generated: 16SEP20:19:40:04).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.13.501. KM Curves of Adverse Events of Interest for Daratumumab - Daratumumab-related Infusion Reaction (AMQ) - Narrow (Event on Same Date or Next Date of Any Daratumumab Dosing)
<Safety Population>

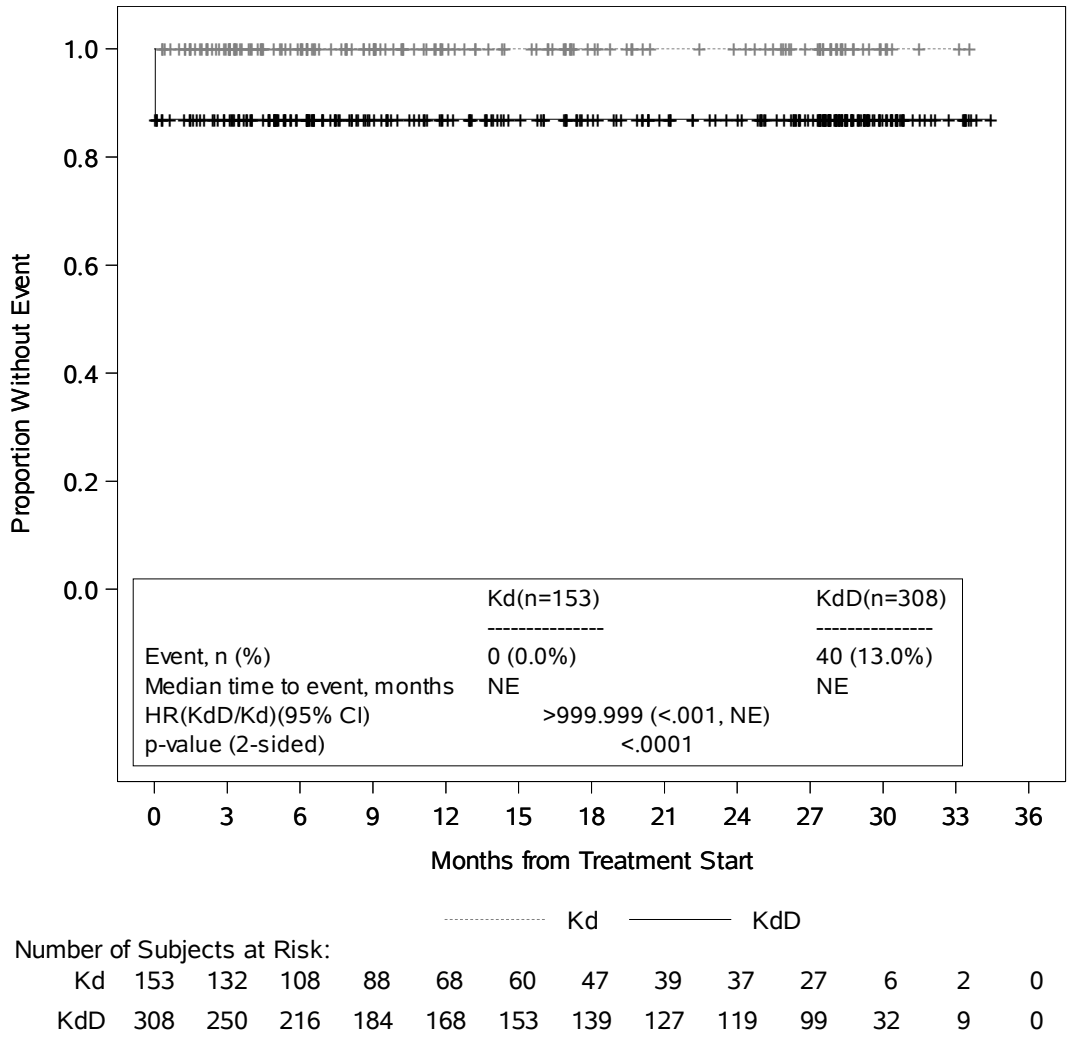


Number of Subjects at Risk:

Kd	153	132	108	88	68	60	47	39	37	27	6	2	0
KdD	308	238	206	173	155	142	131	119	111	91	30	8	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-013-501-ae-km-eoi-infany-dar.rtf (Date Generated: 16SEP20:19:39:53).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.13.502. KM Curves of Adverse Events of Interest for Daratumumab - Daratumumab-related Infusion Reaction (AMQ) - Narrow (Event on Same Date or Next Date of First Daratumumab Dosing)
<Safety Population>

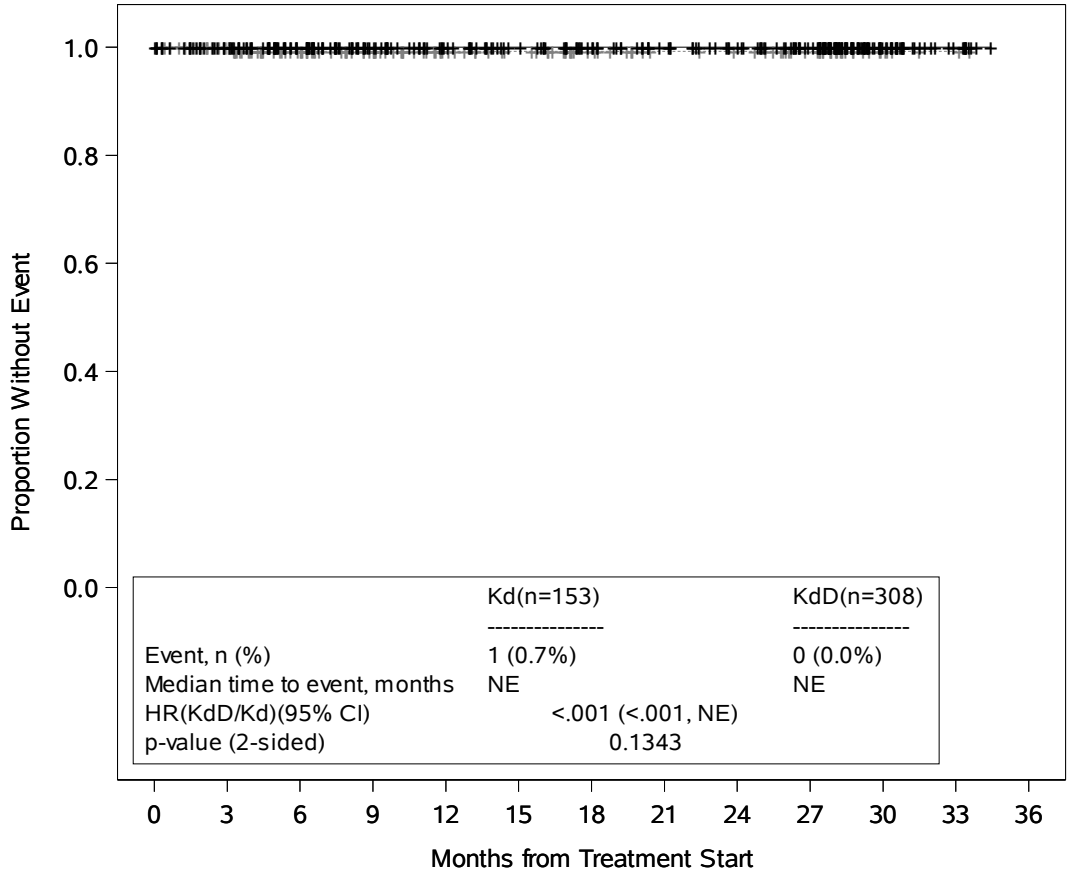


Number of Subjects at Risk:

Kd	153	132	108	88	68	60	47	39	37	27	6	2	0
KdD	308	250	216	184	168	153	139	127	119	99	32	9	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-013-502-ae-km-eoi-inffir-dar.rtf (Date Generated: 16SEP20:19:39:55).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.14.504. KM Curves of Grade ≥3 Adverse Events of Interest for Daratumumab - Intravascular Hemolysis (JMQ)
<Safety Population>

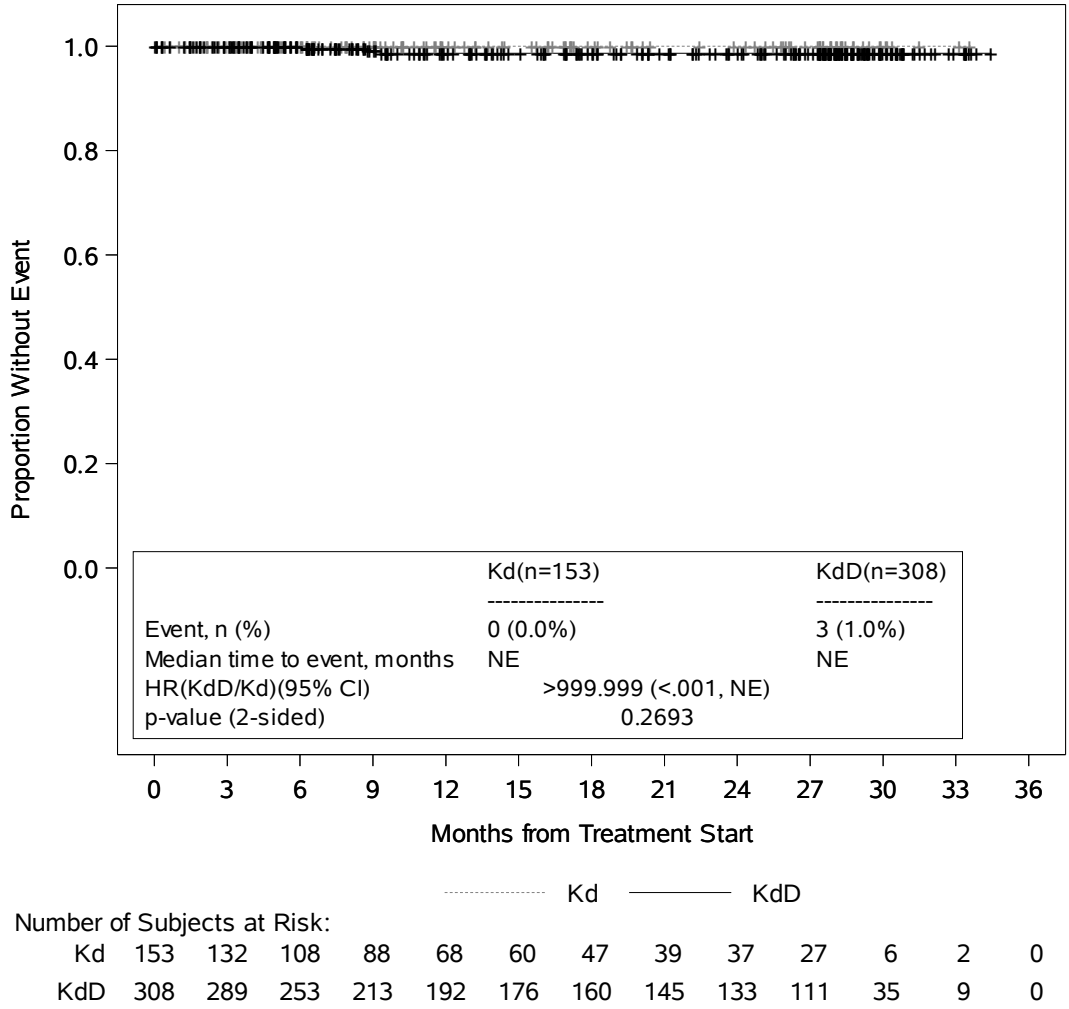


Number of Subjects at Risk:

Kd	153	132	107	87	67	59	46	38	36	27	6	2	0
KdD	308	289	253	214	193	177	161	146	134	112	36	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-014-504-ae-km-eoi-intra-dar-grd345.rtf (Date Generated: 16SEP20:19:40:12).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.14.505. KM Curves of Grade ≥3 Adverse Events of Interest for Daratumumab - Opportunistic Infections (JMQ)
<Safety Population>

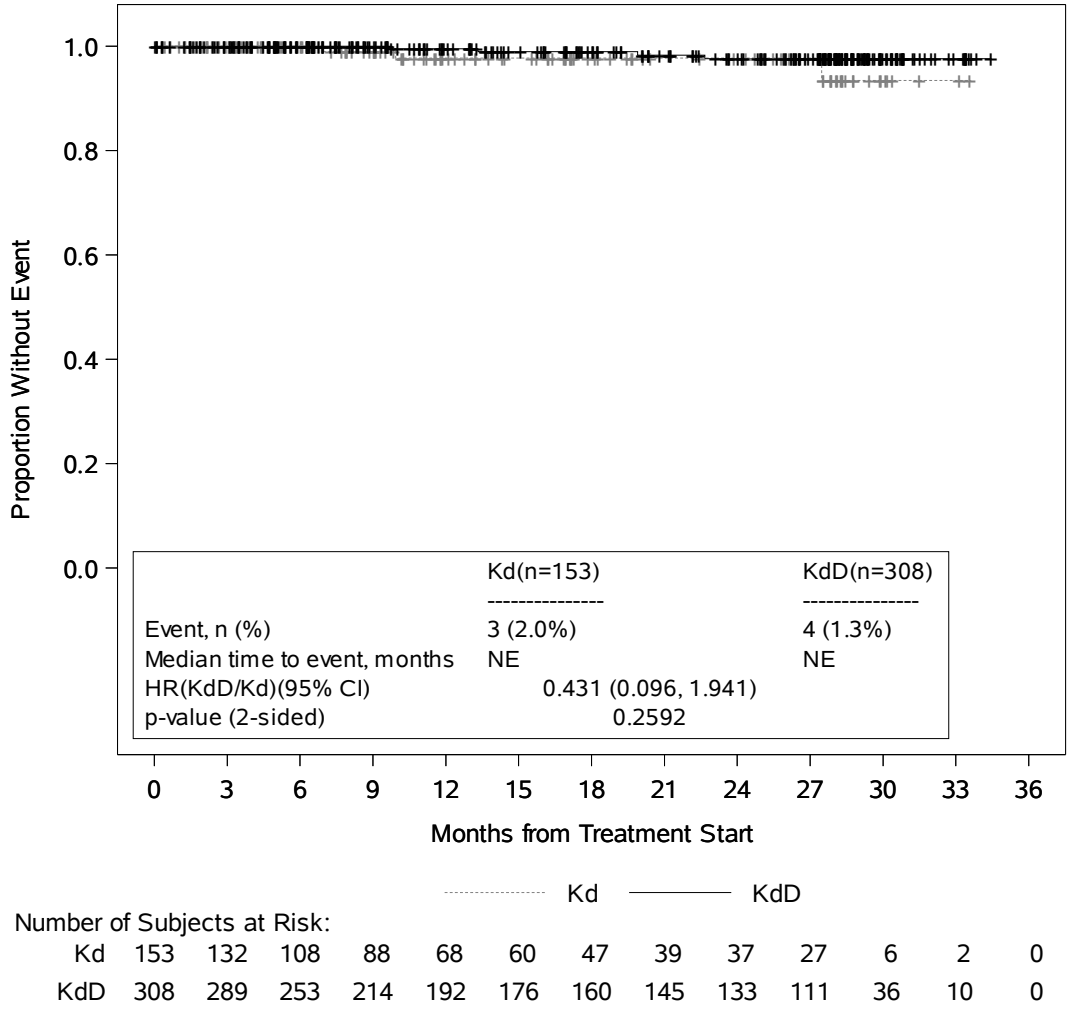


Number of Subjects at Risk:

Kd	153	132	108	88	68	60	47	39	37	27	6	2	0
KdD	308	289	253	213	192	176	160	145	133	111	35	9	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-014-505-ae-km-eoi-oppor-dar-grd345.rtf (Date Generated: 16SEP20:19:40:14).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.14.506. KM Curves of Grade ≥3 Adverse Events of Interest for Daratumumab - Second Primary Malignancies: Malignant Tumours (SMQ) - Narrow <Safety Population>

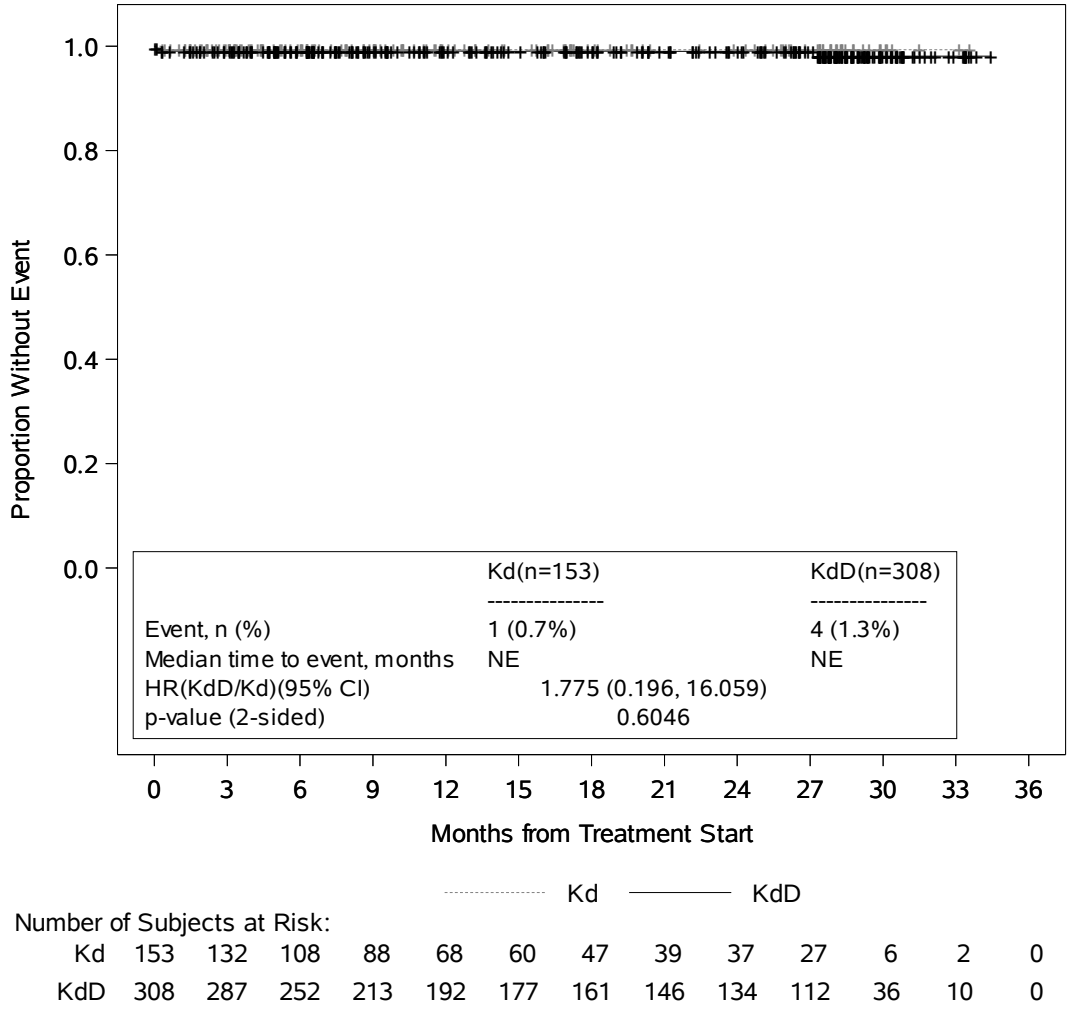


Number of Subjects at Risk:

Kd	153	132	108	88	68	60	47	39	37	27	6	2	0
KdD	308	289	253	214	192	176	160	145	133	111	36	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-014-506-ae-km-eoi-secon-dar-grd345.rtf (Date Generated: 16SEP20:19:40:15).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.14.507. KM Curves of Grade ≥3 Adverse Events of Interest for Daratumumab - Tumour Lysis Syndrome (SMQ) - Narrow <Safety Population>

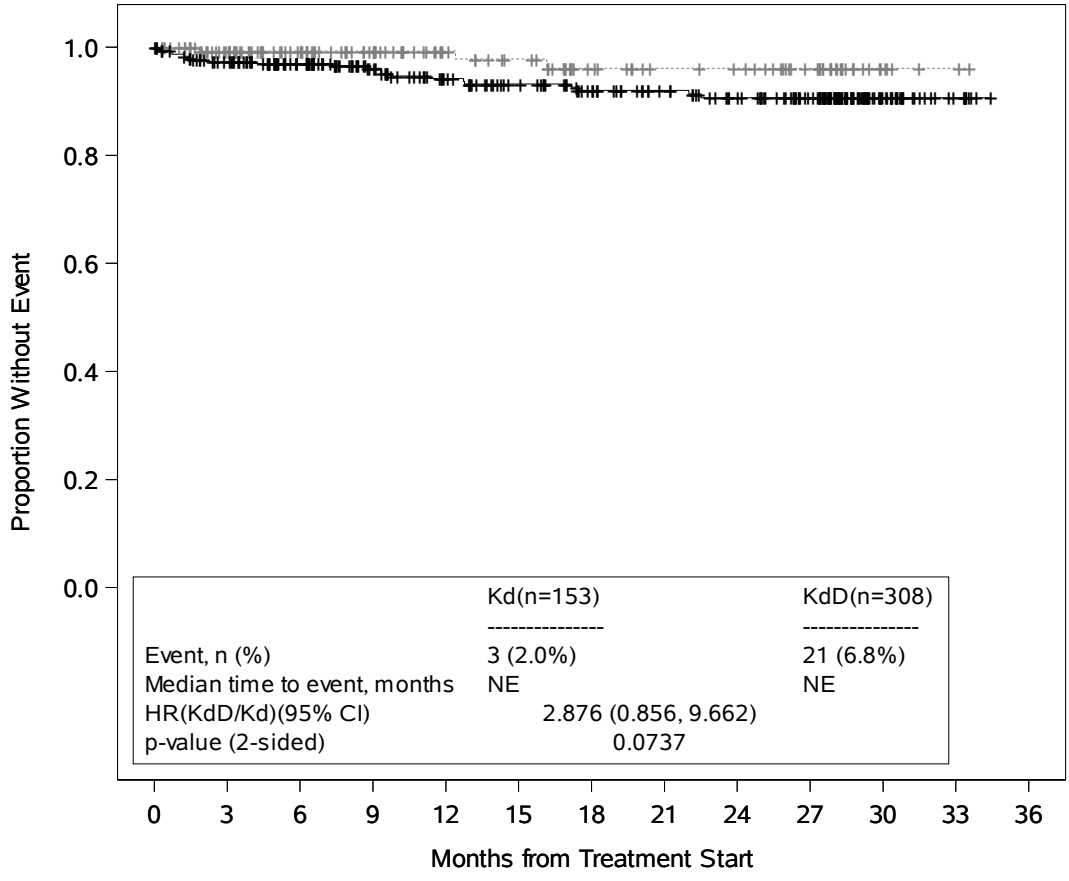


Number of Subjects at Risk:

Kd	153	132	108	88	68	60	47	39	37	27	6	2	0
KdD	308	287	252	213	192	177	161	146	134	112	36	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-014-507-ae-km-eoi-tumou-dar-grd345.rtf (Date Generated: 16SEP20:19:40:17).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.14.508. KM Curves of Grade ≥3 Adverse Events of Interest for Daratumumab - Viral Infection (JMQ)
<Safety Population>

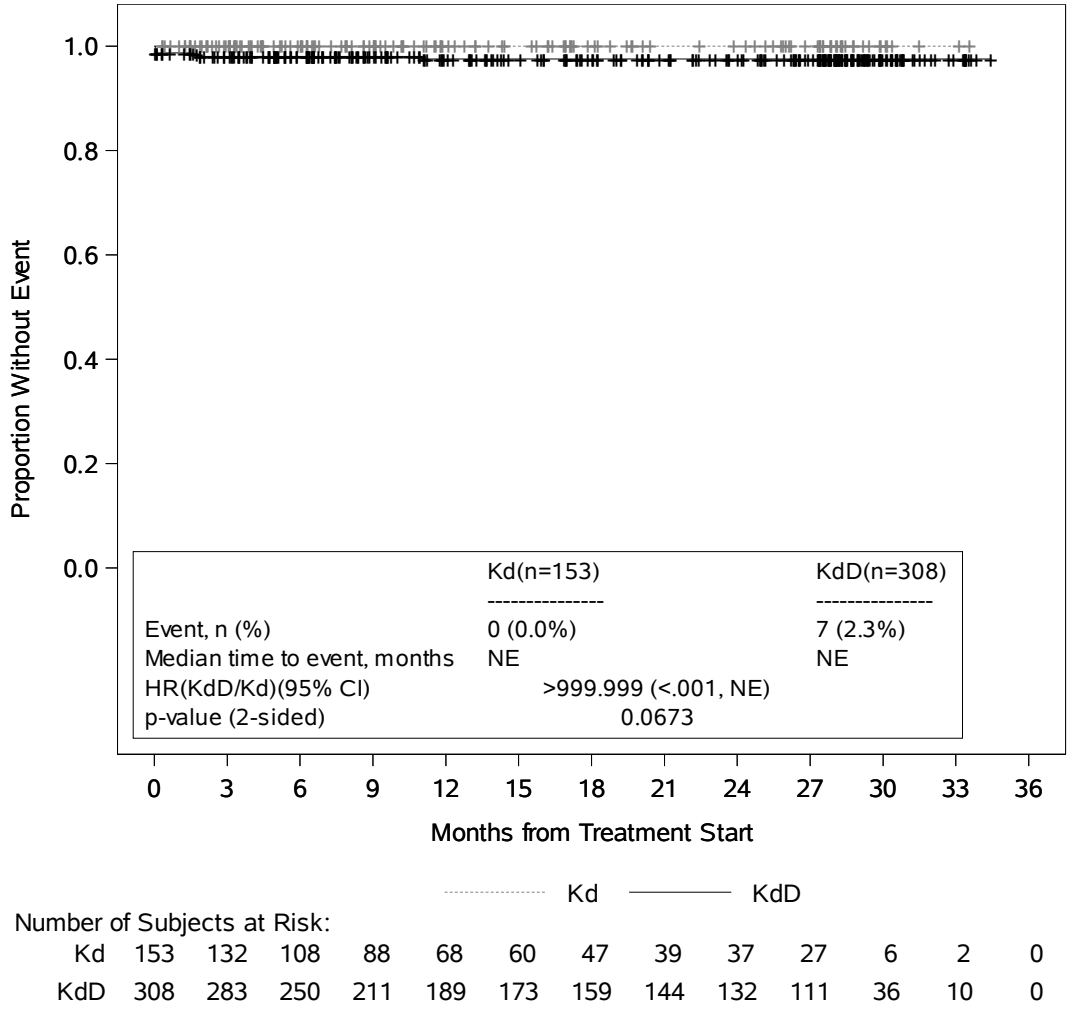


Number of Subjects at Risk:

Kd	153	131	107	87	67	60	46	39	37	27	6	2	0
KdD	308	282	248	209	186	169	153	139	126	105	34	9	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-014-508-ae-km-eoi-viral-dar-grd345.rtf (Date Generated: 16SEP20:19:40:18).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.14.501. KM Curves of Grade ≥3 Adverse Events of Interest for Daratumumab - Daratumumab-related Infusion Reaction (AMQ) - Narrow (Event on Same Date or Next Date of Any Daratumumab Dosing)
<Safety Population>

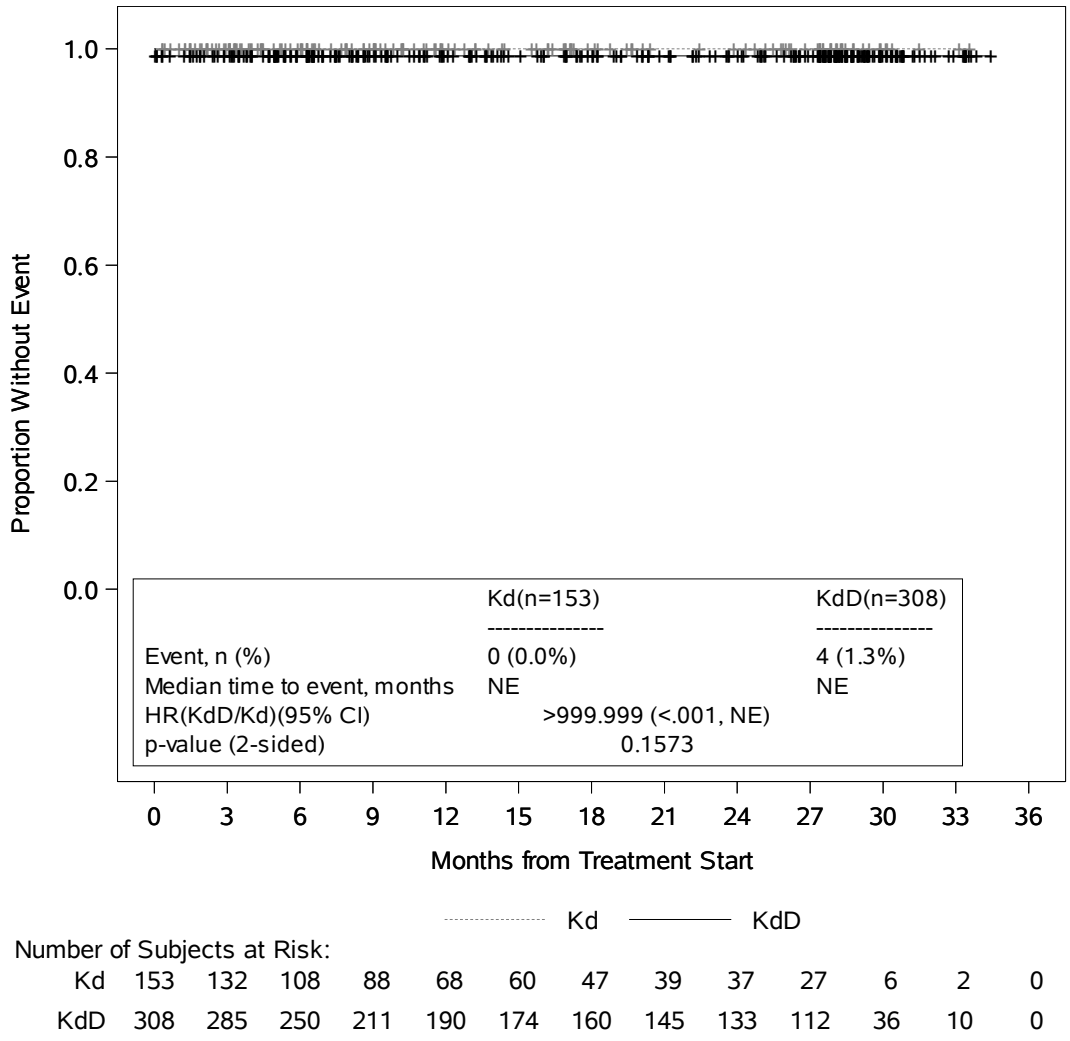


Number of Subjects at Risk:

Kd	153	132	108	88	68	60	47	39	37	27	6	2	0
KdD	308	283	250	211	189	173	159	144	132	111	36	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-014-501-ae-km-eoi-infany-dar-grd345.rtf (Date Generated: 16SEP20:19:40:08).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.14.502. KM Curves of Grade ≥3 Adverse Events of Interest for Daratumumab - Daratumumab-related Infusion Reaction (AMQ) - Narrow (Event on Same Date or Next Date of First Daratumumab Dosing) <Safety Population>

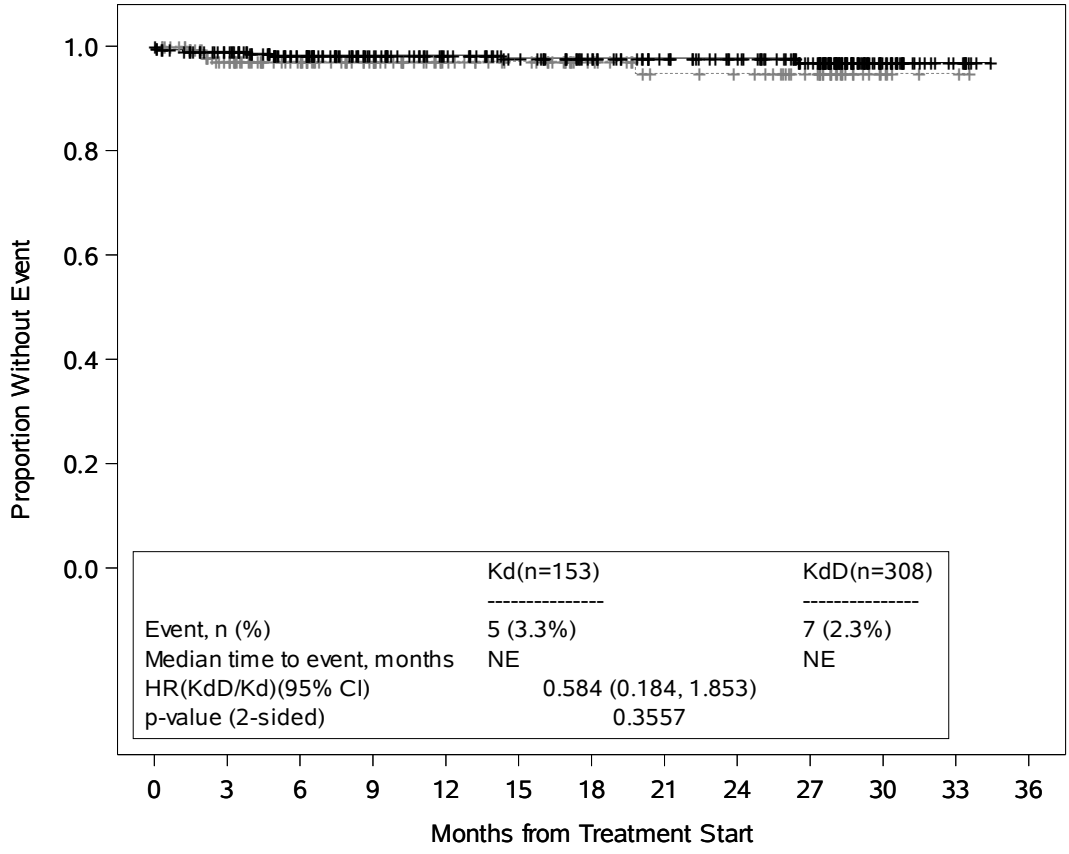


Number of Subjects at Risk:

Kd	153	132	108	88	68	60	47	39	37	27	6	2	0
KdD	308	285	250	211	190	174	160	145	133	112	36	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-014-502-ae-km-eoi-inffir-dar-grd345.rtf (Date Generated: 16SEP20:19:40:10).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.14.503. KM Curves of Grade ≥3 Adverse Events of Interest for Daratumumab - Haemorrhage Terms (Excl Laboratory Terms) (SMQ) - Narrow <Safety Population>

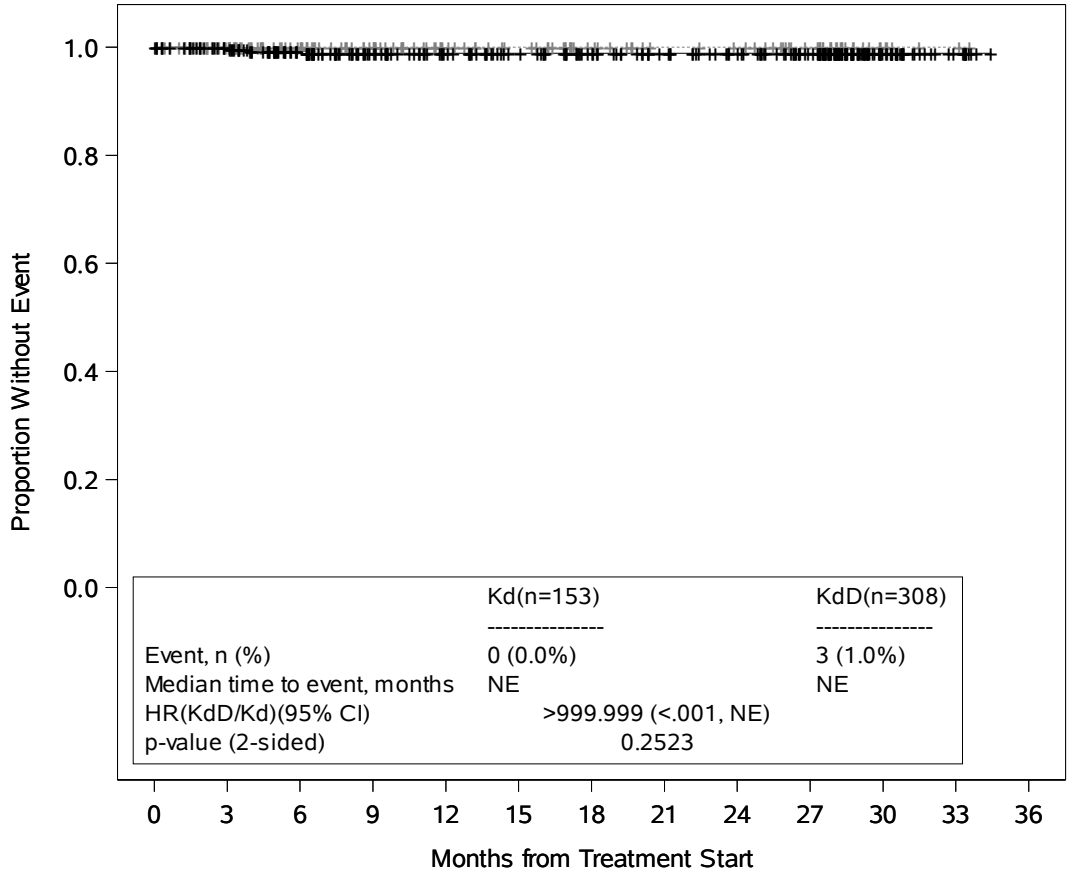


Number of Subjects at Risk:

Kd	153	129	108	88	68	60	47	38	36	27	6	2	0
KdD	308	287	251	213	192	176	161	146	134	111	35	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-014-503-ae-km-eoi-haemo-dar-grd345.rtf (Date Generated: 16SEP20:19:40:11).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.15.504. KM Curves of Serious Adverse Events of Interest for Daratumumab - Opportunistic Infections (JMQ)
<Safety Population>

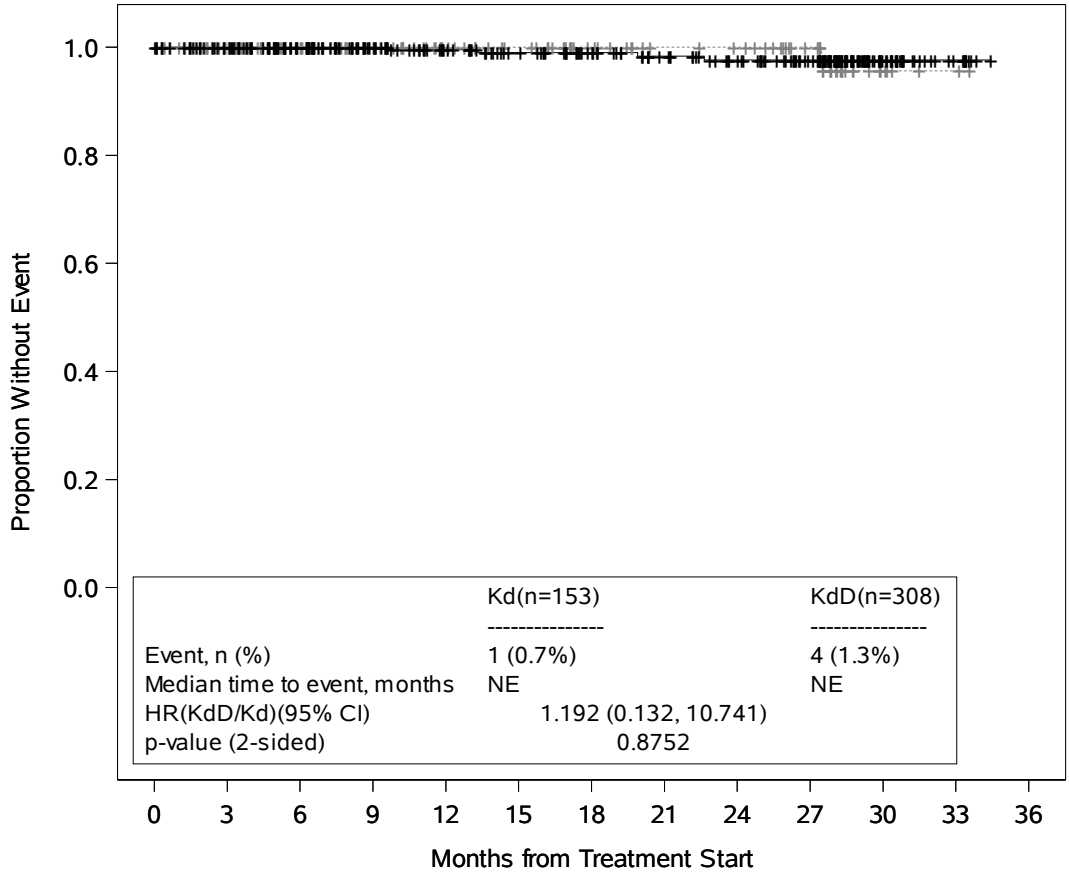


Number of Subjects at Risk:

Kd	153	132	108	88	68	60	47	39	37	27	6	2	0
KdD	308	289	252	214	193	177	161	146	134	112	36	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-015-504-sae-km-eoi-oppor-dar.rtf (Date Generated: 16SEP20:19:40:25).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.15.505. KM Curves of Serious Adverse Events of Interest for Daratumumab - Second Primary Malignancies: Malignant Tumours (SMQ) - Narrow <Safety Population>

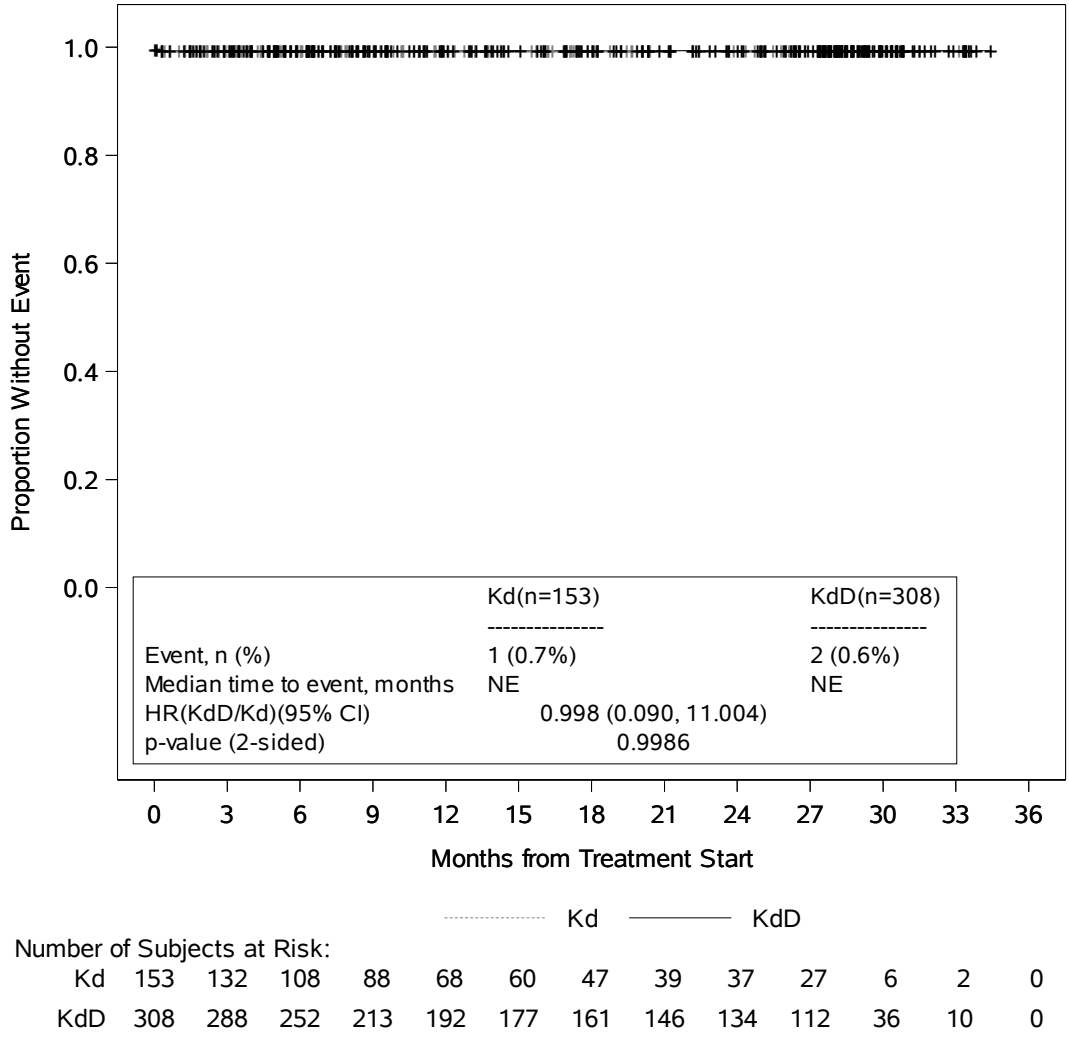


Number of Subjects at Risk:

Kd	153	132	108	88	68	60	47	39	37	27	6	2	0
KdD	308	289	253	214	192	176	160	145	132	111	36	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-015-505-sae-km-eoi-secon-dar.rtf (Date Generated: 16SEP20:19:40:26).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.15.506. KM Curves of Serious Adverse Events of Interest for Daratumumab - Tumour Lysis Syndrome (SMQ) - Narrow <Safety Population>

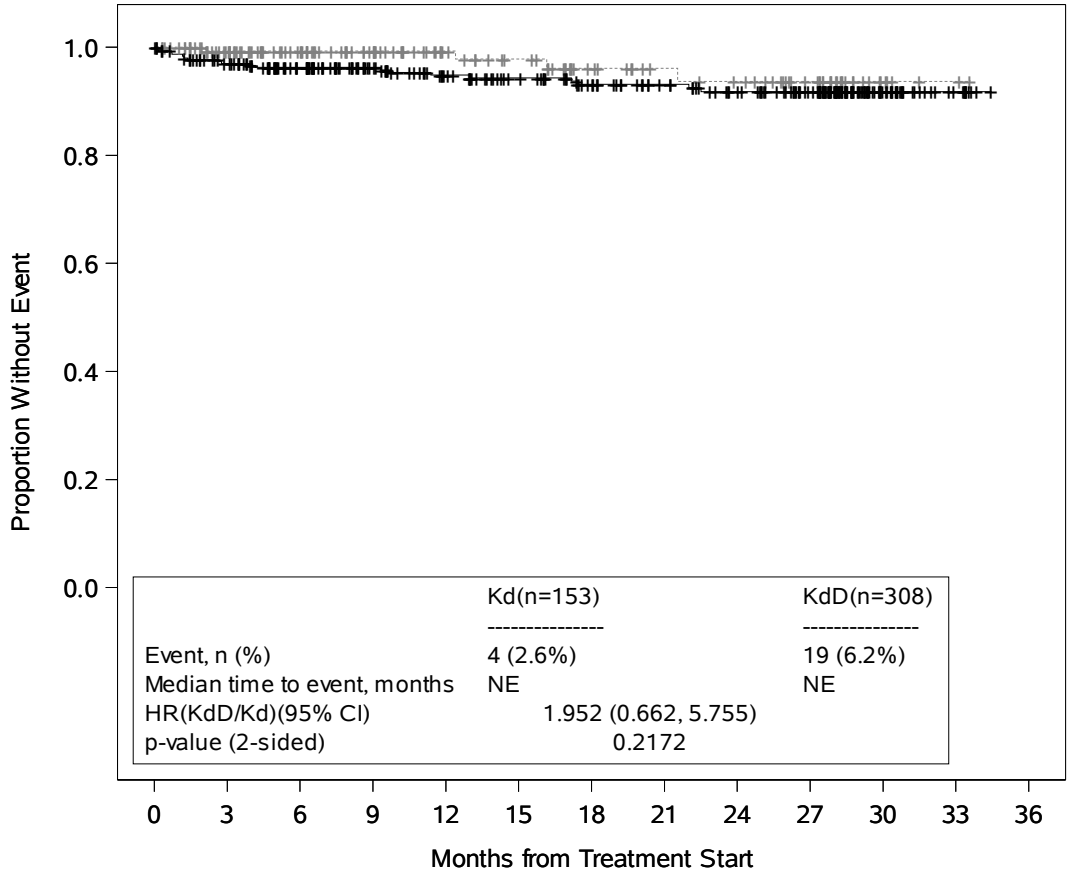


Number of Subjects at Risk:

Kd	153	132	108	88	68	60	47	39	37	27	6	2	0
KdD	308	288	252	213	192	177	161	146	134	112	36	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-015-506-sae-km-eoi-tumou-dar.rtf (Date Generated: 16SEP20:19:40:28).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.15.507. KM Curves of Serious Adverse Events of Interest for Daratumumab - Viral Infection (JMQ)
<Safety Population>

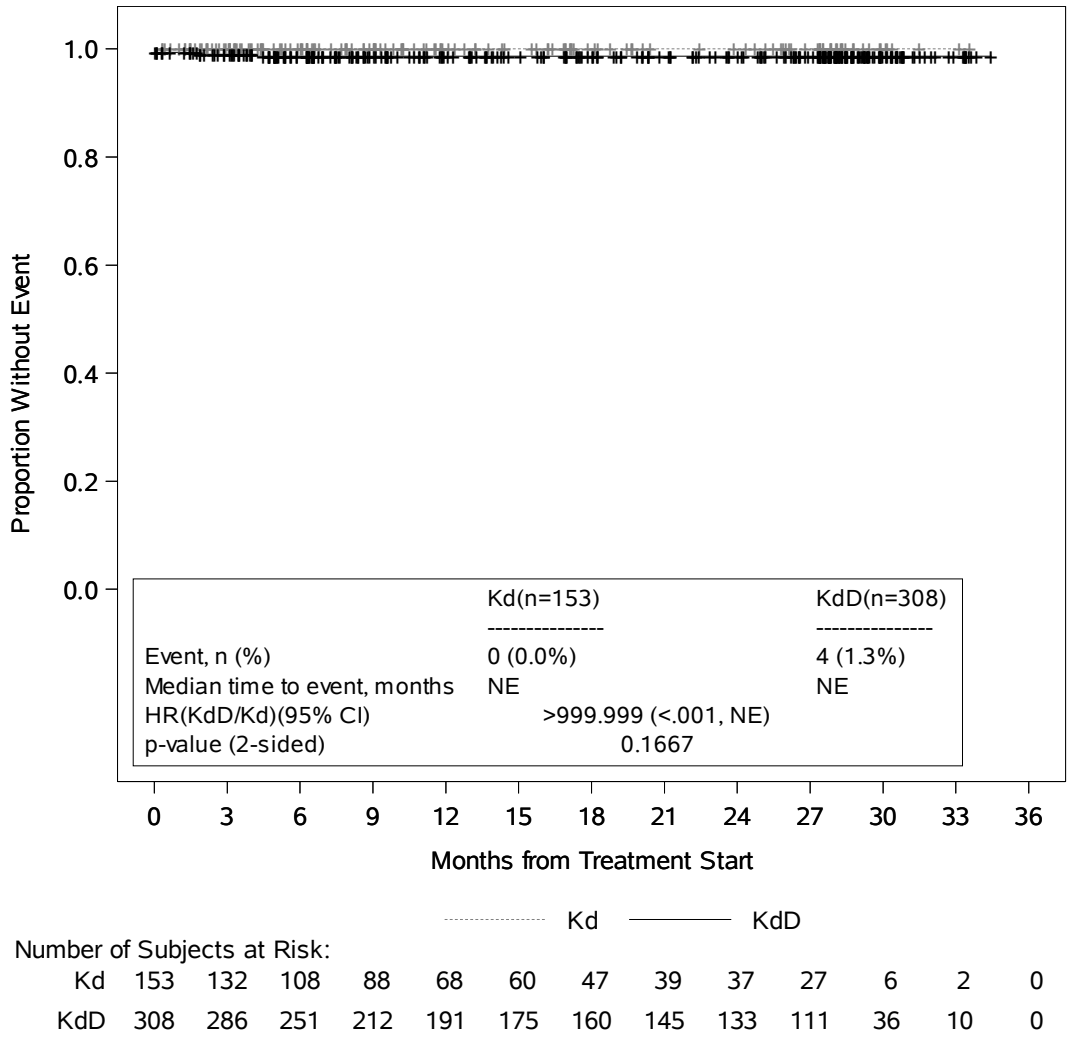


Number of Subjects at Risk:

Kd	153	131	108	88	68	60	46	39	36	26	6	2	0
KdD	308	281	247	209	186	170	154	140	127	106	35	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-015-507-sae-km-eoi-viral-dar.rtf (Date Generated: 16SEP20:19:40:29).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.15.501. KM Curves of Serious Adverse Events of Interest for Daratumumab - Daratumumab-related Infusion Reaction (AMQ) - Narrow (Event on Same Date or Next Date of Any Daratumumab Dosing)
<Safety Population>

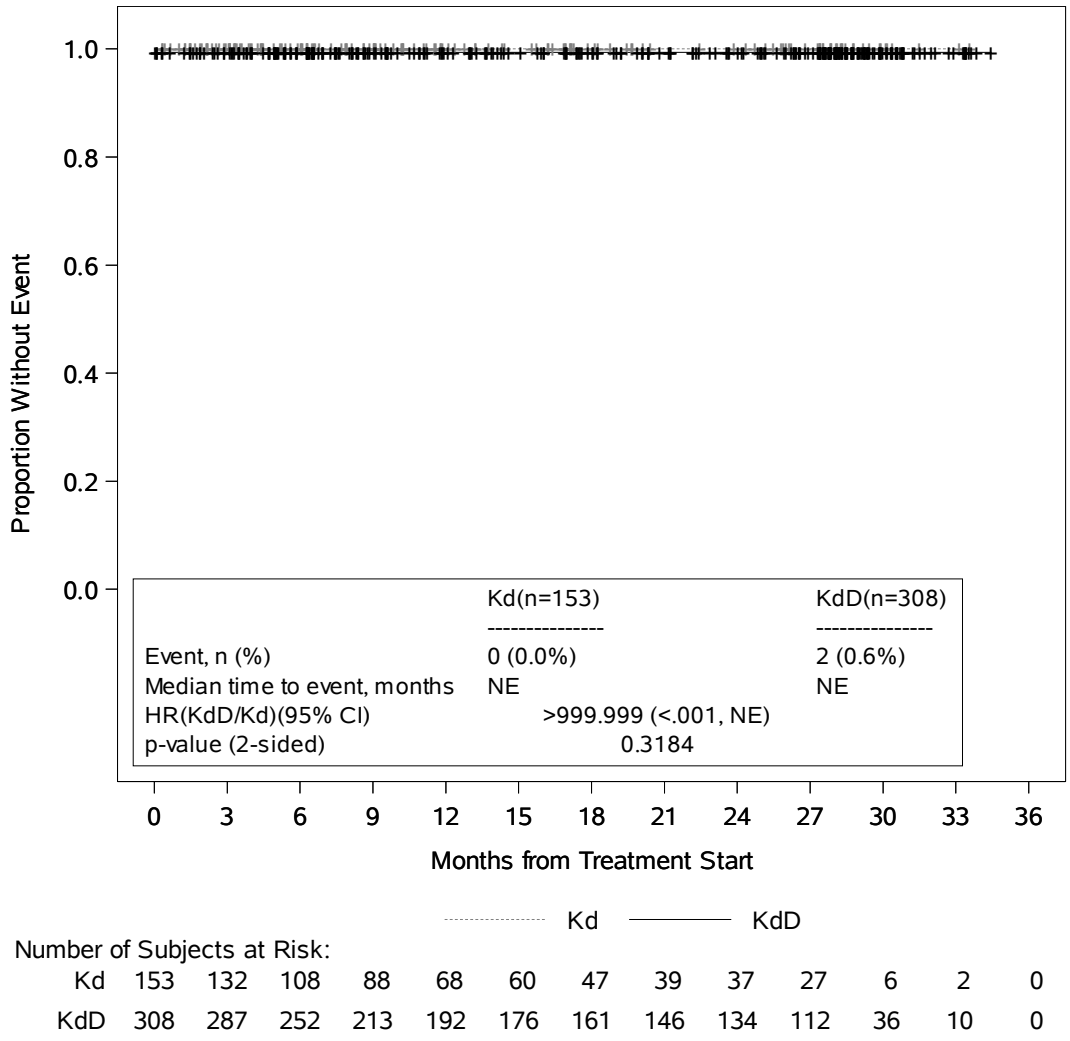


Number of Subjects at Risk:

Kd	153	132	108	88	68	60	47	39	37	27	6	2	0
KdD	308	286	251	212	191	175	160	145	133	111	36	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-015-501-sae-km-eoi-infany-dar.rtf (Date Generated: 16SEP20:19:40:20).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.15.502. KM Curves of Serious Adverse Events of Interest for Daratumumab - Daratumumab-related Infusion Reaction (AMQ) - Narrow (Event on Same Date or Next Date of First Daratumumab Dosing)
<Safety Population>

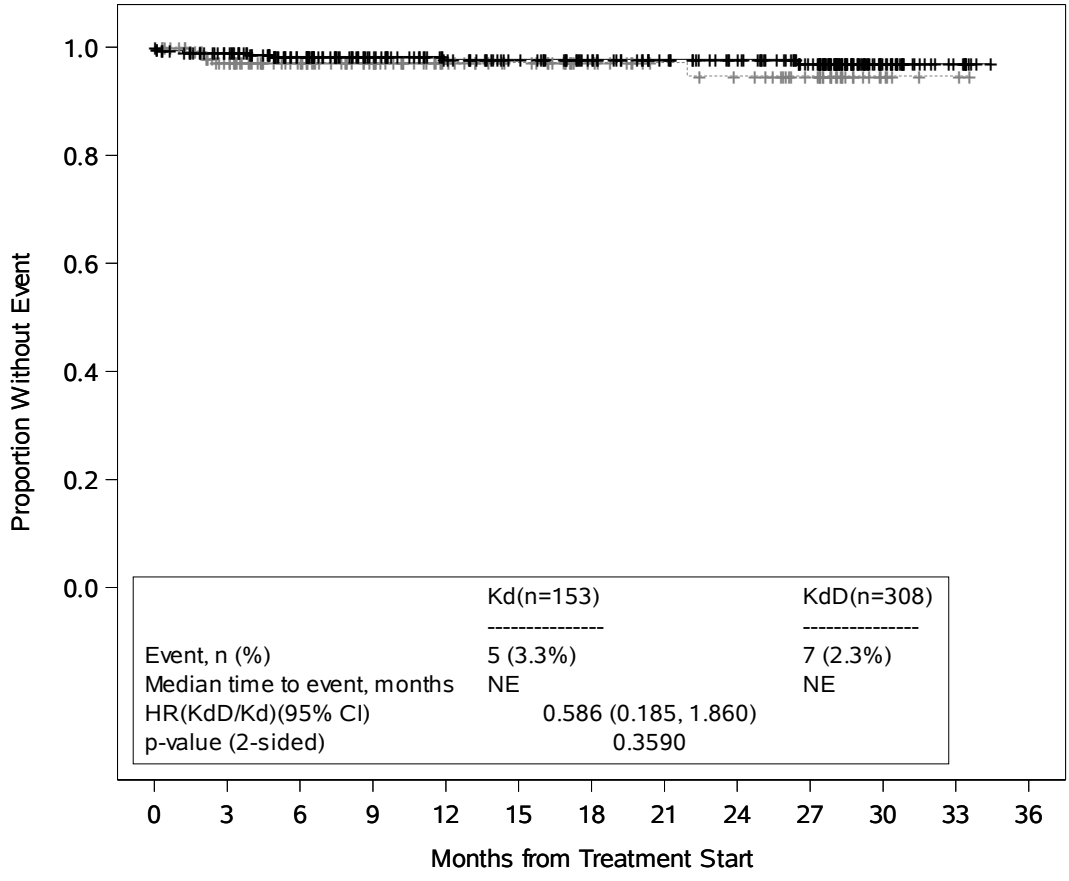


Number of Subjects at Risk:

Kd	153	132	108	88	68	60	47	39	37	27	6	2	0
KdD	308	287	252	213	192	176	161	146	134	112	36	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-015-502-sae-km-eoi-inffir-dar.rtf (Date Generated: 16SEP20:19:40:22).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.15.503. KM Curves of Serious Adverse Events of Interest for Daratumumab - Haemorrhage Terms (Excl Laboratory Terms) (SMQ) - Narrow <Safety Population>

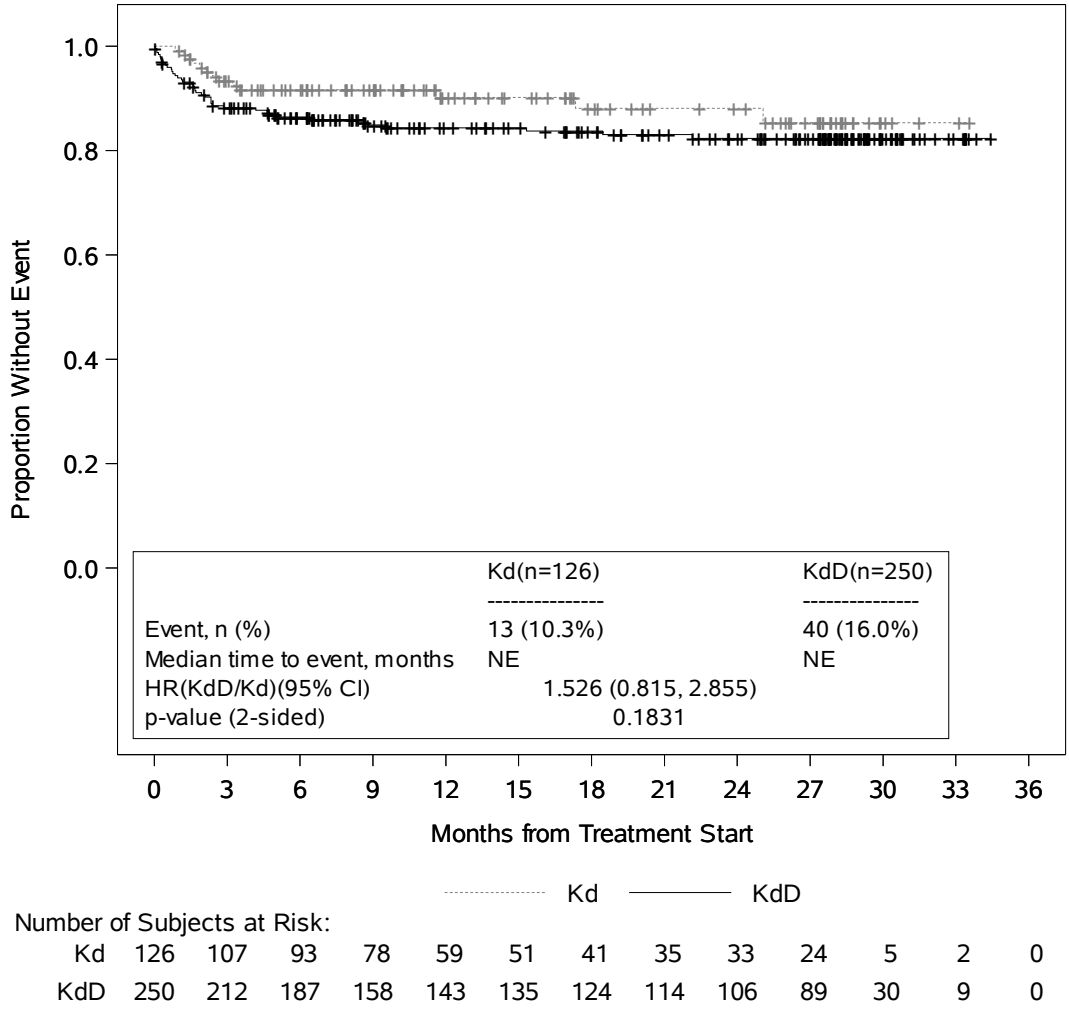


Number of Subjects at Risk:

Kd	153	129	108	88	68	60	47	39	36	27	6	2	0
KdD	308	287	251	213	191	176	160	145	133	110	35	10	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-cox-eoi.sas.
Output: f14-06-015-503-sae-km-eoi-haemo-dar.rtf (Date Generated: 16SEP20:19:40:23).
Source Data:adam.adsl, adam.adae, sdtm.ds.

Figure 14-6.11.603. KM Curves of Grade ≥3 Adverse Events of Interest for Carfilzomib - Haematopoietic Erythropenia (SMQ) - Broad
<Safety Population: Subjects With ISS Stage 1 or 2>

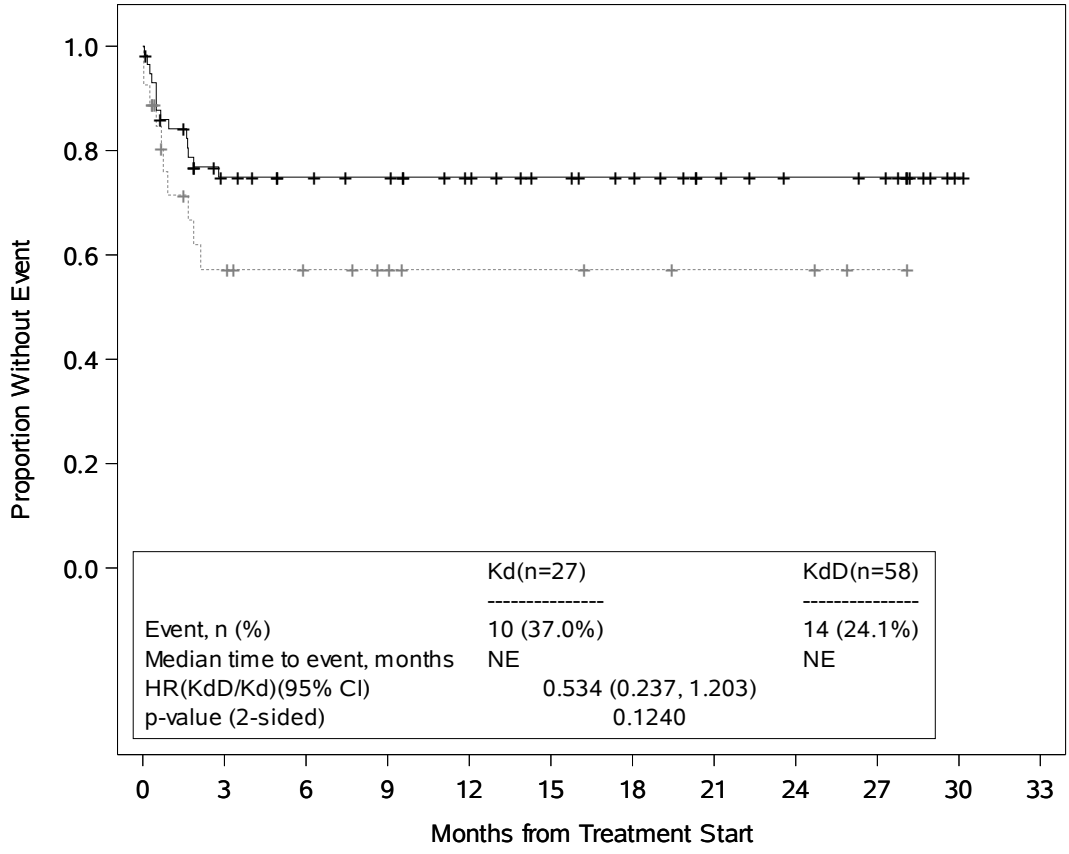


Number of Subjects at Risk:

Kd	126	107	93	78	59	51	41	35	33	24	5	2	0
KdD	250	212	187	158	143	135	124	114	106	89	30	9	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-km.sas.
Output: f14-06-011-603-ae-km-eoi-haema-sub-iss12-cfz-grd345.rtf (Date Generated: 16SEP20:01:21:03).
Source Data:adam.adsl, adam.adbase, adam.adae, sdtm.ds.

Figure 14-6.11.604. KM Curves of Grade ≥3 Adverse Events of Interest for Carfilzomib - Haematopoietic Erythropenia (SMQ) - Broad
<Safety Population: Subjects With ISS Stage 3>

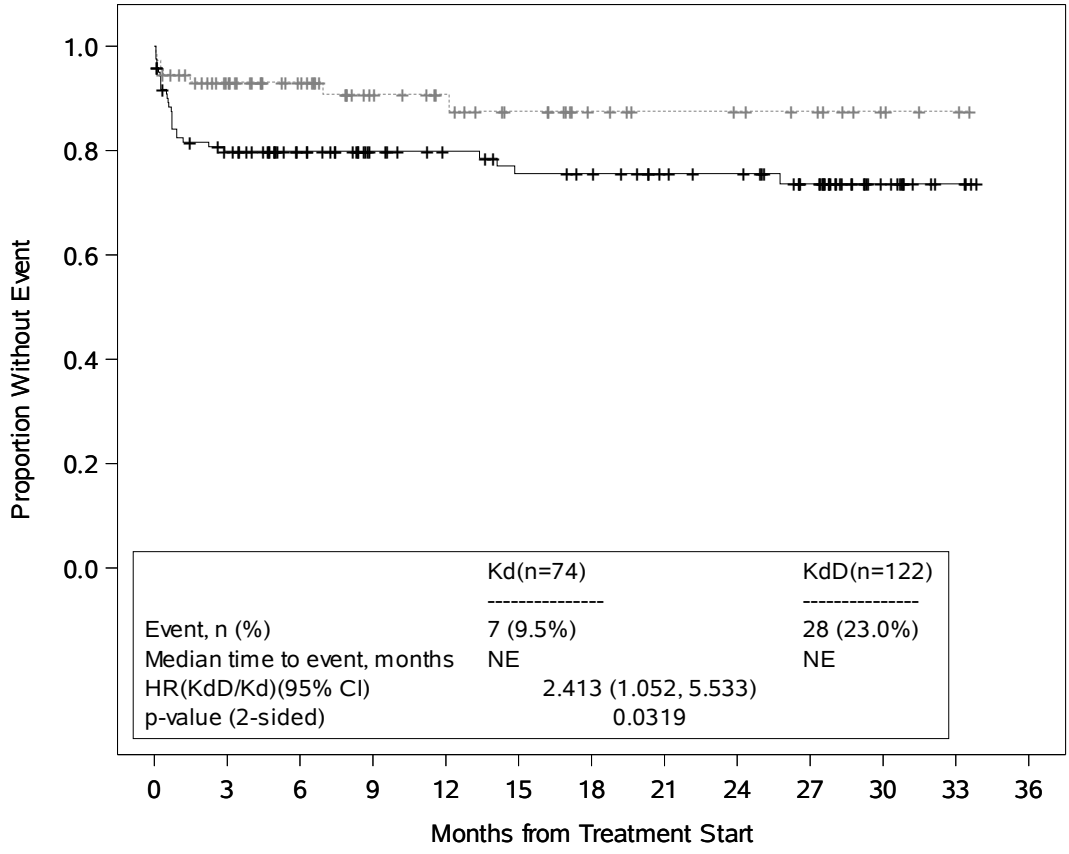


Number of Subjects at Risk:

Kd	27	12	9	7	5	5	4	3	3	1	0	
KdD	58	37	33	31	26	22	19	14	11	10	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-km.sas.
Output: f14-06-011-604-ae-km-eoi-haema-sub-iss3-cfz-grd345.rtf (Date Generated: 16SEP20:01:21:05).
Source Data:adam.adsl, adam.adbase, adam.adae, sdtm.ds.

Figure 14-6.11.605. KM Curves of Grade ≥3 Adverse Events of Interest for Carfilzomib - Haematopoietic leukopenia (SMQ) - Narrow <Safety Population: Subjects With Prior Lenalidomide Exposure>

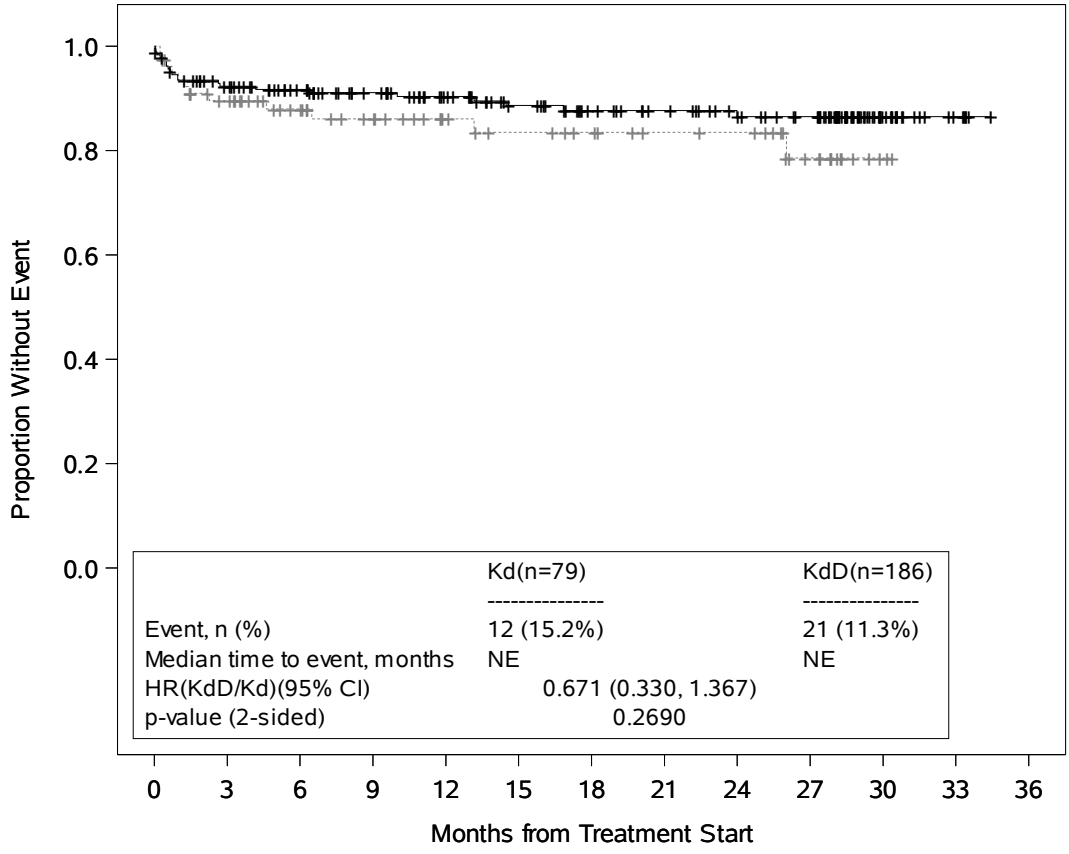


Number of Subjects at Risk:

Kd	74	58	46	33	28	22	15	12	11	9	4	2	0
KdD	122	92	76	62	57	52	50	44	42	33	13	4	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-km.sas.
Output: f14-06-011-605-ae-km-eoi-haema-sub-prelen-cfz-grd345.rtf (Date Generated: 16SEP20:01:21:07).
Source Data:adam.adsl, adam.adbase, adam.adae, sdtm.ds.

Figure 14-6.11.606. KM Curves of Grade ≥3 Adverse Events of Interest for Carfilzomib - Haematopoietic Leukopenia (SMQ) - Narrow <Safety Population: Subjects Without Prior Lenalidomide Exposure>

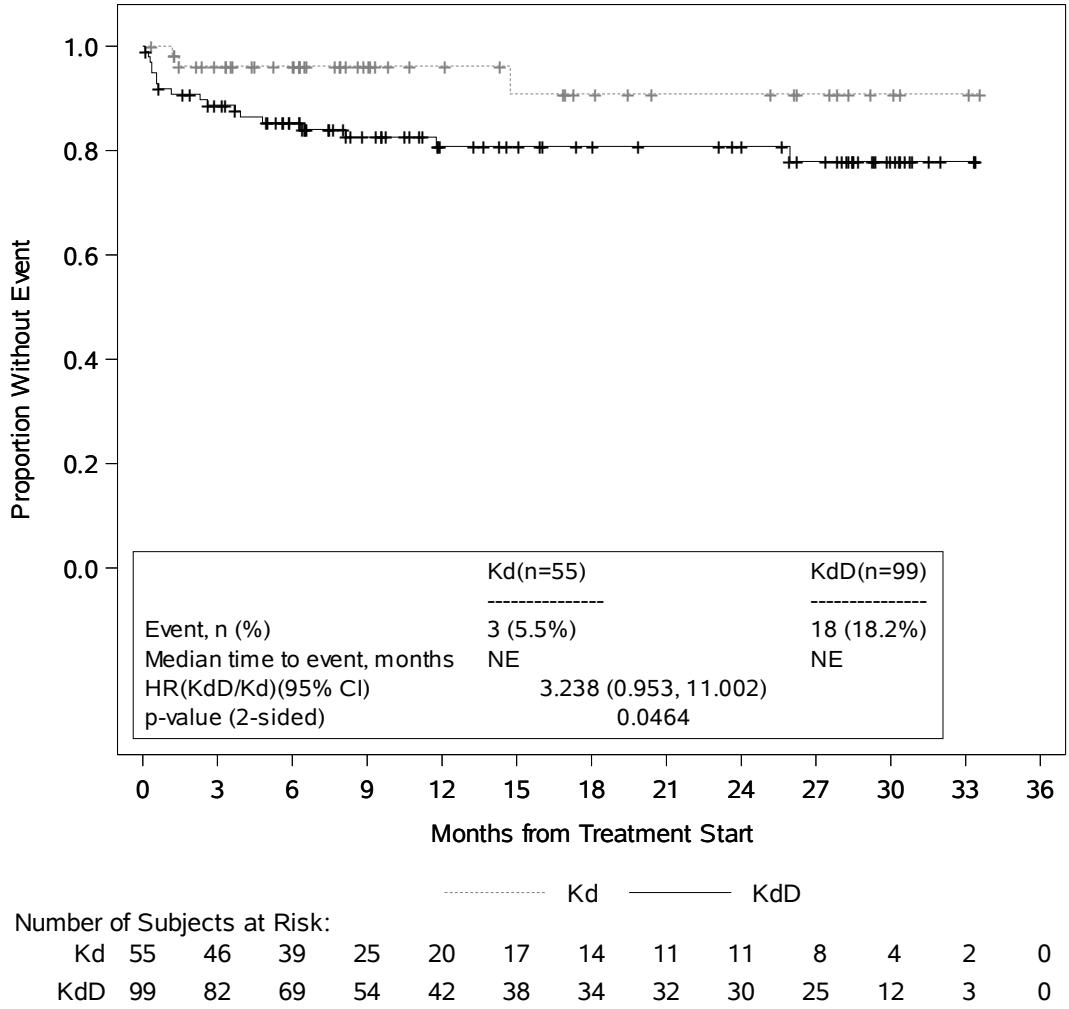


Number of Subjects at Risk:

Kd	79	64	52	43	34	30	27	23	22	13	2	0	
KdD	186	161	145	129	114	99	87	80	72	65	22	6	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-km.sas.
Output: f14-06-011-606-ae-km-eoi-haema-sub-noprel-cfz-grd345.rtf (Date Generated: 16SEP20:01:21:08).
Source Data:adam.adsl, adam.adbase, adam.adae, sdtm.ds.

Figure 14-6.13.601. KM Curves of Adverse Events of Interest for Daratumumab - Haemorrhage Terms (Excl Laboratory Terms) (SMQ) - Narrow <Safety Population: Subjects Refractory to Bortezomib or Ixazomib>

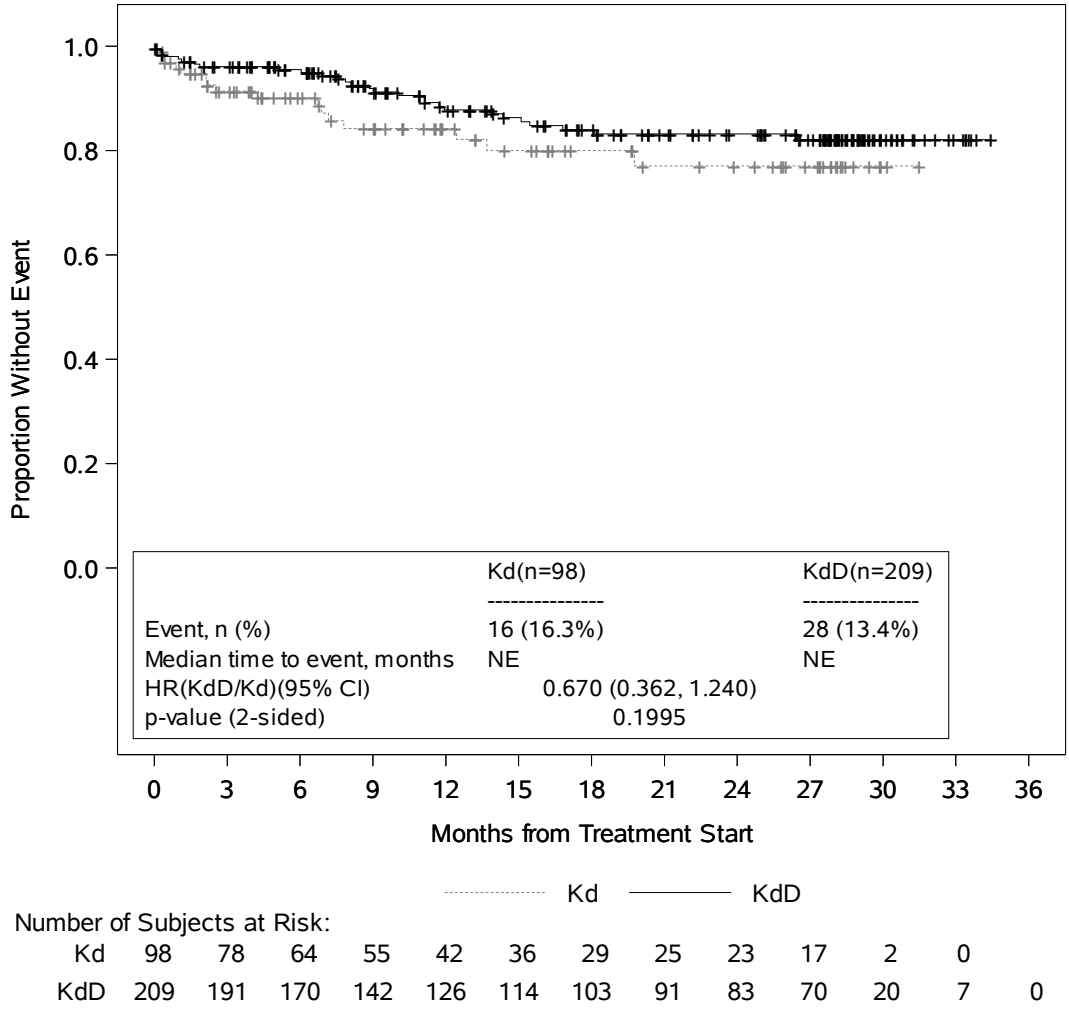


Number of Subjects at Risk:

Kd	55	46	39	25	20	17	14	11	11	8	4	2	0
KdD	99	82	69	54	42	38	34	32	30	25	12	3	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-km.sas.
Output: f14-06-013-601-ae-km-eoi-haemo-sub-refbor-dar.rtf (Date Generated: 16SEP20:01:21:16).
Source Data:adam.adsl, adam.adbase, adam.adae, sdtm.ds.

Figure 14-6.13.602. KM Curves of Adverse Events of Interest for Daratumumab - Haemorrhage Terms (Excl Laboratory Terms) (SMQ) - Narrow
<Safety Population: Subjects Non-refractory to Bortezomib or Ixazomib>

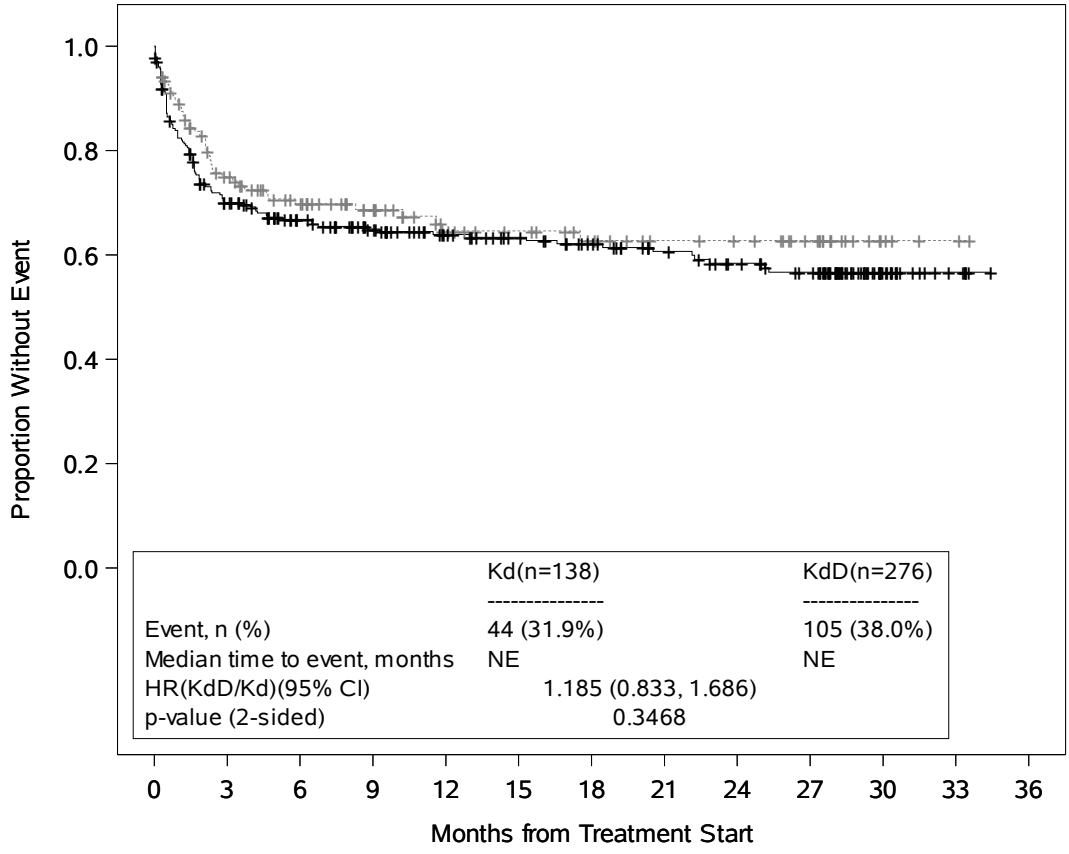


Number of Subjects at Risk:

Kd	98	78	64	55	42	36	29	25	23	17	2	0	
KdD	209	191	170	142	126	114	103	91	83	70	20	7	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-km.sas.
Output: f14-06-013-602-ae-km-eoi-haemo-sub-norefbor-dar.rtf (Date Generated: 16SEP20:01:21:18).
Source Data:adam.adsl, adam.adbase, adam.adae, sdtm.ds.

Figure 14-6.10.603. KM Curves of Adverse Events of Interest for Carfilzomib - Haematopoietic Erythropenia (SMQ) - Broad
<Safety Population: Subjects With Prior Proteasome Inhibitor Exposure>

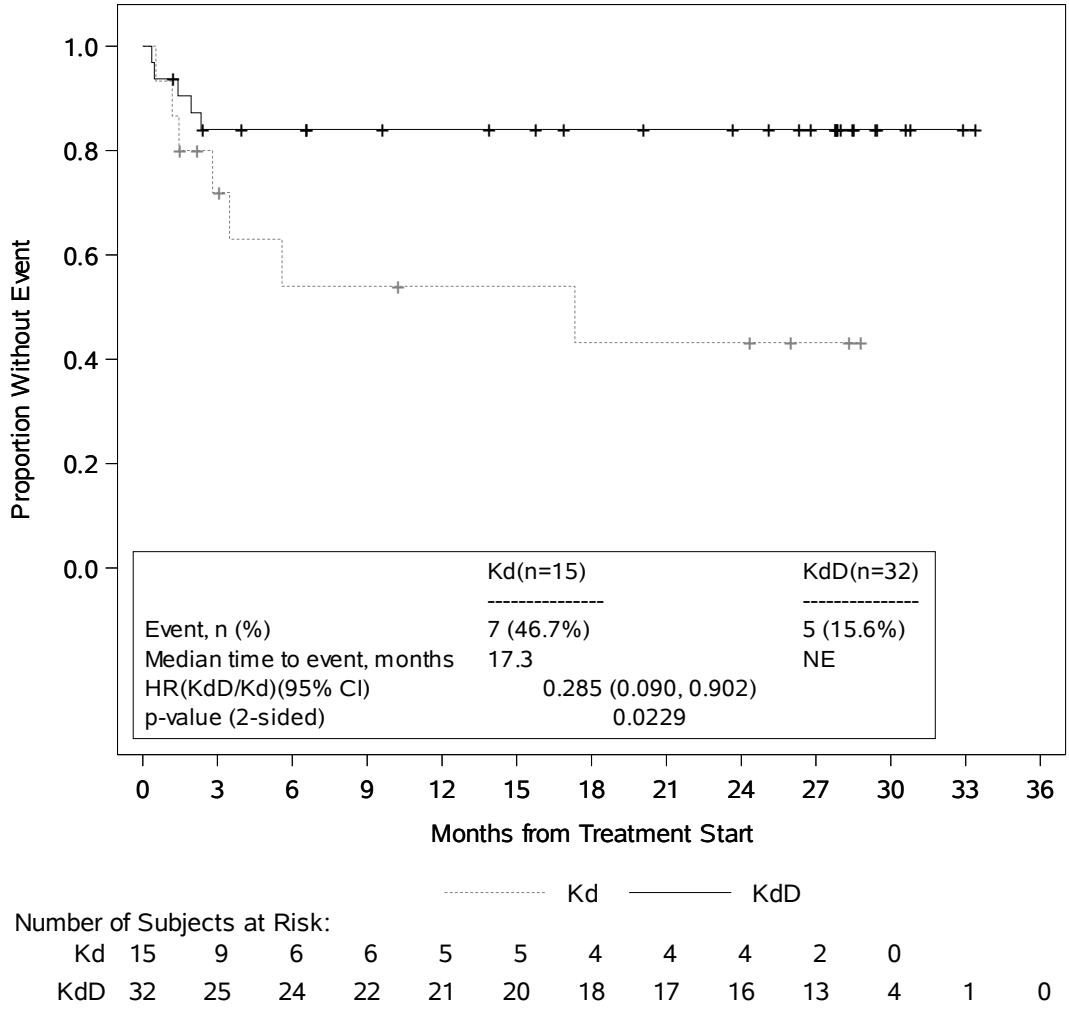


Number of Subjects at Risk:

Kd	138	93	76	60	44	39	33	27	25	19	5	2	0
KdD	276	182	153	133	114	103	93	81	72	64	21	6	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-km.sas.
Output: f14-06-010-603-ae-km-eoi-haema-sub-proinh-cfz.rtf (Date Generated: 16SEP20:01:20:40).
Source Data:adam.adsl, adam.adbase, adam.adae, sdtm.ds.

Figure 14-6.10.604. KM Curves of Adverse Events of Interest for Carfilzomib - Haematopoietic Erythropenia (SMQ) - Broad
<Safety Population: Subjects Without Prior Proteasome Inhibitor Exposure>

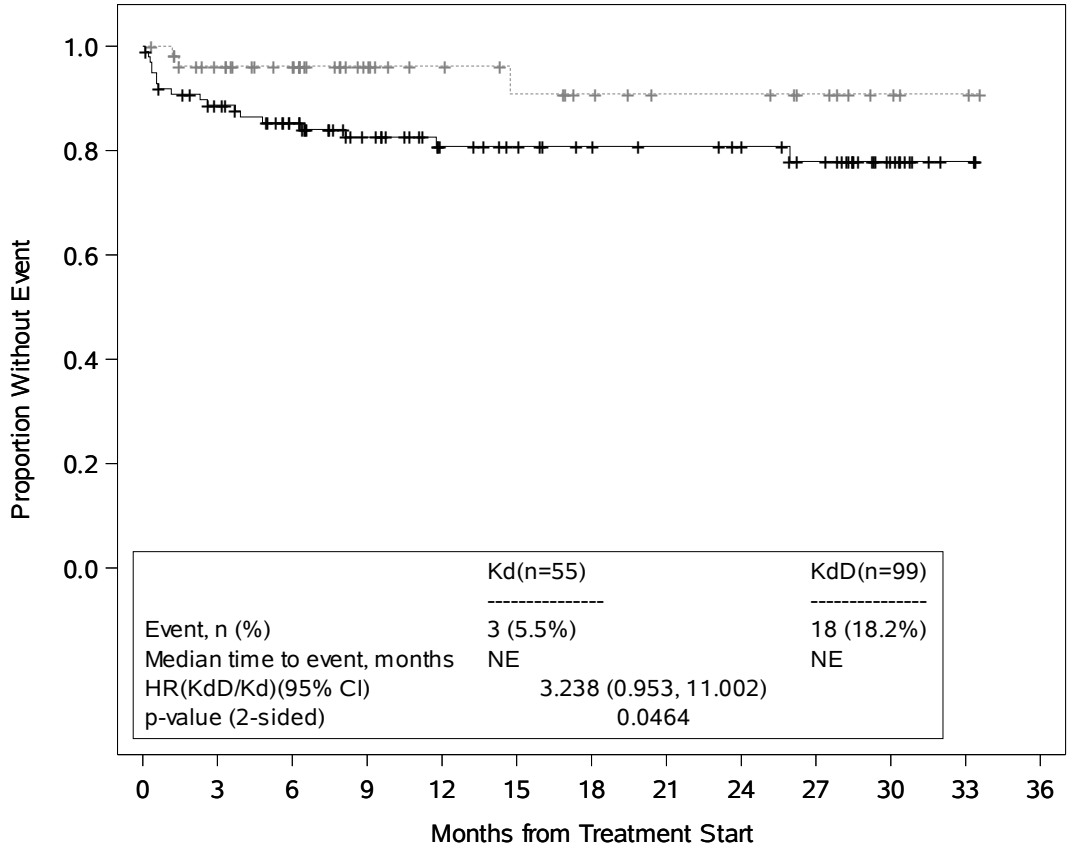


Number of Subjects at Risk:

Kd	15	9	6	6	5	5	4	4	4	2	0		
KdD	32	25	24	22	21	20	18	17	16	13	4	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-km.sas.
Output: f14-06-010-604-ae-km-eoi-haema-sub-noproinh-cfz.rtf (Date Generated: 16SEP20:01:20:42).
Source Data:adam.adsl, adam.adbase, adam.adae, sdtm.ds.

Figure 14-6.10.605. KM Curves of Adverse Events of Interest for Carfilzomib - Haemorrhage Terms (Excl Laboratory Terms) (SMQ) - Narrow <Safety Population: Subjects Refractory to Bortezomib or Ixazomib>

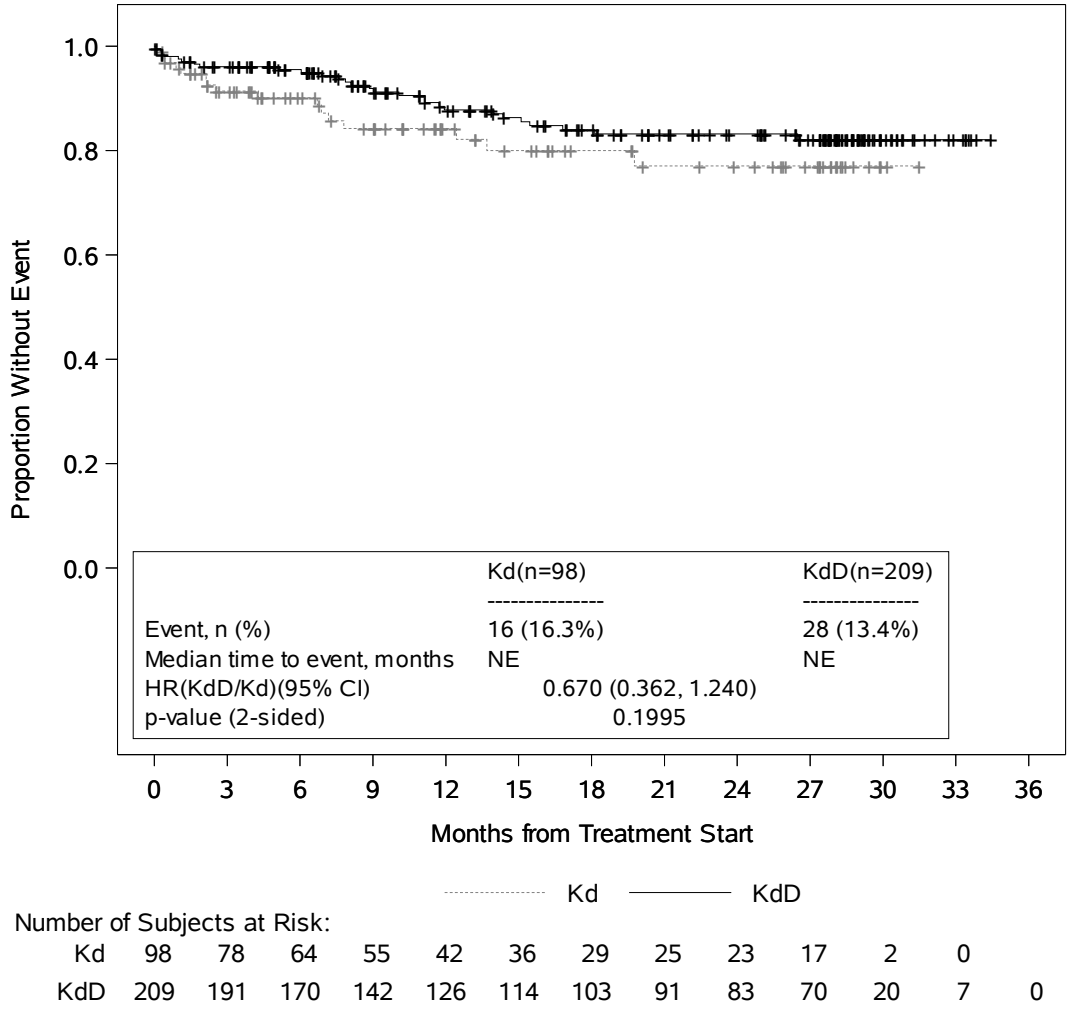


Number of Subjects at Risk:

Kd	55	46	39	25	20	17	14	11	11	8	4	2	0
KdD	99	82	69	54	42	38	34	32	30	25	12	3	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-km.sas.
Output: f14-06-010-605-ae-km-eoi-haeter-sub-refbor-cfz.rtf (Date Generated: 16SEP20:01:20:44).
Source Data:adam.adsl, adam.adbase, adam.adae, sdtm.ds.

Figure 14-6.10.606. KM Curves of Adverse Events of Interest for Carfilzomib - Haemorrhage Terms (Excl Laboratory Terms) (SMQ) - Narrow
<Safety Population: Subjects Non-refractory to Bortezomib or Ixazomib>

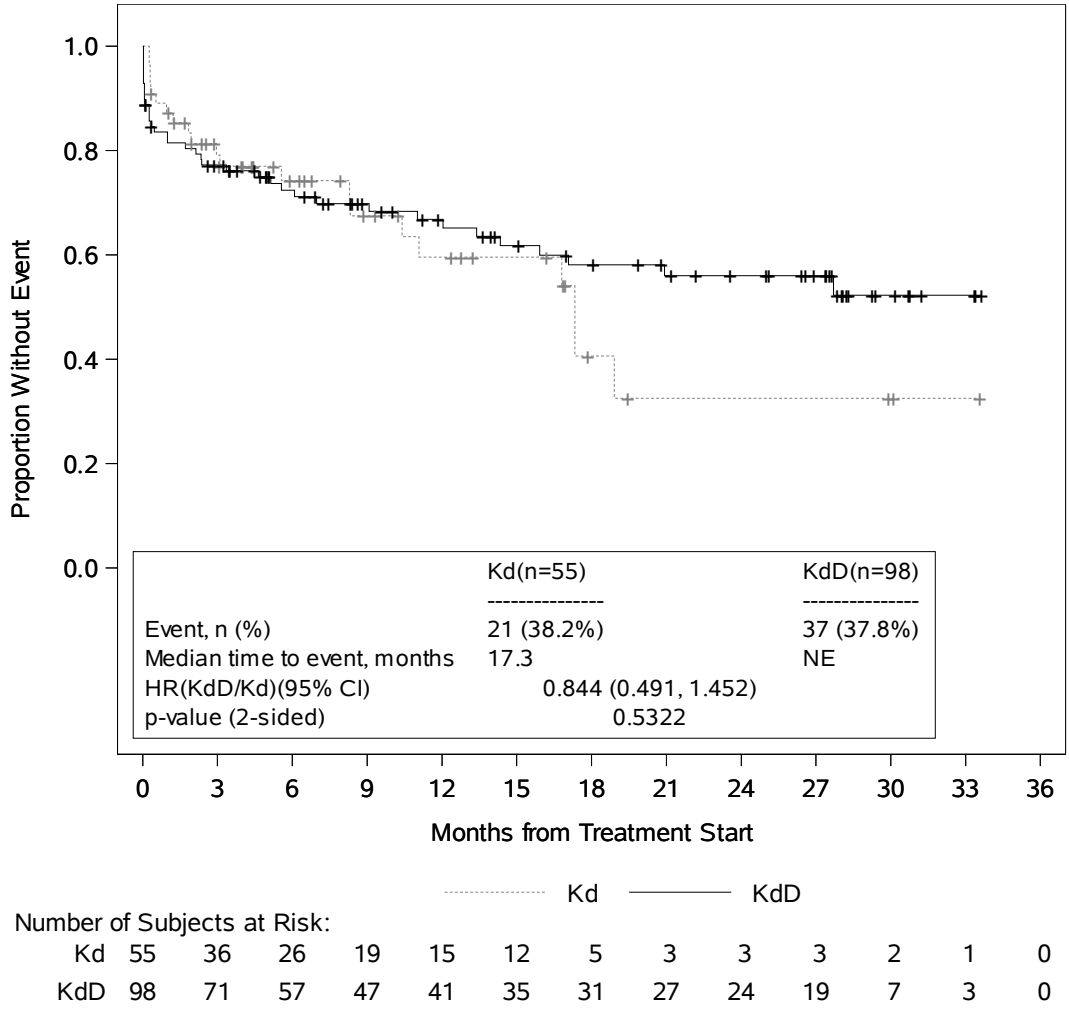


Number of Subjects at Risk:

Kd	98	78	64	55	42	36	29	25	23	17	2	0	
KdD	209	191	170	142	126	114	103	91	83	70	20	7	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-km.sas.
Output: f14-06-010-606-ae-km-eoi-haeter-sub-norefbor-cfz.rtf (Date Generated: 16SEP20:01:20:45).
Source Data:adam.adsl, adam.adbase, adam.adae, sdtm.ds.

Figure 14-6.10.611. KM Curves of Adverse Events of Interest for Carfilzomib - Infusion Reaction (AMQ) - Narrow (Event on Same Date of Any Carfilzomib Dosing)
<Safety Population: Subjects Refractory to Lenalidomide>

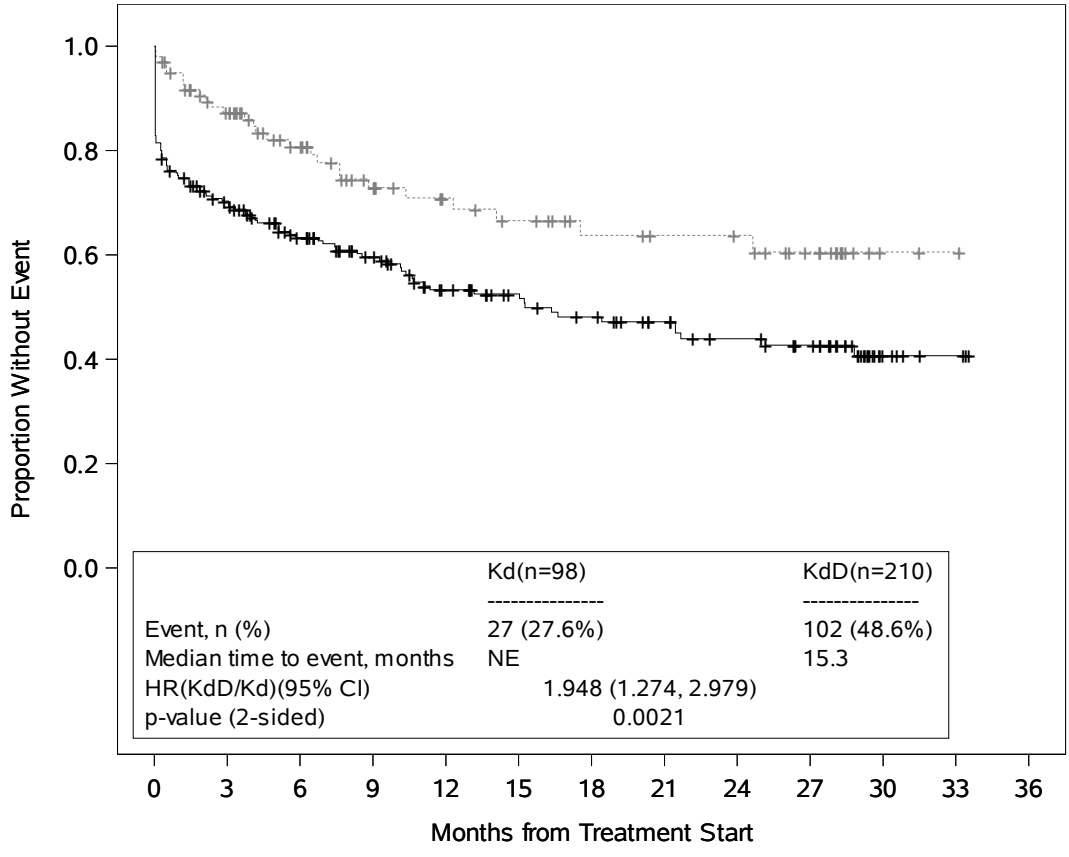


Number of Subjects at Risk:

Kd	55	36	26	19	15	12	5	3	3	3	2	1	0
KdD	98	71	57	47	41	35	31	27	24	19	7	3	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-km.sas.
Output: f14-06-010-611-ae-km-eoi-infany-sub-reflen-cfz.rtf (Date Generated: 16SEP20:01:20:53).
Source Data:adam.adsl, adam.adbase, adam.adae, sdtm.ds.

Figure 14-6.10.612. KM Curves of Adverse Events of Interest for Carfilzomib - Infusion Reaction (AMQ) - Narrow (Event on Same Date of Any Carfilzomib Dosing)
<Safety Population: Subjects Non-refractory to Lenalidomide>

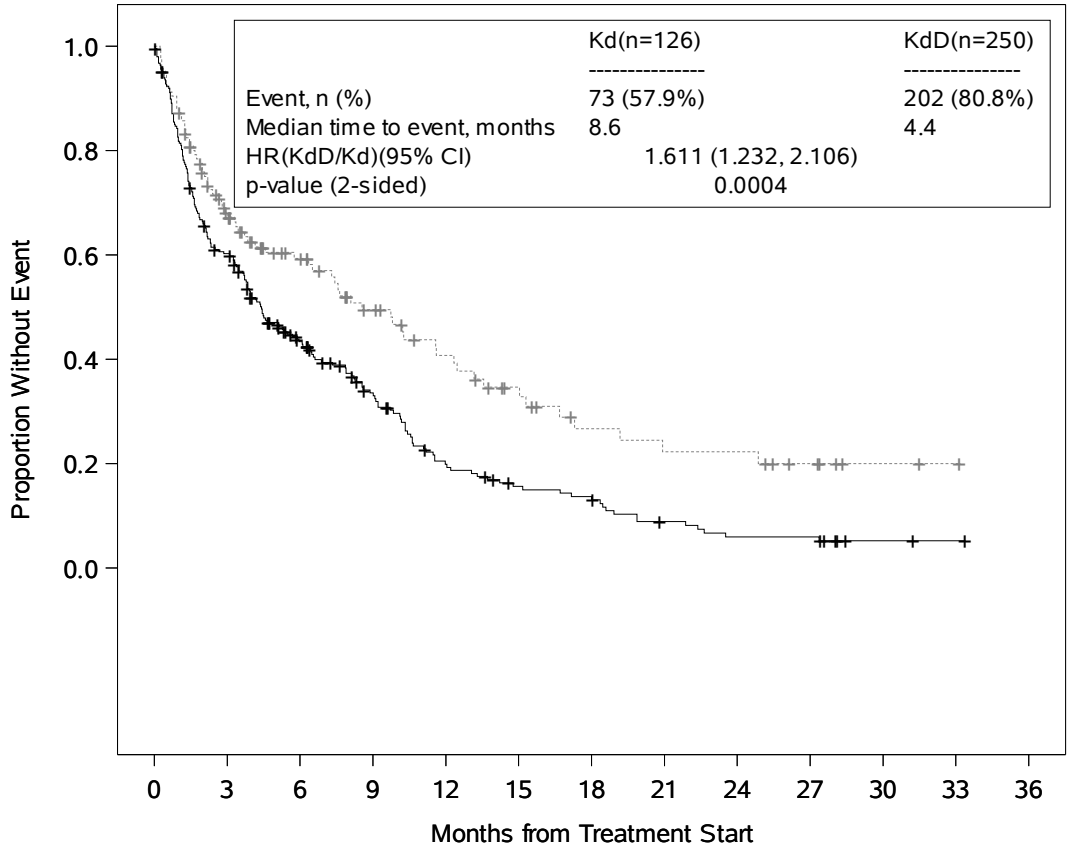


Number of Subjects at Risk:

Kd	98	76	58	43	33	29	23	21	20	14	2	1	0
KdD	210	138	111	91	71	60	53	45	38	32	8	3	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-km.sas.
Output: f14-06-010-612-ae-km-eoi-infany-sub-noreflen-cfz.rtf (Date Generated: 16SEP20:01:20:55).
Source Data:adam.adsl, adam.adbase, adam.adae, sdtm.ds.

Figure 14-6.10.613. KM Curves of Adverse Events of Interest for Carfilzomib - Respiratory Tract Infections (AMQ) - Broad
<Safety Population: Subjects With ISS Stage 1 or 2>

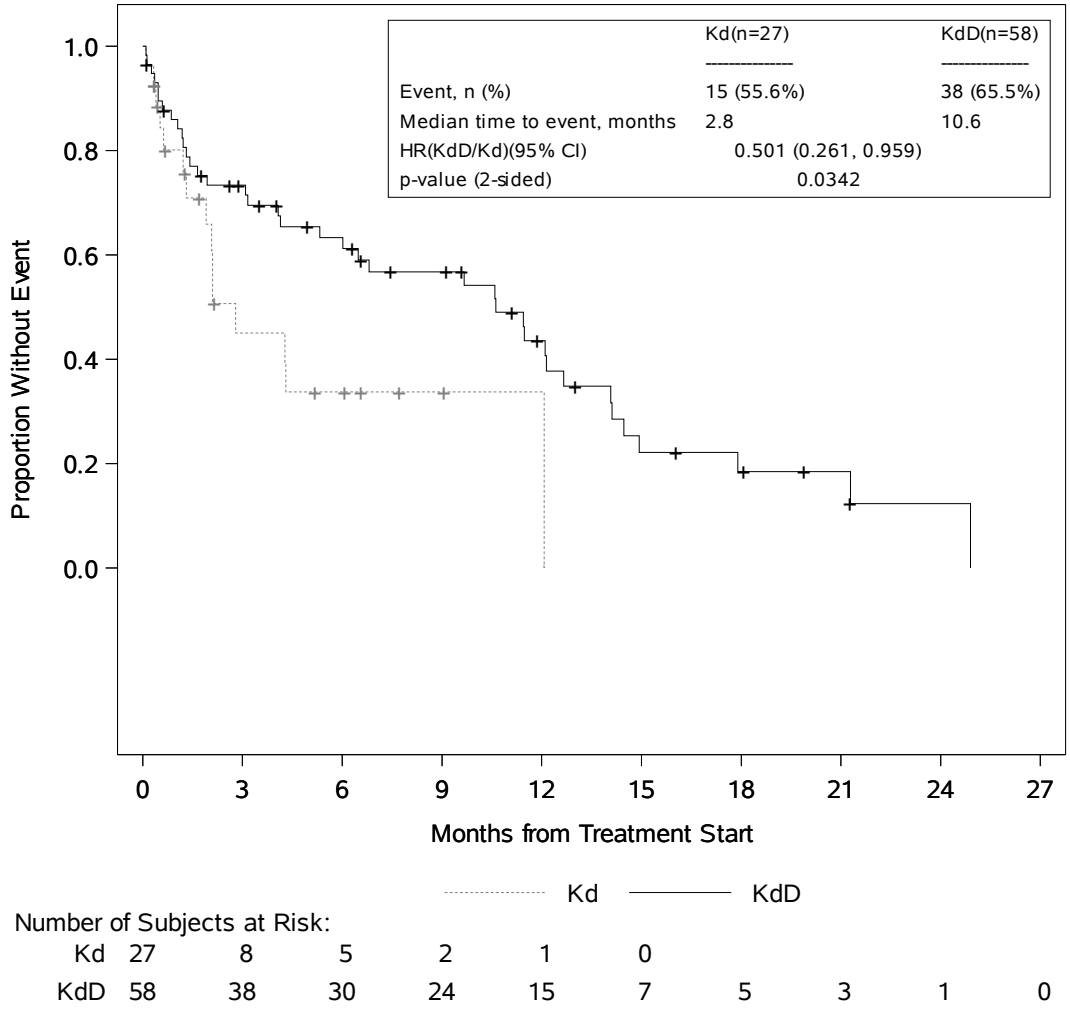


Number of Subjects at Risk:

Kd	126	76	53	37	27	19	12	10	10	6	2	1	0
KdD	250	146	91	61	34	24	20	12	8	8	2	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-km.sas.
Output: f14-06-010-613-ae-km-eoi-restra-sub-iss12-cfz.rtf (Date Generated: 16SEP20:01:20:56).
Source Data:adam.adsl, adam.adbase, adam.adae, sdtm.ds.

Figure 14-6.10.614. KM Curves of Adverse Events of Interest for Carfilzomib - Respiratory Tract Infections (AMQ) - Broad
<Safety Population: Subjects With ISS Stage 3>



Number of Subjects at Risk:

Kd	27	8	5	2	1	0				
KdD	58	38	30	24	15	7	5	3	1	0

Kd: carfilzomib and dexamethasone; KdD: carfilzomib, dexamethasone, and daratumumab.
The survival curves in this plot and the median time to AE in this plot were derived by unstratified Kaplan-Meier method. Hazard ratio and 95% CI reported in the figure were from unstratified Cox proportional hazards model, and 2-sided p-value was from unstratified log-rank test.
Program:/userdata/stat/amg981/onc/20160275/analysis/amnog_2020_os/figures/f-ae-km.sas.
Output: f14-06-010-614-ae-km-eoi-restra-sub-iss3-cfz.rtf (Date Generated: 16SEP20:01:20:58).
Source Data:adam.adsl, adam.adbase, adam.adae, sdtm.ds.