REALiTEC: a multi-country observational retrospective study of teclistamab in patients with relapsed/refractory multiple myeloma outside of clinical trials

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Supplementary material

Methods

Definitions of response

Duration of response (DOR) was defined as the time interval from the date of first response to the date of first evidence of progressive disease based on available data, or death due to any cause, whichever occurs first. For patients who did not progress, their outcome was censored at the last date collected from the medical records before the start of any subsequent antimyeloma therapy.

Progression-free survival (PFS) was defined as the time interval from the date of first response to the date of first evidence of progressive disease, as assessed by the investigator based on available data, or death due to any cause, whichever occurred first. For patients who did not progress, the patient's outcome was censored at the last date collected from the medical records before the start of any subsequent antimyeloma therapy.

PFS2 was defined as the time interval from the date of first dose of teclistamab to the date of progressive disease occurring after the start of subsequent antimyeloma therapy, as assessed by the investigator based on available data, or death from any cause, whichever occurred first. For patients who received subsequent antimyeloma therapy and were alive without documented disease progression, or who did not receive subsequent therapy, or who died before receiving subsequent therapy, the patient's outcome was censored at the last date collected from the medical records.

Overall survival (OS) was defined as the time interval from the date of first dose of teclistamab to the date of patient death due to any cause. If the patient was alive or vital status was unknown, then the patient's outcome was censored at the last date collected from the medical records (not restricted by the start of any subsequent antimyeloma therapy).

Time to next treatment (TTNT) was defined as the time from the date of first dose of teclistamab to the start of the next line of antimyeloma treatment.

Supplementary Table 1. Summary of baseline characteristics that would have made patients ineligible for MajesTEC-1 clinical trial at baseline (N=113) [8]

Baseline characteristics in REALiTEC that are ineligibility criteria for MajesTEC-1	**Number of participants**
Total meeting ineligibility criteria	80 (70.8%)
Prior BCMA therapy received	40 (35.4%)
Baseline ECOG score ≥2	8 (7.1%)
Baseline cytopenia (including either of the following)	31 (27.4%)
Haemoglobin <8.0 g/dL	9 (8.0%)
Platelet count <50 x 10^9/L	22 (19.5%)
Absolute neutrophil count <1.0 x 10^9/L	11 (9.7%)
ALT >3 x ULN	0
AST >3 x ULN	0
Compromised renal status (including either of the following)	23 (20.4%)
Serum creatinine >1.5 mg/dL	19 (16.8%)
Creatinine clearance/GFR <40 mL/min or mL/min/1.73 m^2	14 (12.4%)
Cardiac comorbidities (including any of the following)	3 (2.7%)
NYHA stage III or IV congestive heart failure ≤28 days before starting teclistamab	0
Myocardial infarction or CABG ≤6 months prior to the first dose of teclistamab	1 (0.9%)
History of clinically significant ventricular arrhythmia or unexplained syncope ≤28 days before starting teclistamab	1 (0.9%)
History of severe non-ischaemic cardiomyopathy ≤28 days before starting teclistamab	2 (1.8%)
Active autoimmune disease or a documented history of autoimmune disease ≤28 days before starting teclistamab	1 (0.9%)
Active malignancies other than MM ≤28 days before starting teclistamab (including any of the following)	4 (3.5%)
Plasma cell leukemia (>2.0 x 10^9/L plasma cells by standard differential)	1 (0.9%)
Myelodysplastic syndrome	1 (0.9%)
Other active malignancies	2 (1.8%)

Active CNS involvement or clinical signs of meningeal involvement of MM ≤28 days before starting teclistamab	1 (0.9%)

ALT, alanine aminotransferase; AST, aspartate aminotransferase; BCMA, B cell maturation antigen; CABG, coronary artery bypass graft; CNS, central nervous system; ECOG, Eastern Cooperative Oncology Group; GFR, glomerular filtration rate; MM, multiple myeloma; NYHA, New York Heart Association; ULN, upper limit of normal.

Supplementary Table 2: Summary of overall best confirmed response in overall (all-treated) study population (N=113)

Response category	N (%)	95% CI for %
Stringent complete response (sCR)	6 (5.3)	2.0−11.2
Complete response (CR)	24 (21.2)	14.1−29.9
Very good partial response (VGPR)	29 (25.7)	17.9−34.7
Partial response (PR)	9 (8.0)	3.7−14.6
Minimal response	1 (0.9)	0.0−4.8
Stable disease	11 (9.7)	5.0−16.8
Progressive disease	18 (15.9)	9.7−24.0
Not available / not reported	15 (13.3)	7.6−20.9
Overall response (sCR + CR + VGPR + PR)	68 (60.2)	50.5−69.3
VGPR or better (sCR + CR + VGPR)	59 (52.2)	42.6−61.7
CR or better (sCR + CR)	30 (26.5)	18.7−35.7
Near CR	20 (17.7)	11.2−26.0

Responses were as assessed by the investigator per IMWG response criteria. Near CR is defined as the proportion of patients who have a near CR as assessed by the investigator per IMWG response criteria. Per such criteria, a patient is considered to have a Near CR if both of the following are recorded: 'Very Good Partial Response' and 'Yes, CR can't be confirmed due to missing bone marrow assessment, whereas all other criteria for CR are met.'

Supplementary Table 3: Effectiveness in patients who switched from weekly dosing to either biweekly (N=45) or monthly dosing (N=26)

	Switch to biweekly (n=45)	Switch to monthly (n=26)
Time to switch, median (range)	7.0 months (0–18)	10.5 months (1–22)
Overall response (sCR + CR + VGPR + PR), % (95% CI)	82.2 (67.9–92.0)	88.5 (69.8–97.6)
≥ VGPR (sCR + CR + VGPR), % (95% CI)	80.0 (65.4–90.4)	84.6 (65.1–95.6)
CR or better, % (95% CI)	44.4 (29.6–60.0)	42.3 (23.4–63.1)
Near CR, % (95% CI)	31.1 (18.2–46.6)	34.6 (17.2–55.7)
DoT, months, median (range)	18.9 (2.6–35.8)	18.1 (1.4–35.8)
DoR, median (range)	NE (20.3–NE)	NE (20.3–NE)
PFS, median (range)	NE (22.2–NE)	NE (22.2–NE)
12 month estimate, %	86.7	92.3
OS, median (range)	NE (26.3–NE)	NE (NE–NE)
12 month estimate, %	97.8	96.2

Responses were as assessed by the investigator per IMWG response criteria. Near CR is defined as the proportion of patients who have a near CR as assessed by the investigator per IMWG response criteria. Per such criteria, a patient is considered to have a Near CR if both of the following are recorded: 'Very Good Partial Response' and 'Yes, CR can't be confirmed due to missing bone marrow assessment, whereas all other criteria for CR are met.'
95% CI, 95% confidence interval; CR, complete response; DoR, duration of response; DoT, duration of treatment; NE, not evaluable; OS, overall survival; PFS, progression-free survival; PR, partial response; sCR, stringent complete response; VGPR, very good partial response.

Supplementary Table 4. Listing of fatal (grade 5) treatment-emergent adverse events

Age (years)	Sex	Preferred term	Reported term	Day of AE onset[a]	Duration of AE (days)	Relationship to teclistamab[b]	Action taken	Concomitant or additional therapy
66	Male	Acute kidney injury	Acute renal failure	109	1	Not related	Not applicable	Yes
68	Male	General physical health deterioration	Poor general condition	54	22	Not related	Drug withdrawn	Yes
82	Female	Febrile neutropenia	Febrile neutropenia	165	1	Related	Drug withdrawn	Yes
72	Male	Pneumonia escherichia	Bacteremic pneumonia due to *Escherichia coli*	96	1	Not related	Drug withdrawn	No
70	Male	Respiratory distress	Febrile respiratory distress	94	1	Not related	Not applicable	No
73	Male	Septic shock	Septic shock	131	1	Related	Not applicable	No
66	Male	Hyponatremia Hypovolemia	Hyponatremia Mild hypovolemia	20 20	1 1	Related Not related	Not applicable Drug withdrawn	Unknown Unknown
74	Male	Septic shock	Septic shock	101	1	Not related	Dose not changed	No
62	Female	Septic shock	Septic shock	152	1	Not related	Drug withdrawn	Yes
68	Female	Pneumonia	Lung infection	49	1	Not related	Not applicable	Yes
75	Female	Pneumonia Toxic encephalopathy	Pneumonia Neurotoxicity encephalopathy	104 104	1 1	Related Related	Dose not changed Not applicable	Yes Yes
61	Female	Multiple fractures	Multiple fracture	131	1	Not related	Not applicable	No
72	Female	General physical health deterioration	Progressive multiple myeloma with impaired general condition	110	1	Not related	Not applicable	No

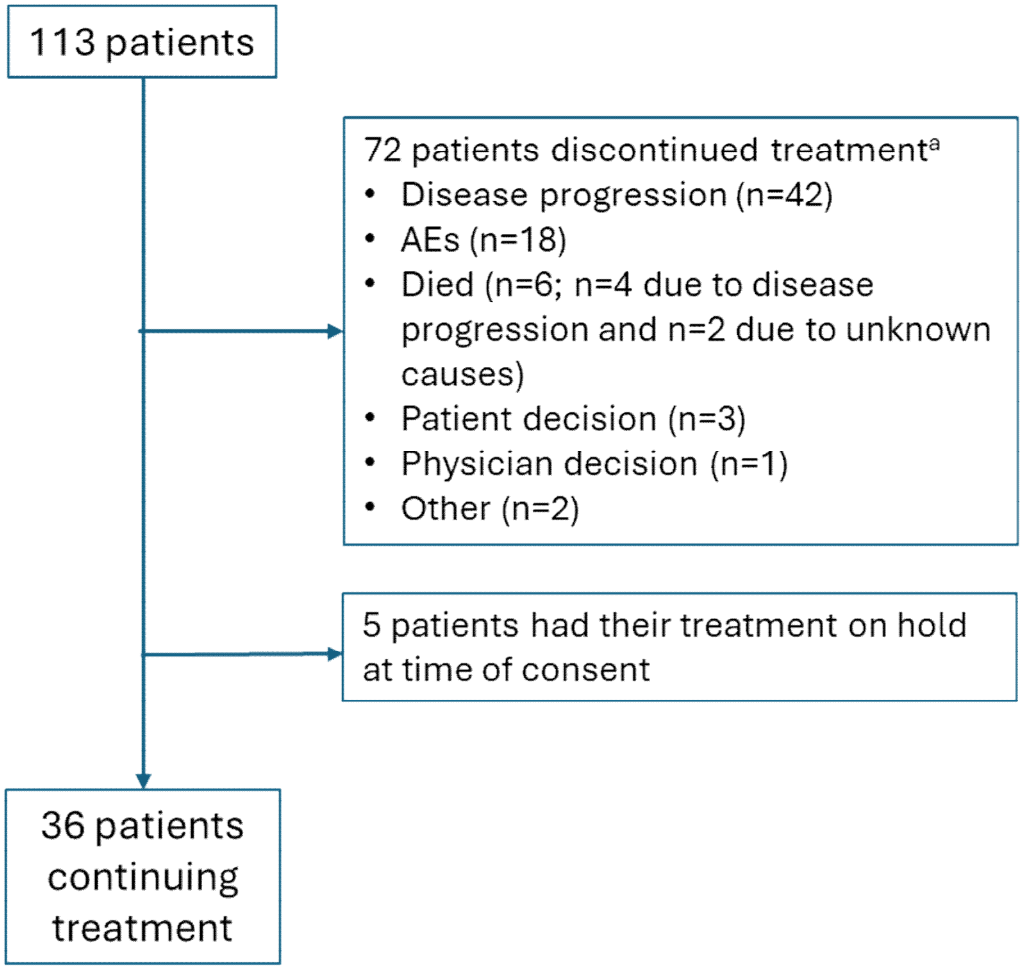
Adverse events are coded using MedDRA Version 26.1.

[a]Day of AE onset is calculated relative to the date of first dose of teclistamab treatment as: AE start date - date of first dose of treatment + 1.

[b]Relationship to teclistamab is assessed by the Investigator.

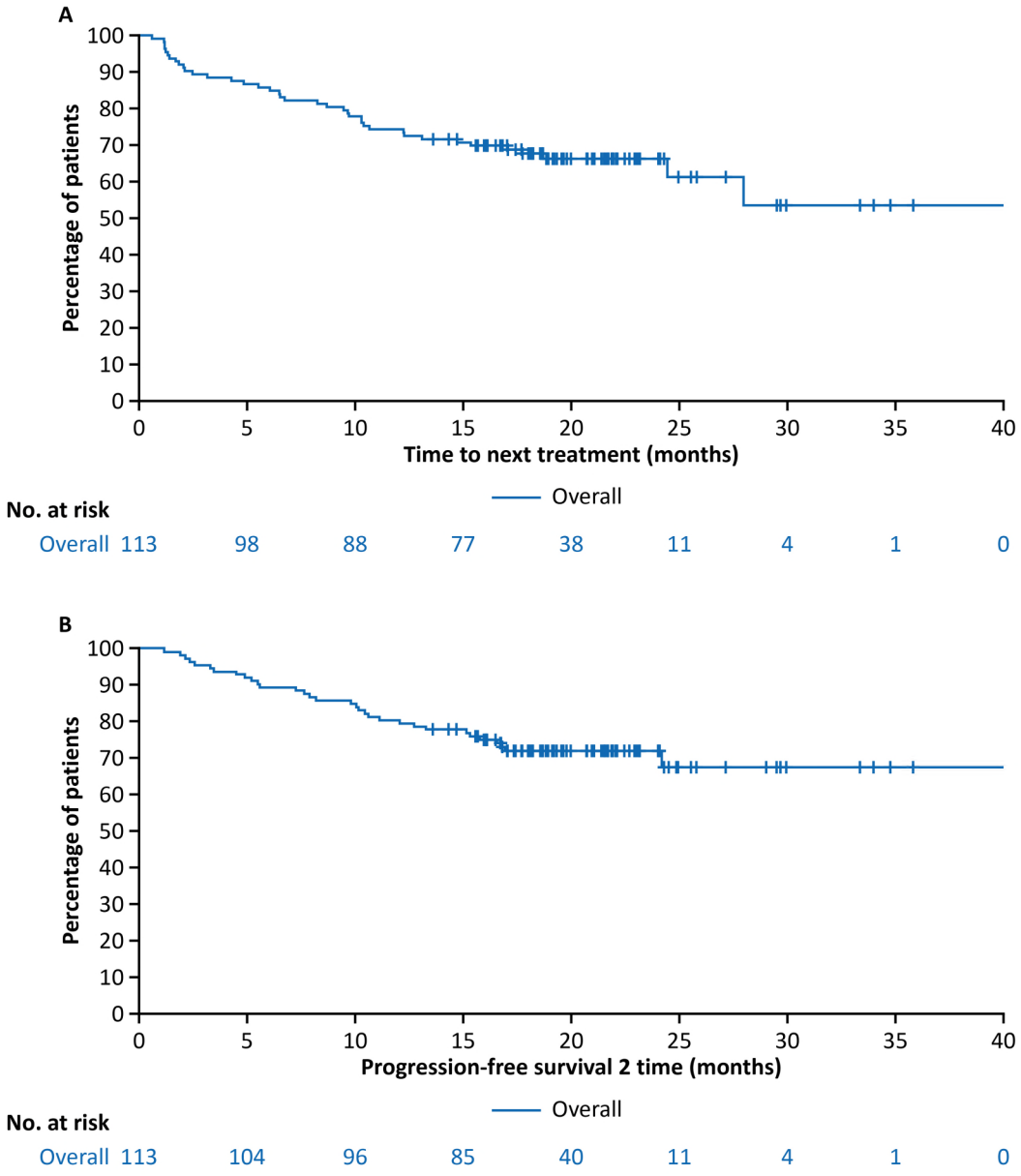
AE, adverse event.

Supplementary Figure 1. Treatment disposition



AE, adverse event.

Supplementary Figure 2. Kaplan–Meier plot showing A) time to next treatment and B) progression-free survival 2 in overall study population



Progression-free survival 2 is defined as the time interval from the date of first dose of teclistamab to the date of event occurring after the start of subsequent antimyeloma therapy, defined as progressive disease, as assessed by the investigator per IMWG response criteria based on available data, or death from any cause, whichever occurs first. For patients who receive subsequent antimyeloma therapy and are alive without documented disease progression, or who do not receive subsequent therapy, or who die

before receiving subsequent therapy, the patient's outcome is censored at the last date collected from the medical records.

IMWG, International Myeloma Working Group.

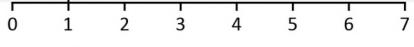
Supplementary Figure 3. Forest plots showing hazard ratios following the subgroup analysis examining each of two categorial variables for each risk factor (with 95% confidence intervals) A) duration of response, B) progression-free survival, C) overall survival across different subgroups analysed

A

Subgroup	Hazard Ratio and 95% CI	n1	n2	Med1	Med2	HR	LCL	UCL	LR pval
Age <75 vs ≥75 yr		56	11	26.12	20.27	1.03	0.40	2.69	0.950
MM diagnosis ≤6 vs >6 yr ago		25	42	16.82	26.12	1.29	0.63	2.64	0.485
ISS Stage I vs II/III		16	40	NE	26.12	0.84	0.33	2.12	0.712
Extramedullary disease N vs Y		30	3	17.41	6.64	0.61	0.14	2.69	0.511
Prior lines of therapy ≤3 vs >3		10	57	NE	20.27	0.80	0.24	2.66	0.720
Prior BCMA therapy N vs Y		46	21	20.27	17.41	0.80	0.38	1.67	0.549
Prior BCMA (ADC) therapy N vs Y		51	16	26.12	16.69	0.51	0.24	1.09	0.083
Prior BCMA (CAR-T) therapy N vs Y		62	5	20.27	NE	0.98	0.23	4.10	0.973
Triple-class refractory N vs Y		15	52	NE	20.27	1.12	0.48	2.61	0.791
Triple-class exposed N vs Y		2	65	NE	NE	NE	NE	NE	NE
Penta-drug refractory N vs Y		38	29	16.82	20.27	1.27	0.62	2.60	0.517
Pentar-drug exposed N vs Y		8	59	NE	20.27	0.48	0.11	2.03	0.320
Cytogenetic risk standard vs high		15	22	20.27	16.82	0.84	0.35	1.99	0.687
Risk (minus amp1q21) standard vs high		19	18	20.27	8.72	0.53	0.22	1.26	0.149
ECOG score 0 vs ≥1		18	14	NE	10.02	0.44	0.15	1.29	0.134
Baseline thrombocytopenia N vs Y		52	14	26.12	12.35	0.56	0.24	1.28	0.168
LDH level ≤245 vs >245 U/L		36	17	NE	16.82	0.46	0.21	1.01	0.054
Response ≥VGPR vs <VGPR		58	9	26.12	3.78	0.42	0.17	1.04	0.061
MajesTEC-1 eligible vs ineligible		22	45	NE	16.69	0.46	0.20	1.07	0.070

B

Subgroup	Hazard Ratio and 95% CI	n1	n2	Med1	Med2	HR	LCL	UCL	LR pval
Age <75 vs ≥75 yr		96	17	9.59	22.21	1.17	0.58	2.36	0.663
MM diagnosis ≤6 vs >6 yr ago		46	67	8.34	10.58	1.07	0.66	1.75	0.771
ISS Stage I vs II/III		32	62	9.26	14.16	1.05	0.60	1.86	0.858
Extramedullary disease N vs Y		50	9	10.58	4.76	0.48	0.21	1.10	0.084
Prior lines of therapy ≤3 vs >3		17	96	15.67	9.59	0.85	0.42	1.72	0.651
Prior BCMA therapy N vs Y		73	40	13.83	3.42	0.75	0.46	1.23	0.250
Prior BCMA (ADC) therapy N vs Y		81	32	15.67	3.14	0.51	0.31	0.85	0.009
Prior BCMA (CAR-T) therapy N vs Y		103	10	9.66	4.99	0.98	0.39	2.44	0.966
Triple-class refractory N vs Y		24	89	10.12	9.59	0.89	0.49	1.60	0.686
Triple-class exposed N vs Y		2	111	NE	NE	NE	NE	NE	NE
Penta-drug refractory N vs Y		63	50	14.16	7.66	0.79	0.49	1.28	0.347
Penta-drug exposed N vs Y		13	100	16.69	9.63	0.93	0.43	2.04	0.861
Cytogenetic risk standard vs high		27	32	10.58	10.61	1.37	0.72	2.61	0.341
Risk (minus amp1q21) standard vs high		32	27	14.00	9.59	1.02	0.53	1.94	0.963
ECOG score 0 vs ≥1		22	27	NE	8.87	0.44	0.19	1.01	0.053
Baseline thrombocytopenia N vs Y		86	26	13.83	4.88	0.60	0.35	1.03	0.062
LDH level ≤245 vs >245 U/L		58	28	22.21	4.88	0.59	0.33	1.04	0.070
Response ≥ VGPR vs < VGPR		59	50	NE	2.56	0.23	0.14	0.39	<0.001
MajesTEC-1 eligible vs ineligible		33	80	NE	7.39	0.47	0.26	0.85	0.013



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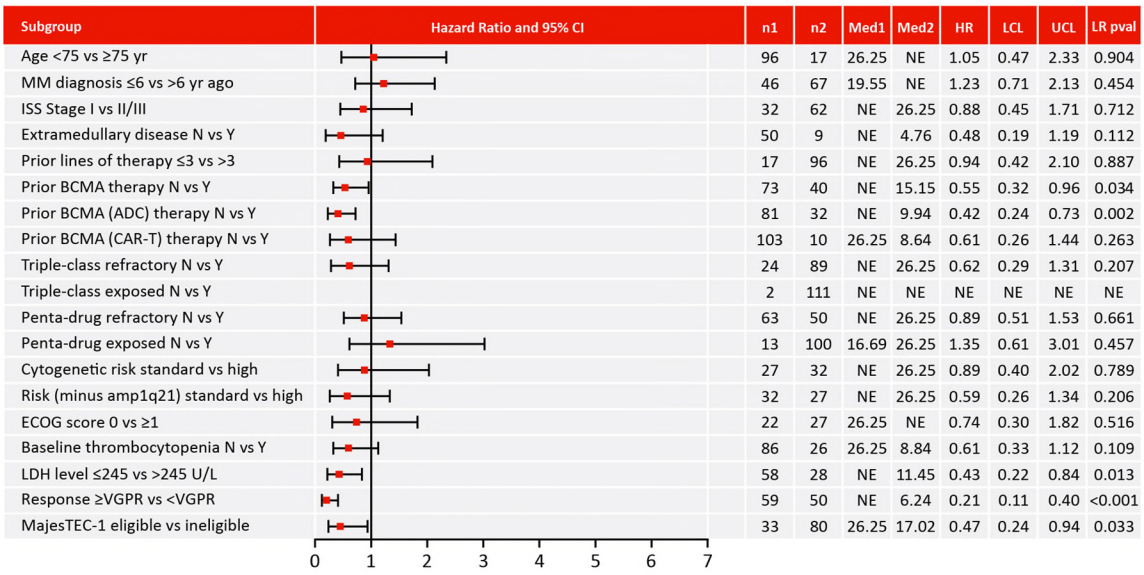

Subgroup	Hazard Ratio and 95% CI	n1	n2	Med1	Med2	HR	LCL	UCL	LR pval
Age <75 vs ≥75 yr		96	17	26.25	NE	1.05	0.47	2.33	0.904
MM diagnosis ≤6 vs >6 yr ago		46	67	19.55	NE	1.23	0.71	2.13	0.454
ISS Stage I vs II/III		32	62	NE	26.25	0.88	0.45	1.71	0.712
Extramedullary disease N vs Y		50	9	NE	4.76	0.48	0.19	1.19	0.112
Prior lines of therapy ≤3 vs >3		17	96	NE	26.25	0.94	0.42	2.10	0.887
Prior BCMA therapy N vs Y		73	40	NE	15.15	0.55	0.32	0.96	0.034
Prior BCMA (ADC) therapy N vs Y		81	32	NE	9.94	0.42	0.24	0.73	0.002
Prior BCMA (CAR-T) therapy N vs Y		103	10	26.25	8.64	0.61	0.26	1.44	0.263
Triple-class refractory N vs Y		24	89	NE	26.25	0.62	0.29	1.31	0.207
Triple-class exposed N vs Y		2	111	NE	NE	NE	NE	NE	NE
Penta-drug refractory N vs Y		63	50	NE	26.25	0.89	0.51	1.53	0.661
Penta-drug exposed N vs Y		13	100	16.69	26.25	1.35	0.61	3.01	0.457
Cytogenetic risk standard vs high		27	32	NE	26.25	0.89	0.40	2.02	0.789
Risk (minus amp1q21) standard vs high		32	27	NE	26.25	0.59	0.26	1.34	0.206
ECOG score 0 vs ≥1		22	27	26.25	NE	0.74	0.30	1.82	0.516
Baseline thrombocytopenia N vs Y		86	26	26.25	8.84	0.61	0.33	1.12	0.109
LDH level ≤245 vs >245 U/L		58	28	NE	11.45	0.43	0.22	0.84	0.013
Response ≥VGPR vs <VGPR		59	50	NE	6.24	0.21	0.11	0.40	<0.001
MajesTEC-1 eligible vs ineligible		33	80	26.25	17.02	0.47	0.24	0.94	0.033

Columns n1 and n2 and columns Med1 and Med2 are the sample sizes and median DOR, PFS, and OS (respectively) for the first and second (reference) subgroups, respectively. Included in extramedullary disease subgroup 'Y' are patients with soft tissue plasmacytomas that were not associated with bone.

ADC, antibody-drug conjugate; BCMA, B cell maturation antigen; CAR-T, chimeric antigen receptor T-cell therapy; DOR, duration of response; ECOG, Eastern Cooperative Oncology Group; HR, hazard ratio; ISS, International Staging System; LCL, lower confidence limit; LDH, lactic acid dehydrogenase; LR, log-rank; MM, multiple myeloma; N, no; n1, n2, number of patients with responses in subgroup 1 versus subgroup 2; NE, not estimable; OS, overall survival; PFS, progression-free survival; UCL, upper confidence limit; VGPR, very good partial response; Y, yes.