MajesTEC-9: A Phase 3 Randomized Study of Teclistamab Monotherapy vs Investigator's Choice of Pomalidomide, Bortezomib, and Dexamethasone or Carfilzomib and Dexamethasone (PVd/Kd) in Patients With Relapsed Refractory Multiple Myeloma

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https://www.congresshub.com/Oncology/AM2026/Teclistamab/Mina-MajesTEC-9

Presented by R Mina at the American Society of Clinical Oncology (ASCO) Annual Meeting; May 29–June 2, 2026; Chicago, IL, USA.

MajesTEC-9: Key Takeaways

1. **Second positive phase 3 study with Tec-based therapy showing significant PFS and OS benefit in 2L+ RRMM**

2. **Tec monotherapy significantly improved PFS (HR, 0.29) and OS (HR, 0.60) vs PVd/Kd**

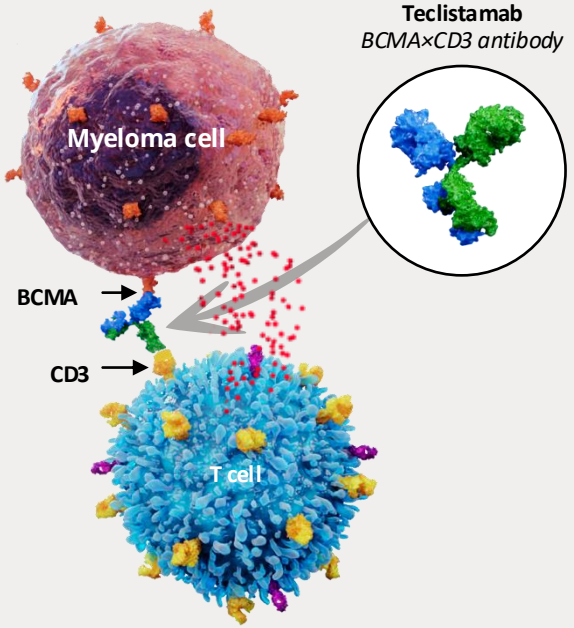
3. **The safety profile of Tec was consistent with the known profile**

MajesTEC-9 supports Tec monotherapy as a new 2L+ SOC along with Tec-Dara

2L+, second-line or higher; Dara, daratumumab; HR, hazard ratio; Kd, carfilzomib and dexamethasone; OS, overall survival; PFS, progression-free survival; PVd, pomalidomide, bortezomib, and dexamethasone; RRMM, relapsed refractory multiple myeloma; SOC, standard-of-care; Tec, teclistamab.

MajesTEC-9: Background

- There is a critical unmet need for therapies that improve survival in earlier LOTs, especially for patients exposed to triplet/quadruplet regimens[1–5]
- Tec demonstrated deep and durable responses in heavily pretreated RRMM in the phase 1/2 MajesTEC-1 study,[6,7] with improved outcomes in earlier LOTs[8]
- The synergistic Tec-Dara combination significantly improved PFS and OS in MajesTEC-3,[9] establishing BCMA-directed immunotherapy as a new 2L+ SOC
- MajesTEC-9 evaluates Tec monotherapy in patients with 1 to 3 prior LOTs and prior anti-CD38 mAb and lenalidomide exposure



MajesTEC-9 is the first phase 3 study of Tec monotherapy in 2L+ RRMM

BCMA, B-cell maturation antigen; LOT, line of therapy; mAb, monoclonal antibody.

1. Ramasamy K, et al. *Clin Lymphoma Myeloma Leuk*. 2025;25(5):337-348.e2. 2. Raje N, et al. *Blood Cancer J.* 2023;13(1):41. 3. Mancuso K, et al. *Cancers*. 2025;17(7):1168. 4. Kumar S, et al. *Blood Cancer J.* 2022;12(6):98. 5. Dimopoulos MA, et al. *Nat Rev Clin Oncol*. 2025;22(9):680-700. 6. Moreau P, et al. *N Engl J Med*. 2022;387(6):495-505. 7. Garfall AL, et al. Presented at: ASCO; May 31-June 4, 2024; Chicago, IL, USA. 8. Costa LJ, et al. Presented at: HEMO; October 23-26, 2024; São Paulo, Brazil. Poster 912. 9. Costa LJ, et al. *N Engl J Med*. 2026;394(8):739-752.

MajesTEC-9: Phase 3 Study Design

Key inclusion criteria

- RRMM
- 1–3 prior LOTs including an anti-CD38 mAb and lenalidomide
- ECOG PS score of 0–2

Key exclusion criteria

- Prior BCMA-directed therapy

1:1 randomization N=593

April 28, 2023–
April 3, 2025

Tec
n=296

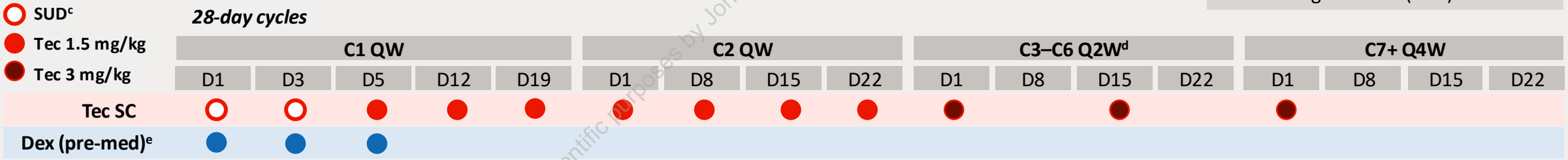
PVd/Kd[a]
by investigator's choice
n=297 (69% Kd)

Primary endpoint
- PFS per IRC[b]

Key secondary endpoints
- ≥CR[b]
- OS
- MySIm-Q total symptom score

Other secondary endpoints
- ORR
- Safety
- PK and immunogenicity

Exploratory endpoints
- MRD-negative ≥CR (10^{-5})



Monthly Tec dosing from C7 (earlier if ≥VGPR); steroid free after C1D5

[a]Administered per the approved schedules. Kd was administered either twice weekly (20/56 mg/m²) or once weekly (20/70 mg/m²) depending on the local clinical practice. [b]Disease progression and response were assessed by an IRC per IMWG 2016 criteria. [c]Patients received SUD of 0.06 mg/kg and 0.3 mg/kg on D1 and D3, respectively. [d]Patients with confirmed ≥VGPR could switch to dosing Q4W earlier than C7 per investigator's discretion. [e]Dexamethasone, acetaminophen, and diphenhydramine pre-med was required on C1 D1, D3, and D5.

C, Cycle; CR, complete response; D, Day; Dex, dexamethasone; ECOG PS, Eastern Cooperative Oncology Group performance status; IMWG, International Myeloma Working Group; IRC, independent review committee; MRD, minimal residual disease; MySIm-Q, Multiple Myeloma Symptom and Impact Questionnaire; ORR, overall response rate; PK, pharmacokinetics; pre-med, pre-medication; QW, weekly; Q2W, every 2 weeks; Q4W, every 4 weeks; SC, subcutaneous; SUD, step-up dosing; VGPR, very good partial response.

MajesTEC-9: Baseline Demographic and Disease Characteristics

Characteristic	Tec (n=296)	PVd/Kd (n=297)
Age		
Median (range), years	70 (34–85)	70 (36–86)
≥75 years, n (%)	**84 (28.4)**	**89 (30.0)**
Sex, n (%)		
Male	150 (50.7)	153 (51.5)
Female	146 (49.3)	144 (48.5)
Race, n (%)		
White	190 (64.2)	198 (66.7)
Asian	62 (20.9)	56 (18.9)
Black or African American	10 (3.4)	10 (3.4)
Other[a]	34 (11.5)	33 (11.1)

Characteristic	Tec (n=296)	PVd/Kd (n=297)
Baseline ECOG PS score, n (%)		
0	156 (52.7)	135 (45.5)
1	121 (40.9)	137 (46.1)
2	19 (6.4)	24 (8.1)
3	0	1 (0.3)
ISS stage, n (%)		
I	168 (56.8)	170 (57.2)
II	86 (29.1)	82 (27.6)
III	**42 (14.2)**	**45 (15.2)**
BMPCs ≥60%,[b] n/N (%)	31/292 (10.6)	40/295 (13.6)
Soft-tissue plasmacytomas, n (%)	**54 (18.2)**	**65 (21.9)**
Extramedullary plasmacytomas[c]	19 (6.4)	22 (7.4)
Paraskeletal plasmacytomas[c]	43 (14.5)	52 (17.5)
High-risk cytogenetics,[d] n/N (%)	**105/294 (35.7)**	**104/296 (35.1)**

Balanced baseline characteristics are reflective of a RRMM population, including high-risk disease

[a]"Other" includes American Indian or Alaska Native (Tec, n=2 [0.7%]; PVd/Kd, n=0), not reported (Tec, n=18 [6.1%]; PVd/Kd, n=23 [7.7%]), unknown (Tec, n=7 [2.4%]; PVd/Kd, n=6 [2.0%]), and multiple (Tec, n=7 [2.4%]; PVd/Kd, n=4 [1.3%]). [b]Maximum value from bone marrow biopsy or bone marrow aspirate was selected if both results were available. [c]A patient may have both extramedullary and paraskeletal plasmacytomas.
[d]Presence of ≥1 of del(17p), t(4;14), or t(14;16).
BMPC, bone marrow plasma cell; ISS, International Staging System.
From The New England Journal of Medicine, Touzeau C, et al., Teclistamab in Multiple Myeloma with One to Three Previous Lines of Therapy.

MajesTEC-9: Prior LOTs

Characteristic	Tec (n=296)	PVd/Kd (n=297)
Prior LOTs, n (%)		
Median (range), n	**2 (1–3)**	**2 (1–3)**
1 prior LOT	64 (21.6)	64 (21.5)
2 prior LOTs	131 (44.3)	137 (46.1)
3 prior LOTs	101 (34.1)	96 (32.3)
Prior transplantation, n (%)	145 (49.0)	147 (49.5)
Autologous	145 (49.0)	146 (49.2)
Prior therapy exposure, n (%)		
PI	256 (86.5)	254 (85.5)
IMiD	296 (100)	297 (100)
Anti-CD38	296 (100)	297 (100)

Characteristic	Tec (n=296)	PVd/Kd (n=297)
Refractory status, n (%)		
To last prior LOT	**274 (92.6)**	**273 (91.9)**
Any PI	122 (41.2)	128 (43.1)
Any IMiD	245 (82.8)	251 (84.5)
Lenalidomide	**234 (79.1)**	**240 (80.8)**
Any anti-CD38	**253 (85.5)**	**252 (84.8)**
Double refractory (IMiD and anti-CD38)	218 (73.6)	221 (74.4)
Triple refractory (IMiD, anti-CD38, and PI)	102 (34.5)	98 (33.0)

Approximately 75% of patients were double refractory to an IMiD and anti-CD38 mAb

IMiD, immunomodulatory drug; PI, proteasome inhibitor.

MajesTEC-9: Patient Disposition and Exposure

- Median follow-up, 17.3 months
- Median Tec relative dose intensity across all cycles: 98.3%
- 33.7% of Tec patients switched to Q4W dosing prior to C7

	Tec (n=296)	PVd/Kd (n=297)
Number of patients treated,[a] n (%)	291 (98.3)	283 (95.3)
Still on study treatment,[b] n (%)	190 (65.3)	68 (24.0)
Discontinued study treatment,[b] n (%)	101 (34.7)	215 (76.0)
Reason for discontinuation,[b,c] n (%)		
AE[d]	31 (10.7)	37 (13.1)
Physician decision	0	7 (2.5)
PD	60 (20.6)	153 (54.1)
Patient refused further treatment	8 (2.7)	18 (6.4)
Median treatment duration, months	13.1	7.0

Median treatment duration was nearly double with Tec, without an increase in AE-related discontinuations

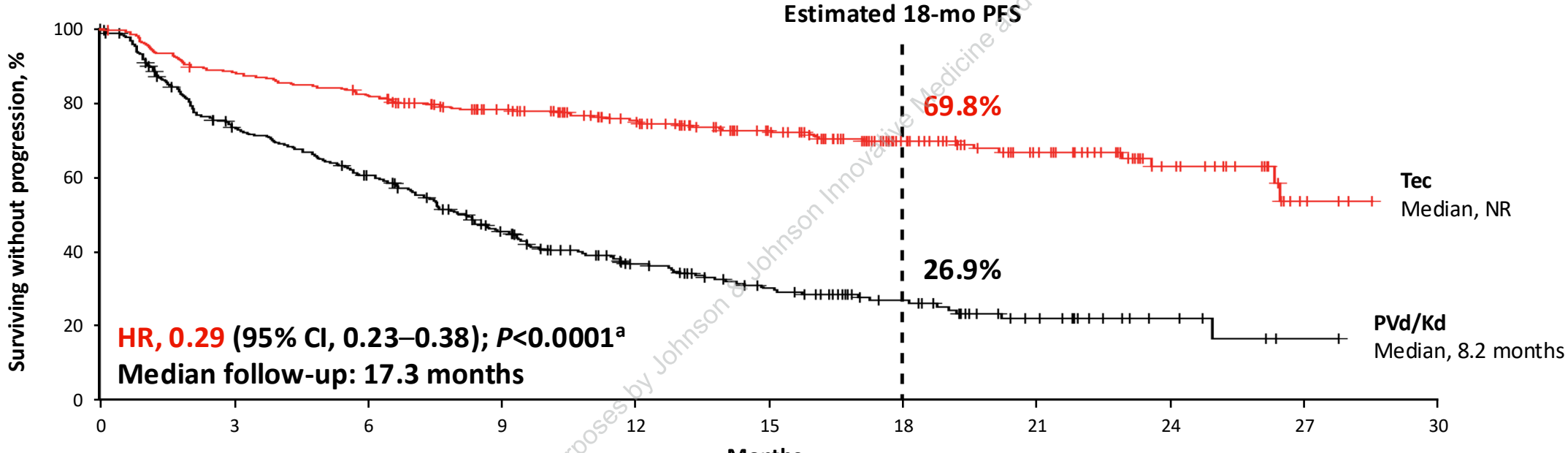
Clinical cutoff: October 13, 2025.

[a]Patients in the safety analysis set. [b]Percentages are based on the number of patients treated. [c]2 (0.7%) patients in the Tec group discontinued due to "other" reasons. [d]Deaths attributed to AEs were included in the total number of discontinuations due to AEs.

AE, adverse event; PD, progressive disease.

From The New England Journal of Medicine, Touzeau C, et al., Teclistamab in Multiple Myeloma with One to Three Previous Lines of Therapy.

MajesTEC-9: Tec Significantly Improved PFS (Primary Endpoint)

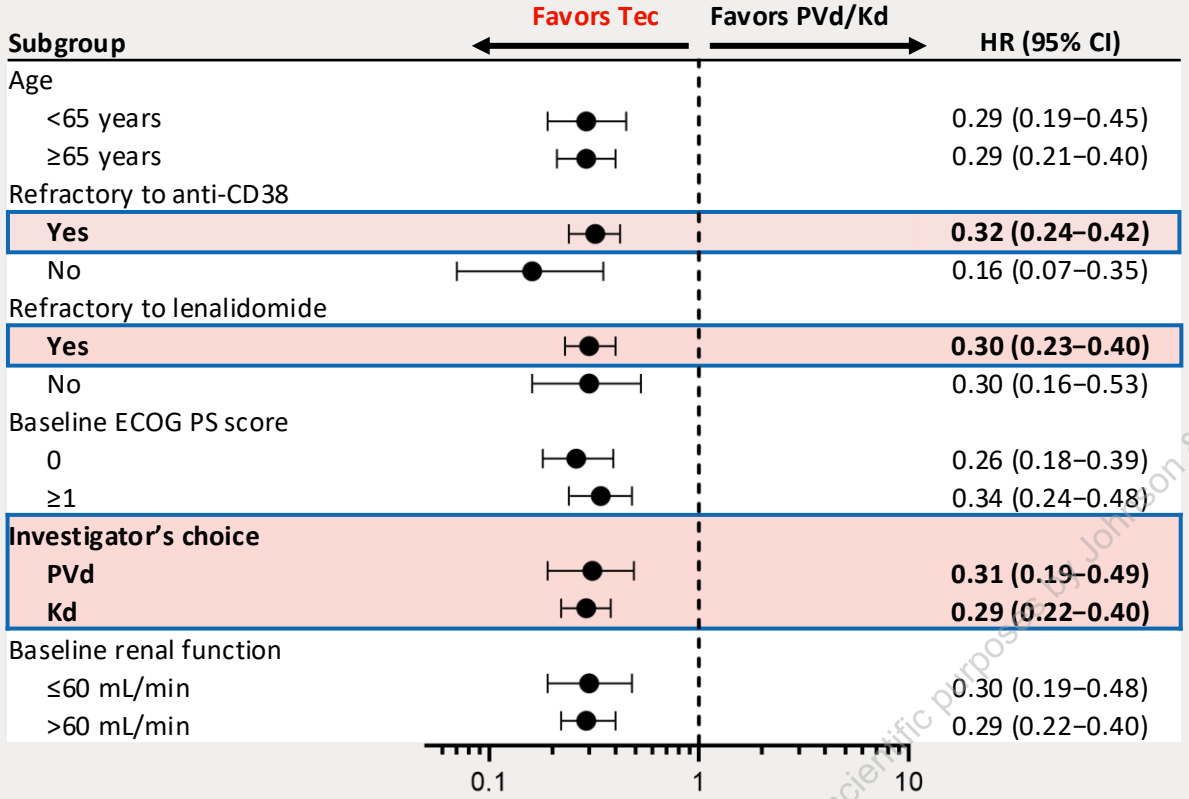


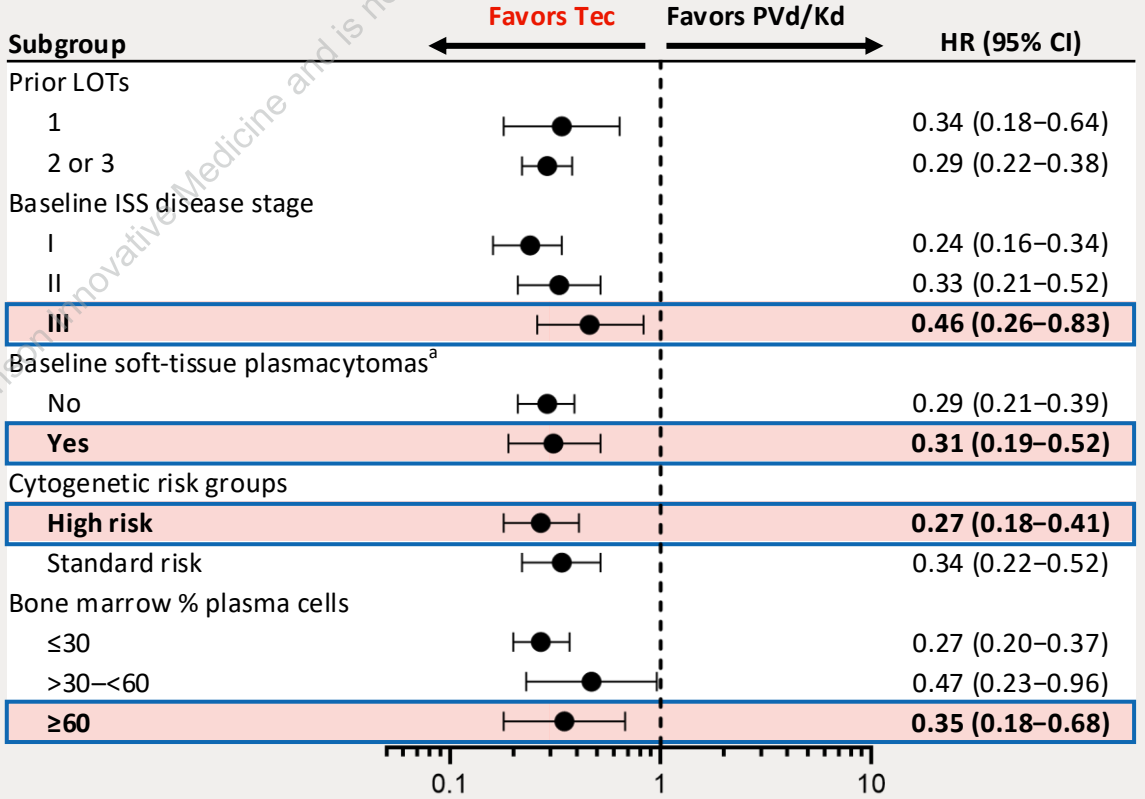
No. at risk											
Tec	296	258	239	206	172	141	92	57	27	6	0
PVd/Kd	297	199	162	112	74	51	33	16	6	1	0

Tec significantly improved PFS, with a 71% reduction in the risk of disease progression or death in a highly refractory population

[a]The *P* value crossed the prespecified stopping boundary for superiority for the first interim analysis (*P*=0.0197).
CI, confidence interval; NR, not reached.
From The New England Journal of Medicine, Touzeau C, et al., Teclistamab in Multiple Myeloma with One to Three Previous Lines of Therapy.

MajesTEC-9: PFS Subgroup Analysis





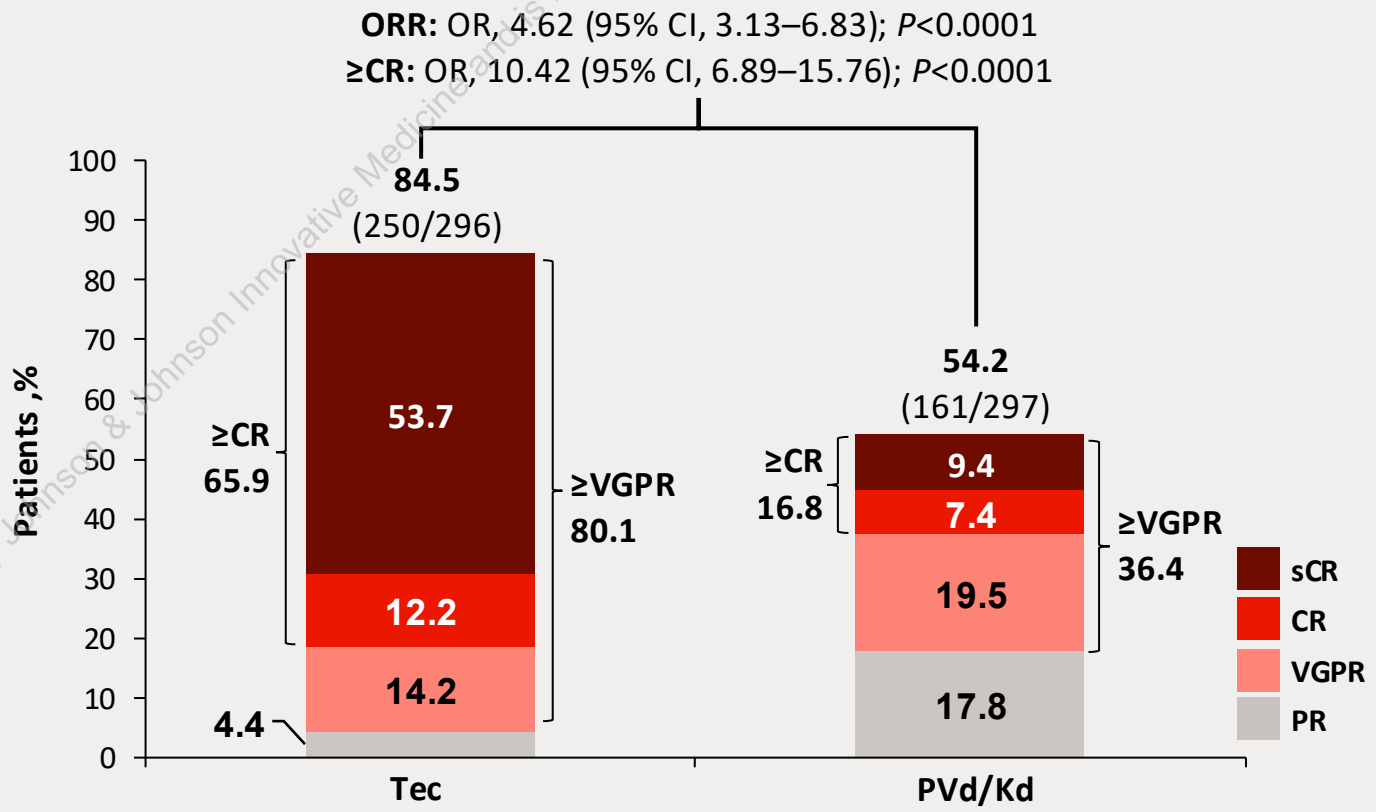
PFS favored Tec across all subgroups,[b] including high-risk cytogenetics and anti-CD38 or lenalidomide refractory disease

[a]Baseline soft-tissue plasmacytomas contain both extramedullary and paraskeletal plasmacytomas. [b]Not all clinically meaningful and prespecified subgroups that were assessed are shown; however, PFS was improved vs PVd/Kd across all subgroups.

From The New England Journal of Medicine, Touzeau C, et al., Teclistamab in Multiple Myeloma with One to Three Previous Lines of Therapy.

MajesTEC-9: Treatment Response[a] and Response Duration

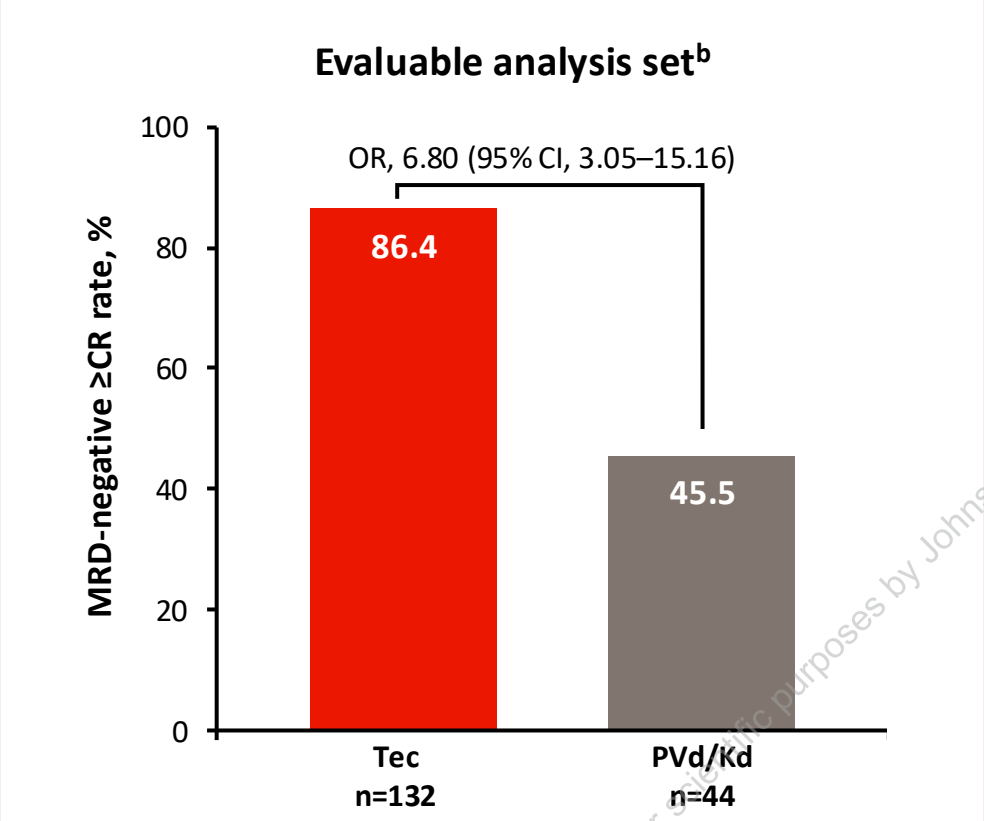
	Tec (n=250)	PVd/Kd (n=161)
Median (range) time to first response, months	1.2 (0.9–7.9)	1.1 (0.7–11.1)
Median (range) time to first ≥CR, months	5.8 (1.0–23.0)	5.6 (0.9–16.3)
Median (95% CI) DOR, months	NE (25.2–NE)	13.4 (10.4–17.3)
Estimated 18-month DOR, % (95% CI)	80.6 (74.1–85.5)	40.1 (30.8–49.1)

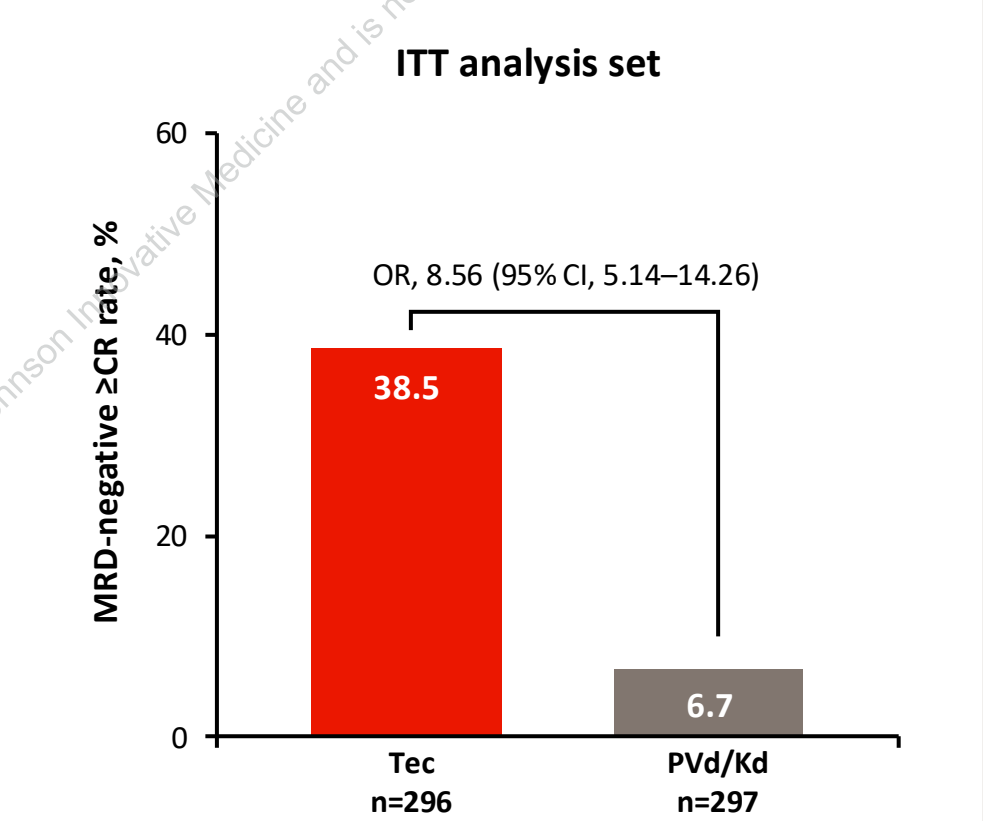


Tec demonstrated significantly higher ORR, a ≥CR rate nearly 4× that of control, and more durable responses

Median follow-up, 17.3 months.
[a]Response and disease progression were assessed by a blinded IRC per IMWG criteria.
DOR, duration of response; NE, not estimable; OR, odds ratio; PR, partial response; sCR, stringent complete response.

MajesTEC-9: MRD-Negative (10^{-5}) ≥CR Rate[a]

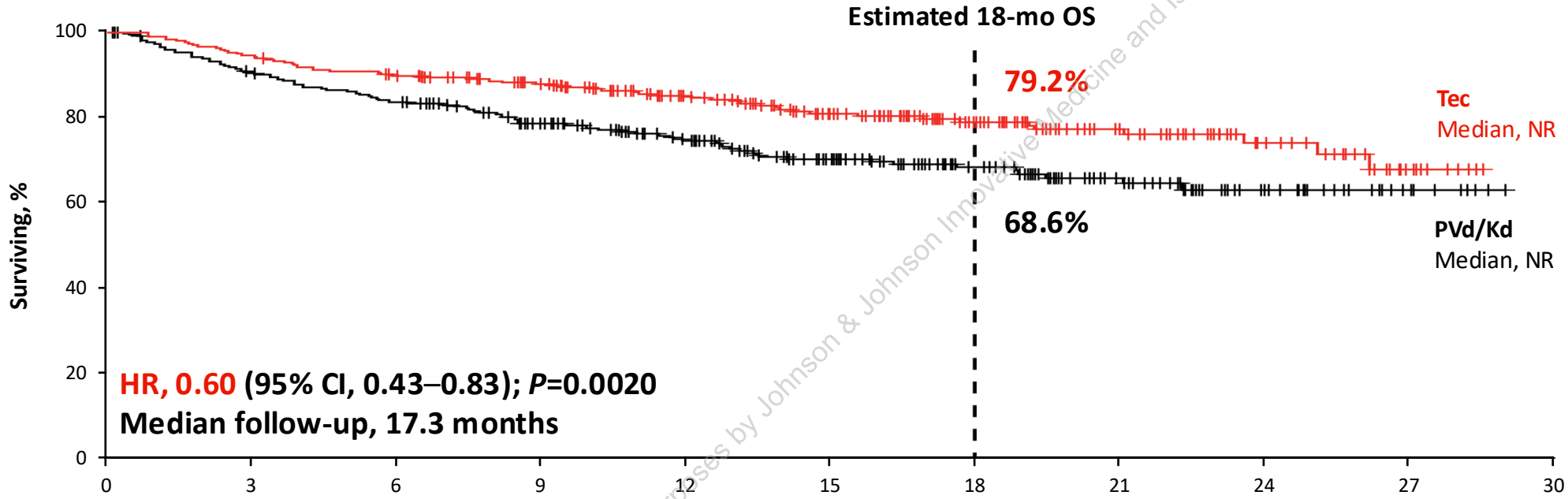




Tec drives deep responses, with an ~86% MRD-negative ≥CR rate among MRD-evaluable patients

[a]Defined as the proportion of patients who achieved MRD-negative status at 10^{-5} by NGF in bone marrow aspirate within 3 months prior to achieving ≥CR or at any time after ≥CR and prior to disease progression or subsequent antimyeloma therapy, provided that the sample contained a sufficient number of cells to meet the prespecified testing threshold. [b]Includes all randomized patients with ≥1 MRD sample collected after the date of randomization and prior to disease progression or subsequent antimyeloma therapy, resulting in either a positive MRD call or a negative MRD call if the sample contained a sufficient number of cells to meet the prespecified testing threshold.
ITT, intent-to-treat; NGF, next-generation flow cytometry.

MajesTEC-9: Tec Significantly Improved OS



Tec significantly improved OS vs PVd/Kd, despite over two-thirds of PVd/Kd patients who initiated subsequent therapy receiving a BsAb or CAR-T

BsAb, bispecific antibody; CAR-T, chimeric antigen receptor T cell.

From The New England Journal of Medicine, Touzeau C, et al., Teclistamab in Multiple Myeloma with One to Three Previous Lines of Therapy.

MajesTEC-9: Overall Safety Profile

TEAE, n (%)[a]	Tec (n=291)		PVd/Kd (n=283)	
	Any grade	Grade 3/4	Any grade	Grade 3/4
Any TEAE	290 (99.7)	247 (84.9)	277 (97.9)	216 (76.3)
Hematologic				
Neutropenia	182 (62.5)	158 (54.3)	81 (28.6)	63 (22.3)
Anemia	110 (37.8)	52 (17.9)	119 (42.0)	46 (16.3)
Thrombocytopenia	80 (27.5)	31 (10.7)	110 (38.9)	60 (21.2)
Lymphopenia	71 (24.4)	59 (20.3)	49 (17.3)	32 (11.3)
Nonhematologic[b]				
CRS	192 (66.0)	2 (0.7)	0	0
Diarrhea	124 (42.6)	15 (5.2)	72 (25.4)	4 (1.4)
Cough	80 (27.5)	2 (0.7)	39 (13.8)	0
Injection-site erythema	71 (24.4)	0	8 (2.8)	0
Hypertension	20 (6.9)	13 (4.5)	51 (18.0)	32 (11.3)

CRS mostly low grade; all resolved with no discontinuation

- Grade 1/2 (48.8%/16.5%), grade 3 (0.7%), no grade 4/5

ICANS was infrequent, generally low grade

- Grade 1/2 (2.4%/1.4%), grade 3 (0.3%)[c]

Discontinuations due to TEAEs: 10.7% Tec vs 13.1% PVd/Kd[d]

Death due to PD: 8.6% Tec vs 18.7% PVd/Kd

Grade 5 TEAEs: 6.5% Tec vs 3.5% PVd/Kd

The safety profile was consistent with the known profile of Tec monotherapy

[a]Most common TEAEs of any grade occurring in ≥20% of patients in either treatment group and the most common grade 3/4 TEAEs occurring in ≥10% of patients in either treatment group. [b]Hypogammaglobulinemia, URTI, and pneumonia were also reported but are discussed on the following summary of infections slide. [c]One patient had a grade 3 ICANS event that led to Tec discontinuation. [d]Discontinuation of all components of study treatment.
CRS, cytokine release syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome; TEAE, treatment emergent adverse event; URTI, upper respiratory tract infection.
From The New England Journal of Medicine, Touzeau C, et al., Teclistamab in Multiple Myeloma with One to Three Previous Lines of Therapy.

MajesTEC-9: Summary of Infections

Hypogammaglobulinemia[a] was common

- 69.1% Tec and 50.2% PVd/Kd

Infections were more frequent when disease burden was high

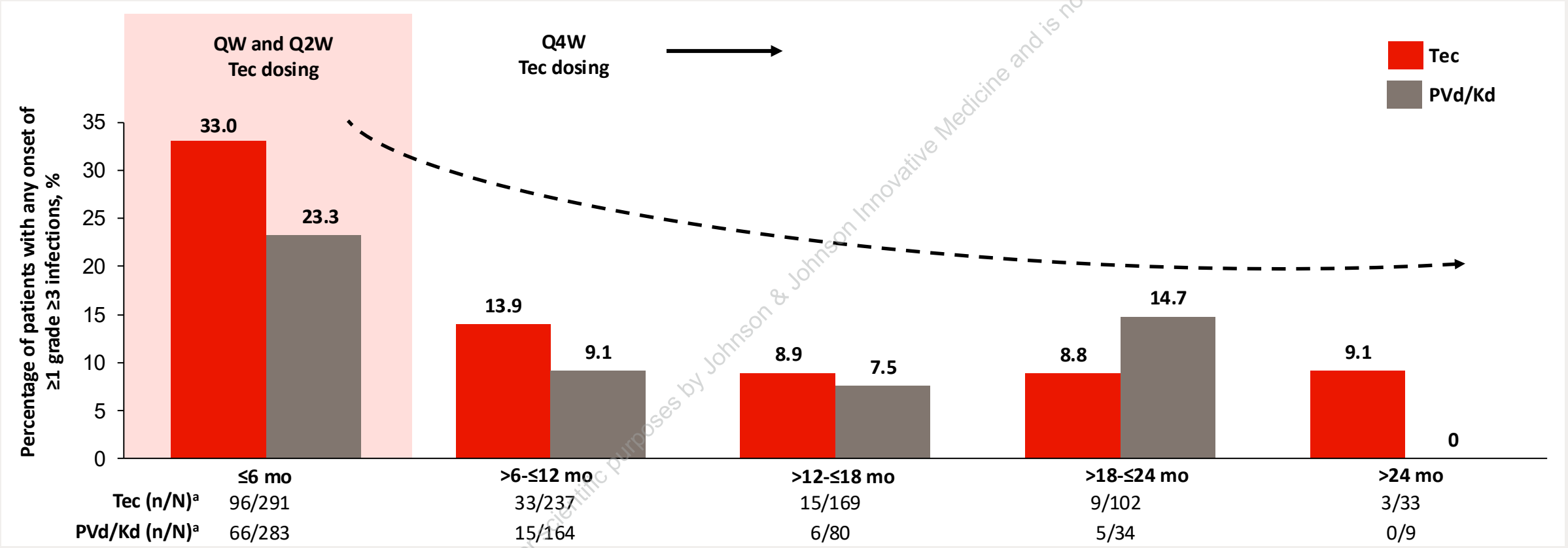
- Grade 5 infections: 16 (5.5%) with Tec vs 8 (2.8%) with PVd/Kd
  - 14/16 vs 8/8 in first 6 months
  - 5/16 vs 6/8 had no IgRT
  - 8/16 vs 2/8 had last IgG <400 mg/dL

TEAE, n (%)	Tec (n=291)			PVd/Kd (n=283)		
	Any grade	Grade 3/4	Grade 5	Any grade	Grade 3/4	Grade 5
Any infection	241 (82.8)	121 (41.6)	16 (5.5)	193 (68.2)	82 (29.0)	8 (2.8)
Most common infection or infestation[c]						
URTI	77 (26.5)	7 (2.4)	0	58 (20.5)	6 (2.1)	0
Pneumonia	64 (22.0)	42 (14.4)	3 (1.0)	43 (15.2)	30 (10.6)	4 (1.4)
COVID-19	45 (15.5)	10 (3.4)	1 (0.3)	22 (7.8)	3 (1.1)	0
Nasopharyngitis	37 (12.7)	0	0	24 (8.5)	0	0
UTI	30 (10.3)	4 (1.4)	0	12 (4.2)	2 (0.7)	0

Grade 3/4 infections were frequent and required diligent use of established IgRT and antimicrobial prophylaxis

[a]Defined as patients with ≥1 TEAE of hypogammaglobulinemia or a post-baseline IgG value <400 mg/dL. [b]Includes patients who received ≥1 dose of subcutaneous or intravenous immunoglobulin up to the last dose of study treatment +30 days or the start of subsequent therapy –1 day, whichever occurred first, or for a TEAE. [c]Defined as occurring in ≥10% of patients in either treatment group.
IgG, immunoglobulin G; IgRT, immunoglobulin replacement therapy; UTI, urinary tract infection.
From The New England Journal of Medicine, Touzeau C, et al., Teclistamab in Multiple Myeloma with One to Three Previous Lines of Therapy.

MajesTEC-9: Grade ≥3 Infections Declined Over Time



Grade ≥3 infections decreased from 6 months, consistent with disease control

[a]Includes patients who are in the TEAE-reporting period for the specific window. Noting that patients are counted only once in a window for any given event, regardless of the number of times they actually experienced the event within the specific time window.

MajesTEC-9: MySIm-Q Total Symptom Score[a]

18-month event-free rate:

- Tec: 73.5% (95% CI: 66.5–79.2)
- PVd/Kd: 55.1% (95% CI: 45.2–64.0)

	Tec (n=293)[a]	PVd/Kd (n=293)[a]
Kaplan-Meier estimate, months		
Median (95% CI)	NE (23.85–NE)	19.48 (16.13–NE)
P value[b]	<0.0001	
HR (95% CI)[c]	0.50 (0.36–0.71)	

Tec preserved HRQoL by delaying time to worsening of MM symptoms

Median follow-up, 17.3 months

[a]The ITT-/PRO-evaluable population included patients who are in the ITT population, excluding patients from 1 study site due to nonadherence to protocol requirements. All PRO data collected at this site were excluded from the PRO analyses. [b]Based on a stratified log-rank test stratified by investigator's choice (PVd vs Kd), ISS staging (I vs II/III), number of prior LOTs (1 vs 2/3), and anti-CD38 mAb refractory status (yes vs no). [c]From a Cox proportional hazards model with treatment as the sole explanatory variable and stratified by investigator's choice (PVd vs Kd), ISS staging (I vs II/III), number of prior LOTs (1 vs 2/3), and anti-CD38 mAb refractory status (yes vs no). An HR<1 indicates an advantage for Tec.

HRQoL, health-related quality of life; MM, multiple myeloma; PRO, patient-reported outcome.

From The New England Journal of Medicine, Touzeau C, et al., Teclistamab in Multiple Myeloma with One to Three Previous Lines of Therapy.

MajesTEC-9: Tec vs PVd/Kd in 1–3 prior LOTs RRMM

With Tec monotherapy, a steroid-sparing regimen with monthly dosing:

- Superior PFS (HR, 0.29) and OS (HR, 0.60) in a highly exposed and refractory population
  - PFS favored Tec in all subgroups, including anti-CD38 and lenalidomide-refractory disease
- Superior ORR and ≥CR and increased MRD-negative ≥CR rates
- CRS and ICANS were mostly grade 1 and managed with established protocols
- Infections were common
  - Grade ≥3 infections declined after 6 months, consistent with disease control
  - Patients should be supported with infection prophylaxis, monitoring, and IgRT

Significant PFS and OS advantage seen in MajesTEC-9, as well as MajesTEC-3, support Tec-based therapy as a new 2L+ SOC across practice settings

Costa LJ, et al. *N Engl J Med*. 2026;394(8):739-752.

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Teclistamab in Multiple Myeloma with One to Three Previous Lines of Therapy

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