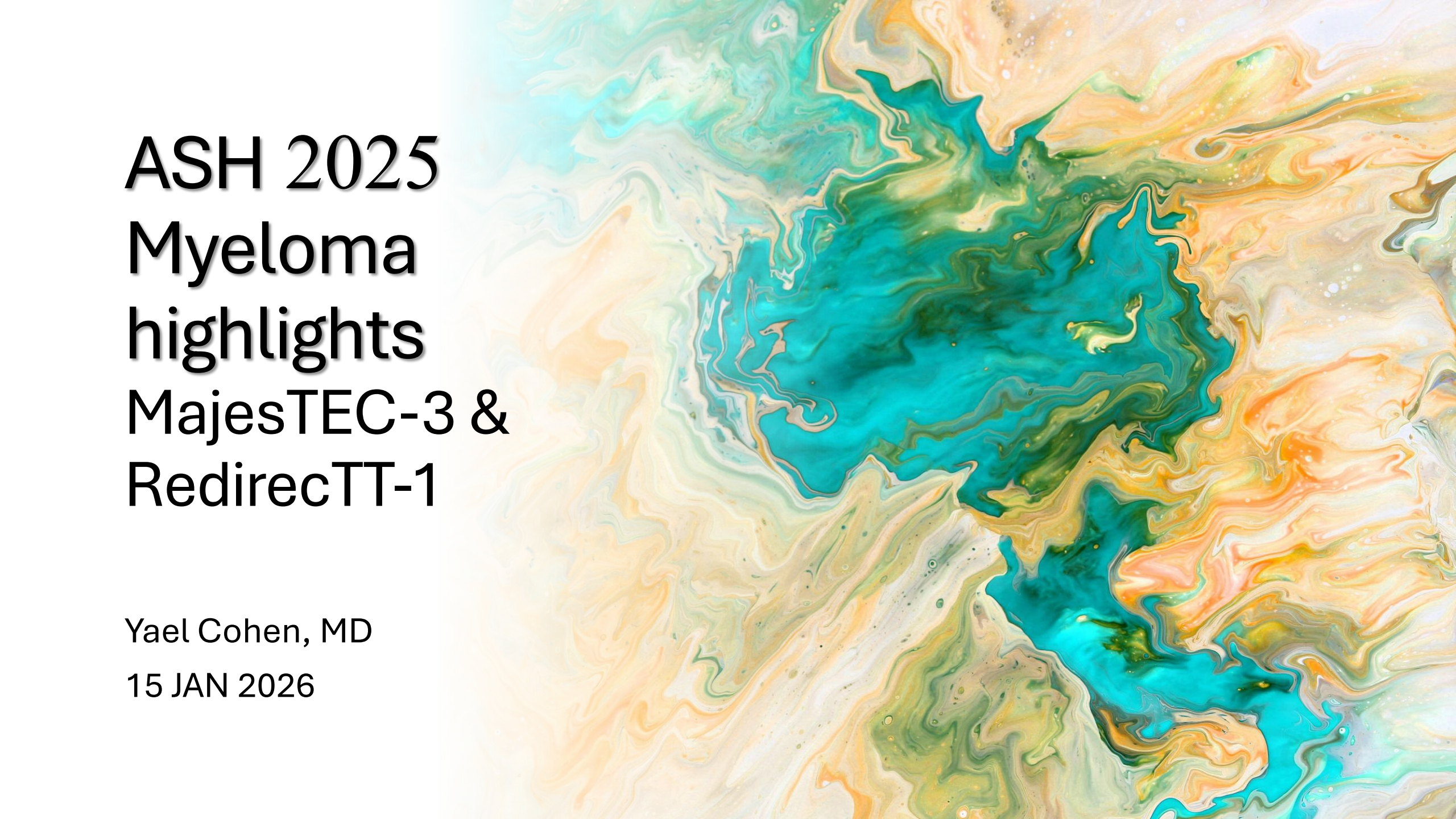
ASH 2025 Myeloma highlights

MajesTEC-3 & RedirecTT-1

Yael Cohen, MD

15 JAN 2026



Phase 3 Randomized Study of Teclistamab Plus Daratumumab Versus Investigator's Choice of Daratumumab and Dexamethasone With Either Pomalidomide or Bortezomib (DPd/DVd) in Patients With Relapsed Refractory Multiple Myeloma (RRMM): Results of MajesTEC-3

Maria-Victoria Mateos,[1] Nizar J. Bahlis,[2] Aurore Perrot,[3] Ajay K. Nooka,[4] Jin Lu,[5] Charlotte Pawlyn,[6,7] Roberto Mina,[8] Gaston Caeiro,[9] Alain Kentos,[10] Vania Hungria,[11] Donna Reece,[12] Ting Niu,[13] Anne K. Mylin,[14] Charlotte Toftmann Hansen,[15] Raphael Teipel,[16] Britta Besemer,[17] Meletios A. Dimopoulos,[18,19] Elena Zamagni,[20,21] Satoshi Yoshihara,[22] Kihyun Kim,[23] Chang Ki Min,[24] Paul Geerts,[25] Elena Van Leeuwen-Segarceanu,[26] Agata Tyczynska,[27] Juan Luis Reguera Ortega,[28] Magnus Johansson,[29] Markus Hansson,[30] Mehmet Turgut,[31] Mark Grey,[32] Surbhi Sidana,[33] Paula Rodriguez-Otero,[34] Joaquin Martinez-Lopez,[35] Hamza Hashmi,[36] Robin Carson,[37] Rachel Kobos,[38] Weili Sun,[39] Kristen Lantz,[37] Anne Seifert,[40] Deborah Briseno-Toomey,[41] Lisa O'Rourke,[37] Maria Rubin,[38] Diego Vieyra,[37] Lijuan Kang,[39] Luciano J. Costa[42]

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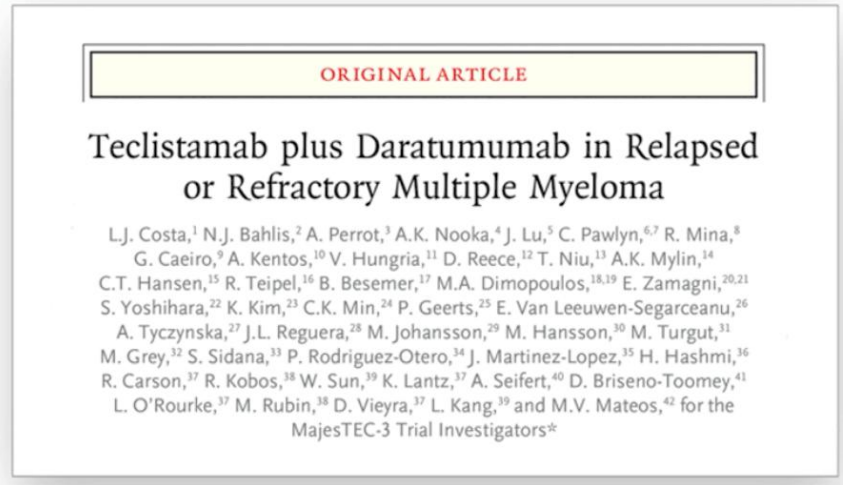
Late Breaking Abstract



ORIGINAL ARTICLE

Teclistamab plus Daratumumab in Relapsed or Refractory Multiple Myeloma

L.J. Costa,[1] N.J. Bahlis,[2] A. Perrot,[3] A.K. Nooka,[4] J. Lu,[5] C. Pawlyn,[6,7] R. Mina,[8] G. Caeiro,[9] A. Kentos,[10] V. Hungria,[11] D. Reece,[12] T. Niu,[13] A.K. Mylin,[14] C.T. Hansen,[15] R. Teipel,[16] B. Besemer,[17] M.A. Dimopoulos,[18,19] E. Zamagni,[20,21] S. Yoshihara,[22] K. Kim,[23] C.K. Min,[24] P. Geerts,[25] E. Van Leeuwen-Segarceanu,[26] A. Tyczynska,[27] J.L. Reguera,[28] M. Johansson,[29] M. Hansson,[30] M. Turgut,[31] M. Grey,[32] S. Sidana,[33] P. Rodriguez-Otero,[34] J. Martinez-Lopez,[35] H. Hashmi,[36] R. Carson,[37] R. Kobos,[38] W. Sun,[39] K. Lantz,[37] A. Seifert,[40] D. Briseno-Toomey,[41] L. O'Rourke,[37] M. Rubin,[38] D. Vieyra,[37] L. Kang,[39] and M.V. Mateos,[42] for the MajesTEC-3 Trial Investigators*

MajesTEC-3: Tec + Dara
Synergistic[1] Immunotherapy Combination

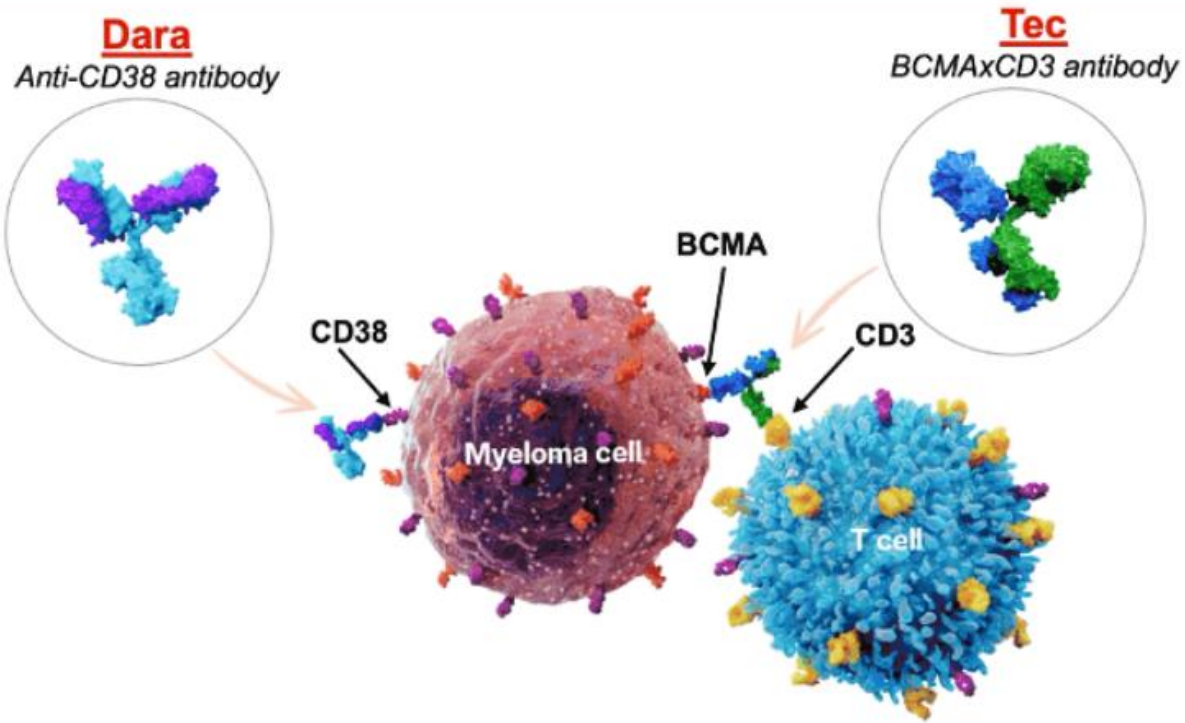
Dara PRIMES
the microenvironment by clearing immunosuppressive CD38+ T_{regs} and B_{regs}, in addition to Dara's direct on-tumor effects[2]

+

Tec + Dara ACTIVATE
CD8+ T cells for sustained immune enhancement

+

Tec REDIRECTS
activated CD8+ T cells to effectively kill myeloma cells



Dara primes and enables the optimal Tec-Dara immune-mediated killing of myeloma cells[1,3]

Breg, regulatory B cell; Treg, regulatory T cell.

1. Vishwamitra D, et al. Presented at: ASH Annual Meeting and Exposition; December 7-10, 2024; San Diego, CA, USA. Oral 594. 2. van de Donk NWCJ, et al. *Front Immunol.* 2018;9:2134. 3. Frerichs KA, et al. *Clin Cancer Res.* 2020;26:2203-2215.

Presented by M-V Mateos at the 67th American Society of Hematology (ASH) Annual Meeting and Exposition; December 6-9, 2025; Orlando, FL, USA.

MajesTEC-3: Phase 3 Study Design

Key inclusion criteria

- RRMM
- 1-3 prior LOTs including a PI and lenalidomide
  - Patients with only 1 prior LOT must have been lenalidomide refractory per IMWG criteria
- ECOG PS score of 0-2

Key exclusion criteria

- Prior BCMA-directed therapy
- Refractory to anti-CD38 mAbs[a]

1:1 randomization N=587

22 Oct 2021 to 29 Sept 2023[b]

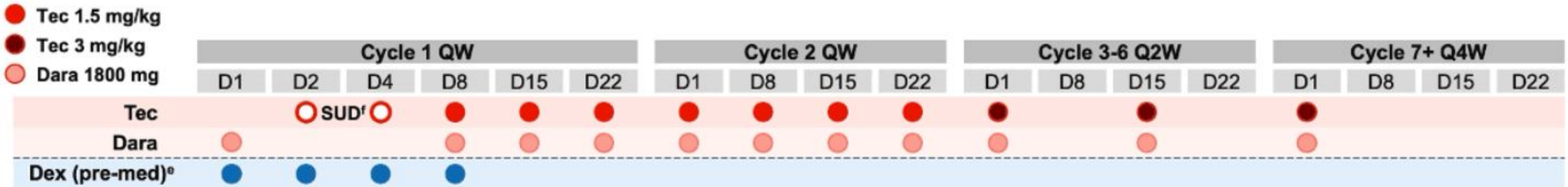
Tec-Dara
N=291
SC dosing following Dara schedule

DPd/DVd
N=296 (91% DPd)
by investigator's choice[c]

Primary endpoint
- PFS per IRC

Key secondary endpoints
- ≥CR[d] and ORR[d]
- MRD negativity (10^{-5})
- OS
- MySIm-Q Total Symptom score

Other secondary endpoints
- Safety
- PK and immunogenicity



SC dosing aligned with Dara schedule, with monthly dosing after 6 cycles; steroid sparing after Cycle 1 Day 8

[a]Prior exposure to anti-CD38 mAbs was permitted. [b]During the COVID-19 pandemic. [c]DPd/DVd were administered per the approved schedules. [d]Response and disease progression were assessed by a blinded IRC per IMWG criteria. [e]Dexamethasone, acetaminophen, and diphenhydramine pre-medication was required for the first 2 weeks; subsequent dexamethasone was not required thereafter. [f]Patients received SUD of 0.06 mg/kg and 0.3 mg/kg on Days 2 and 4, respectively.

CR, complete response; D, day; Dex, dexamethasone; DPd, daratumumab, pomalidomide, and dexamethasone; DVd, daratumumab, bortezomib, and 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; PFS, progression-free survival; PI, proteasome inhibitor; PK, pharmacokinetics; pre-med, pre-medication; QW, weekly; Q2W, every 2 weeks; Q4W, every 4 weeks; SC, subcutaneous; SUD, step-up dosing.

Presented by M-V Mateos at the 67th American Society of Hematology (ASH) Annual Meeting and Exposition; December 6-9, 2025; Orlando, FL, USA.

MajesTEC-3: Baseline Demographic and Disease Characteristics

Characteristic	Tec-Dara (n=291)	DPd/DVd (n=296)
Age		
Median (range), years	64 (36–88)	63 (25–84)
≥75 years, n (%)	31 (10.7)	25 (8.4)
Sex, n (%)		
Male	156 (53.6)	169 (57.1)
Female	135 (46.4)	127 (42.9)
Race, n (%)		
White	190 (65.3)	194 (65.5)
Asian	68 (23.4)	63 (21.3)
Black or African American	13 (4.5)	20 (6.8)
Other[a]	20 (6.9)	19 (6.4)

Characteristic	Tec-Dara (n=291)	DPd/DVd (n=296)
Baseline ECOG PS score, n (%)		
0	167 (57.4)	160 (54.1)
1	108 (37.1)	127 (42.9)
2	16 (5.5)	9 (3.0)
ISS stage, n (%)		
I	182 (62.5)	185 (62.5)
II	85 (29.2)	88 (29.7)
III	24 (8.2)	23 (7.8)
BMPCs ≥60%,[b] n/N (%)	28/286 (9.8)	24/293 (8.2)
Presence of soft-tissue plasmacytomas, n (%)	41 (14.1)	41 (13.9)
Extramedullary plasmacytomas[c]	14 (4.8)	17 (5.7)
Paraskeletal plasmacytomas	32 (11.0)	31 (10.5)
High-risk cytogenetics,[d] n/N (%)	104/285 (36.5)	104/294 (35.4)

Baseline demographics were well balanced and reflective of patients seen in real-world practice

[a]"Other" includes Native Hawaiian or Pacific Islander (Tec-Dara, n=1 [0.3%]; DPd/DVd, n=0; total, n=1 [0.2%]), American Indian or Alaska Native (Tec-Dara, n=0; DPd/DVd, n=1 [0.3%]; total, n=1 [0.2%]), not reported (Tec-Dara, n=14 [4.8%]; DPd/DVd, n=16 [5.4%]; total, n=30 [5.1%]), and unknown (Tec-Dara, n=5 [1.7%]; DPd/DVd, n=2 [0.7%]; total, n=7 [1.2%]). [b]Maximum value from bone marrow biopsy or bone marrow aspirate was selected if both results were available. [c]From metastatic or hematogenous spread involving only soft tissues. [d]Presence of ≥1 of del(17p), t(4;14), or t(14;16).
BMPC, bone marrow plasma cell; ISS, International Staging System.

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MajesTEC-3: Prior Lines of Therapy

Characteristic	Tec-Dara (n=291)	DPd/DVd (n=296)
Prior LOTs, n (%)		
Median (range), n	2 (1–3)	2 (1–3)
1 prior LOT	108 (37.1)	114 (38.5)
2 prior LOTs	134 (46.0)	134 (45.3)
3 prior LOTs	49 (16.8)	48 (16.2)
Prior transplantation, n (%)	210 (72.2)	226 (76.4)

- 5% of patients were Dara exposed
- In real-world data sets, 70% of patients in 2L are Dara naïve or exposed[1]

Characteristic	Tec-Dara (n=291)	DPd/DVd (n=296)
Prior therapy exposure, n (%)		
PI	290 (99.7)	296 (100)
IMiD	291 (100)	296 (100)
Anti-CD38	15 (5.2)	16 (5.4)
Refractory status, n (%)		
To last prior LOT	250 (85.9)	251 (84.8)
Any PI	117 (40.2)	104 (35.1)
Any IMiD	247 (84.9)	253 (85.5)
Lenalidomide	240 (82.5)	251 (84.8)
Double (PI and IMiD)	99 (34.0)	88 (29.7)

Median of 2 prior LOTs and >85% of patients were refractory to an IMiD

2L, second-line; IMiD, immunomodulatory drug.
1. Johnson & Johnson, data on file.
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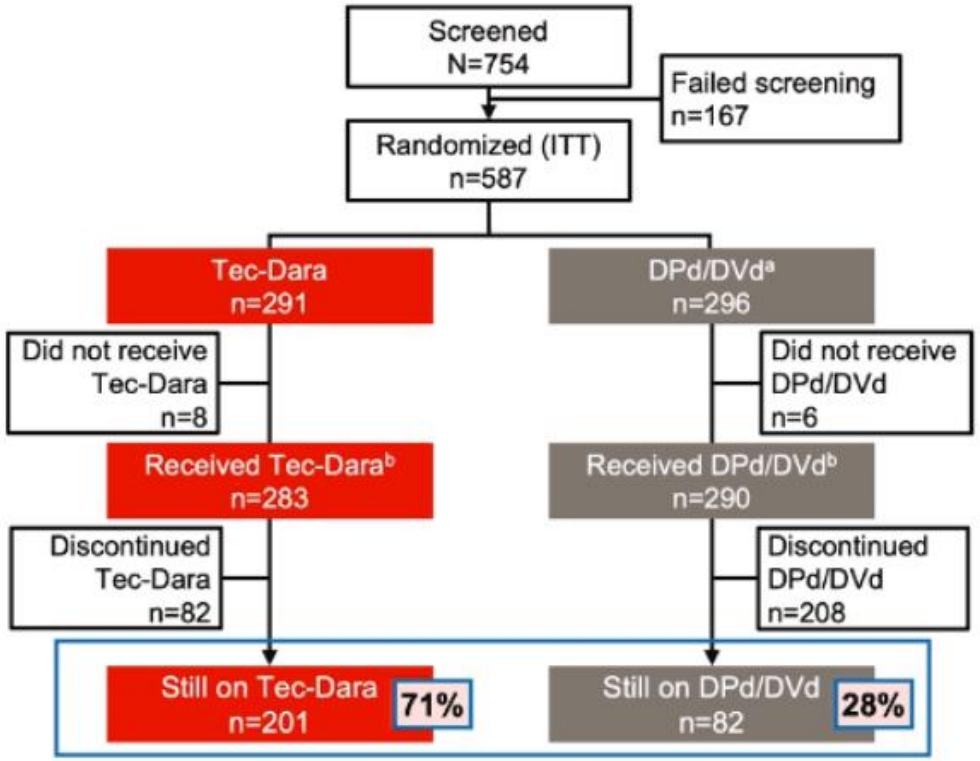
MajesTEC-3: Patient Disposition and Exposure



Median follow-up: 34.5 months

	Tec-Dara (n=291)	DPd/DVd (n=296)
Number of patients treated, n (%)	283 (97.3)	290 (98.0)
Still on study treatment,[c] n (%)	201 (71.0)	82 (28.3)
Discontinued study treatment,[c] n (%)	82 (29.0)	208 (71.7)
Reason for discontinuation,[c,d] n (%)		
AE	13 (4.6)	16 (5.5)
Death	20 (7.1)	13 (4.5)
Physician decision	11 (3.9)	5 (1.7)
PD	21 (7.4)	168 (57.9)
Patient refused further treatment	13 (4.6)	6 (2.1)
Median treatment duration, months	32.4	16.1
Overall deaths due to PD,[e] n/N (%)	13/283 (4.6)	59/290 (20.3)

- Of the 201 patients remaining on Tec-Dara, >95% remained on both drugs
- Median relative dose intensity across all cycles
  - Tec: 91.7%
  - Dara: 90.0%–97.8% across groups

Low and comparable treatment discontinuations due to AEs with Tec-Dara and DPd/DVd; 71% still on study treatment in the Tec-Dara group

Clinical cutoff: August 1, 2025.
[a]In the DPd/DVd group, 269 patients were randomized to receive DPd and 27 to receive DVd per investigator's choice. [b]Patients in the safety analysis set. [c]Percentages are based on number of patients treated. [d]4 (1.4%) patients in the Tec-Dara group discontinued due to "Other" reasons. [e]Percentage of deaths due to PD is based on the number of patients in the safety analysis set.
AE, adverse event; ITT, intent-to-treat; PD, progressive disease.

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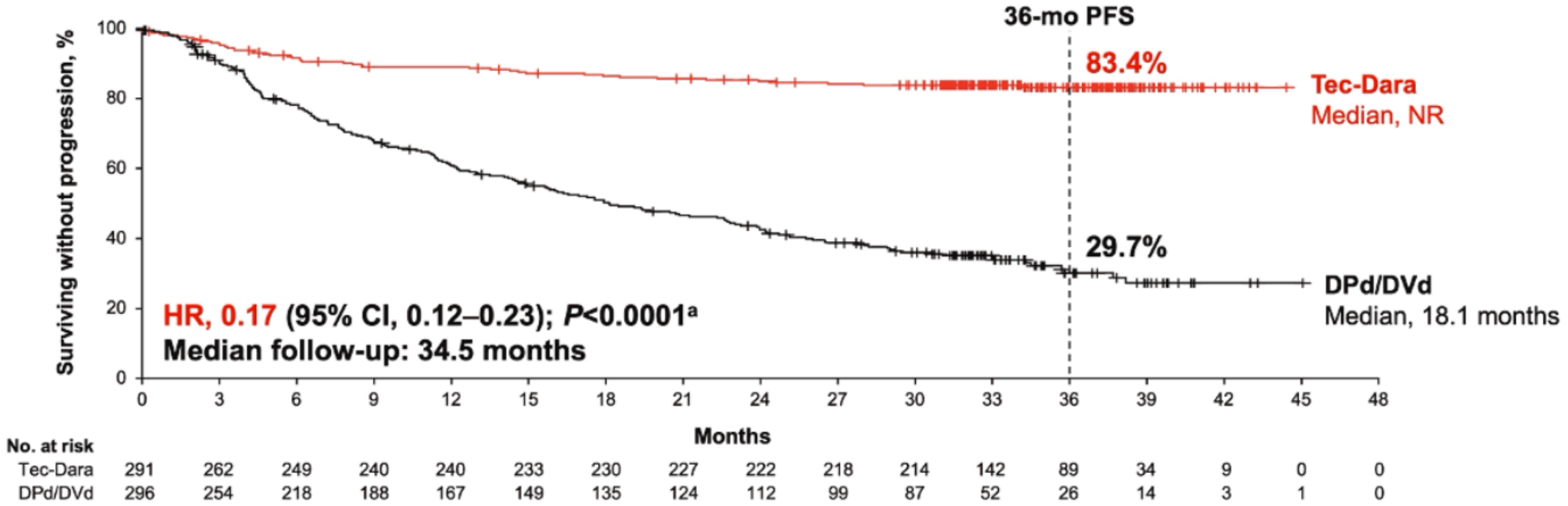
MajesTEC-3: PFS (Primary Endpoint)



Tec-Dara significantly improved PFS, with a plateauing curve after ~6 months and >90% of patients progression-free at 6 months sustaining such a benefit at 3 years

[a]The *P* value crossed the prespecified stopping boundary for superiority for the first interim analysis (*P*=0.0139).
CI, confidence interval; HR, hazard ratio; NR, not reached.

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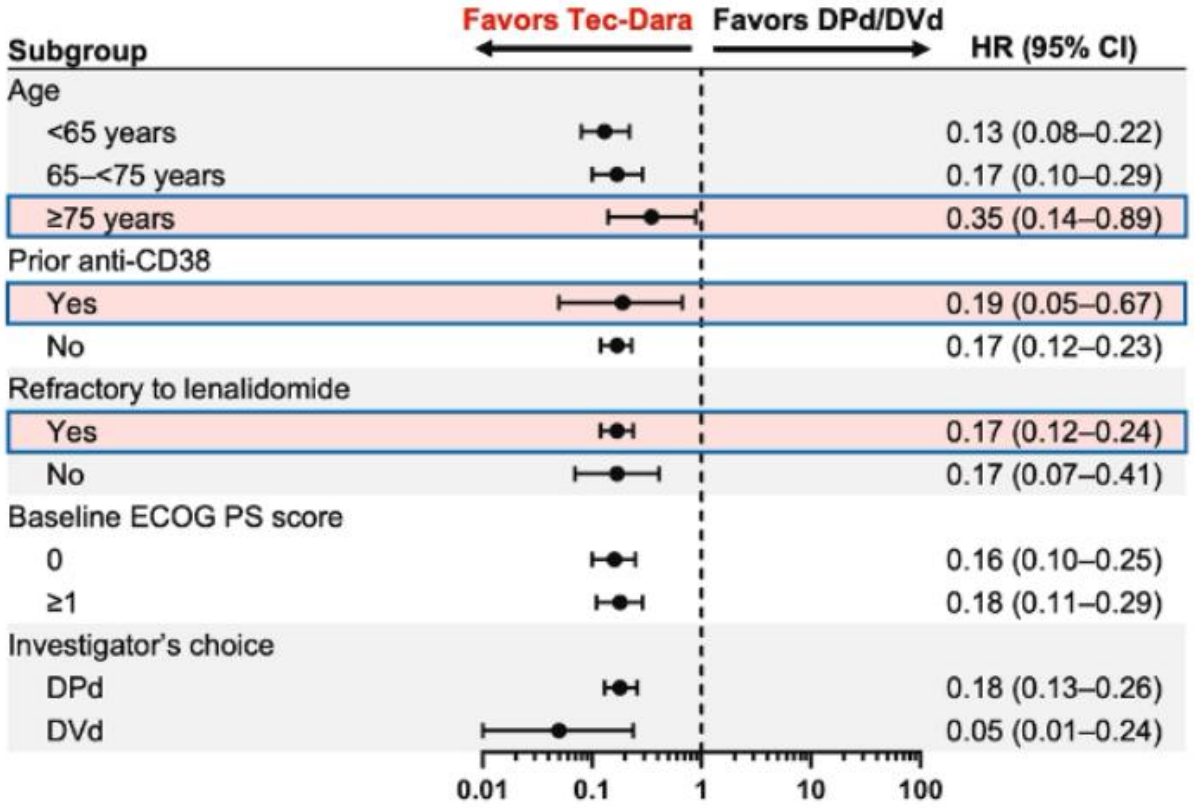
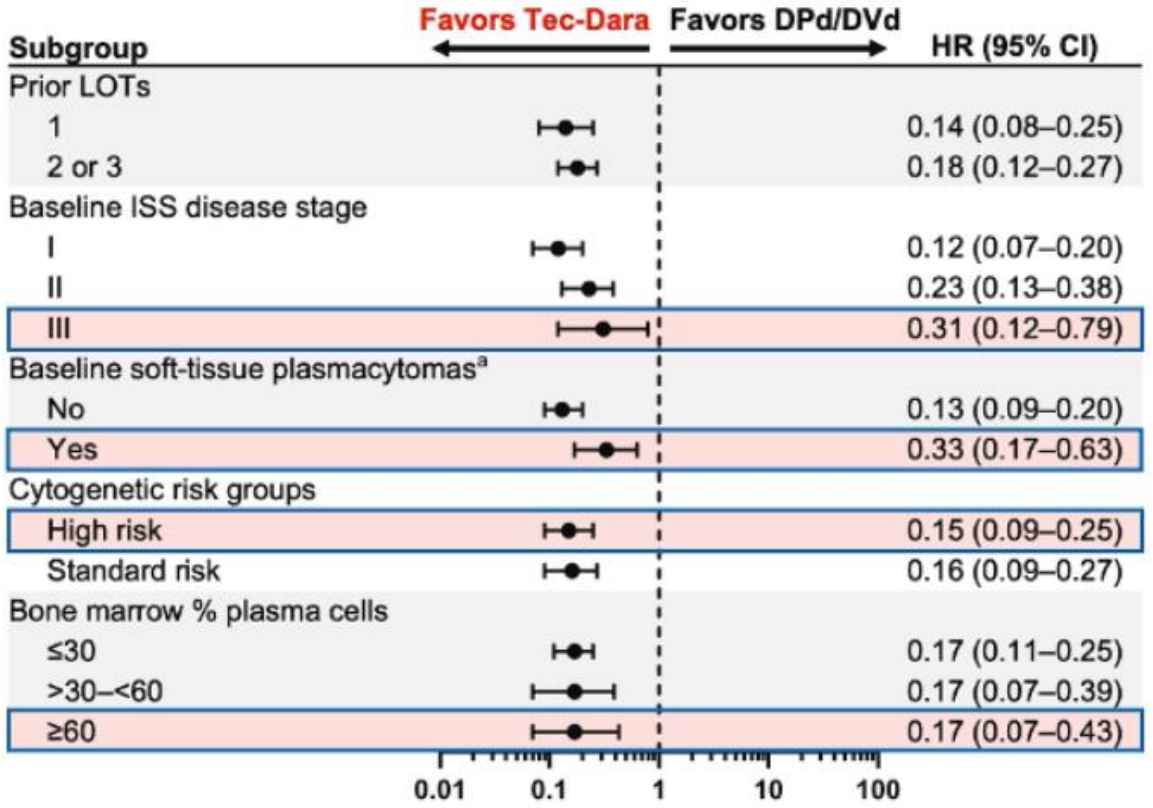
MajesTEC-3: PFS Subgroup Analysis





Superior PFS with Tec-Dara was consistent across all subgroups[b]

[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 versus DPd/DVd across all subgroups.

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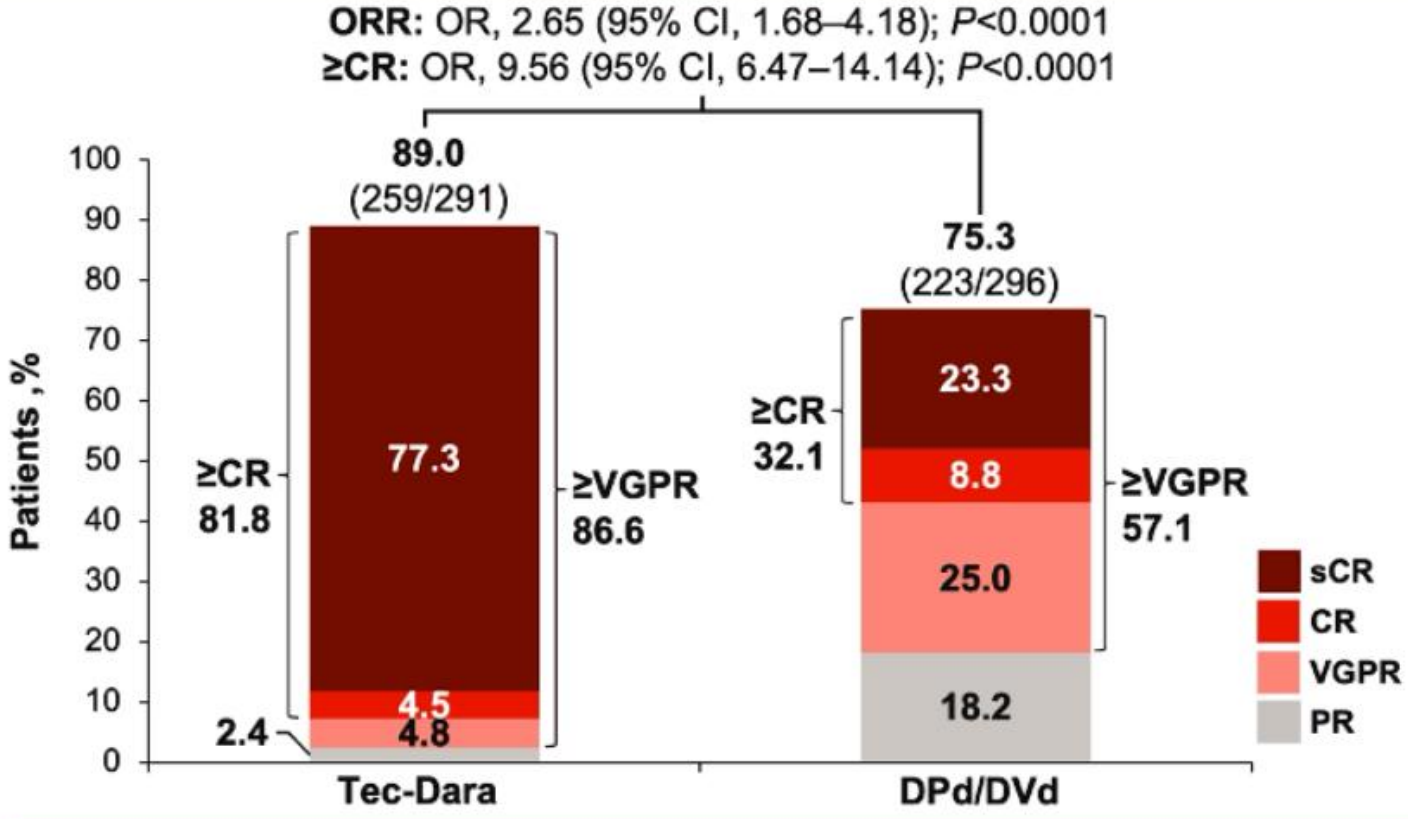
MajesTEC-3: Treatment Response[a] and Response Duration



	Tec-Dara (n=259)	DPd/DVd (n=223)
Median (range) time to first response, months	1.2 (0.9–25.0)	1.2 (0.7–6.3)
Median (range) time to first ≥CR, months	6.9 (1.0–34.5)	6.9 (1.5–18.8)
Median (95% CI) DOR, months	NE (NE–NE)	23.5 (19.8–29.9)
36-month DOR, % (95% CI)	88.5 (83.7–92.0)	36.4 (28.9–43.9)

Tec-Dara demonstrated significantly higher ORR and ≥CR rate versus DPd/DVd

Median follow-up: 34.5 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; VGPR, very good partial response.

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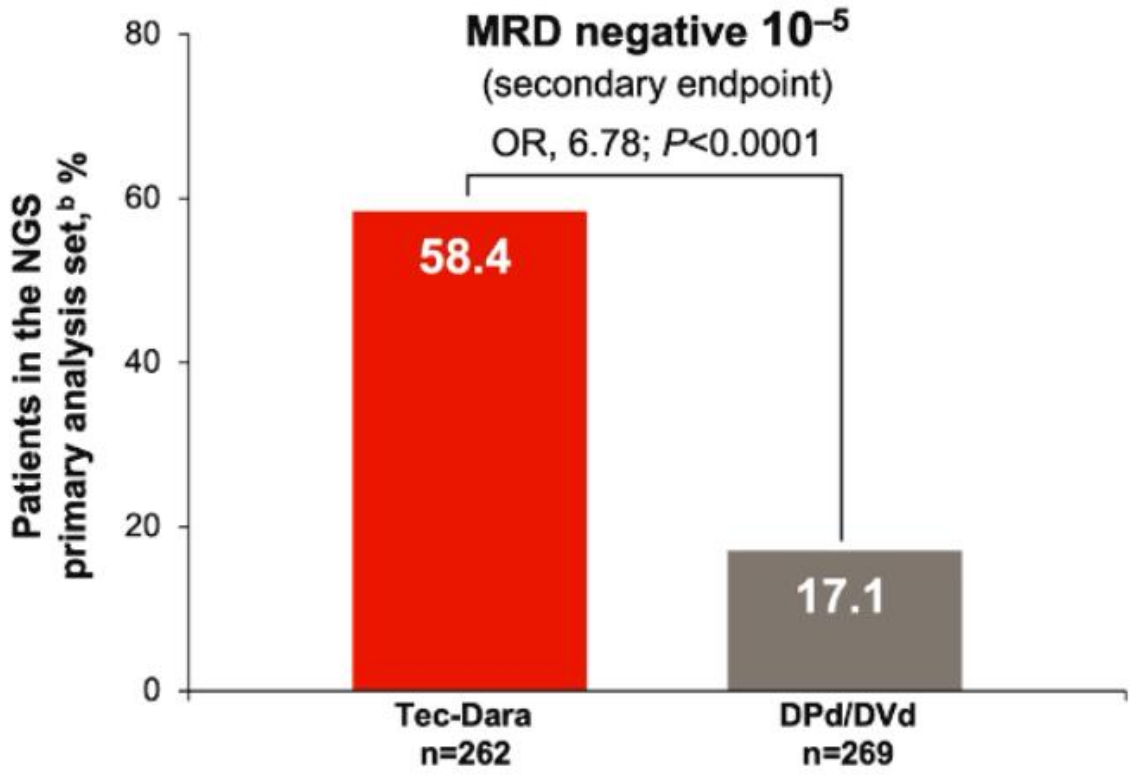
MajesTEC-3: MRD Negativity[a]



	MRD-negative ≥CR (10^{-5})	MRD-negative ≥CR (10^{-6})
Tec-Dara, %		
Primary NGS[b]	57.6	53.8
Evaluable[c]	**89.3**	**87.5**
DPd/DVd, %		
Primary NGS[b]	17.1	10.4
Evaluable[c]	63.0	41.8

~90% MRD-negative ≥CR with Tec-Dara in MRD-evaluable patients

Median follow-up: 34.5 months.
[a]MRD was assessed in the bone marrow by NGS in accordance with IMWG guidelines. [b]The MRD NGS primary analysis set was defined as all randomized patients in the study except those recruited in China (due to China instead utilizing NGF for MRD assessment; Tec-Dara, n=262; DPd/DVd, n=269). [c]The MRD NGS evaluable set was defined as patients who achieved ≥CR, had a successful baseline calibration, and had ≥1 post-baseline MRD sample with a positive or negative result (per NGS) at the indicated threshold (10^{-5}: Tec-Dara, n=168; DPd/DVd, n=73; 10^{-6}: Tec-Dara, n=160; DPd/DVd, n=67).
NGF, next-generation flow cytometry; NGS, next-generation sequencing.

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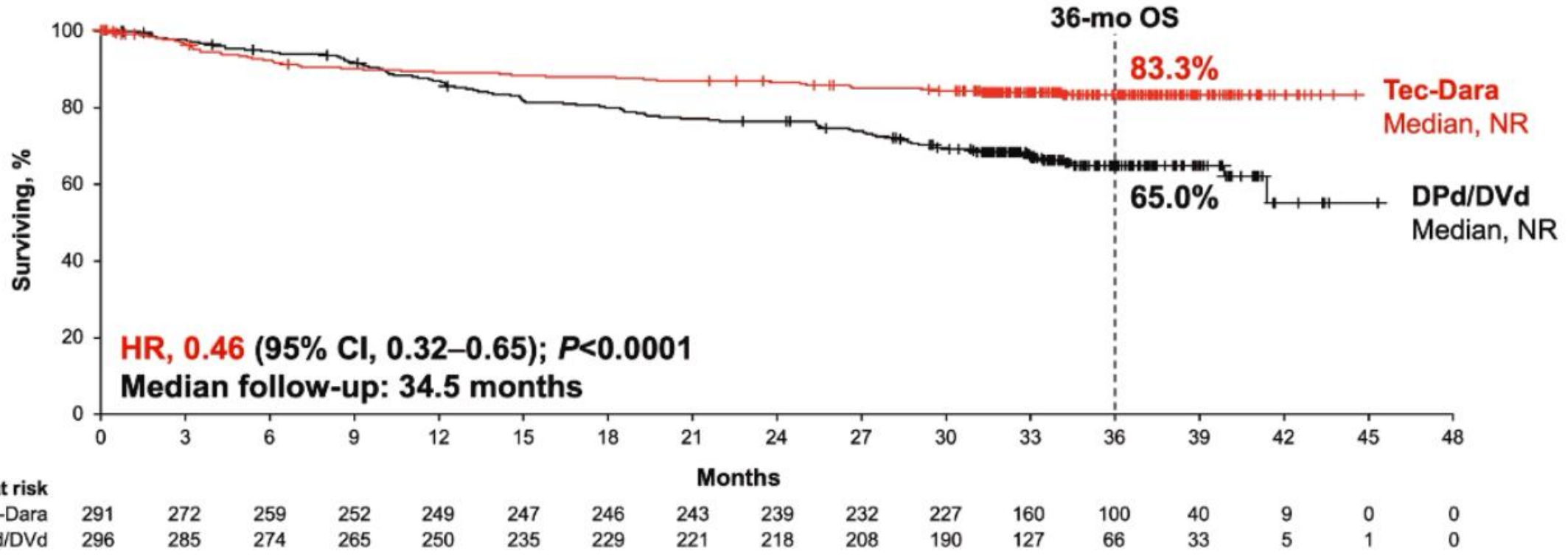
MajesTEC-3: OS



Tec-Dara significantly improved OS versus DPd/DVd, with 83% of patients alive at 3 years

Analysis of RMST demonstrated an OS benefit for Tec-Dara versus DPd/DVd (RMST difference, 2.15 months; *P*=0.0088).
RMST, restricted mean survival time.

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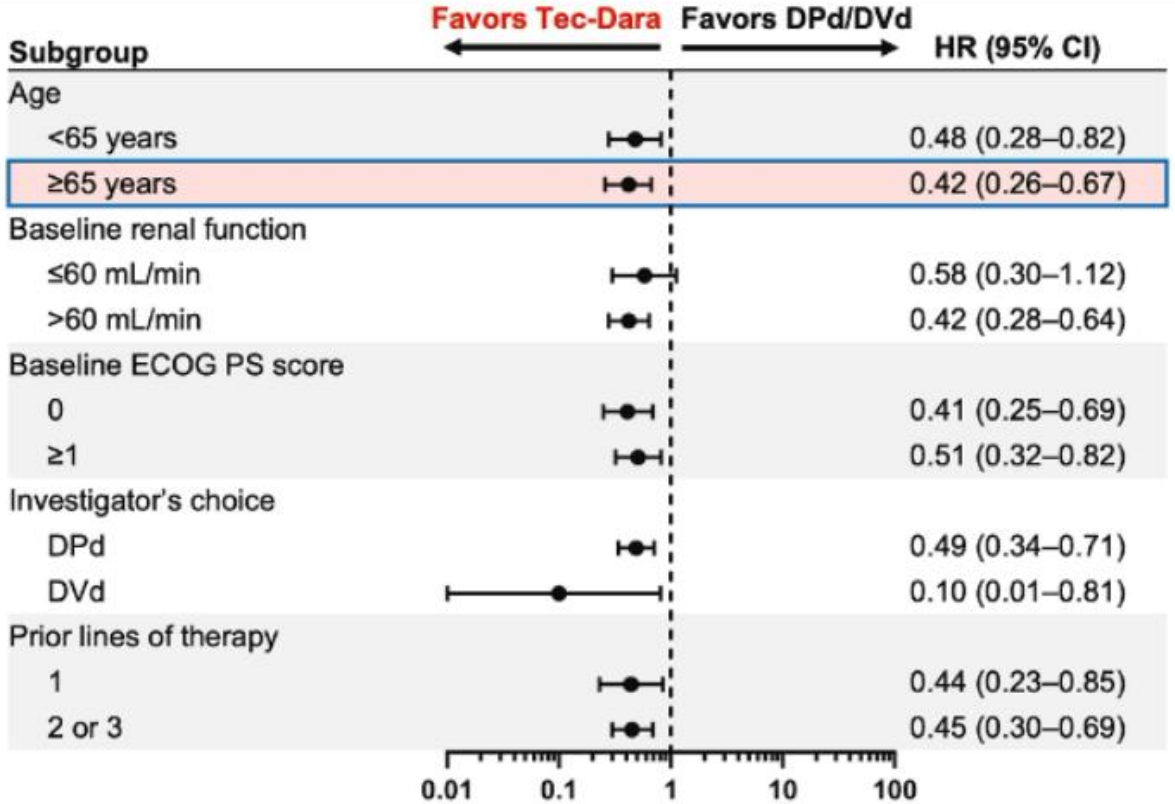
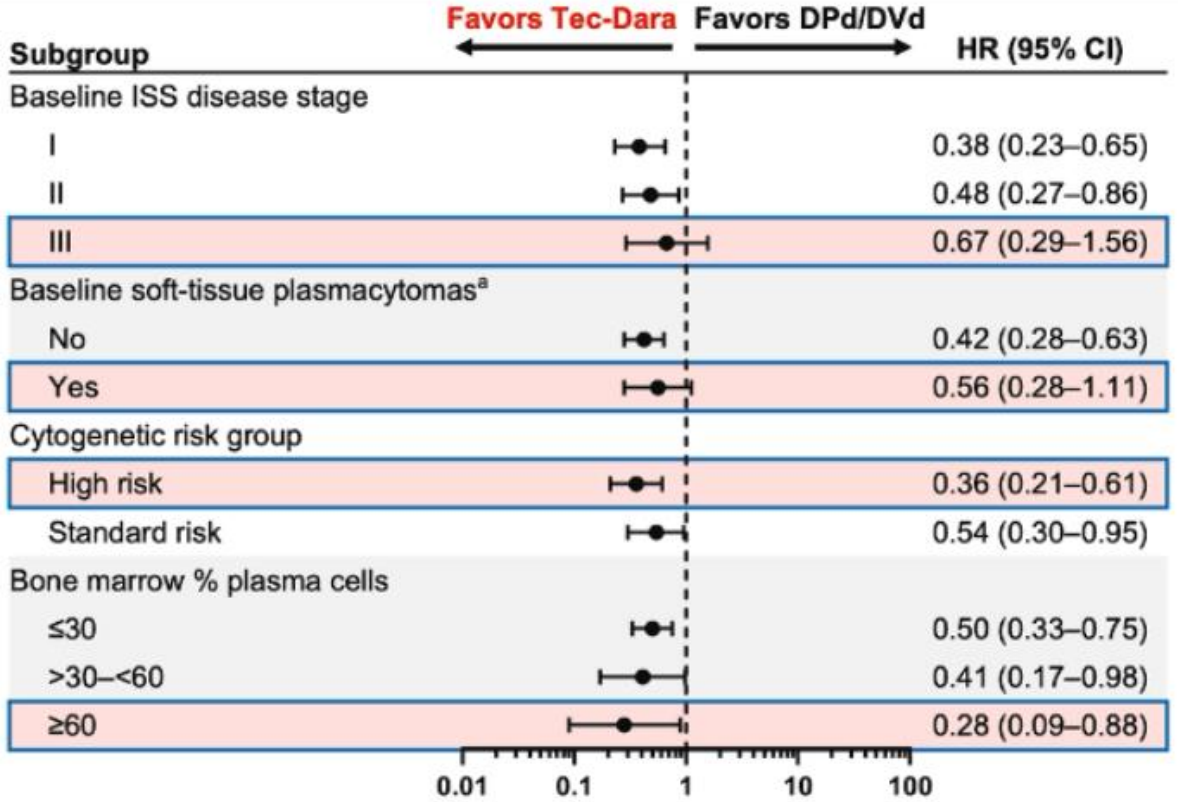
MajesTEC-3: OS Subgroup Analysis





Superior OS with Tec-Dara across prespecified subgroups[b]

[a]Baseline soft-tissue plasmacytomas contain both extramedullary and paraskeletal plasmacytomas. [b]Not all prespecified subgroups that were assessed are shown; however, OS favored Tec-Dara versus DPd/DVd across all subgroups.

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MajesTEC-3: Overall Safety Profile

- Mostly grade 1 CRS (44.2%), with 15.9% grade 2
  - All CRS resolved; no grade 2 after first cycle
  - No grade ≥3 CRS events
  - No prophylactic tocilizumab given per protocol
- 1.1% ICANS[a]; all resolved
- Low rate of TEAEs leading to discontinuation[b] in both Tec-Dara (4.6%) and DPd/DVd (5.5%) groups
- Serious AEs: 70.7% vs 62.4%
- Similar rates of deaths due to TEAEs: 7.1% vs 5.9%

TEAE, n (%)[c]	Tec-Dara (n=283)		DPd/DVd (n=290)	
	Any grade	Grade 3/4	Any grade	Grade 3/4
Any TEAE	283 (100)	269 (95.1)	290 (100)	280 (96.6)
Hematologic				
Neutropenia	222 (78.4)	214 (75.6)	240 (82.8)	228 (78.6)
Anemia	111 (39.2)	58 (20.5)	103 (35.5)	50 (17.2)
Thrombocytopenia	103 (36.4)	55 (19.4)	126 (43.4)	68 (23.4)
Lymphopenia	63 (22.3)	59 (20.8)	50 (17.2)	32 (11.0)
Leukopenia	51 (18.0)	30 (10.6)	61 (21.0)	46 (15.9)
Nonhematologic[d]				
CRS[e]	170 (60.1)	0	-	-
Diarrhea	147 (51.9)	10 (3.5)	89 (30.7)	7 (2.4)
Cough	136 (48.1)	1 (0.4)	66 (22.8)	0
Pyrexia	104 (36.7)	4 (1.4)	55 (19.0)	1 (0.3)

TEAE profile was generally comparable between Tec-Dara and DPd/DVd

[a]In the Tec-Dara group, grade 1, n=2; grade 4, n=1 (led to discontinuation of teclistamab). [b]Patients who discontinued all components of study treatment. [c]Includes the most common TEAEs of any grade occurring in ≥30% of patients in either treatment group and the most common grade 3/4 TEAEs occurring in ≥10% of patients in either treatment group. [d]Hypogammaglobulinemia, COVID-19, COVID-19 pneumonia, URTI, and pneumonia were also reported but are discussed on the following summary of infections slide. [e]CRS is not applicable for the DPd/DVd group.
CRS, cytokine release syndrome; ICANS, immune effector cell–associated neurotoxicity syndrome; TEAE, treatment-emergent adverse event; URTI, upper respiratory tract infection.
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MajesTEC-3: Summary of Infections

- Study started during the COVID-19 pandemic and prior to bispecific treatment guidelines
- Hypogammaglobulinemia[a]: 84.5% with Tec-Dara
- 13 (4.6%) deaths due to infection with Tec-Dara[b]
  - 12 occurred within 6 months of treatment (3 due to COVID-19); 9 of 12 patients did not receive IgRT
  - Protocol was subsequently amended in Feb 2023 to reinforce IgRT supplementation and antimicrobial prophylaxis[c]
    - 87.3% received ≥1 dose of Ig[d]
    - 1 infectious death occurred post amendment

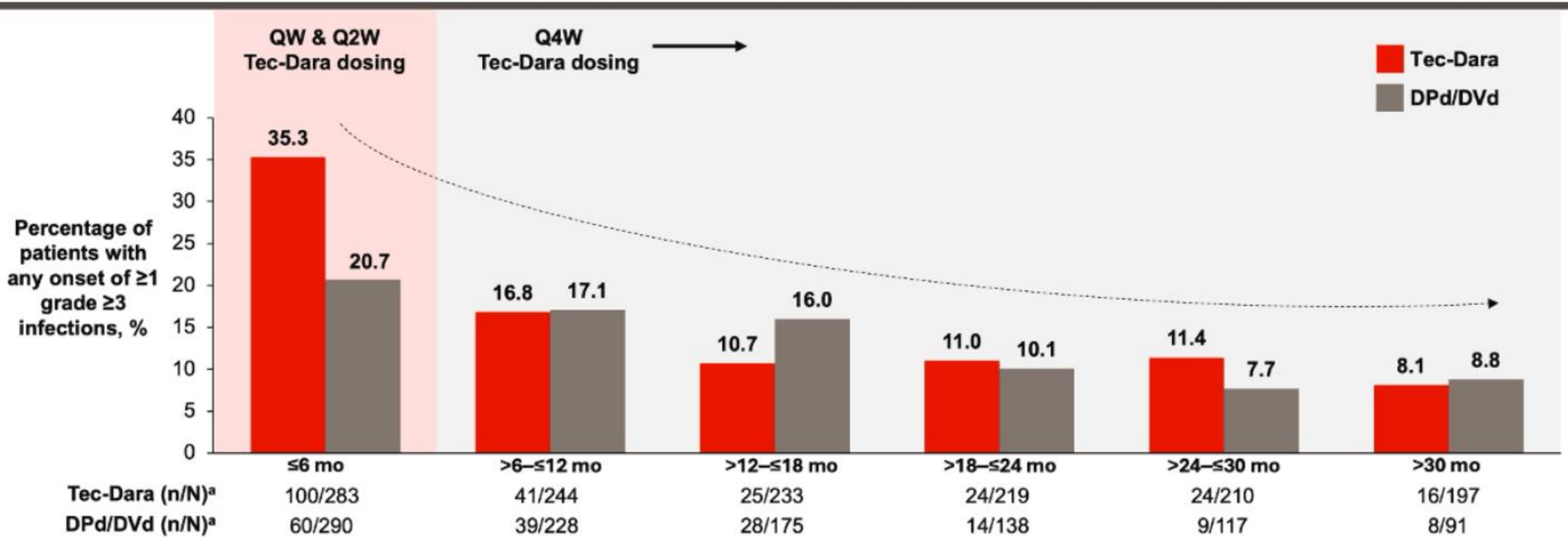
TEAE, n (%)	Tec-Dara (n=283)		DPd/DVd (n=290)	
	Any grade	Grade 3/4	Any grade	Grade 3/4
Any infection	273 (96.5)	153 (54.1)	244 (84.1)	126 (43.4)
Treatment-emergent infection or infestation[e]				
COVID-19	124 (43.8)	17 (6.0)	97 (33.4)	6 (2.1)
URTI	115 (40.6)	12 (4.2)	88 (30.3)	7 (2.4)
Pneumonia	65 (23.0)	47 (16.6)	53 (18.3)	43 (14.8)
Nasopharyngitis	62 (21.9)	0	57 (19.7)	0
Sinusitis	52 (18.4)	5 (1.8)	17 (5.9)	3 (1.0)
Rhinovirus infection	44 (15.5)	5 (1.8)	10 (3.4)	1 (0.3)
Bronchitis	40 (14.1)	2 (0.7)	31 (10.7)	6 (2.1)
Influenza	38 (13.4)	8 (2.8)	43 (14.8)	10 (3.4)
COVID-19 pneumonia	34 (12.0)	32 (11.3)	12 (4.1)	7 (2.4)
UTI	29 (10.2)	4 (1.4)	27 (9.3)	1 (0.3)

Infections with Tec-Dara require diligent use of established IgRT and prophylaxis protocols

[a]Hypogammaglobulinemia was defined as patients with ≥1 TEAE of hypogammaglobulinemia or a post-baseline IgG value <400 mg/dL. Rate of hypogammaglobulinemia in the DPd/DVd arm was 60.3%. [b]In the DPd/DVd group, 4 patients had a fatal infection, 2 of which occurred after the implementation of protocol amendment #6. [c]Protocol amendment #6 affirmed the importance of medical monitoring of IgG levels and adherence to protocol-specified Ig supplementation guidance. [d]Percentage at clinical cutoff. [e]Most common defined as occurring in ≥10% of patients in either treatment group; shown with percent occurrence of respective grade 3/4 infection.
Ig, immunoglobulin; IgG, immunoglobulin G; IgRT, immunoglobulin replacement therapy; UTI, urinary tract infection.

Presented by M-V Mateos at the 67th American Society of Hematology (ASH) Annual Meeting and Exposition; December 6-9, 2025; Orlando, FL, USA.

MajesTEC-3: Grade ≥3 Infections Over Time



	≤6 mo	>6–≤12 mo	>12–≤18 mo	>18–≤24 mo	>24–≤30 mo	>30 mo
Tec-Dara (n/N)[a]	100/283	41/244	25/233	24/219	24/210	16/197
DPd/DVd (n/N)[a]	60/290	39/228	28/175	14/138	9/117	8/91

Any onset grade ≥3 infections were comparable across arms after 6 months and decreased over time

[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.

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MajesTEC-3: Conclusions

Synergistic[1] immunotherapy combination of Tec-Dara versus DPd/DVd in 1-3 prior LOTs in RRMM:

- Greatest PFS treatment effect to date (HR, 0.17),[2-6] with plateauing curve after ~6 months suggesting potential for functional cure
  - Benchmark 83.4% PFS rate at 3 years, with clear benefit in patients with high-risk cytogenetics, EMD, ISS stage III, and prior anti-CD38 exposure
- Superior OS (HR, 0.46)
- Grade ≥3 infections were highest in the first 6 months, then declined over time; patients should be supported with infection prophylaxis, monitoring, and established IgRT supplementation protocols
- CRS profile and combinability of Tec with Dara on approved Dara schedule support potential for community adoption

Tec-Dara showed unprecedented efficacy, supporting a new 2L+ SOC with broad potential across academic and community settings

1. Vishwamitra D, et al. Presented at: ASH Annual Meeting and Exposition; December 7-10, 2024; San Diego, CA, USA. Oral 594. 2. San-Miguel J, et al. *N Engl J Med*. 2023;389:335-347. 3. Usmani SZ, et al. *Blood Adv*. 2023;7:3737-3748. 4. Hungria V, et al. *N Engl J Med*. 2024;391:393-407. 5. Dimopoulos MA, et al. *N Engl J Med*. 2024;391:408-421. 6. Martin T, et al. *Blood Cancer J*. 2023;13:72.
EMD, extramedullary disease.

Presented by M-V Mateos at the 67th American Society of Hematology (ASH) Annual Meeting and Exposition; December 6-9, 2025; Orlando, FL, USA.

Safety and Efficacy of Talquetamab + Teclistamab in Patients With Relapsed/Refractory Multiple Myeloma From Phase 1b of RedirecTT-1: Results With an Extended Median Follow-Up of 3 Years

María-Victoria Mateos[1]*, Hila Magen[2], Moshe Gatt[3], Michael Sebag[4], Kihyun Kim[5], Chang-Ki Min[6], Enrique M Ocio[7], Sung-Soo Yoon[8], Michael P Chu[9], Paula Rodríguez-Otero[10], Irit Avivi[11], Natalia A Quijano Cardé[12], Maria Krevvata[12], Todd Henninger[13], Payal Thakkar[13], Mariacristina Festa[14], Guoqiang Zhang,[12] Sheetal Khedkar,[15] Lin Huang[12], Jiangxiu Zhou[12], Mikihiro Takamoto[16], Lixia Pei[13], Jiashen Lu[17], Carmela Maffucci[13], Emma Scott[12], Albert Oriol[18], Daniel Morillo[19], Yael C Cohen[11]

[1]University Hospital of Salamanca/IBSAL/CIC/CIBERONC, Salamanca, Spain; [2]Chaim Sheba Medical Center, Ramat-Gan, Faculty of Medical and Health Sciences, Tel Aviv University, Tel Aviv, Israel; [3]Hadassah Medical Cener, Hebrew University of Jerusalem, Jerusalem, Israel; [4]McGill University and MUHC, Montreal, Quebec, Canada; [5]Samsung Medical Center, Sungkyunkwan University School of Medicine, Seoul, South Korea; [6]Seoul St. Mary's Hospital, The Catholic University of Korea, Seoul, South Korea; [7]Hospital Universitario Marqués de Valdecilla (IDIVAL), Universidad de Cantabria, Santander, Spain; [8]Seoul National University College of Medicine, Seoul, South Korea; [9]Alberta Health Services, Edmonton, Alberta, Canada; [10]Cancer Center Clínica Universidad de Navarra, Cima, Pamplona, Spain; [11]Tel Aviv Sourasky (Ichilov) Medical Center, Gray Faculty of Medical and Health Sciences, Tel Aviv University, Tel Aviv, Israel; [12]Johnson & Johnson, Spring House, PA, USA; [13]Johnson & Johnson, Raritan, NJ, USA; [14]Johnson & Johnson, Leiden, Netherlands; [15]Johnson & Johnson, Horsham, PA; [16]Johnson & Johnson, Tokyo, Japan; [17]Johnson & Johnson, Shanghai, China; [18]Institut Català d'Oncologia and Josep Carreras Research Institute, Hospital Germans Trias i Pujol, Badalona, Barcelona, Spain; [19]University Hospital Fundación Jiménez Díaz, START Madrid-FJD early phase unit, Madrid, Spain

*Presenting author.

Presented by M-V Mateos at the 67th American Society of Hematology (ASH) Annual Meeting; December 6–9, 2025; Orlando, FL, USA

RedirecTT-1 Phase 1 (Tal + Tec): First Study of a Bispecific Combination in RRMM

- Talquetamab (Tal; anti-GPRC5D×CD3) and teclistamab (Tec; anti-BCMA×CD3) are the first BsAbs approved as monotherapies for TCE RRMM[1-5]
- Dual-targeting GPRC5D and BCMA with Tal + Tec may improve response rate, depth and durability compared with either monotherapy by mitigating primary resistance, tumor heterogeneity and antigen-related escape
  - Tal's B-cell sparing mechanism has minimal impact on humoral immunity, supporting combination with anti-BCMA therapies[6]
- In previous results from RedirecTT-1 phase 1b (median follow-up, 20.3 months), Tal + Tec elicited deep, durable responses and demonstrated a safety profile generally consistent with each monotherapy in RRMM[7]

We report efficacy and ongoing safety from phase 1b of RedirecTT-1 at an extended median follow-up of 38.0 months (all doses) and 34.5 months (RP2R)

BCMA, B-cell maturation antigen; BsAb, bispecific antibody; GPRC5D, G protein–coupled receptor class C group 5 member D; RP2R, recommended phase 2 regimen; RRMM, relapsed/refractory multiple myeloma; TCE, triple-class exposed.

1. Chari A, et al. *N Engl J Med 2022;*387:2232-44. 2. Chari A, et al. *Lancet Haematol* 2025;12:e269-81. 3. Moreau P, et al. *N Engl J Med* 2022;387:495-505. 4. TALVEY (talquetamab-tgvs). Prescribing information. Horsham, PA: Janssen Biotech, Inc; 2023. 5. TECVAYLI (teclistamab-cqyv). Prescribing information. Horsham, PA: Janssen Biotech, Inc; 2024. 6. Schinke C, et al. *Blood Adv* 2025:bloodadvances.2025016613. Epub ahead of print. 7. Cohen YC, et al. *N Engl J Med.* 2025;392:138-49.

Presented by M-V Mateos at the 67th American Society of Hematology (ASH) Annual Meeting; December 6–9, 2025; Orlando, FL, USA

RedirecTT-1 Phase 1 (Tal + Tec): Study Design and RP2R selection

Screening

Key eligibility criteria

- Triple-class exposed RRMM[a] with measurable disease per IMWG criteria
- EMD permitted (≥1 nonradiated, bone-independent soft tissue plasmacytoma ≥2 cm in greatest dimension)
- RR or intolerant to established therapies, including last LOT

Treatment

Phase 1 dose escalation → **RP2R**

+ SUD[d]

- **Tal 0.8 mg/kg + Tec 3.0 mg/kg Q2W (DL 5)**
- Tal 0.8 mg/kg + Tec 1.5 mg/kg Q2W (DL 4)
- Tal 0.4 mg/kg + Tec 1.5 mg/kg QW (DL 3)
- Tal 0.2 mg/kg + Tec 1.5 mg/kg QW (DL 2)
- Tal 0.2 mg/kg + Tec 0.75 mg/kg QW (DL 1)

Patients could transition from QW to Q2W and from Q2W to Q4W dosing after achieving a ≥PR after cycle 4

RP2R step-up dosing[d] 2–4 days apart (Tal + Tec)

SUD1: 0.01 mg/kg + 0.06 mg/kg

SUD2: 0.06 mg/kg + 0.3 mg/kg

SUD3: 0.3 mg/kg + 1.5 mg/kg

Key objectives

- Safety, including DLTs[b]
- Identify RP2R(s)
- ORR[c]
- DOR
- PFS
- OS

[a]Prior proteasome inhibitor, immunomodulatory drug, anti-CD38 monoclonal antibody. [b]CRS and ICANS AEs were graded per American Society for Transplantation and Cellular Therapy criteria; all other AEs were graded per CTCAE v5.0. [c]Investigator-assessed confirmed response per IMWG criteria was reported. [d]Tal and Tec administered on the same day, 30 (±10) minutes apart, for all step-up and full treatment doses. AE, adverse event; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; DL, dose level; DLT, dose-limiting toxicity; DOR, duration of response; EMD, extramedullary disease; ICANS, immune effector cell–associated neurotoxicity syndrome; IMWG, International Myeloma Working Group; LOT, line of therapy; ORR, overall response rate; OS, overall survival; PFS, progression-free survival; PR, partial response; Q4W, every 4 weeks; QW, weekly; RR, relapsed/refractory, SUD, step-up dose.

Cohen YC, et al. *N Engl J Med* 2025;392:138-49.

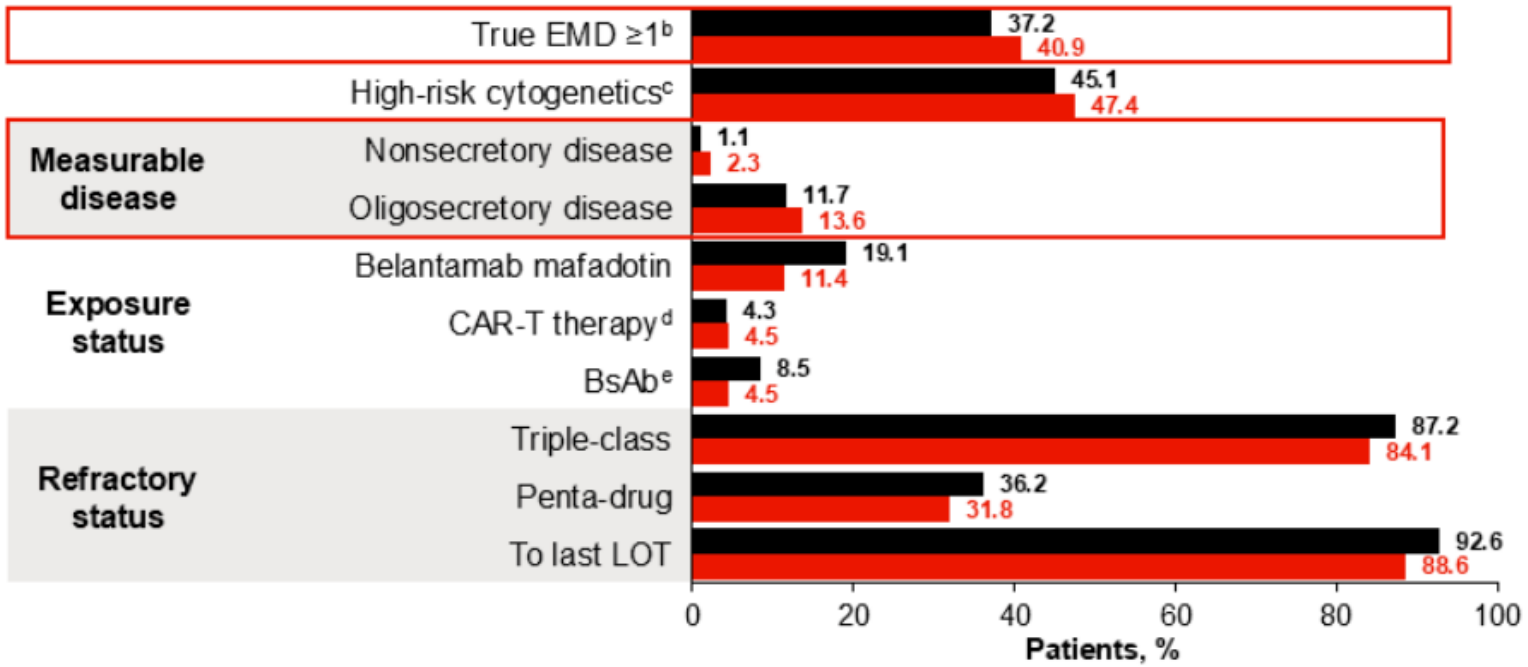
Presented by M-V Mateos at the 67th American Society of Hematology (ASH) Annual Meeting; December 6–9, 2025; Orlando, FL, USA

RedirecTT-1 Phase 1 (Tal + Tec): Baseline Characteristics

Patients treated with Tal + Tec	N=94 n=44
Age[a] (years)	64.5 (39–81) 63.0 (41–80)
Male	52.1% 52.3%
Years since diagnosis[a]	6.0 (0.3–14.6) 5.5 (0.3–12.8)
Prior LOT[a]	4 (1–11) 4 (2–10)

- As of July 2025:
  - 37.2% (all dose levels) and 47.4% (RP2R) remained on study treatment
  - mFU was 38.0 mo (all dose levels) and 34.5 mo (RP2R)

Baseline characteristics[1]



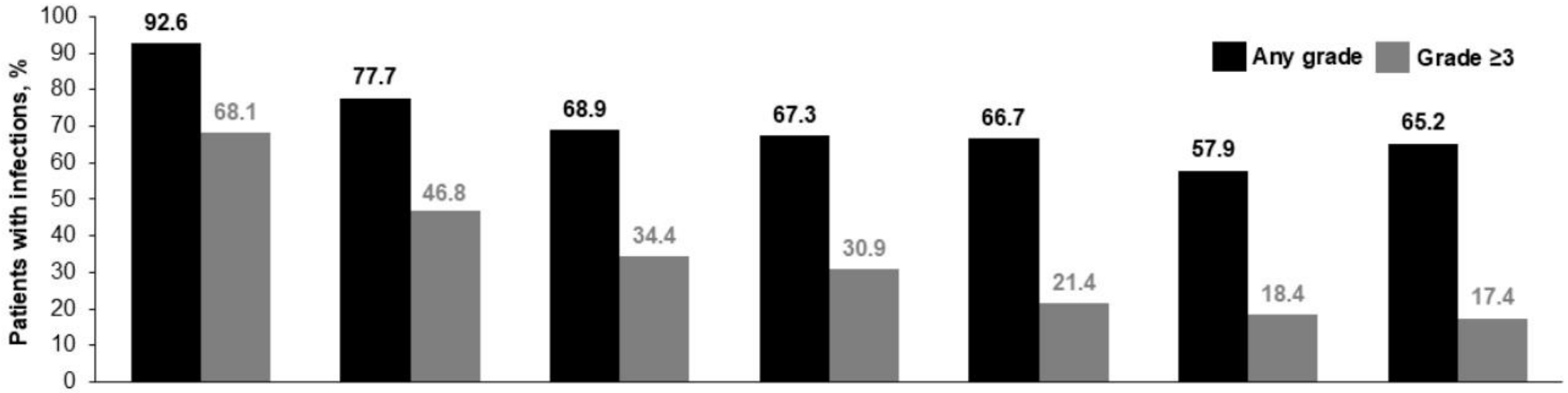
Baseline characteristics were reflective of triple-class exposed RRMM,[1] inclusive of patients with significant unmet needs

[a]Data are presented as median (range). [b]≥1 nonradiated bone-independent soft tissue plasmacytoma (≥2 cm in greatest dimension). [c]FISH or karyotype testing in n=51 (all dose levels) and n=19 [RP2R; defined as del(17p), t(4;14), or t(14;16)]. [d]2.1% (all doses) and 4.5% (RP2R) received BCMA CAR-T. [e]Across all doses, 4 patients received alnuctamab, 2 patients received WV-T078, 1 patient received teclistamab, and 1 patient received cevostamab. CAR, chimeric antigen receptor; FISH, fluorescence in situ hybridization; mFU, median follow-up.

1. Cohen YC, et al. *N Engl J Med* 2025;392:138-49.

Presented by M-V Mateos at the 67th American Society of Hematology (ASH) Annual Meeting; December 6–9, 2025; Orlando, FL, USA

RedirecTT-1 Phase 1 (Tal + Tec): Timing of New-Onset Infections Across All Dose Levels



New onset infection within:	Total	≤6 mo	>6 to ≤12 mo	>12 to ≤18 mo	>18 to ≤24 mo	>24 to ≤36 mo	>36 mo
Any grade (n/N)[a]	87/94	73/94	42/61	37/55	28/42	22/38	15/23
Grade ≥3 (n/N)[a]	64/94	44/94	21/61	17/55	9/42	7/38	4/23

Any-grade infection risk peaked early and stabilized by ~6 months; grade ≥3 infection risk was highest in the first 6 months and decreased over time

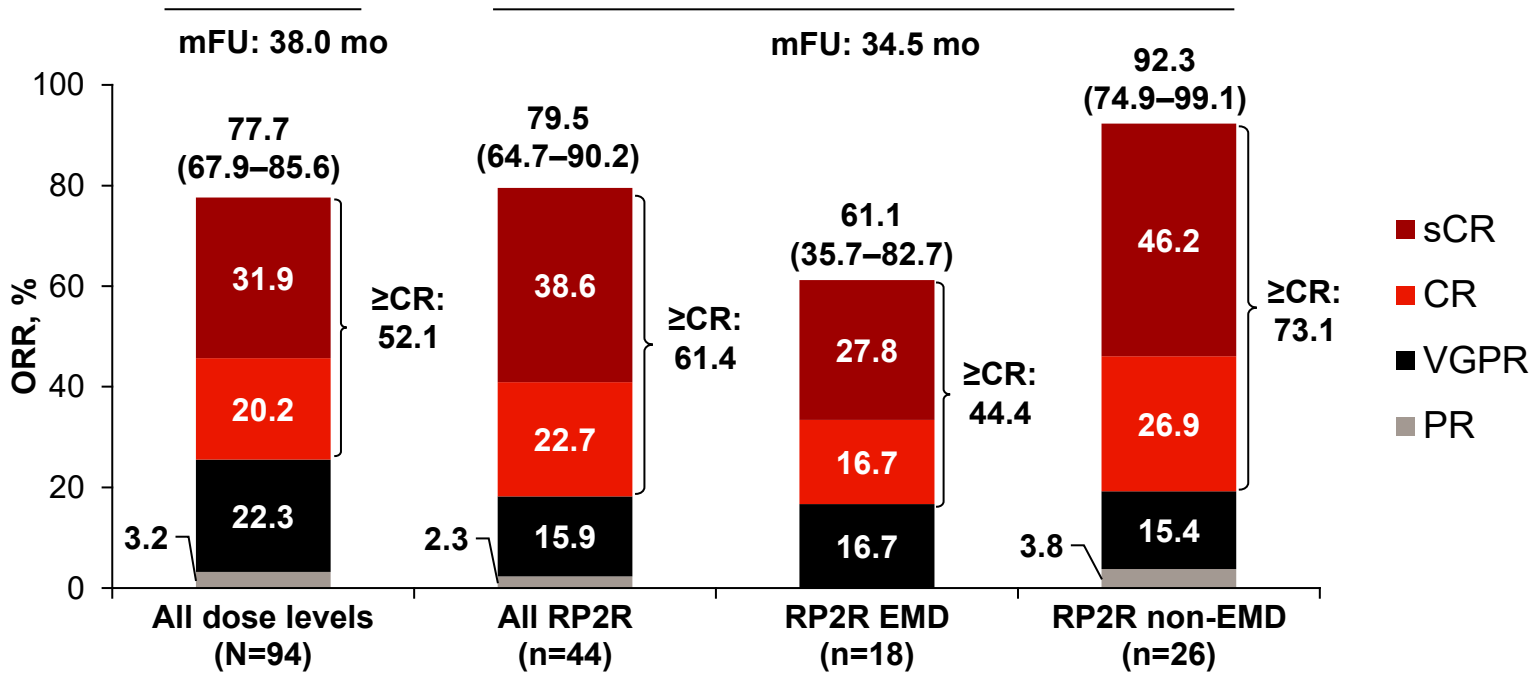
Data cut-off: July 2025. Median follow-up: 38.0 months (all dose levels). [a]Includes patients who either received study treatment or who experienced any treatment-emergent adverse event of infection within the specific window. Data shown are System Organ Class treatment-emergent infections and infestations and graded by Common Terminology Criteria for Adverse Events v5.0.

Presented by M -V Mateos at the 67th American Society of Hematology (ASH) Annual Meeting; December 6–9, 2025; Orlando, FL, USA

RedirecTT-1 Phase 1 Tal + Tec: Patients Achieved High ORR[a] and Deep Responses

At the last report:[1]

- All dose levels[b]
  - ORR: 78%
  - ≥CR: 48%
- RP2R[c]
  - ORR: 80%
  - ≥CR: 52%



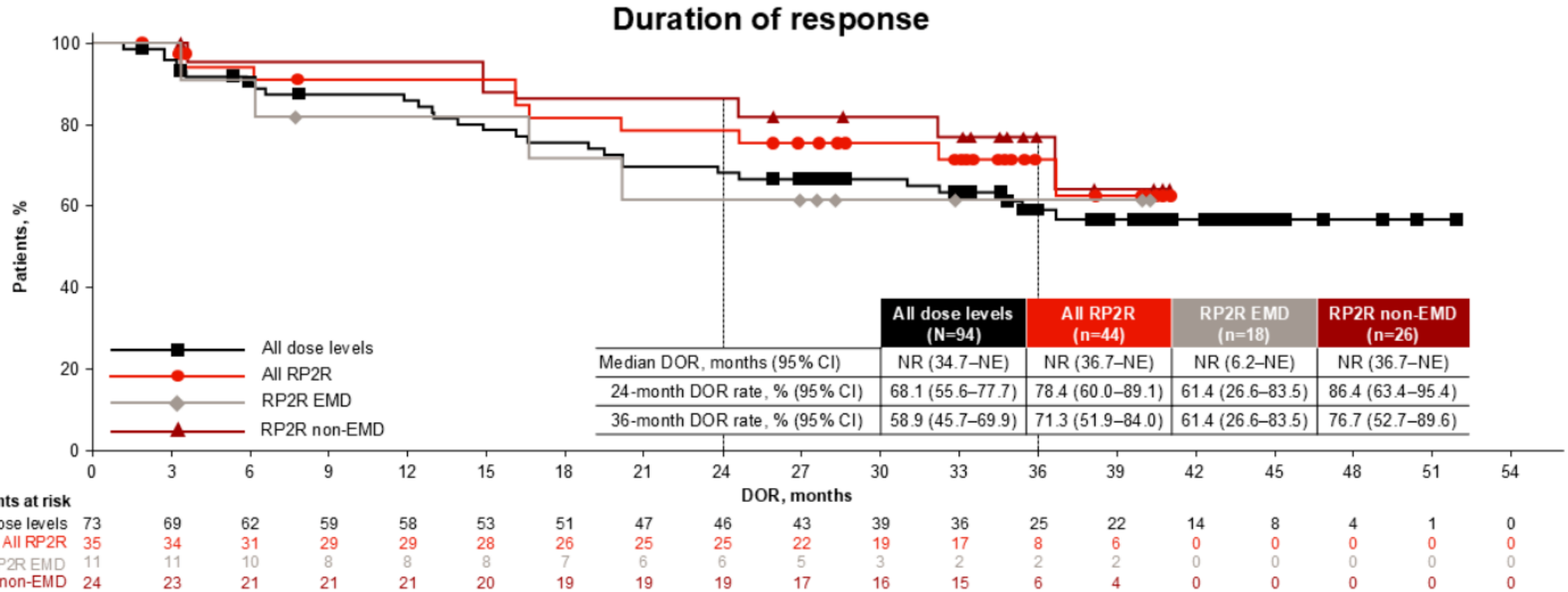
At ~3 years of follow-up, patients achieved a high ORR[a] and deepening responses since the last report,[1] including at the RP2R

Data cut-off: July 2025. [a]All treated patients were included in the estimation of ORR. Individual response rates may not sum to the ORR due to rounding. ORR was assessed as sCR, CR, VGPR, or PR. Response was assessed by the investigator per IMWG criteria. [b]Median follow-up 20.3 months. [c]Median follow-up 18.2 months.

1. Cohen YC, et al. *N Engl J Med* 2025;392:138-49.

Presented by M-V Mateos at the 67th American Society of Hematology (ASH) Annual Meeting; December 6–9, 2025; Orlando, FL, USA

RedirecTT-1 Phase 1 (Tal + Tec): Median DOR Not Reached at 38 Months of Follow-Up Across All Dose Levels



	All dose levels (N=94)	All RP2R (n=44)	RP2R EMD (n=18)	RP2R non-EMD (n=26)
Median DOR, months (95% CI)	NR (34.7–NE)	NR (36.7–NE)	NR (6.2–NE)	NR (36.7–NE)
24-month DOR rate, % (95% CI)	68.1 (55.6–77.7)	78.4 (60.0–89.1)	61.4 (26.6–83.5)	86.4 (63.4–95.4)
36-month DOR rate, % (95% CI)	58.9 (45.7–69.9)	71.3 (51.9–84.0)	61.4 (26.6–83.5)	76.7 (52.7–89.6)

Patients at risk

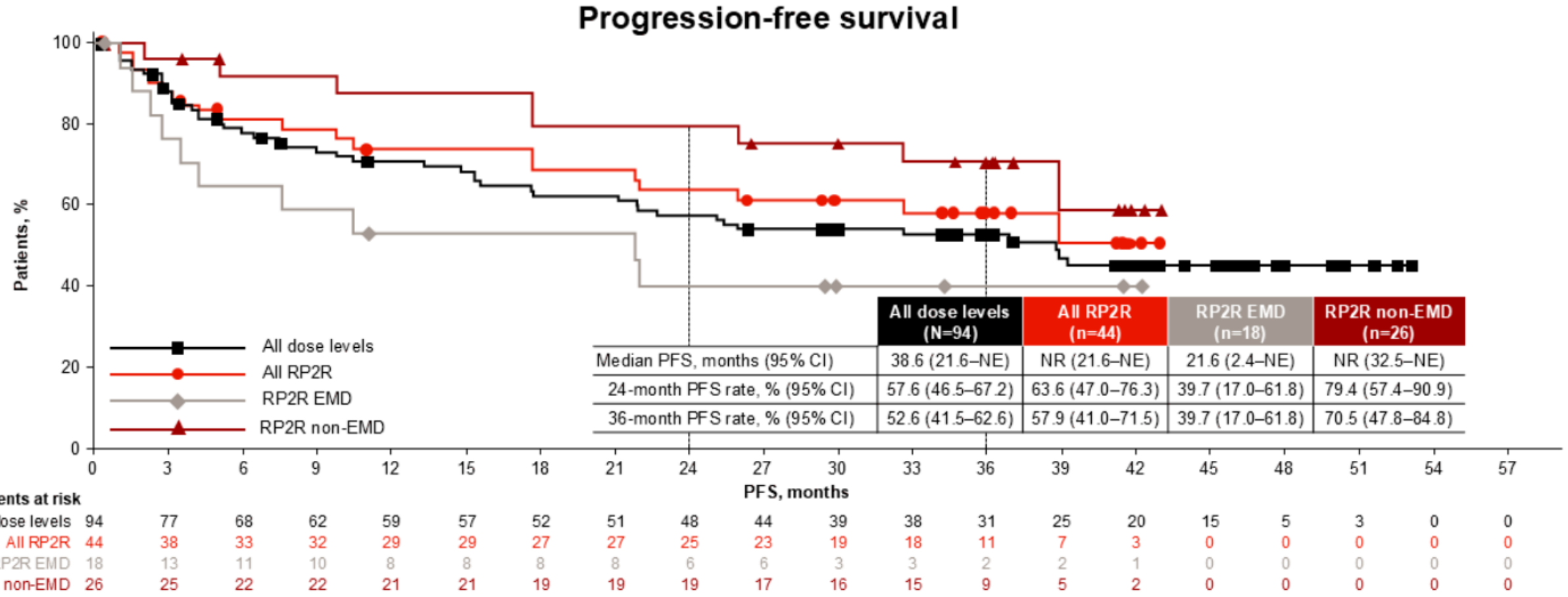
All dose levels	73	69	62	59	58	53	51	47	46	43	39	36	25	22	14	8	4	1	0
All RP2R	35	34	31	29	29	28	26	25	25	22	19	17	8	6	0	0	0	0	0
RP2R EMD	11	11	10	8	8	8	7	6	6	5	3	2	2	2	0	0	0	0	0
RP2R non-EMD	24	23	21	21	21	20	19	19	19	17	16	15	6	4	0	0	0	0	0

At RP2R, 71% of responders remained in response at 3 years; responses were more durable in non-EMD

Data cut-off: July 2025. Median follow-up: 38.0 months (all dose levels), 34.5 months (RP2R). NR, not reached.

Presented by M -V Mateos at the 67th American Society of Hematology (ASH) Annual Meeting; December 6–9, 2025; Orlando, FL, USA

RedirecTT-1 Phase 1 (Tal + Tec): Median PFS 38.6 Months at 38 Months of Follow-Up Across All Dose Levels



	All dose levels (N=94)	All RP2R (n=44)	RP2R EMD (n=18)	RP2R non-EMD (n=26)
Median PFS, months (95% CI)	38.6 (21.6–NE)	NR (21.6–NE)	21.6 (2.4–NE)	NR (32.5–NE)
24-month PFS rate, % (95% CI)	57.6 (46.5–67.2)	63.6 (47.0–76.3)	39.7 (17.0–61.8)	79.4 (57.4–90.9)
36-month PFS rate, % (95% CI)	52.6 (41.5–62.6)	57.9 (41.0–71.5)	39.7 (17.0–61.8)	70.5 (47.8–84.8)

Patients at risk

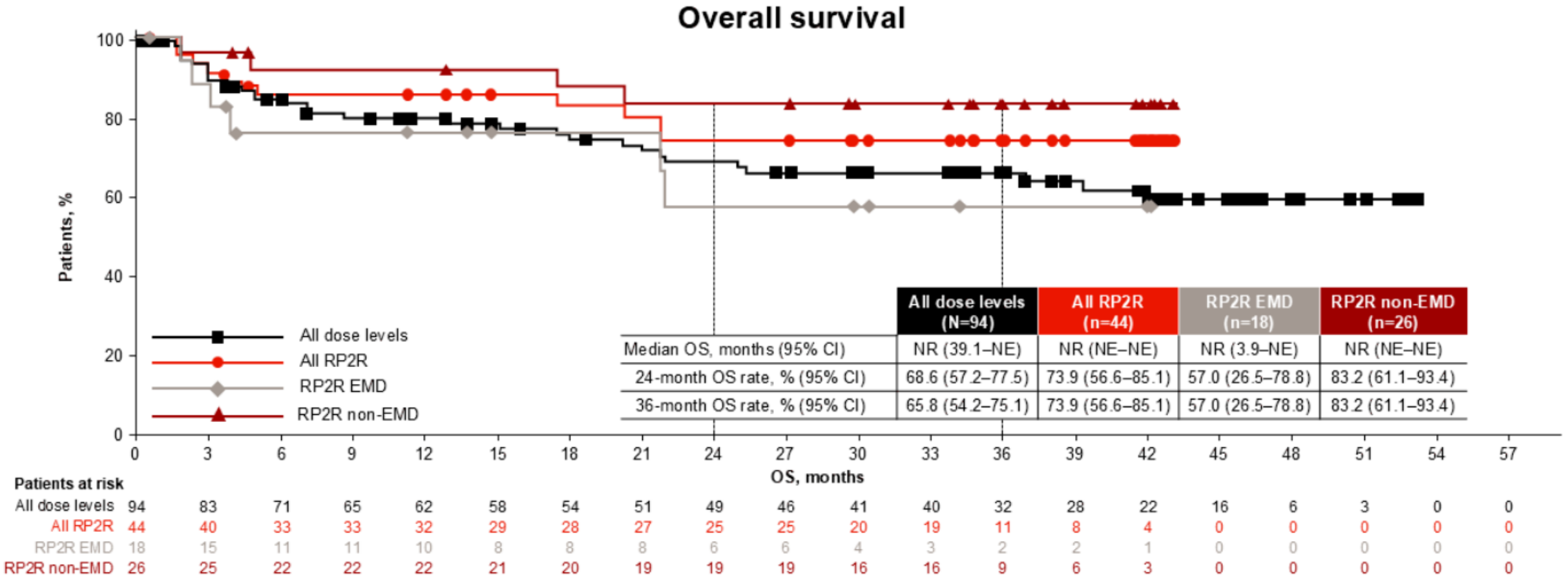
All dose levels	94	77	68	62	59	57	52	51	48	44	39	38	31	25	20	15	5	3	0	0
All RP2R	44	38	33	32	29	29	27	27	25	23	19	18	11	7	3	0	0	0	0	0
RP2R EMD	18	13	11	10	8	8	8	8	6	6	3	3	2	2	1	0	0	0	0	0
RP2R non-EMD	26	25	22	22	21	21	19	19	19	17	16	15	9	5	2	0	0	0	0	0

At RP2R, 58% of patients were progression free and alive at 3 years

Data cut-off: July 2025. Median follow-up: 38.0 months (all dose levels), 34.5 months (RP2R).

Presented by M-V Mateos at the 67th American Society of Hematology (ASH) Annual Meeting; December 6–9, 2025; Orlando, FL, USA

RedirecTT-1 Phase 1 (Tal + Tec): Median OS Not Reached at 38 Months of Follow-Up Across All Dose Levels



	All dose levels (N=94)	All RP2R (n=44)	RP2R EMD (n=18)	RP2R non-EMD (n=26)
Median OS, months (95% CI)	NR (39.1–NE)	NR (NE–NE)	NR (3.9–NE)	NR (NE–NE)
24-month OS rate, % (95% CI)	68.6 (57.2–77.5)	73.9 (56.6–85.1)	57.0 (26.5–78.8)	83.2 (61.1–93.4)
36-month OS rate, % (95% CI)	65.8 (54.2–75.1)	73.9 (56.6–85.1)	57.0 (26.5–78.8)	83.2 (61.1–93.4)

Patients at risk

All dose levels	94	83	71	65	62	58	54	51	49	46	41	40	32	28	22	16	6	3	0	0
All RP2R	44	40	33	33	32	29	28	27	25	25	20	19	11	8	4	0	0	0	0	0
RP2R EMD	18	15	11	11	10	8	8	8	6	6	4	3	2	2	1	0	0	0	0	0
RP2R non-EMD	26	25	22	22	22	21	20	19	19	19	16	16	9	6	3	0	0	0	0	0

At RP2R, 74% of patients were alive at 3 years, including 83% of patients without EMD

Data cut-off: July 2025. Median follow-up: 38.0 months (all dose levles), 34.5 months (RP2R).

Presented by M-V Mateos at the 67th American Society of Hematology (ASH) Annual Meeting; December 6–9, 2025; Orlando, FL, USA

RedirecTT-1 Phase 1: Tal + Tec

- At ~3 years of follow-up, the dual BsAb combination of Tal + Tec at RP2R of Tal 0.8 mg/kg + Tec 3.0 mg/kg Q2W demonstrated:
  - 80% ORR and 61% ≥CR rate, with responses deepening over time[1]
  - At 3 years, 58% PFS rate and 71% DOR rate
  - Combinability, with safety profile of the RP2R consistent with each of the monotherapies
- Support patients with vigilant monitoring and management of infections, including Ig replacement and infection prophylaxis
- The ongoing phase 3 MonumenTAL-6 study is evaluating fixed-duration Tal 0.8 mg/kg Q2W + Tec 3.0 mg/kg Q4W vs Tal + Pom vs EPd or PVd in patients with 1–4 prior LOT

Long-term data demonstrate safety, efficacy, and combinability of the novel, dual-antigen targeting combination of Tal + Tec in TCE RRMM, including patients with EMD

EPd, elotuzumab, pomalidomide, and dexamethasone; Pom, pomalidomide; PVd, pomalidomide, bortezomib, and dexamethasone; TCE, triple-class exposed.

1. Cohen YC, et al. *N Engl J Med* 2025;392:138-49.

Presented by M-V Mateos at the 67th American Society of Hematology (ASH) Annual Meeting; December 6–9, 2025; Orlando, FL, USA

Efficacy and Safety of Talquetamab + Teclistamab in Patients With Relapsed/Refractory Multiple Myeloma and Extramedullary Disease: Updated Phase 2 Results From the RedirecTT-1 Study With Extended Follow-Up

Saad Z Usmani[1]*, Shaji Kumar[2]*, María-Victoria Mateos[3], Jing Christine Ye[4], Shebli Atrash[5], Hila Magen[6], Hang Quach[7], Michael P Chu[8], Suzanne Trudel[9], Joshua Richter[10], Paula Rodríguez-Otero[11], Hun Chuah[12], Moshe Gatt[13], Eva Medvedova[14], Shahzad Raza[15], Dok Hyun Yoon[16], Tadao Ishida[17], Jeffrey V Matous[18], Laura Rosiñol[19], Koichi Onodera[20], Carmela Maffucci[21], Emma Scott[22], Christoph Heuck[22], Jenny Zhang[22], Todd Henninger[21], Lisa O'Rourke[22], Payal Thakkar[21], Mariacristina Festa[23], Guoqiang Zhang[22], Sheetal Khedkar[24], Lin Huang[22], Jiangxiu Zhou[22], Mikihiro Takamoto[25], Lixia Pei[21], Jiashen Lu[26], Nicholas Au[22], Maria Krevvata[22], Yael C Cohen[27]

[1]Memorial Sloan Kettering Cancer Center, New York, NY, USA; [2]Mayo Clinic Rochester, Rochester, MN, USA; [3]University Hospital of Salamanca/IBSAL/CIC/CIBERONC, Salamanca, Spain; [4]MD Anderson Cancer Center, University of Texas, Houston, TX, USA; [5]Levine Cancer Institute-Atrium Health, Charlotte, NC, USA; [6]Chaim Sheba Medical Center, Ramat-Gan, Faculty of Medical and Health Sciences, Tel Aviv University, Tel Aviv, Israel; [7]University of Melbourne, St Vincent's Hospital, Melbourne, VIC, Australia; [8]Alberta Health Services, Edmonton, AB, Canada; [9]Princess Margaret Cancer Centre, Toronto, ON, Canada; [10]Mount Sinai Medical Center, New York, NY, USA; [11]Cancer Center Clínica Universidad de Navarra, Cima, Pamplona, Spain; [12]Royal Perth Hospital, Perth, WA, Australia; [13]Hadassah Medical Cener, Hebrew University of Jerusalem, Jerusalem, Israel; [14]Knight Cancer Institute, Oregon Health and Science University, Portland, OR, USA; [15]Taussig Cancer Institute, Cleveland Clinic, Cleveland, OH, USA; [16]Asan Medical Center, University of Ulsan College of Medicine, Seoul, Republic of Korea; [17]Japanese Red Cross Medical Center, Tokyo, Japan; [18]Colorado Blood Cancer Institute and Sarah Cannon Research Institute, Denver, CO, USA; [19]Hospital Clínic de Barcelona, IDIBAPS, Barcelona, Spain; [20]Tohoku University Hospital, Sendai shi, Miyagi, Japan; [21]Johnson & Johnson, Raritan, NJ, USA; [22]Johnson & Johnson, Spring House, PA, USA; [23]Johnson & Johnson, Leiden, Netherlands; [24]Johnson & Johnson, Horsham, PA, USA; [25]Johnson & Johnson, Tokyo, Japan; [26]Johnson & Johnson, Shanghai, China; [27]Tel Aviv Sourasky (Ichilov) Medical Center, Gray Faculty of Medical and Health Sciences, Tel Aviv University, Tel Aviv, Israel

*Contributed equally.

Presented by S Usmani at the 67th American Society of Hematology (ASH) Annual Meeting; December 6–9, 2025; Orlando, Florida, USA

RedirecTT-1 Phase 2 EMD (Tal + Tec): Largest Dedicated Study in Patients With True EMD

Screening

Eligibility criteria

- Triple-class exposed RRMM[a]
- True EMD, defined as ≥1 nonradiated bone-independent soft tissue plasmacytoma ≥2 cm in greatest dimension confirmed by central review of PET-CT scans[b,c]
- Prior CAR-T and non-BCMA/-GPRC5D bispecific antibody therapies were permitted
- Nonsecretory and oligosecretory disease were permitted

Treatment

Tal 0.8 mg/kg Q2W SC[d,e]
+
Tec 3.0 mg/kg Q2W SC[d,e]

Option to switch to monthly dosing after 4 cycles and ≥VGPR, or after 6 cycles (irrespective of response)

Step-up dosing[d] 2–4 days apart (Tal + Tec)

SUD1: 0.01 mg/kg + 0.06 mg/kg

SUD2: 0.06 mg/kg + 0.3 mg/kg

SUD3: 0.4 mg/kg + 1.5 mg/kg

Endpoints

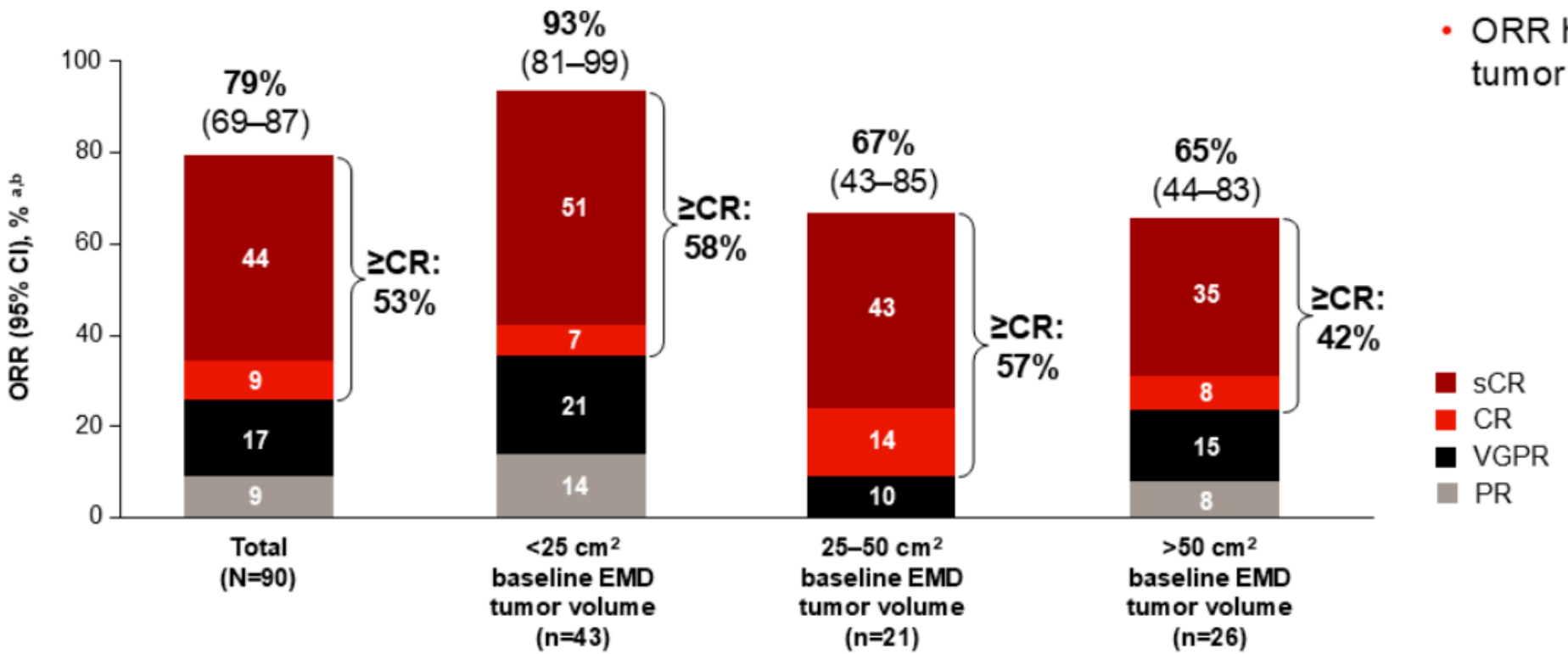
Primary endpoint: ORR[f]

Secondary endpoints:

- DOR[f]
- PFS[f]
- OS
- Safety

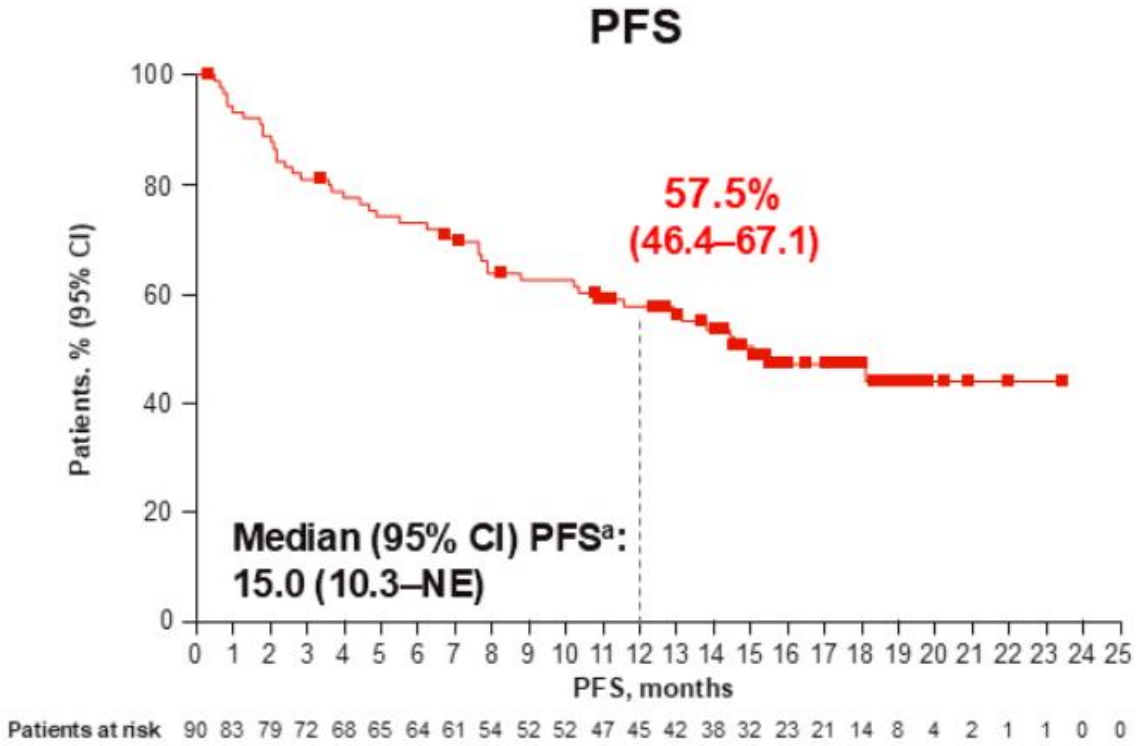
[a]Includes prior exposure to a proteasome inhibitor, immunomodulatory drug, anti-CD38 monoclonal antibody. [b]Patients may have had paramedullary plasmacytomas in addition to true EMD. [c]Whole-body MRI permitted with sponsor approval. [d]Tal and Tec administered on the same day, 30 (±10) minutes apart, for all step-up and full treatment doses. [e]Until disease progression. [f]Response and PFS were assessed by an independent review committee per IMWG criteria; EMD response was assessed by PET-CT or MRI whole-body scans. CAR, chimeric antigen receptor; DOR, duration of response; MRI, magnetic resonance imaging; PET-CT, positron emission

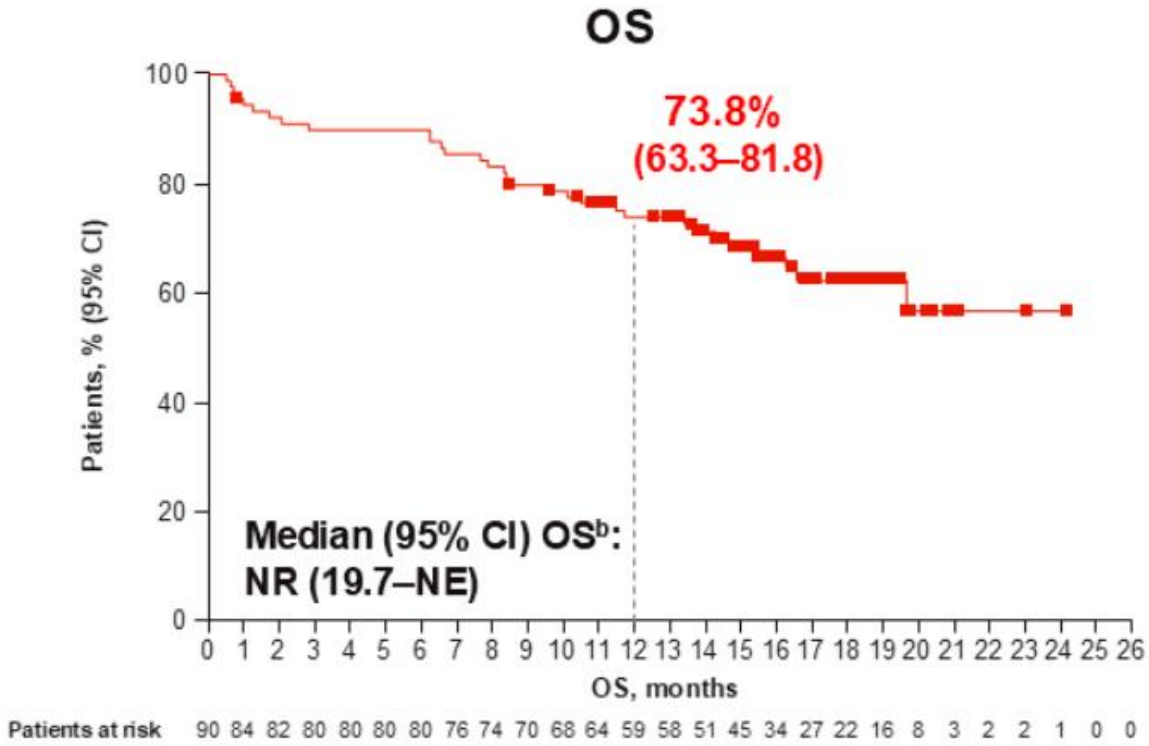
RedirecTT-1 Phase 2 EMD (Tal + Tec): ORR Was High Across All Baseline EMD Tumor Volume Subgroups



Highest responses with lowest baseline volumes; responses at higher volumes were generally comparable with the total population

RedirecTT-1 Phase 2 EMD (Tal + Tec): PFS and OS at 16.8 Months Median Follow-up





With over 1 year of median follow-up, median PFS was 15 months and median OS was not reached

RedirecTT-1 Phase 2 EMD (Tal + Tec): Transformative Efficacy in Largest Dedicated EMD Study to Date

- **Deep and durable responses in true EMD with Tal + Tec; enhanced efficacy with an additional 4 months follow-up in a population with significant unmet clinical need**
  - ORR, 79% (≥CR, 53%)
  - 12-month DOR rate, 62.1%
  - Median PFS, 15.0 months
  - 12-month OS rate, 73.8%
- High ORR regardless of EMD location (organ, 78%; non-organ, 79%)
- Lower EMD tumor volume was associated with higher ORR
- The safety profile of Tal + Tec was generally consistent with observations for each agent alone
  - Infections common; critical to follow established protocols for prophylaxis and management

Dual targeting of GPRC5D and BCMA with Tal + Tec: a new SOC for patients with triple-class exposed RRMM with true EMD

Presented by S Usmani at the 67th American Society of Hematology (ASH) Annual Meeting; December 6–9, 2025; Orlando, FL, USA

ORIGINAL ARTICLE

Dual Targeting of Extramedullary Myeloma with Talquetamab and Teclistamab

Shaji Kumar, M.D.,[1] María-Victoria Mateos, Ph.D.,[2-5] Jing Christine Ye, M.D.,[6] Shebli Atrash, M.D.,[7] Hila Magen, M.D.,[8] Hang Quach, M.D.,[9] Michael P. Chu, M.D.,[10] Suzanne Trudel, M.D.,[11] Joshua Richter, M.D.,[12] Paula Rodríguez-Otero, M.D., Ph.D.,[13] Hun Chuah, M.D., Ph.D.,[14] Moshe Gatt, M.D.,[15] Eva Medvedova, M.D.,[16] Shahzad Raza, M.D.,[17] Dok Hyun Yoon, M.D., Ph.D.,[18] Tadao Ishida, M.D., Ph.D.,[19] Jeffrey V. Matous, M.D.,[20] Laura Rosiñol, M.D., Ph.D.,[21] Koichi Onodera, M.D., Ph.D.,[22] Emma Scott, M.D.,[23] Christoph Heuck, M.D.,[23] Jenny Zhang, Ph.D.,[23] Todd Henninger, Ph.D.,[24] Lisa O'Rourke, M.S.,[23] Payal Thakkar, M.S.,[24] Mariacristina Festa, M.S.,[25] Lin Huang, Ph.D.,[23] Jiangxiu Zhou, Ph.D.,[23] Mikihiro Takamoto, M.P.H.,[26] Lixia Pei, Ph.D.,[24] Jiashen Lu, Ph.D.,[27] Nicholas Au, Pharm.D., Ph.D.,[23] Maria Krevvata, Ph.D.,[23] Saad Z. Usmani, M.D.,[28] and Yael C. Cohen, M.D.,[29] for the RedirecTT-1 Investigators Study Group*


The End !