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

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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 first-in-class BsAbs that have demonstrated deep, durable efficacy in triple-class exposed RRMM[1-5]
  - Tal's B-cell sparing mechanism preserves humoral immunity (grade 3/4 infection risk, 16–28%)[6]
  - Tec demonstrated comparable safety in community and academic treatment settings[7]
- Dual-targeting GPRC5D and BCMA with the combination of Tal + Tec may improve response rate, depth, and durability compared with either monotherapy by mitigating primary resistance, tumor heterogeneity, and antigen-related escape
- In previous results, Tal + Tec elicited deep, durable responses at the RP2R (Tal 0.8 mg/kg + Tec 3.0 mg/kg Q2W) and demonstrated a safety profile generally consistent with each monotherapy in RRMM at a median follow-up of 20.3 months[8]

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

BCMA, B-cell maturation antigen; BsAb, bispecific antibody; GPRC5D, G protein–coupled receptor class C group 5 member D; Q2W, every other week; RP2R, recommended phase 2 regimen; RRMM, relapsed/refractory multiple myeloma.

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;9:5752-62. 7. Beer TC, et al. Presented at ASH; December 7–10, 2024; San Diego, CA, USA. 8. Cohen YC, et al. *N Engl J Med* 2025;392:138-49.

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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**

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)

+ SUD[d]

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.

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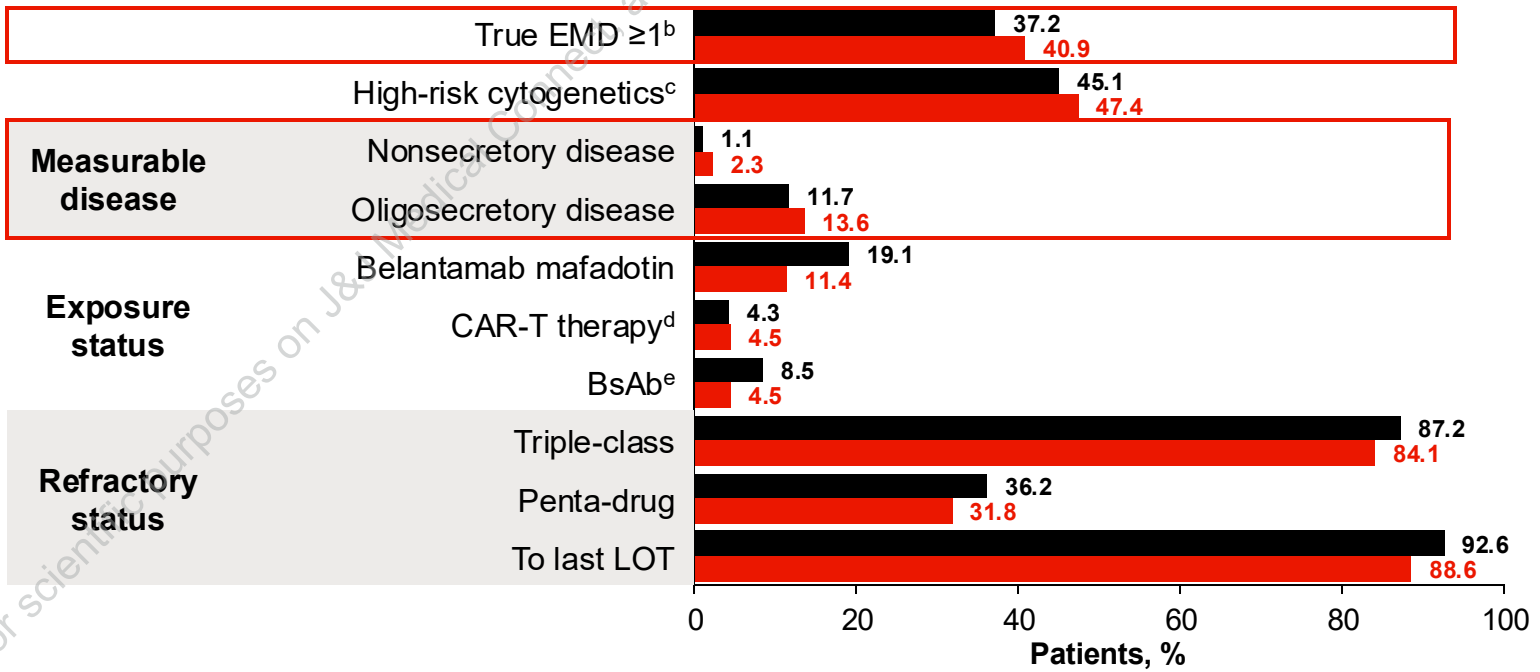
RedirecTT-1 Phase 1 (Tal + Tec): Baseline Characteristics

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.

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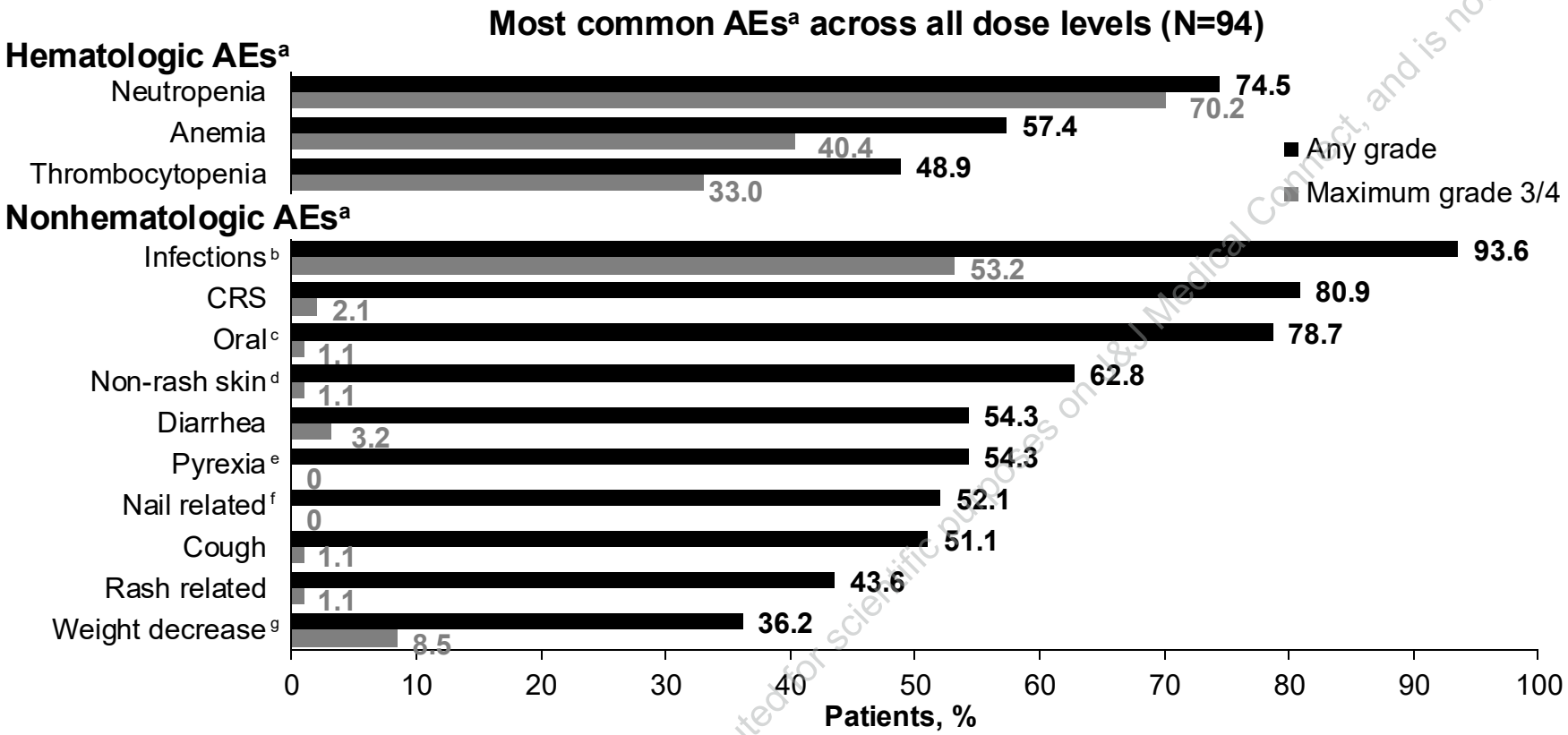
RedirecTT-1 Phase 1 (Tal + Tec): Summary of Common AEs[a]



- 7.4% discontinuations due to AEs
  - Tal + Tec (n=1 each): multiple organ dysfunction, pulmonary toxicity, odynophagia, PML,[h] leptomeningeal myelomatosis, myelodysplastic syndrome
  - Tal only (n=1): gingival bleeding, tongue discomfort, dysgeusia, pain in extremity

The safety profile was consistent with each monotherapy with low rates of discontinuations due to AEs

Data cut-off: July 2025. Median follow-up: 38.0 months (all dose levels), 34.5 months (RP2R). [a]AEs occurring in ≥30% of patients are shown. [b]The most common infections were COVID-19 (40.4%) and upper respiratory tract infection (30.9%); patients were screened for enrollment between 2020 to 2023, concurrent with the pandemic. [c]Including ageusia, cheilitis, dry mouth, dysgeusia, dysphagia, glossitis, glossodynia, hypogeusia, mouth ulceration, oral discomfort, oral mucosal erythema, oral pain, stomatitis, swollen tongue, taste disorder, tongue discomfort, tongue erythema, tongue edema, and tongue ulceration. [d]Includes skin exfoliation, dry skin, pruritus, and palmar-plantar erythrodysesthesia syndrome. [e]Excludes symptoms of CRS or ICANS. [f]Includes nail discoloration, nail disorder, onycholysis, onychomadesis, onychoclasis, nail dystrophy, nail toxicity, and nail ridging. [g]Includes rash, maculopapular rash, erythematous rash, and erythema. [h]PML event onset occurred 301 days after the most recent dose of Tal + Tec. PML, progressive multifocal leukoencephalopathy.

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RedirecTT-1 Phase 1 (Tal + Tec): Summary of Infections

Most common AEs (≥15% overall), n (%)	All dose levels (N=94)		RP2R (n=44)	
	Any Grade	Maximum Grade 3/4	Any Grade	Maximum Grade 3/4
Median follow-up	38.0 months		34.5 months	
Infections	88 (93.6)	50 (53.2)	41 (93.2)	19 (43.2)
COVID-19[a]	38 (40.4)	15 (16.0)	20 (45.5)	7 (15.9)
URTI	29 (30.9)	4 (4.3)	15 (34.1)	1 (2.3)
Pneumonia	25 (26.6)	10 (10.6)	11 (25.0)	4 (9.1)
Nasopharyngitis	16 (17.0)	0	4 (9.1)	0
Rhinovirus infection	16 (17.0)	3 (3.2)	6 (13.6)	0
UTI	12 (12.8)	2 (2.1)	8 (18.2)	1 (2.3)

- Grade 3/4 infection rate was consistent with Tec monotherapy[1]
  - Median duration of any-grade infection: 13.5 days, most (87.2%) resolved
- 16 (17.0%) patients had opportunistic infections
  - CMV reactivation (n=5), PML (n=4), adenovirus infection (n=2), esophageal candidiasis (n=2), other[b] (1 each for total of n=10)
- 84 (89.4%) patients had hypogammaglobulinemia[c]
- 65 (69.1%) of all patients received ≥1 dose of Ig replacement

At RP2R, grade 3/4 infection rate was 43%, consistent with Tec monotherapy in MajesTEC-1[1]

Data cut-off: July 2025. Infection prophylaxis, including Ig replacement, was strongly recommended and given per institutional guidelines: 84.0% received antiviral prophylaxis (all doses). [a]Patient recruitment began in December 2020, running concurrently with the COVID-19 pandemic and overlapping with peak infection and death rates worldwide, based on World Health Organization data.[2] [b]CMV colitis, disseminated varicella-zoster virus infection, hepatitis B reactivation, human herpesvirus-6 encephalitis, listeriosis, adenoviral pneumonia, CMV pneumonia, fungal pneumonia, pulmonary nocardiosis, and Kaposi's sarcoma. Patients could experience ≥1 opportunistic infection. [c]Posttreatment hypogammaglobulinemia AEs or IgG <400 mg/dL. CMV, cytomegalovirus; Ig, immunoglobulin; URTI, upper respiratory tract infection; UTI, urinary tract infection.

1. Moreau P, et al. *N Engl J Med* 2022;387:495-505. 2. World Health Organization. WHO COVID-19 dashboard. WHO Global. https://data.who.int/dashboards/covid19/cases.

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RedirecTT-1 Phase 1 (Tal + Tec): Summary of Grade 5 AEs

- All dose levels (including QW dosing; N=94): 18 (19.1%) grade 5 AEs, including 15 infections[a]
- Confounding factors for grade 5 infections at RP2R:
  - No COVID-19 vaccination in 2 of 3 COVID-19 pneumonia cases
  - Severe hypogammaglobulinemia in 3 of 5 cases

Grade 5 infections	Study day of death	Calendar year of death	Received ≥1 dose of Ig replacement	IgG level prior to death, mg/dL	Response at time of death
At RP2R					
COVID-19 pneumonia[b]	96	2022	No	109	PR
COVID-19 pneumonia[c,d]	144	2022	No	159	sCR
COVID-19 pneumonia[b]	51	2022	No	596	NA
Fungal pneumonia	57	2022	No	217	NA
PML[e,f]	661	2023	Yes	514	sCR
At non-RP2R dose levels					
Adenovirus infection[d]	395	2022	Yes	16	CR
Aspiration pneumonia	70	2022	Yes	1325	SD→NE
CMV pneumonia[d]	117	2021	No	69	VGPR
COVID-19[b]	264	2021	Yes	911	PR
PML[d,e]	217	2021	Yes	823	PD→NE
PML[d,e]	296	2022	No	16	VGPR
Respiratory tract infection[d]	217	2021	No	39	CR
Sepsis[d]	110	2021	No	167	PR
Septic shock[d]	1274	2024	Yes	399	NE
Septic shock	91	2021	No	153	MR

At RP2R (n=44): 6 (13.4%) grade 5 AEs, including 5 (11.3%) infections[f], highlight need for active IgG monitoring and vigilant infection management, including vaccination and Ig replacement as needed

Data cut-off: July 2025. Median follow-up: 38.0 months (all dose levels), 34.5 months (RP2R). [a]Grade 5 AEs at non-RP2R dose levels included 2 noninfectious AEs (leptomeningeal myelomatosis, myelodysplastic syndrome). [b]Patient did not receive COVID-19 vaccination. [c]Patient received COVID-19 vaccination. [d]Deemed related to Tal or Tec by the investigator. [e]PML onset occurred 62, 5, and 226 days, respectively, after the most recent dose of Tal + Tec. [f]The noninfectious death was due to cardiac arrest. CR, complete response; MR, minimal response; NA, not applicable; NE, not estimable; PD, progressive disease; PR, partial response; sCR, stringent complete response; SD, stable disease; VGPR, very good partial response.

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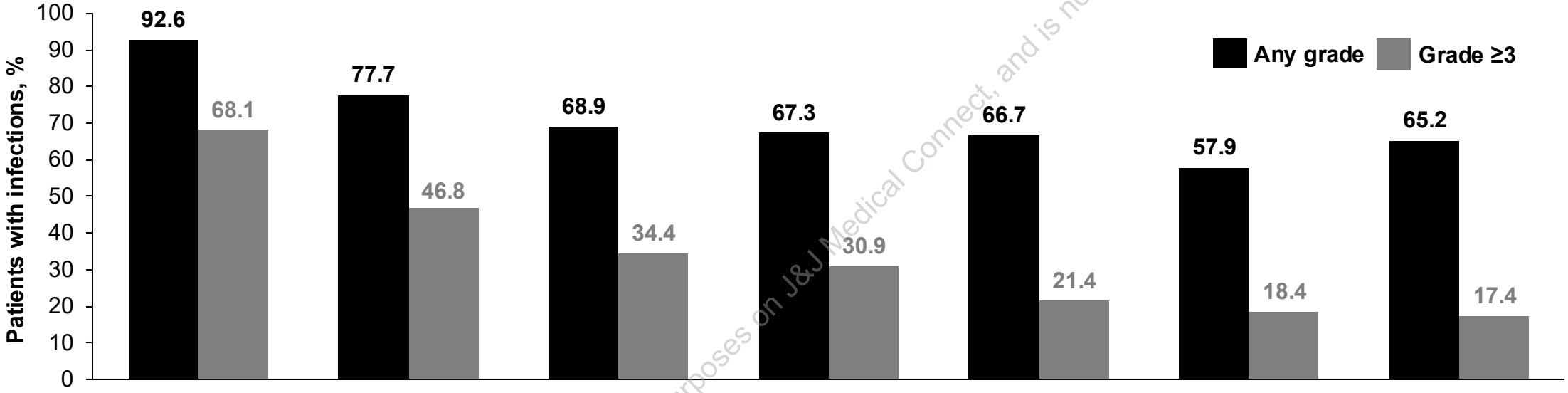
RedirecTT-1 Phase 1 (Tal + Tec): Timing of New-Onset Infections Across All Dose Levels



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.

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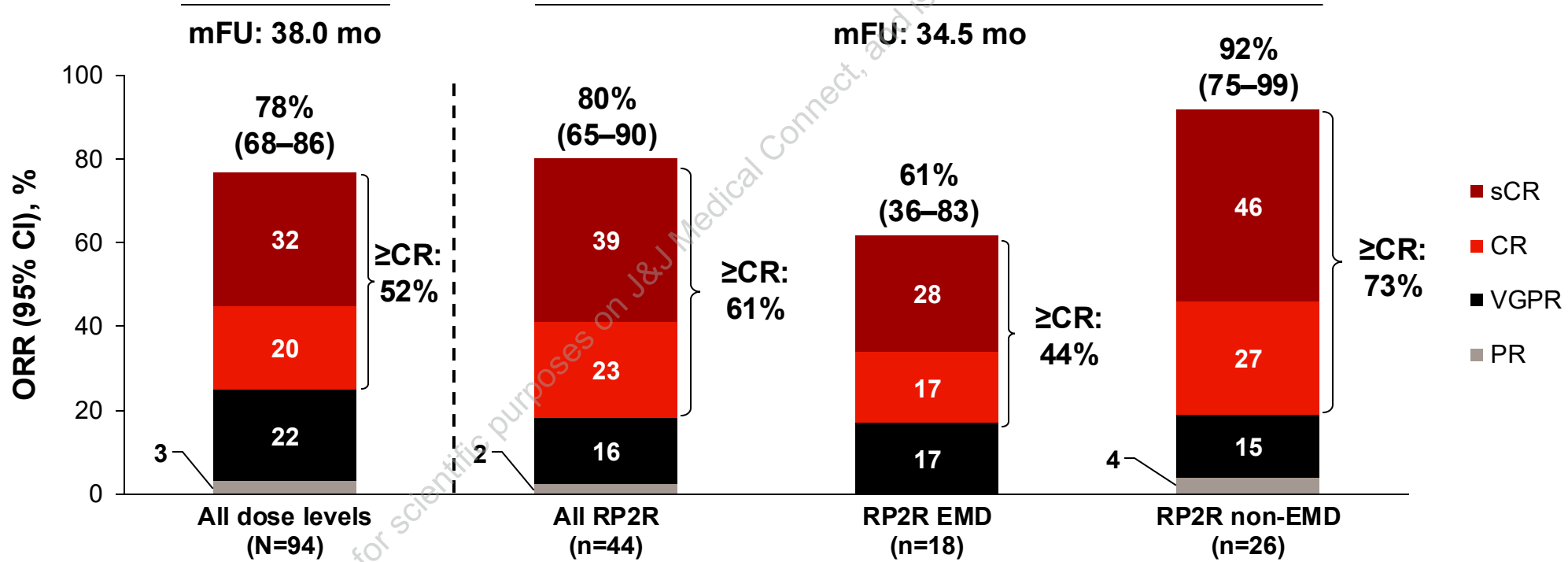
RedirecTT-1 Phase 1 (Tal + Tec): Patients Achieved High ORR[a] and Deep Responses

At the last report[1]:

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



More than 60% of patients achieved a ≥CR 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.

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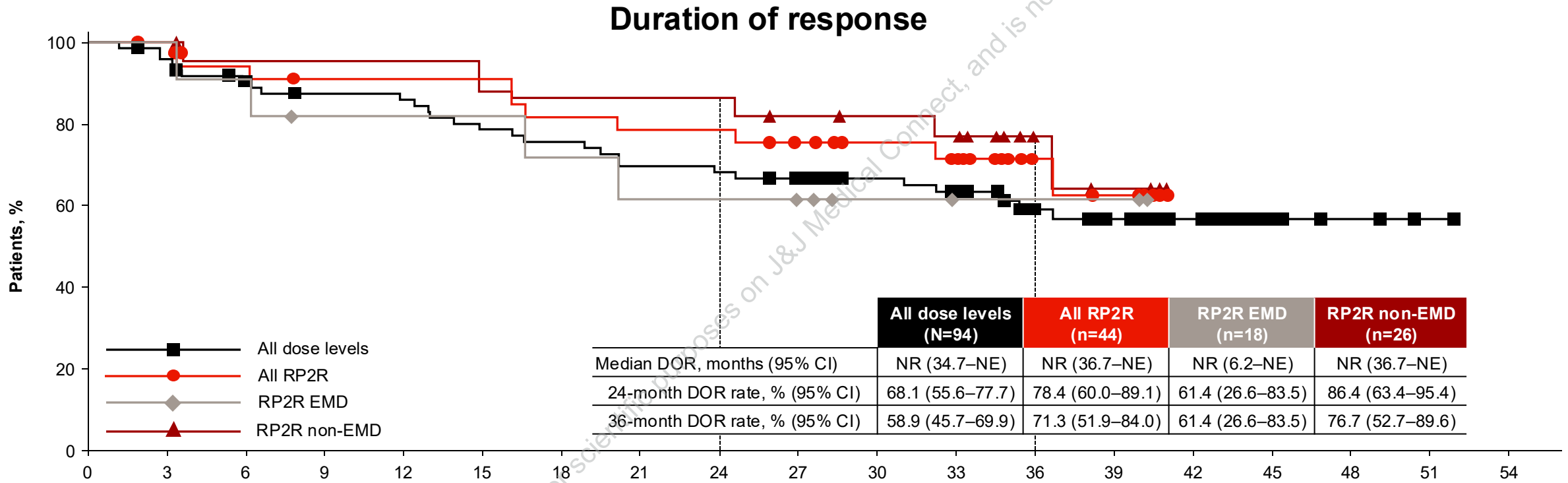
RedirecTT-1 Phase 1 (Tal + Tec): Median DOR Not Reached at 38 Months of Follow-Up Across All Dose Levels



	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.

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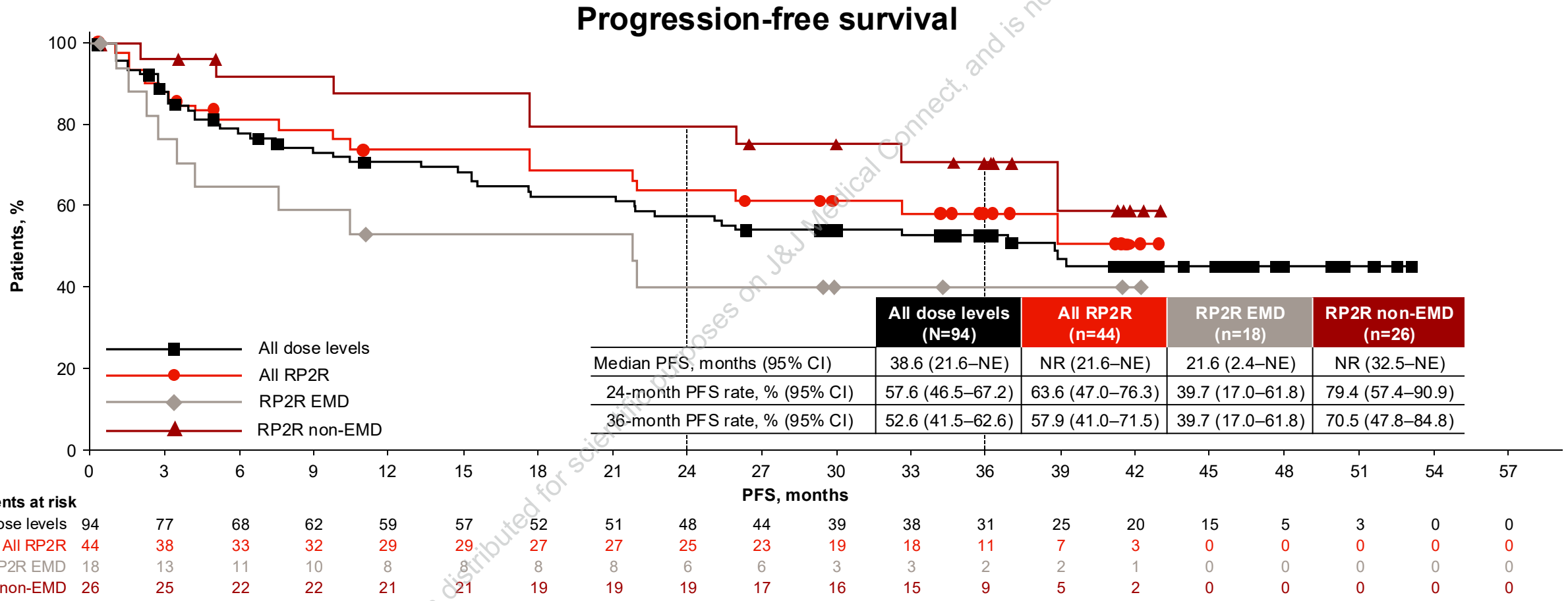
RedirecTT-1 Phase 1 (Tal + Tec): Median PFS 38.6 Months at 38 Months of Follow-Up Across All Dose Levels



	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).

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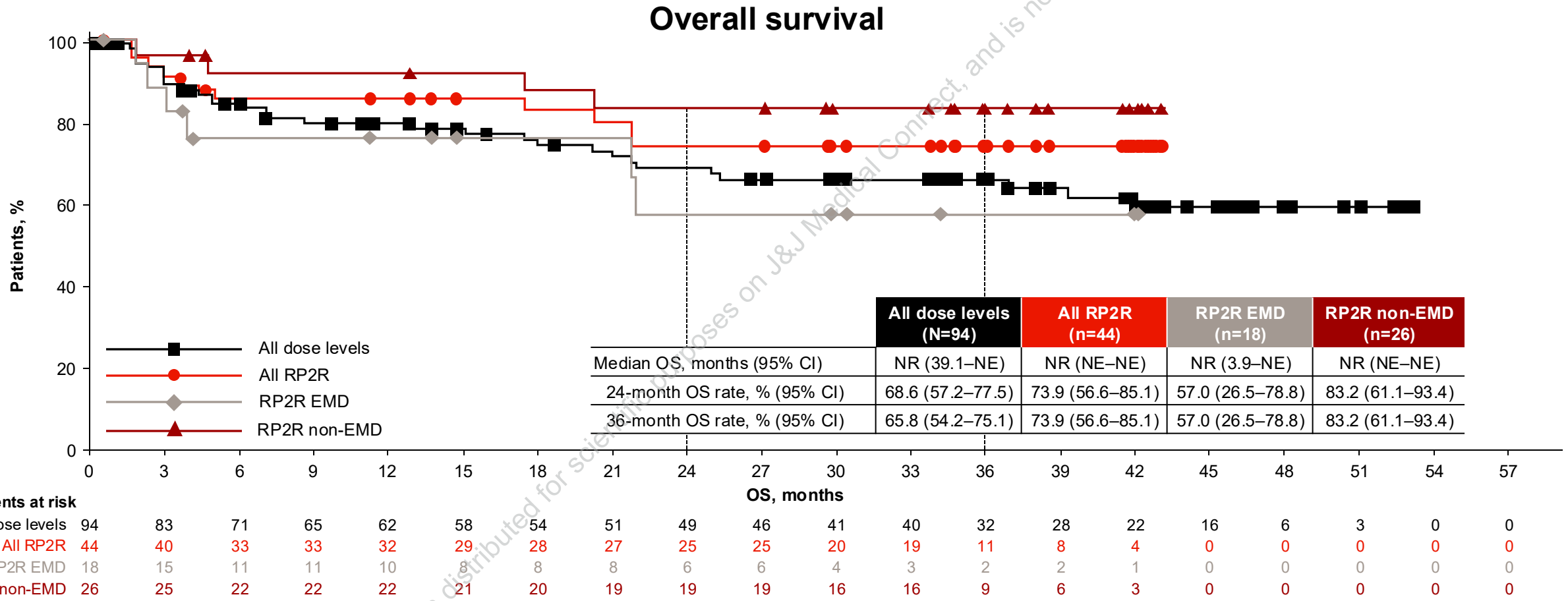
RedirecTT-1 Phase 1 (Tal + Tec): Median OS Not Reached at 38 Months of Follow-Up Across All Dose Levels



	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).

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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.

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Future Directions: Phase 3 MonumenTAL-6 Tal + Tec in RRMM with 1–4 Prior LOT

MonumenTAL-6 study design

Key eligibility criteria

- 1–4 prior LOT, including anti-CD38 mAb and Len
- ECOG PS ≤2
- Naive to Tec, Pom, GPRC5D-directed therapy
- Naive to Elo (EPd arm)

1:1:1 randomization

- **Tal + Tec**
- **Tal + Pom**
- **Investigator's choice: EPd or PVd**

Primary endpoint

- PFS

Key secondary endpoints

- ORR
- ≥CR
- MRD-negative CR
- OS

ClinicalTrials.gov identifier: NCT06208150.
ECOG PS, Eastern Cooperative Oncology Group performance status; Elo, elotuzumab; Len, lenalidomide; mAb, monoclonal antibody; MRD, minimal residual disease.

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