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

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Extramedullary Disease (EMD) Is Associated With Poor Survival in Myeloma

BONE DEPENDENT

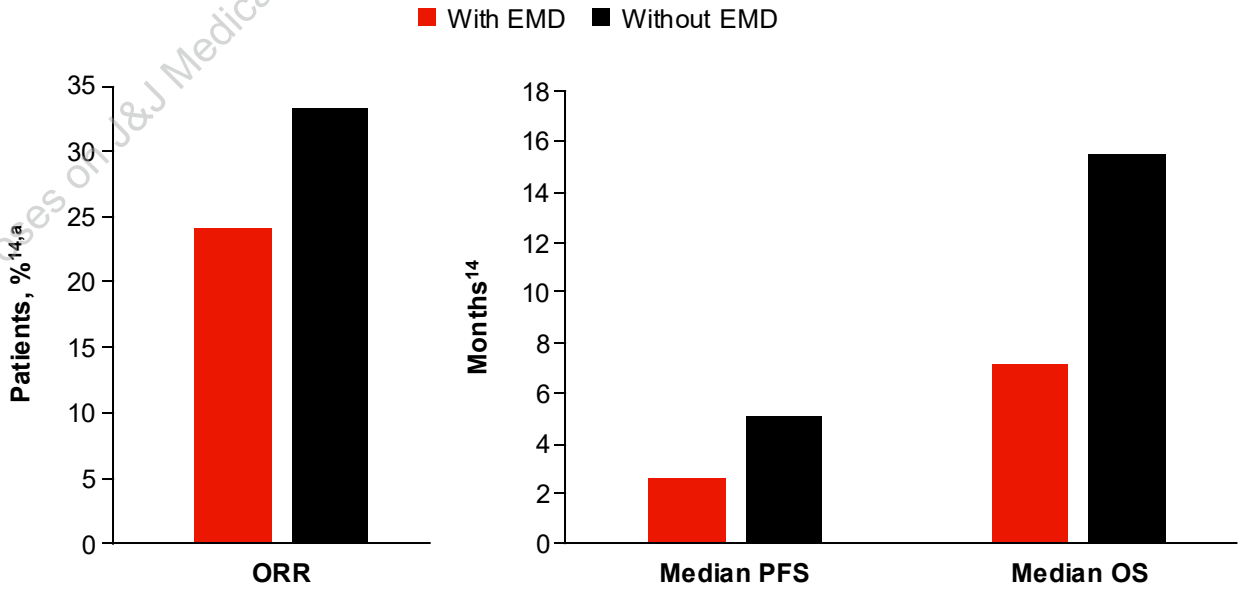
Paramedullary disease[1,2]
Plasmacytomas growing contiguously with bone and extending into soft tissue after cortical disruption

BONE INDEPENDENT

True EMD[1,2]
Soft tissue/organ-associated plasmacytomas noncontiguous with bony structures

Inferior outcomes vs patients with paramedullary plasmacytomas and patients with myeloma without EMD[3-14]

Patients with true EMD are 87% less likely to respond to real-world SOC treatments[13] and have worse outcomes vs patients without EMD[14]



[a]Defined as the proportion of patients who achieved a PR or better. ORR, overall response rate; OS, overall survival; PFS, progression-free survival; PR, partial response; SOC, standard-of-care.

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RedirecTT-1: Dual Myeloma Antigen Targeting of GPRC5D and BCMA With Tal + Tec in Patients With True EMD

- EMD lesions are highly complex and exhibit heterogeneous GPRC5D and BCMA expression[1,2]; a dual-targeting approach may mitigate antigen-related escape
- Talquetamab (Tal; anti-GPRC5D) and teclistamab (Tec; anti-BCMA) are first-in-class BsAbs approved as monotherapies for RRMM, including difficult-to-treat disease[3-7]
- With a median follow-up of 12.6 months, primary analysis of Tal + Tec in the dedicated RedirecTT-1 phase 2 EMD cohort showed[8,a]:
  - ORR,[b] 79%
  - 12-month PFS, 61%

We report updated efficacy[b] and safety from RedirecTT-1 phase 2 with a median follow-up of 16.8 months, including EMD location data and a novel tumor burden analysis as a prognostic indicator of ORR

[a]Data cut-off date: March 15, 2025. [b]Assessed by independent review committee per IMWG criteria.
BCMA, B-cell maturation antigen; BsAb, bispecific antibody; GPRC5D, G protein–coupled receptor family C group 5 member D; IMWG, International Myeloma Working Group; RRMM, relapsed/refractory multiple myeloma.
1. John M, et al. *Blood* 2024;144:2121-35. 2. Zanwar, S. et al. *Blood Adv* 2025;9:3979-87. 3. Chari A, et al. *Lancet Hematol* 2025;e269-81. 4. Chari A, et al. *N Engl J Med* 2022;387:2232-42. 5. TALVEY (talquetamab-tgvs). Prescribing information. Horsham, PA: Janssen Biotech, Inc.; 2023. 6. Moreau P, et al. *N Engl J Med* 2022;387:495-505. 7. TECVAYLI (teclistamab-cqyv). Prescribing information. Horsham, PA: Janssen Biotech, Inc; 2024. 8. Kumar S, et al. *N Engl J Med* 2025; doi:10.1056/NEJMoa2514752.

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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 tomography–computed tomography; Q2W, every other week; SC, subcutaneous; SUD, step-up dose; VGPR, very good partial response.

Kumar S, et al. *N Engl J Med* 2025; doi:10.1056/NEJMoa2514752.

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RedirecTT-1 Phase 2 EMD (Tal + Tec): EMD Response Assessment Incorporating Gold Standard Deauville and IMPETUS Criteria

- IMWG 2016 response criteria were assessed by an independent review committee
- As IMWG criteria do not provide PET-CT–specific response criteria, an FDG-PET 5-point scale per Deauville and IMPETUS criteria was incorporated for radiographic criteria for EMD response:
  - CR: disappearance of all plasmacytomas or persistence of fibrotic disease with PET score 1–3
  - VGPR and PR: a ≥90% or ≥50% reduction in size, respectively, in all plasmacytomas with a reduction in PET avidity compared to baseline
- In nonsecretory disease, response was evaluated by functional imaging, and IMWG criteria also had to be met for CR

Prospective EMD response assessed by central radiology using FDG PET-CT, Deauville scale, and IMPETUS criteria

CR, complete response; FDG, fluorodeoxyglucose.
Kumar S, et al. *N Engl J Med* 2025; doi:10.1056/NEJMoa2514752.

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RedirecTT-1 Phase 2 EMD (Tal + Tec): Baseline Characteristics Reflective of Triple-Class Exposed RRMM With EMD

90 patients received Tal + Tec

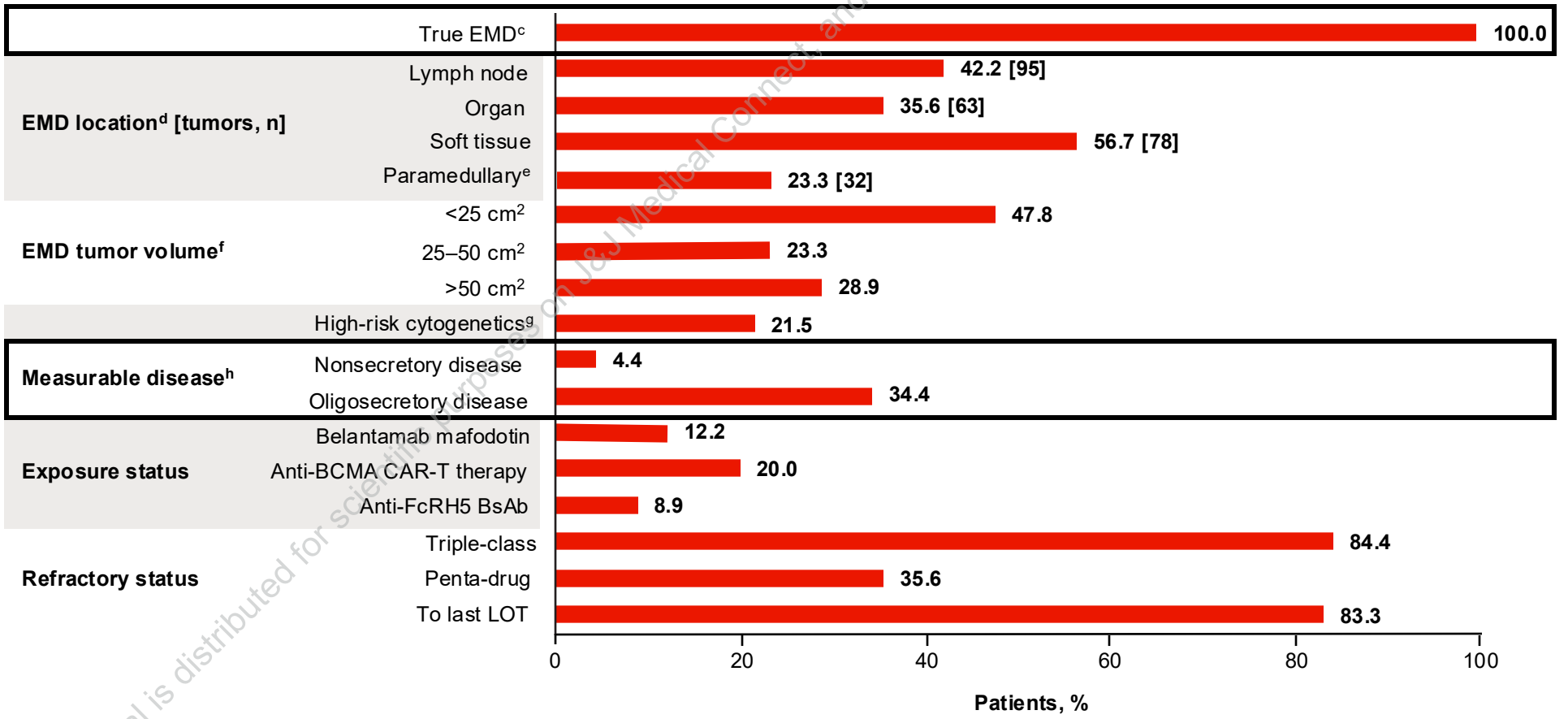
Age[a]
64.5 (42–84) years

Male
63.3%

Years since diagnosis[a,b]
4.7 (0.7–21.4)

Prior LOT[a]
4 (1–10)

Baseline characteristics



Data cut-off date: July 18, 2025.

[a]Data are presented as median (range). [b]Calculated in n=89. [c]≥1 nonradiated bone-independent soft tissue plasmacytoma (≥2 cm in greatest dimension) confirmed by PET-CT scans. [d]Patients could have ≥1 EMD location. [e]Paramedullary lesions were also present alongside true EMD in 21 (23.3%) patients. [f]Volume assessed for true EMD only. [g]FISH or karyotype testing in n=65; defined as del(17p), t(4;14), or t(14;16). [h]Per IMWG criteria.
FcRH5, Fc receptor-homolog 5; FISH, fluorescence in situ hybridization; LOT, line of therapy.
Kumar S, et al. *N Engl J Med* 2025; doi:10.1056/NEJMoa2514752.

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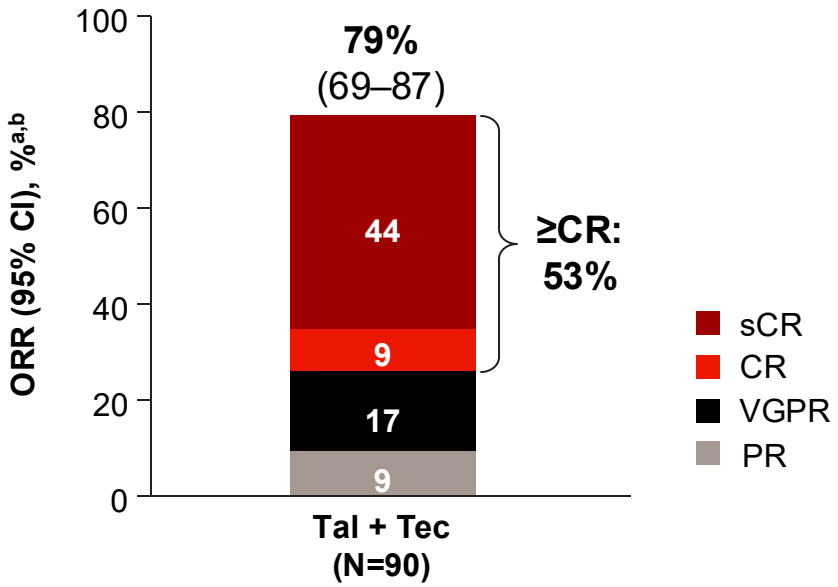
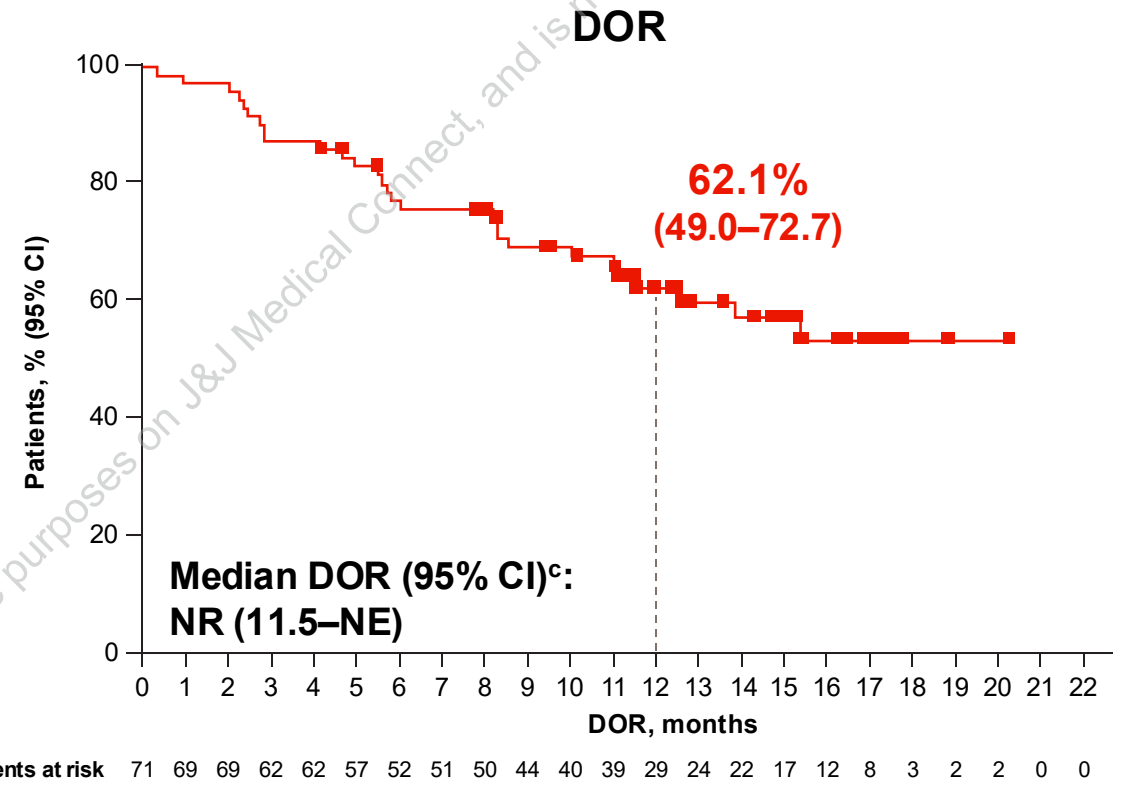
RedirecTT-1 Phase 2 EMD (Tal + Tec): Deep, Durable Responses at 16.8 Months Median Follow-up



Median (range) time to:

- First response, 2.6 (1.0–5.8) months
- Best response, 5.1 (1.0–16.6) months

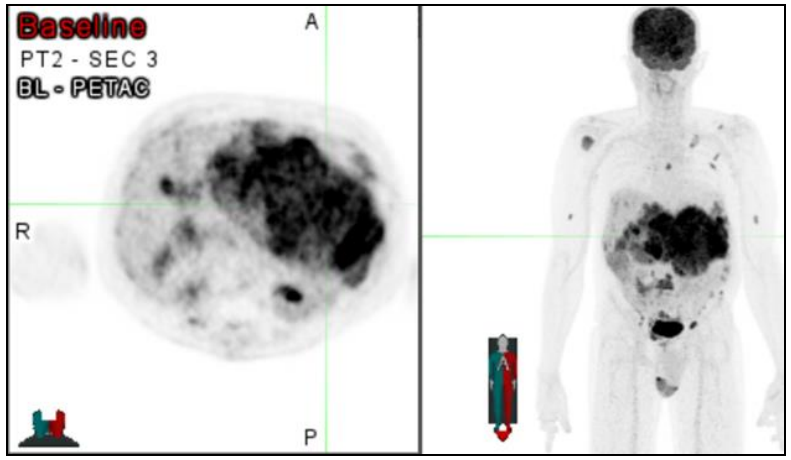
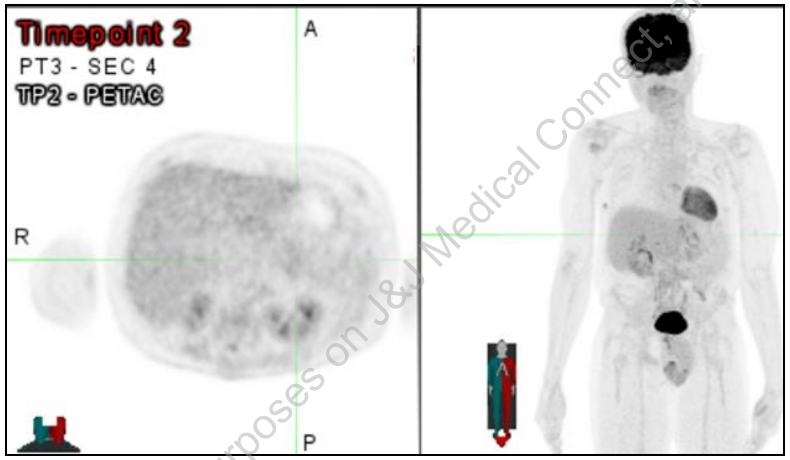
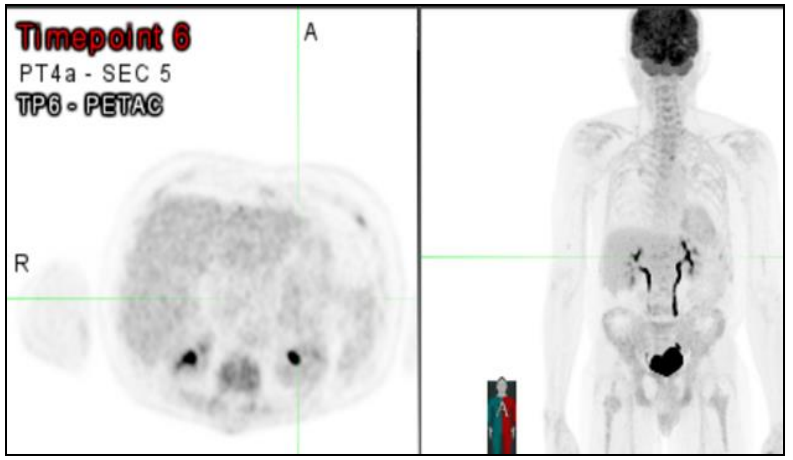


With additional ~4 months of median follow-up, ORR approached 80%; 62% of responders remained in response at 1 year

Data cut-off date: July 18, 2025. [a]ORR was assessed by independent review committee per IMWG criteria. [b]Due to rounding, individual response rates may not sum to the ORR. [c]At time of data cut-off, 43 (60.6%) patients were censored. NE, not estimable; NR, not reached; sCR, stringent complete response.

RedirecTT-1 Phase 2 EMD (Tal + Tec): Integration of Central PET-CT for EMD Response Assessment

EMD peritoneal mass

Day 1[a] (baseline)	Day 76	Day 419
		

Characteristic	Day 1[a] (baseline)	Day 76	Day 167	Day 250	Day 419
Overall EMD tumor response	**NA**	**VGPR**	VGPR	CR[b]	**CR[b]**
5-point Deauville scale[c]	**5**	**5**	4	1	**1**

Accurate EMD assessment by high-sensitivity FDG PET-CT using 5-point Deauville scale[b] and IMWG criteria to confirm treatment efficacy; patient remains in CR[b] with Tal + Tec

[a]Represents day 1 of imaging, not day 1 of study per protocol. [b]Per independent review committee, radiographic CR corresponds with sCR. [c]Used in combination with the IMPETUS criteria. NA, not applicable.

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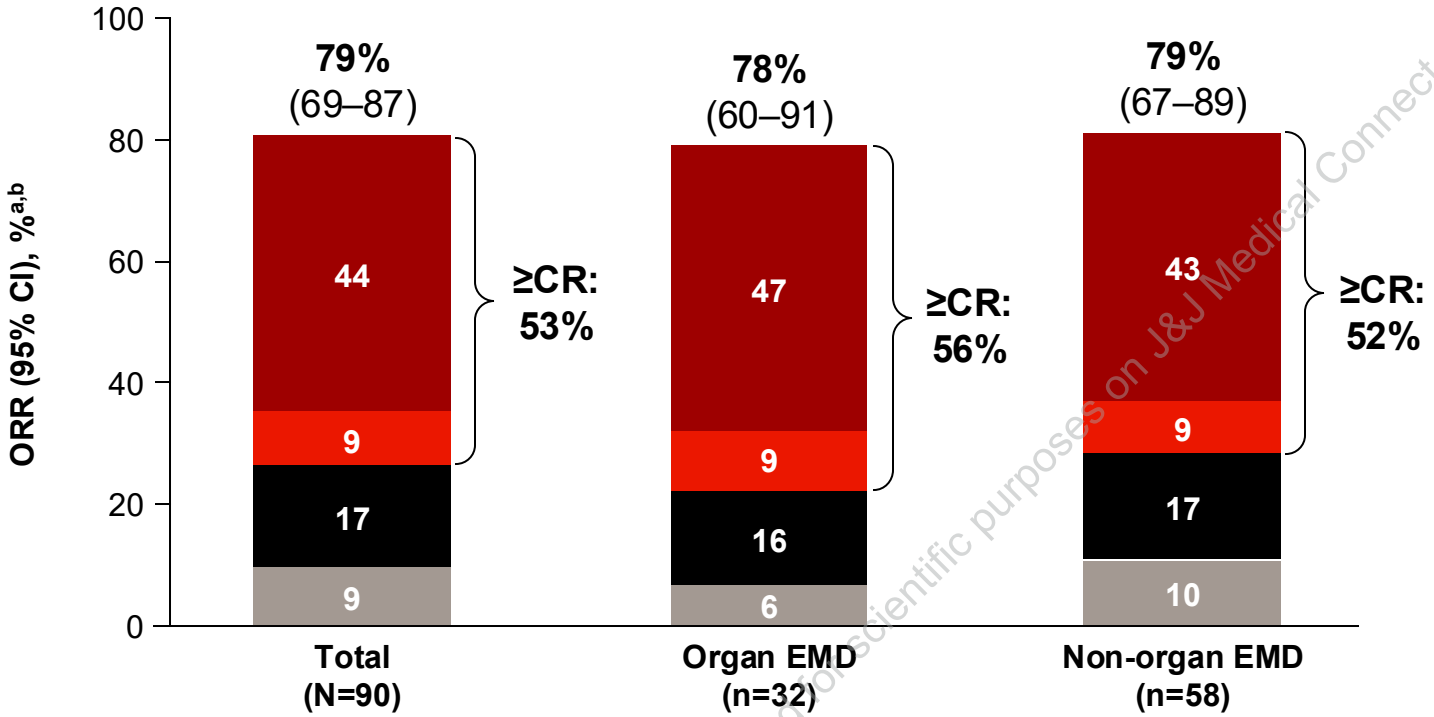
RedirecTT-1 Phase 2 EMD (Tal + Tec): High ORR Regardless of EMD Location



- At an overall median follow-up of 16.8 months, median DOR was not reached in organ EMD and 15.4 months in non-organ EMD
  - Organ EMD[c]: kidney, liver, lung, and others
  - Non-organ EMD[d]: lymph node and soft tissue

Patients with true EMD achieved deep responses with dual-antigen targeting Tal and Tec

Data cut-off date: July 18, 2025. [a]ORR was assessed by independent review committee per IMWG criteria. [b]Due to rounding, individual response rates may not sum to the ORR. [c]Full list of organ EMD locations include adrenal gland, kidney, liver (left lobe, right lobe), lung (left, left lower lobe), pancreas, pericardium, peritoneum, and pleura. [d]Full list of non-organ EMD locations include lymph node (axillary, cervical, iliac, inguinal, lymph, mediastinal, mesenteric, para-aortic, pelvic, peripancreatic, porta hepatis, retrocrural, retroperitoneal, and supraclavicular) and soft tissue (abdominal, breast, chest wall, mediastinum, muscle, omentum, other, pelvis, retroperitoneum, and skin).

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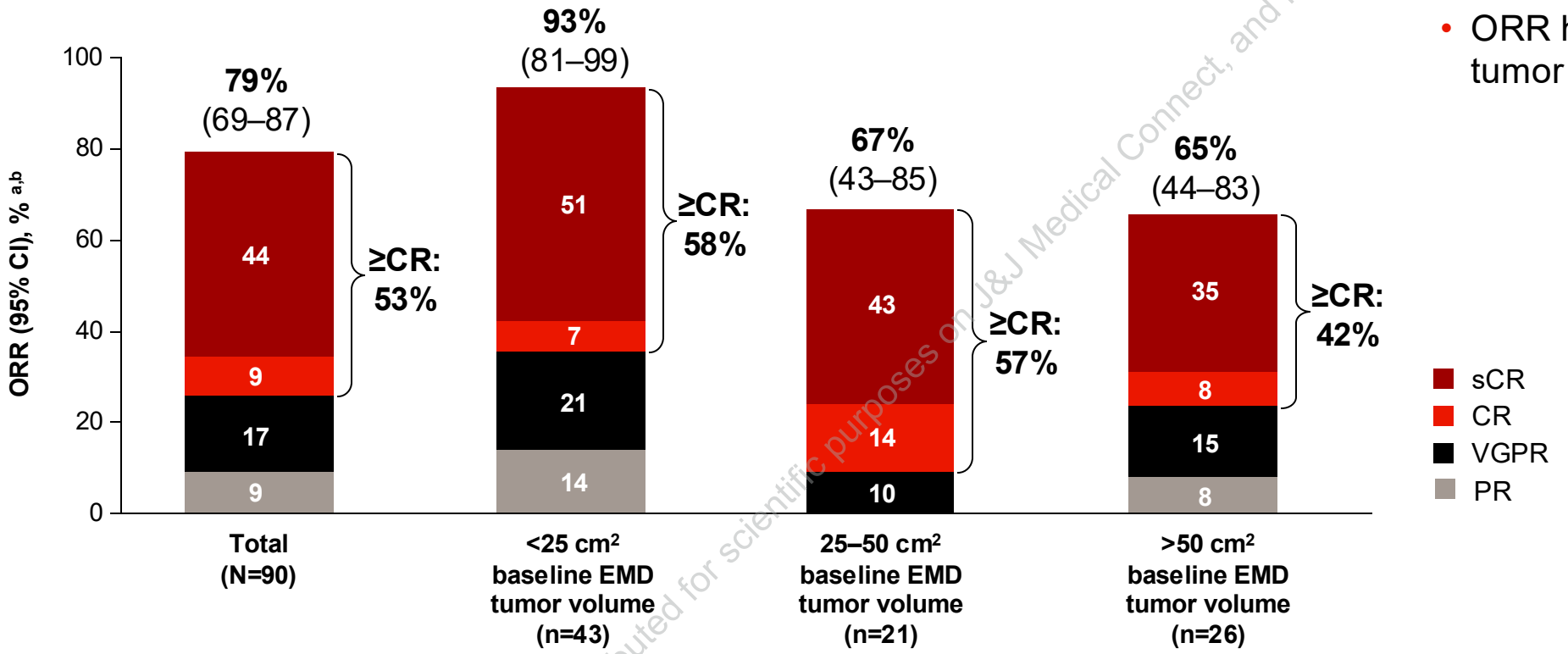
RedirecTT-1 Phase 2 EMD (Tal + Tec): ORR Was High Across All Baseline EMD Tumor Volume Subgroups



- ORR highest in patients with tumor volume <25 cm^2

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

Data cut-off date: July 18, 2025. [a]ORR was assessed by independent review committee per IMWG criteria. [b]Due to rounding, individual response rates may not sum to the ORR.

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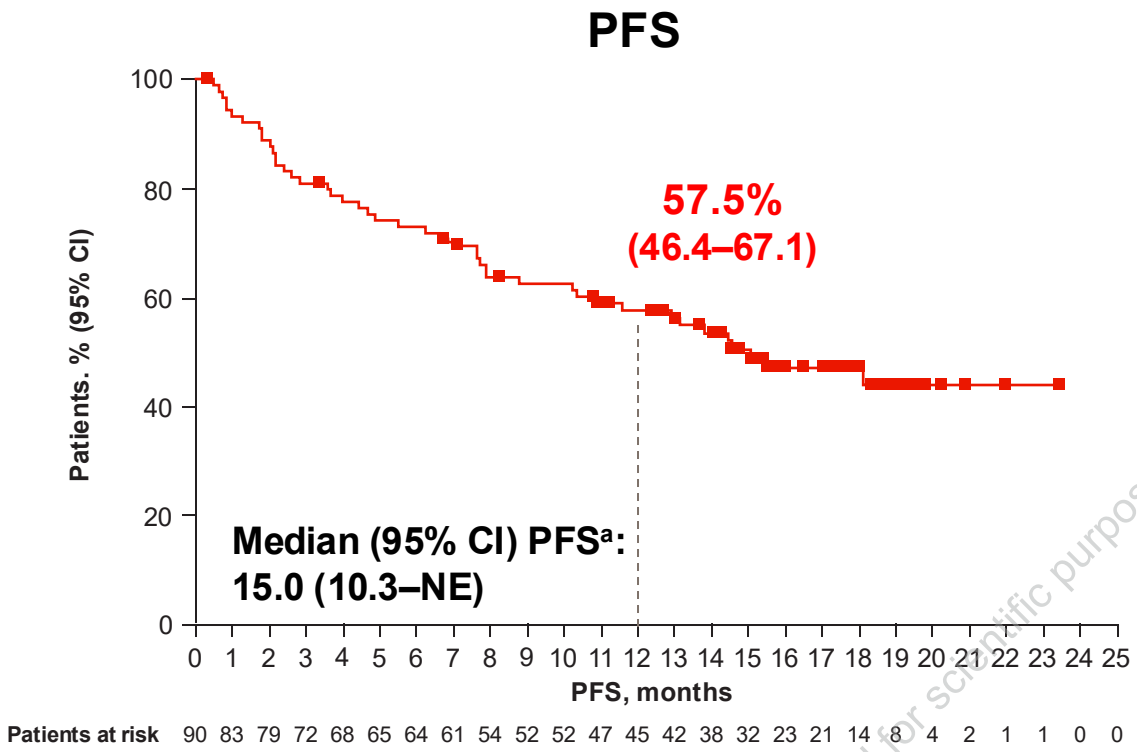
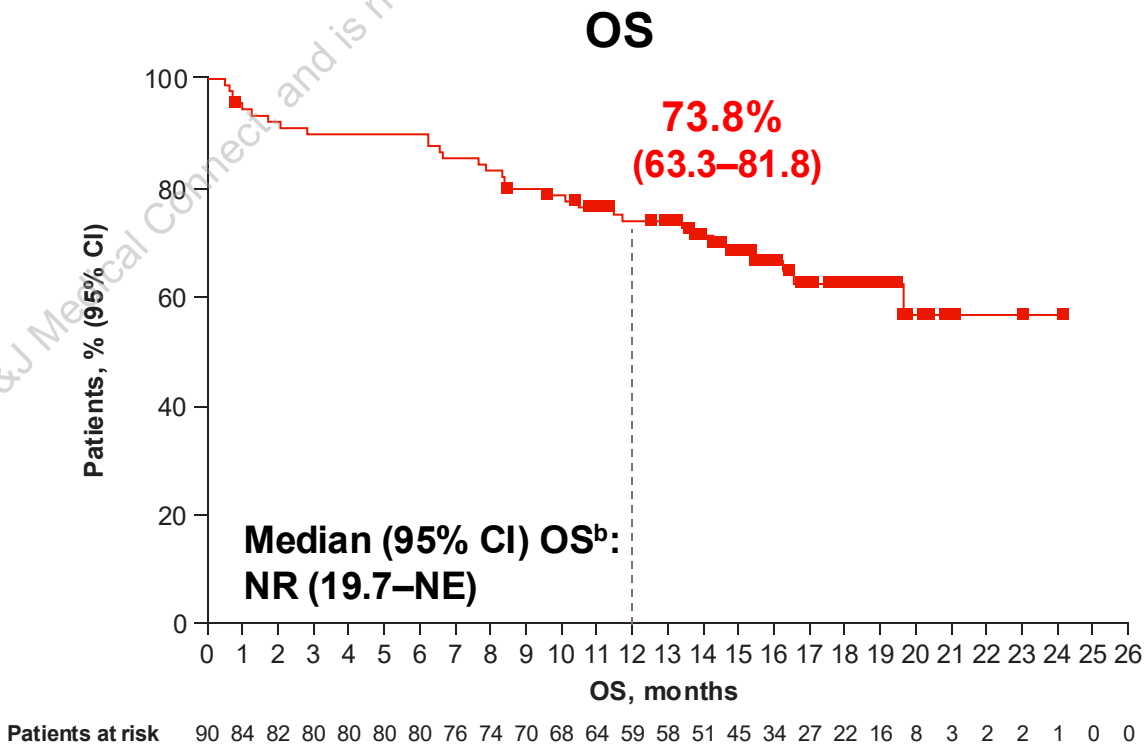
RedirecTT-1 Phase 2 EMD (Tal + Tec): PFS and OS at 16.8 Months Median Follow-up





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

Data cut-off date: July 18, 2025. [a]At time of data cut-off, 45 (50.0%) patients were censored for PFS. [b]At time of data cut-off, 59 (65.6%) patients were censored for OS.

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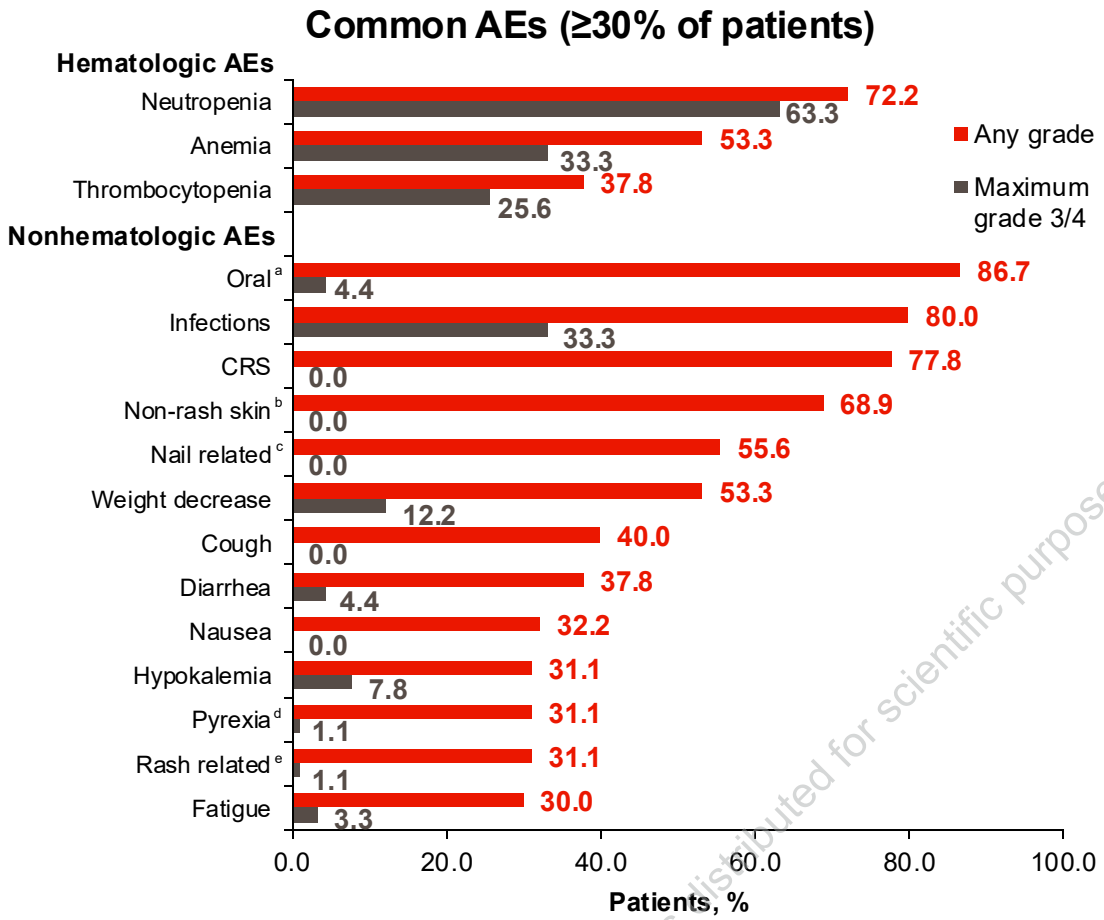
RedirecTT-1 Phase 2 EMD (Tal + Tec): AEs Were Consistent With Safety Profiles of Tal and Tec



Outcome,[f] n (%)	Initial Q2W dosing (N=90)	After adjustment to Q4W dosing (n=56)[g]
Any-grade infections	65 (72.2)	34 (60.7)
Grade ≥3 infections	29 (32.2)	14 (25.0)
Weight decrease	46 (51.1)	15 (26.8)
Grade 3/4 weight decrease	8 (8.9)	5 (8.9)
Oral AEs[a]	77 (85.6)	12 (21.4)
Grade 3/4 oral AEs[a]	3 (3.3)	2 (3.6)

New onset of key any-grade AEs were less common with adjusted Q4W dosing

Data cut-off date: July 18, 2025. Median follow-up: 16.8 months.
AEs listed are those occurring in ≥30% of the total study population. AEs were reported as treatment-emergent AEs recorded up to 30 days after the patient received last study treatment dose or until start of subsequent therapy.
[a]Includes 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. [b]Includes skin exfoliation, dry skin, pruritus, and palmar-plantar erythrodysesthesia syndrome. [c]Includes nail discoloration, nail disorder, onycholysis, onychomadesis, onychoclasis, nail dystrophy, nail toxicity, and nail ridging. [d]Excludes symptoms of CRS or ICANS. [e]Includes rash, maculopapular rash, erythematous rash, and erythema. [f]New-onset AEs only; AEs are only counted once either before or after switch. [g]34 patients did not switch to Q4W dosing.
AE, adverse event; CRS, cytokine release syndrome; ICANS, immune effector cell–associated neurotoxicity syndrome; Q4W, every 4 weeks.

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RedirecTT-1 Phase 2 EMD (Tal + Tec): Summary of Infections

Most common AEs (≥10% overall),[a] n (%)	Tal + Tec (N=90)	
	Any Grade	Maximum Grade 3/4
Infections	72 (80.0)	30 (33.3)
URTI	27 (30.0)	4 (4.4)
COVID-19	20 (22.2)	5 (5.6)
Pneumonia	19 (21.1)	8 (8.9)
UTI	12 (13.3)	4 (4.4)
Viral upper respiratory tract infection	9 (10.0)	2 (2.2)

- 6.7% of patients had opportunistic infections,[b] 3.3% were grade 3/4

- Infections were common; however, grade 3/4 infections were consistent with Tec monotherapy[1]
  - Grade 3/4 infections mostly limited to first 6 months and then declined
  - Median duration of infection, 13.0 days
- At baseline, 22.2% of patients had Ig values <400 mg/dL
- 71.1% of patients had posttreatment hypogammaglobulinemia[c]
- 75.6% of all patients received ≥1 dose of Ig replacement
  - Ig replacement was highly recommended to prevent infection

Grade 3/4 infection rate was 33%, generally consistent with Tec monotherapy in MajesTEC-1[1]

[a]AEs were graded by CTCAE v5.0; patients could experience ≥1 infection. [b]Patients could experience ≥1 opportunistic infection; CMV infection reactivation (n=4), CMV infection (n=2), CMV esophagitis (n=1), esophageal candidiasis (n=1), and polyomavirus viremia (n=1). [c]Posttreatment IgG <400 mg/dL or hypogammaglobulinemia treatment-emergent AE. Ig, immunoglobulin; CMV, cytomegalovirus; URTI, upper respiratory tract infection; UTI, urinary tract infection.

1. Moreau P, et al. *N Engl J Med* 2022;387:495-505.

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RedirecTT-1 Phase 2 EMD (Tal + Tec): Summary of Treatment Discontinuations and Grade 5 AEs

- 8 (8.9%) patients discontinued Tal or Tec due to AEs
  - Tal + Tec, n=6[a]
  - Tal only, n=2[b]
- 11 (12.2%) patients had grade 5 AEs
  - 5 (5.6%) noninfection AEs
  - 6 (6.7%) infections

Outcome, n (%)	Study day of death	IgG level prior to death, mg/dL	Received ≥1 dose of Ig replacement	Response at time of death
Noninfections				
Aspiration*	15	1450	No	SD
Respiratory failure	19	221	No	SD
General physical health deterioration	21	6731	Yes	SD
Cerebral hemorrhage	25	2575	No	SD
Euthanasia	233	379	Yes	PD
Infections				
Klebsiella sepsis	38	70	No	PR
COVID-19 pneumonia[c,*]	63	2455	No	SD
Klebsiella pneumonia*	86	892	Yes	PR
Pseudomonal sepsis*	190	246	No	PR
Escherichia sepsis*	240	449	Yes	VGPR
Pneumonia*	254	346	Yes	PD

Of the 11 patients with EMD who had grade 5 AEs (6 were drug related[c]), 7 were nonresponders with poor overall prognosis

Data cut-off date: July 18, 2025. Median follow-up: 16.8 months.*Deemed related to Tal or Tec by the investigator.
[a]Not resolved: esophageal adenocarcinoma (n=1), Hodgkin's disease* (n=1), pseudomonal pneumonia* and pseudomonal sepsis* (n=1), dry mouth*, dysphagia*, and decreased weight* (n=1). Resolved: CMV infection* (n=1) and ICANS* (n=1). [b]Resolved: dysgeusia* and dysphagia* (n=1) and hypohidrosis* (n=1). [c]Patient declined COVID-19 vaccine prior to study entry. PD, progressive disease; SD, stable disease

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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

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ORIGINAL ARTICLE

Dual Targeting of Extramedullary Myeloma with Talquetamab and Teclistamab

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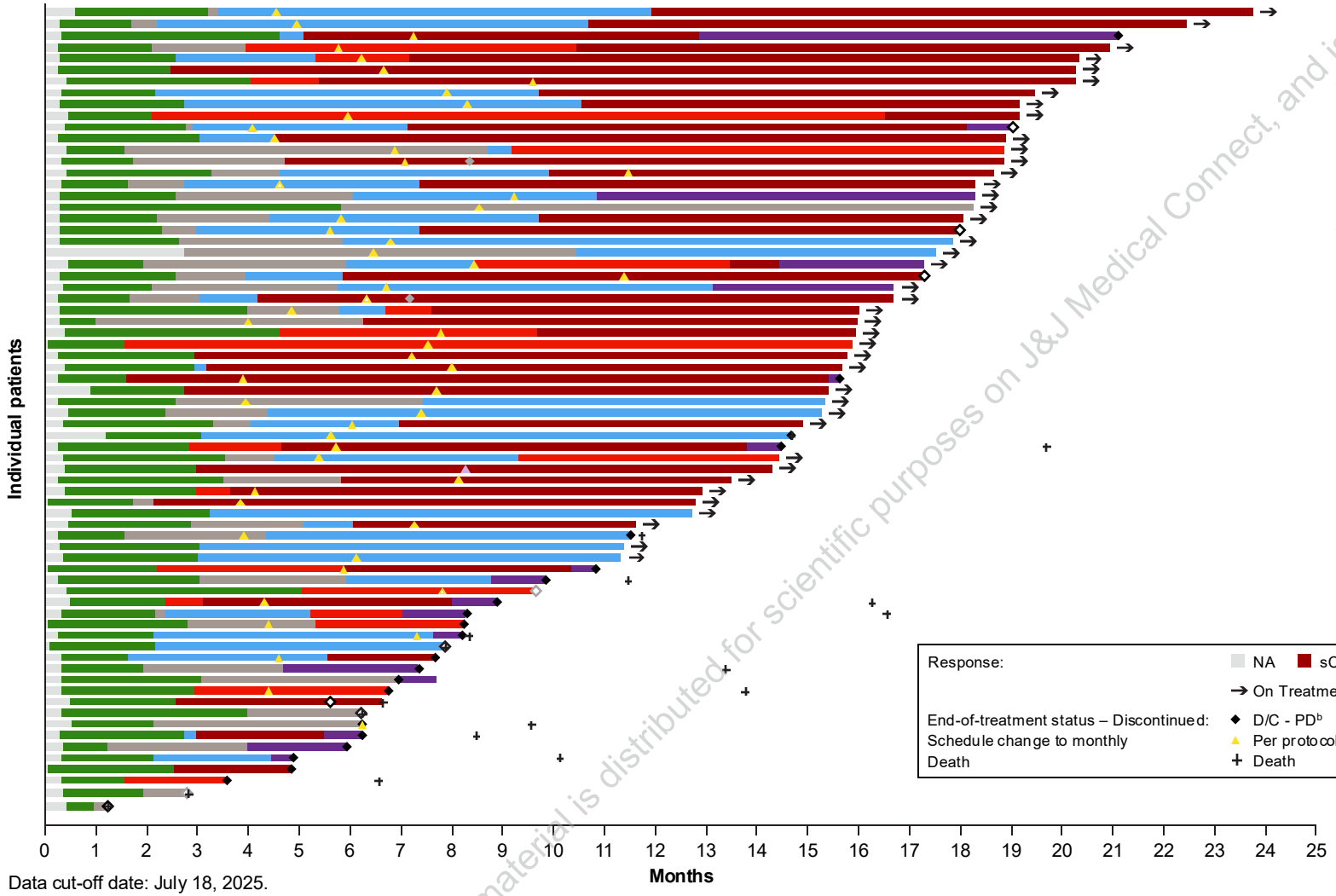
RedirecTT-1 Phase 2 EMD (Tal + Tec): Responses Deepened or Maintained in Most Patients With True EMD



- 58% of responders remain on therapy at data cut-off, with median follow-up of 17.6 months
- 55 (78%) responders switched to monthly dosing[a]
  - 91% maintained or deepened responses in the 6 months after switching to monthly dosing[a]

Data cut-off date: July 18, 2025.

[a]Tal 0.8 mg/kg Q4W + Tec 3.0 mg/kg Q4W or Tec 3.0 mg/kg Q4W only, following discontinuation of Tal. [b]Assessed by the investigator. AE, adverse event; D/C, discontinued; MR, minimal response; PD, progressive disease; Q4W, monthly; SD, stable disease.

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RedirecTT-1 Phase 2 EMD (Tal + Tec): Rates of Infection

Tal + Tec (N=90)	New event onset					
	Total	≤6 months	>6 to ≤12 months	>12 to ≤18 months	>18 to ≤24 months	>24 to ≤36 months
All patients treated within window,[a] n	90	90	65	43	14	0
Total number of patients with infection,[b] n (%)	72 (80.0)	65 (72.2)	34 (52.3)	20 (46.5)	2 (14.3)	0
Total number of patients with grade ≥3 infection,[b] n (%)	36 (40.0)	29 (32.2)	10 (15.4)	6 (14.0)	0	0

[a]Includes patients who either received study treatment or who experienced any treatment-emergent adverse event of infection within the specific window. [b]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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