Updated Safety and Efficacy of Ramantamig (JNJ-5322) at the Recommended Phase 2 Dose Demonstrating Feasibility of Outpatient Dosing in Relapsed/Refractory Multiple Myeloma

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Presented by JV Matous at the 23rd International Myeloma Society (IMS) Annual Meeting; September 23–26, 2026; Glasgow, UK

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Disclosure Statement: Jeffrey V. Matous, MD

Consultant & Honoraria: Johnson & Johnson

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TRIlogy-1 Update: Background

- Ramantamig (Ram), a first-in-class dual-antigen targeting trispecific Ab, targets the myeloma antigens BCMA and GPRC5D through CD3 T-cell engagement using all novel binding domains[1]
- Simultaneous dual BCMA/GPRC5D antigen targeting may broaden myeloma cell coverage, mitigating potential antigen escape associated with single myeloma antigen targeting[2-5]
- In the phase 1 TRIlogy-1(NCT05652335) study, Ram demonstrated robust efficacy and a potentially favorable safety profile compared with BCMA/GPRC5D-targeting BsAbs in patients with triple-class exposed RRMM[6-10]
  - Low rates of CRS at the RP2D (single 5 mg SUD followed by 100 mg SC Q4W), particularly with prophylactic tocilizumab
- To support development of Ram as a fully outpatient treatment option, TRIlogy-1 proactively assessed the feasibility of outpatient dosing with Ram at the start of treatment in a dedicated phase 1 cohort

We report updated efficacy and safety data from an expanded RP2D cohort and findings from a dedicated cohort evaluating Ram's RP2D dosing schedule in the outpatient setting

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Ab, antibody; BCMA, B-cell maturation antigen; BsAb, bispecific antibody CRS, cytokine release syndrome; GPRC5D, G protein–coupled receptor class C group 5 member D; Q4W, every 4 weeks; Ram, ramantamig; RP2D, recommended phase 2 dose; RRMM, relapsed/refractory multiple myeloma; SC, subcutaneous; SUD, step-up dose.

1. Pillarisetti K, et al. *Blood* 2026;147:834-47. 2. Truger MA, et al. *Blood Adv*. 2021;5(19):3794-3798. 3. Lee H, et al. *Nat Med*. 2023;29(9):2295-2306. 4. Derrien J, et al. *Nat Cancer*. 2023;4(11):1536-1543. 5. Lee H, et al. *Nat Med*. 2026;32(3):964-977. 6. Krishnan A, et al. *Blood* 2025;146 (Supplement 1):4042-4045. 7. Moreau P, et al. *N Engl J Med* 2022;387:495-505. 8. Chari A, et al. *N Engl J Med* 2022;387:2232-44. 9. Bahlis NJ, et al. *Nat Med* 2023;29:2570-6. 10. Bumma N, et al. *J Clin Oncol* 2024;42:2702-12.

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TRIlogy-1 Update: Study Design and Outpatient Considerations

Key eligibility criteria

- Triple-class exposed RRMM
- ≥18 years of age
- ECOG PS of 0 or 1
- Prior BCMA- or GPRC5D- targeted therapy permitted with sponsor approval

Treatment at the Ram RP2D

5 mg SC SUD → **100 mg SC Q4W treatment dose** → **Option to switch to 100 mg SC Q8W[a]**

- Prophylactic tocilizumab permitted[b]
- Infection prophylaxis recommended[c]

Outpatient dosing at the start of treatment was evaluated in dedicated RP2D cohorts

Endpoints

- **Primary**
  - Safety
- **Secondary**
  - ORR[d]
- **Exploratory**
  - PFS,[d] MRD negativity
- **Outpatient dosing outcomes**
  - Outpatient completion of SUD and dose 1
  - CRS
  - HCRU within 2 days of outpatient

Outpatient administration at start of treatment (SUD and first treatment dose)

Protocol-defined patient selection and eligibility

- Patients eligible for outpatient dosing regardless of tumor burden
- No rapidly progressing disease or deterioration in neurologic status
- Outpatient dosing at the start of treatment was not offered to all RP2D cohorts

Protocol-defined monitoring and management

- Assessments for CRS, ICANS, and other clinically significant events
- Stringent criteria for hospitalization for CRS

[a]Patients can switch to Q8W with sponsor approval. [b]Tocilizumab could be used prophylactically or considered for fever after other causes are excluded; early use could be considered in patients at high risk of severe CRS. [c]Infection prophylaxes were administered per institutional guidelines. [d]Response and disease progression were assessed by International Myeloma Working Group 2016 criteria. BCMA, B-cell maturation antigen; CRS, cytokine release syndrome; ECOG PS, Eastern Cooperative Oncology Group performance status; GPRC5D, G protein–coupled receptor class C group 5 member D; HCRU, healthcare resource utilization; ICANS, immune effector cell–associated neurotoxicity syndrome; MRD, measurable residual disease; ORR, overall response rate; PFS, progression-free survival; Q8W, every 8 weeks; Ram, ramantamig; RP2D, recommended phase 2 dose; RRMM, relapsed/refractory multiple myeloma; SC, subcutaneous; SUD, step-up dose.

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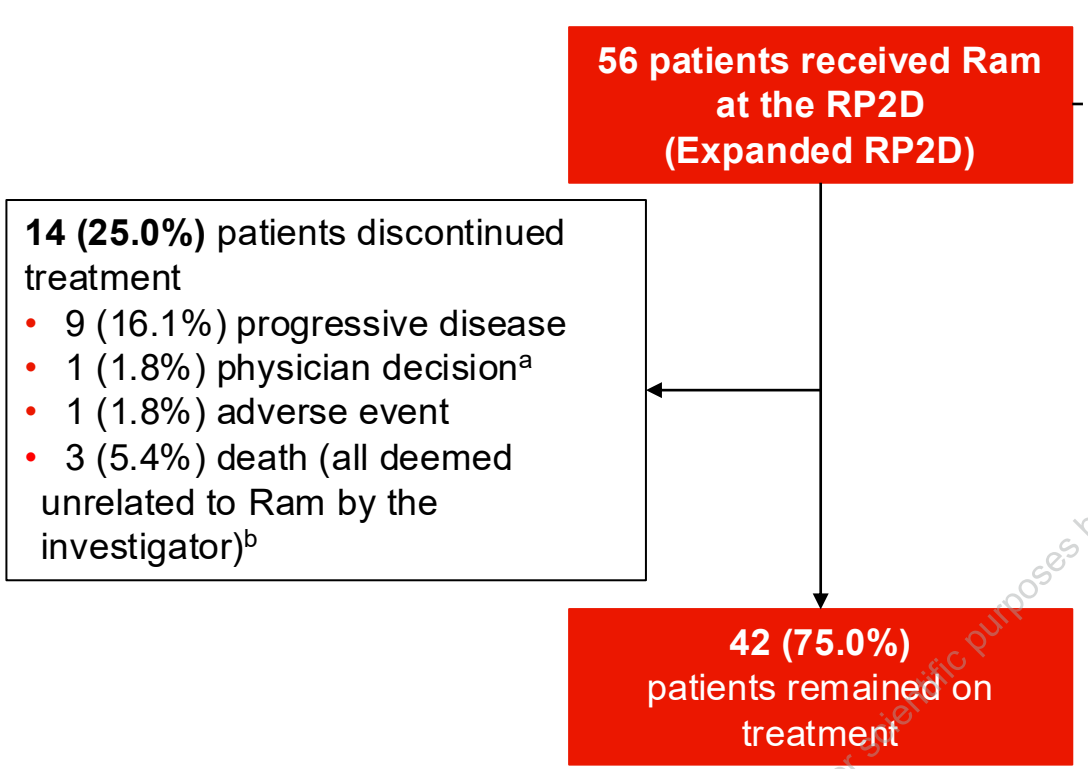
TRIlogy-1 Update: Expanded RP2D Cohort Disposition



- Median (range) follow-up:
  - 17.0 (0.4–34.1) months
- 20 additional patients (all BCMA/GPRC5D-naive) at the RP2D vs prior reports[1]

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Clinical cut-off date: July 15, 2026.

[a]Patient had grade 3 myelomatous meningitis, which did not meet IMWG 2016 criteria for disease progression and discontinued treatment due to physician decision. [b]Causes of death leading to treatment discontinuation included AEs of pneumonia in 2 patients (these deaths occurred 89 and 55 days after the last dose of Ram, were not considered treatment-emergent, and adjudicated as unrelated to Ram by the investigator) and other (refractory disease; this patient had prior BCMA-direct therapy exposure and received teclistamab as the immediate prior line of therapy). AE, adverse event; BCMA, B-cell maturation antigen; GPRC5D, G protein–coupled receptor class C group 5 member D; IMWG, International Myeloma Working Group; Ram, ramantamig; RP2D, recommended phase 2 dose; SUD, step-up dose.

1. Krishnan A, et al. *Blood* 2025;146(Supplement 1):4042.

TRIlogy-1 Update: Baseline Characteristics Consistent With Triple-Class Exposed RRMM

Characteristic	RP2D	
	Expanded (n=56)	Outpatient (n=30)
Age, years, median (range)	68 (43–87)	69 (47–87)
Male, n (%)	34 (60.7)	21 (70.0)
Race, n (%)		
White	40 (71.4)	21 (70.0)
Black/African American	2 (3.6)	2 (6.7)
Asian	1 (1.8)	0
Multiple	2 (3.6)	0
Unknown/not reported	11 (19.6)	8 (26.7)
Extramedullary plasmacytomas ≥1,[a] n (%)	4 (7.1)	2 (6.7)
High-risk cytogenetics,[b] n (%)	18 (41.9)	12 (57.1)
ISS stage,[c] n (%)		
I	27 (48.2)	15 (50.0)
II	22 (39.3)	11 (36.7)
III	7 (12.5)	4 (13.3)
Years since diagnosis, median (range)[d]	7.0 (0.1–18.7)	7.0 (0.1–11.3)
Median prior LOT, n (range)	3 (1–11)	3 (1–11)

Characteristic	RP2D	
	Expanded (n=56)	Outpatient (n=30)
Exposure status, n (%)		
Triple-class[e]	56 (100.0)	30 (100.0)
Penta-drug[f]	22 (39.3)	12 (40.0)
BCMA/GPRC5D exposed	9 (16.1)	4 (13.3)
Prior BCMA	8 (14.3)	4 (13.3)
Prior GPRC5D	1 (1.8)	0
Antibody-drug conjugate	2 (3.6)	1 (3.3)
CAR-T therapy	4 (7.1)	3 (10.0)
Bispecific antibody	6 (10.7)	2 (6.7)
Refractory status, n (%)		
PI	30 (53.6)	16 (53.3)
IMiD	52 (92.9)	26 (86.7)
Anti-CD38 mAb	54 (96.4)	27 (90.0)
Triple-class[e]	29 (51.8)	15 (50.0)
Penta-drug[f]	3 (5.4)	1 (3.3)
To last LOT	51 (91.1)	25 (83.3)

Patient characteristics generally similar among all patients and those in the outpatient dosing cohort

Clinical cut-off date: July 15, 2026. [a]≥1 nonradiated, bone-independent lesion ≥2 cm. [b]Cytogenetic risk is based on FISH or karyotype testing. Defined as del(17p), t(4;14), or t(14;16). Percentages are based on patients with available data (n=46 in the expanded RP2D cohort and n=21 in the outpatient cohort). [c]ISS staging is derived based on serum β2-microglobulin and albumin. [d]Based on n=55 patients at the RP2D and n=29 patients in the outpatient dosing cohort. [e]PI, IMiD, and anti-CD38 mAb. [f]≥2 PIs, ≥2 IMiDs, and anti-CD38 mAb.

BCMA, B-cell maturation antigen; CAR, chimeric antigen receptor; FISH, fluorescence in situ hybridization; GPRC5D, G protein–coupled receptor class C group 5 member D; IMiD, immunomodulatory drug; ISS, International Staging System; LOT, line of therapy; mAb, monoclonal antibody; PI, proteasome inhibitor; RP2D, recommended phase 2 dose.

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TRIlogy-1 Update: Safety Consistent with Prior Reports[1]

Common TEAEs,[a] ≥30% (any Grade) or 10% (Grade 3/4), n (%)	Expanded RP2D (n=56)	
	Any Grade	Grade 3/4
Hematologic TEAEs		
Neutropenia	27 (48.2)	23 (41.8)
Lymphopenia	21 (37.5)	20 (35.7)
Nonhematologic TEAEs		
Infections	48 (85.7)	14 (25.0)
Non-rash skin[b]	38 (67.9)	0
Taste changes[c]	37 (66.1)	–
Nail related[d]	36 (64.3)	0
CRS	22 (39.3)	1 (1.8)
Fatigue	22 (39.3)	4 (7.1)
Cough	21 (37.5)	0
Diarrhea	21 (37.5)	2 (3.6)
Injection site erythema	19 (33.9)	0
Hypertension	10 (17.9)	7 (12.5)

- 1 DLT (grade 4 neutropenia)
- CRS mostly low grade (grade 1, 30.4%; grade 2, 7.1%)
  - All at SUD or treatment dose 1, except for 1 grade 3 event at dose 2 in a nonresponder with PD
  - 52% received prophylactic tocilizumab at SUD
- No ICANS
- 1 treatment discontinuation due to AEs[e]
- No treatment-related deaths

CRS remains predominantly low grade and confined to SUD and first treatment dose

Clinical cut-off date: July 15, 2026. Median follow-up: 17.0 (0.4–34.1) months. [a]TEAEs graded by CTCAE v5.0; CRS per ASTCT criteria. [b]Skin exfoliation, dry skin, pruritus, and palmar-plantar erythrodysesthesia syndrome. [c]Taste changes included dysgeusia, ageusia, hypogeusia, and taste disorder. Per the CTCAE, the maximum severity for taste changes is grade 2. [d]Nail-related adverse events included nail discoloration, nail disorder, onycholysis, onychomadesis, onychoclasis, and nail ridging. [e]Pruritus and maculopapular rash.

AE, adverse event; ASTCT, American Society for Transplantation and Cellular Therapy; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; DLT, dose limiting toxicity; ICANS, immune effector cell–associated neurotoxicity syndrome; PD, progressive disease; RP2D, recommended phase 2 dose; SUD, step-up dose; TEAE, treatment-emergent adverse event.

1. Krishnan A, et al. *Blood* 2025;146(Supplement 1):4042.

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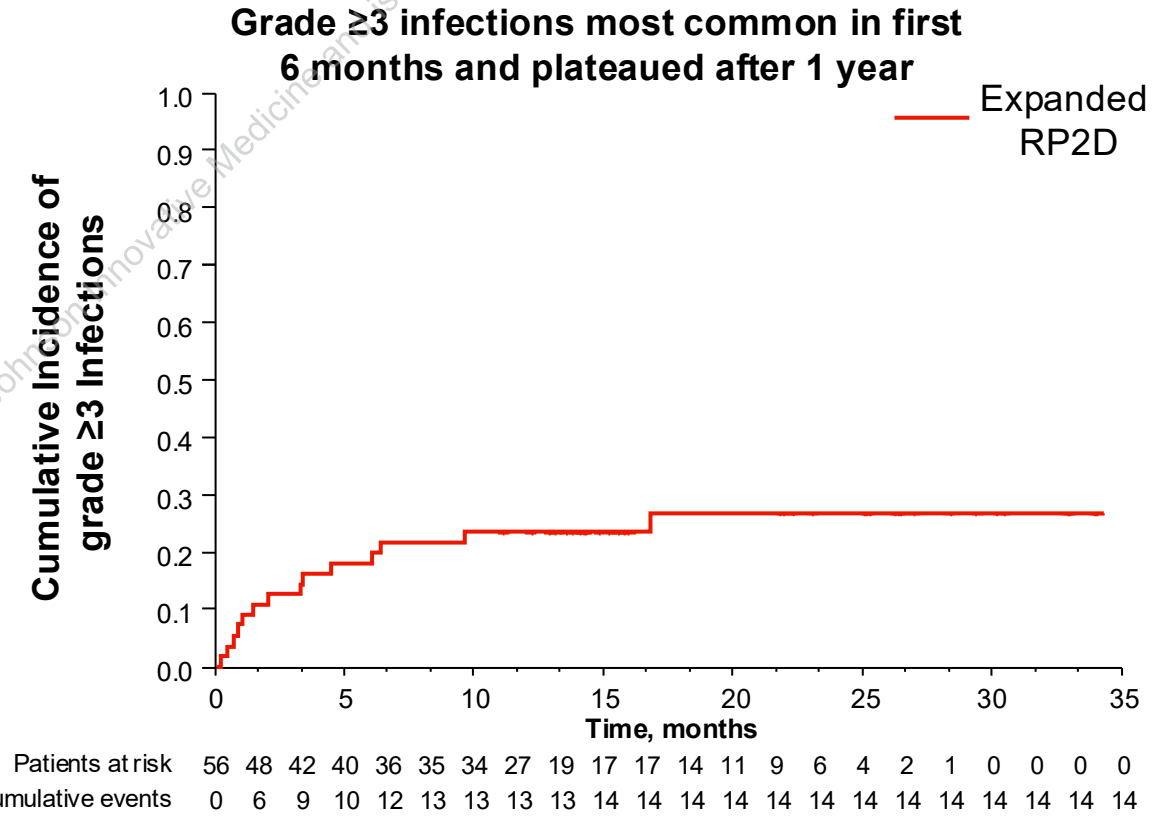
TRIlogy-1 Update: Severe infections plateaued by 12 months

Patients, n (%)	Expanded RP2D (n=56)	
	Any Grade	Grade 3/4
Infections[a]	48 (85.7)	14 (25.0)
Upper respiratory tract infection	26 (46.4)	1 (1.8)
Pneumonia	11 (19.6)	6 (10.7)
Urinary tract infection	7 (12.5)	1 (1.8)
Nasopharyngitis	6 (10.7)	0
Covid-19	6 (10.7)	0
Hypogammaglobulinemia[b]	30 (53.6)	
Received ≥1 dose IgRT	51 (91.1)	

- If serum IgG <400 mg/dL, IgRT used to maintain levels regardless of active or history of infection



Incidence of grade ≥3 infections was 25% with proactive infection management

Clinical cut-off date: July 15, 2026. Median follow-up: 17.0 months. [a]TEAEs graded by CTCAE v5.0. Shown are infections occurring in ≥10% (any grade) or 5% (grade 3/4). TEAEs listed by descending order of frequency in the total population.
[b]Patients with ≥1 TEAE of hypogammaglobulinemia or postbaseline IgG value <400 mg/dL. CTCAE, Common Terminology Criteria for Adverse Events; IgG, immunoglobulin G; IgRT; immunoglobulin replacement therapy; RP2D, recommended phase 2 dose; TEAE, treatment-emergent adverse event.

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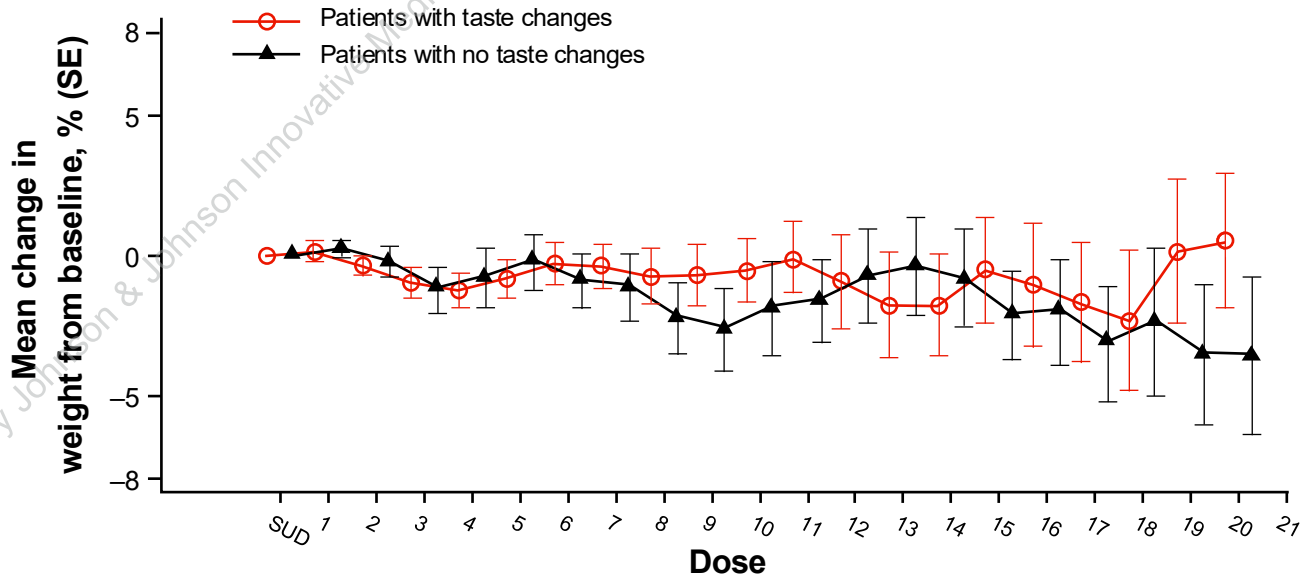
TRIlogy-1 Update: Taste Changes, Skin AEs, Nail AEs, and Weight Loss Were Low Grade

AE, n (%)	Expanded RP2D (n=56)
Taste changes[a]	37 (66.1)
Grade 1/2, %	42.9 / 23.2
Leading to discontinuation of treatment	0
Leading to dose modification[b]	2 (3.6)
Non-rash skin[c]	38 (67.9)
Grade 1/2,[d] %	50.0 / 17.9
Leading to discontinuation of treatment	1 (1.8)[e]
Leading to dose modification[b]	1 (1.8)
Nail related[f]	36 (64.3)
Grade 1/2,[d] %	62.5 / 1.8
Leading to discontinuation of treatment	0
Leading to dose modification[b]	0
Rash related[g]	15 (26.8)
Grade 1/2, %	16.1 / 8.9
Grade ≥3	1 (1.8)[e]
Leading to discontinuation of treatment	1 (1.8)[e]
Leading to dose modification[b]	0

Mean weight loss from baseline was <5%, independent of taste changes



Number of patients																						
Patients with taste changes	0	37	31	34	34	34	34	31	29	30	27	26	22	18	16	18	16	15	15	14	11	12	11
Patients with no taste changes		19	16	18	16	13	13	13	11	11	9	9	10	7	7	7	6	6	6	6	6	6	5

Majority of taste changes, skin, and nail AEs were grade 1, with only 1 patient discontinuing treatment; mean weight loss from baseline was <5%

Clincal cut-off: July 15, 2026. Median follow-up: 17.0 (0.4–34.1) months. [a]Taste changes included dysgeusia, ageusia, hypogeusia, and taste disorder. Per the Common Terminology Criteria for Adverse Events, the maximum severity for taste changes is grade 2. [b]Includes dose delays, skips, and reductions. [c]Non-rash skin adverse events included skin exfoliation, dry skin, palmar plantar erythrodysesthesia syndrome, and pruritus. [d]There were no grade ≥3 events. [e]These events occurred in the same patient. [f]Nail-related adverse events included nail discoloration, nail disorder, onycholysis, onychomadesis, onychoclasis, and nail ridging. [g]Rash adverse events included rash, maculopapular rash, erythematous rash, and erythema. AE, adverse event; RP2D, recommended phase 2 dose; SE, standard error.

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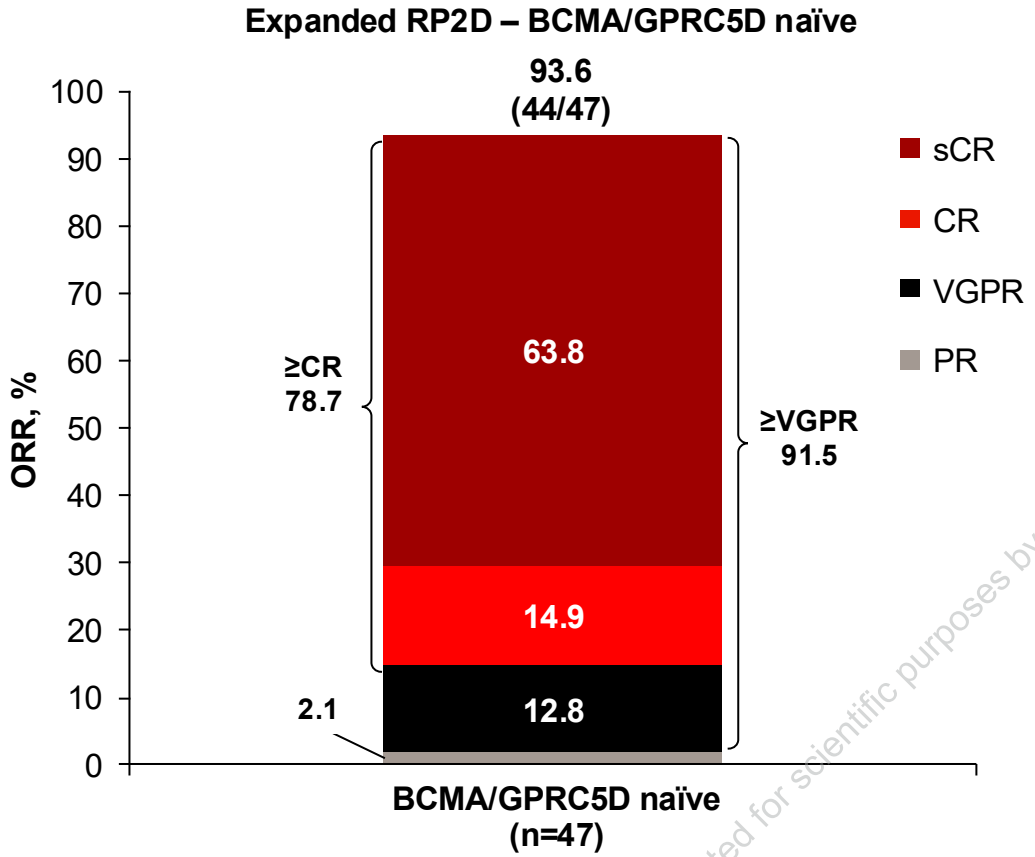
TRIlogy-1 Update: High Rate of Deep Responses[a] and MRD Negativity



- 19/20 (95%) evaluable BCMA/GPRC5D-naïve patients MRD negative at 10^{-5}
  - 14/15 (93.3%) at 10^{-6}

	BCMA/GPRC5D naive (n=44)
Time to first response, months, median (range)	1.1 (0.3–5.2)
Time to best response, months, median (range)	6.9 (0.3–22.9)

Nearly 80% ≥CR rate and >90% of evaluable patients MRD negative (10^{-6})

Clinical cut-off: July 15, 2026. Median follow-up: 21.8 months. [a]Response was assessed by the investigator using IMWG 2016 criteria. BCMA, B-cell maturation antigen; CR, complete response; GPRC5D, G protein–coupled receptor class C group 5 member D; MRD, minimal residual disease;
ORR, overall response rate; PR, partial response; RP2D, recommended phase 2 dose; sCR, stringent complete response; VGPR, very good partial response.

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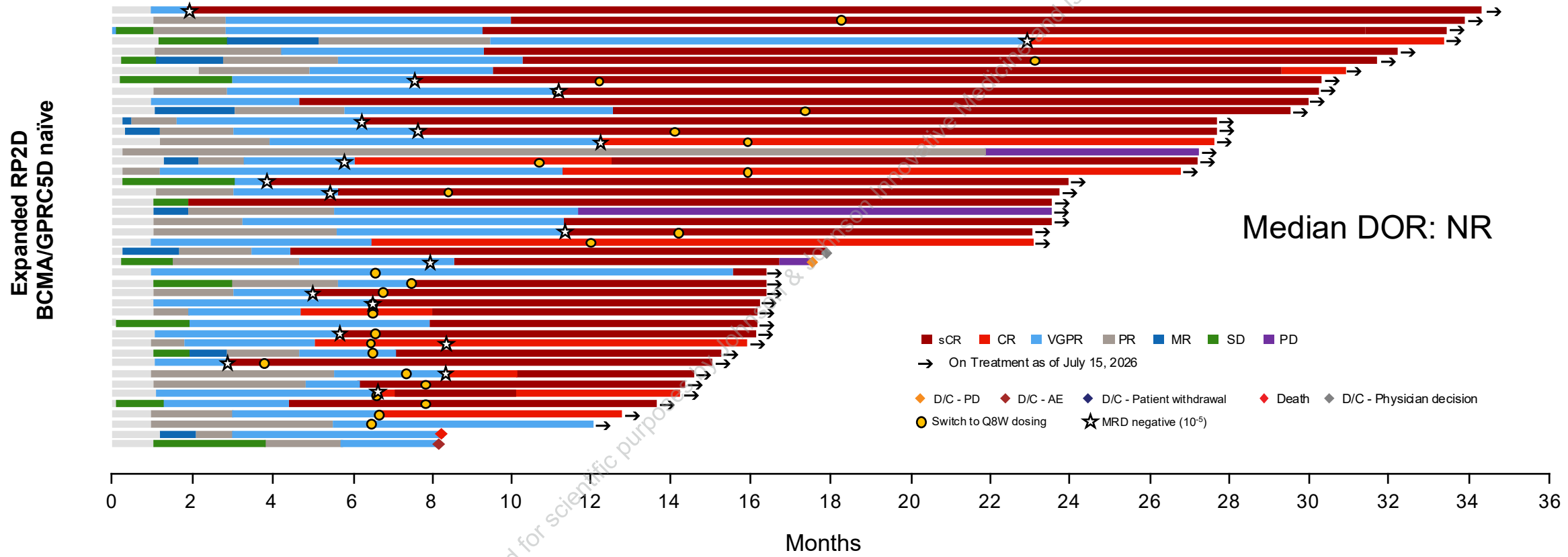
TRIlogy-1 Update: Durable, Deepening Responses[a] Over Time Even With Switch to Q8W dosing



61.4% of responders switched to Q8W dosing, with responses sustained or deepening post switch

Clinical cut-off: July 15, 2026. Median follow-up: 21.8 months. [a]Response was assessed by the investigator using IMWG 2016 criteria.
AE, adverse event; BCMA, B-cell maturation antigen; CR, complete response; D/C, discontinued; GPRC5D, G protein–coupled receptor class C group 5 member D; MR, minimal response; MRD, minimal residual disease; NR, not reached; PD, progressive disease; PR, partial response; Q8W, every 8 weeks; RP2D, recommended phase 2 dose; sCR, stringent complete response; SD, stable disease; VGPR, very good partial response; Q8W, every 8 weeks.

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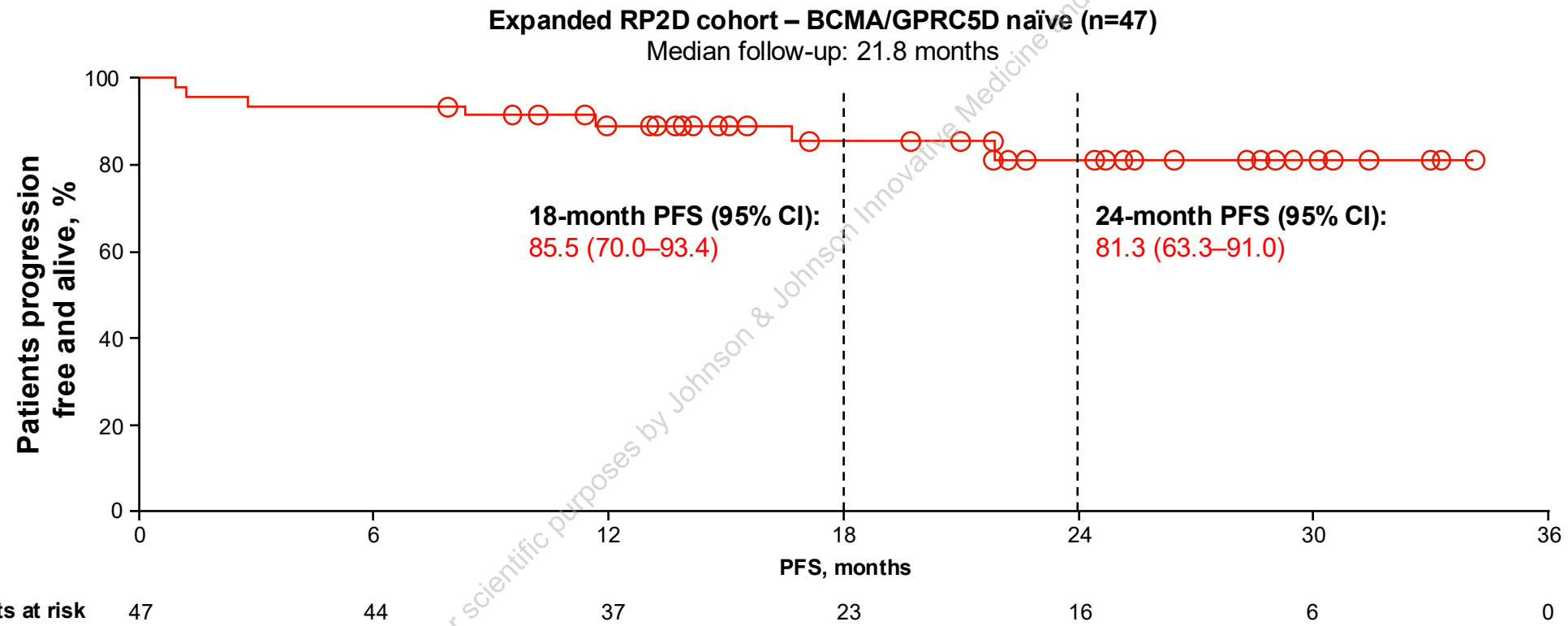
TRIlogy-1 Update: Durable PFS in the Expanded RP2D Cohort



Majority of patients progression free and alive at 2 years

Clinical cut-off: July 15, 2026.
BCMA, B-cell maturation antigen; GPRC5D, G protein–coupled receptor class C group 5 member D; PFS, progression-free survival; RP2D, recommended phase 2 dose.

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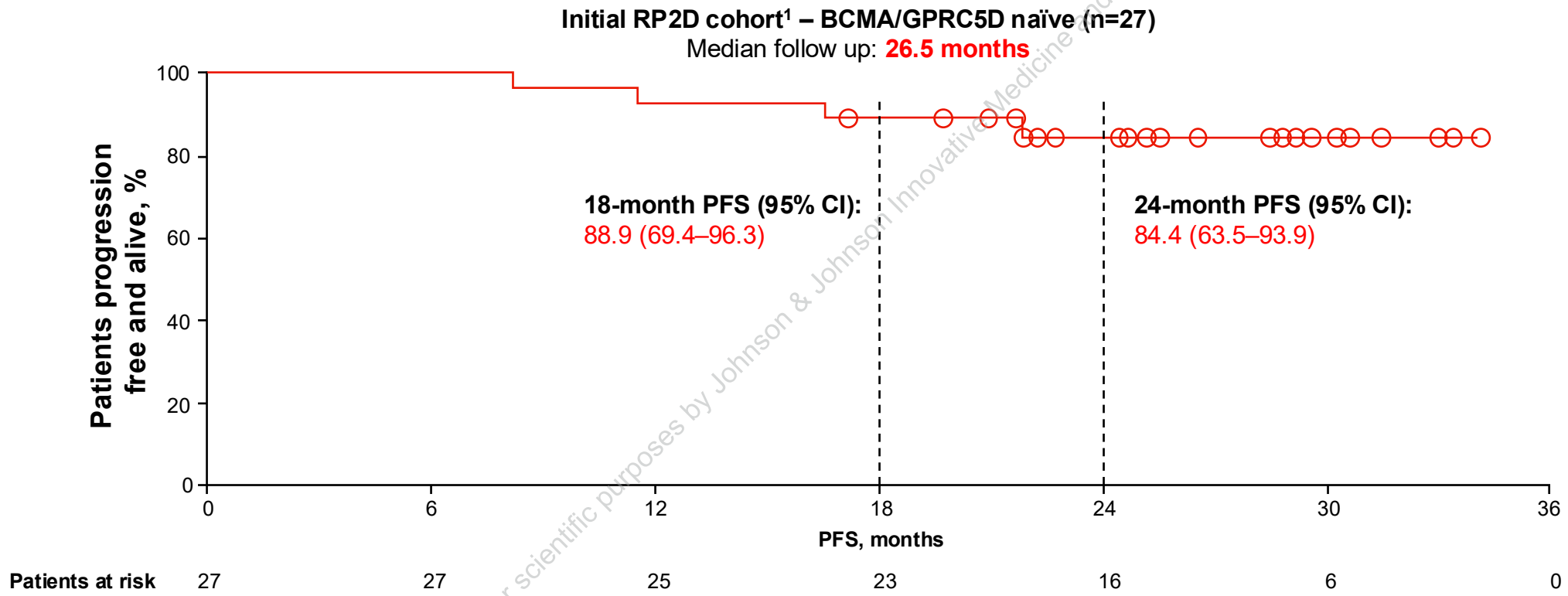
TRIlogy-1 Update: >80% 2-year PFS in the Initial RP2D Cohort (median 26.5 months follow-up)



Majority of patients progression free and alive at 2 years

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Clinical cut-off: July 15, 2026.
BCMA, B-cell maturation antigen; GPRC5D, G protein–coupled receptor class C group 5 member D; PFS, progression-free survival; RP2D, recommended phase 2 dose.
1. Krishnan A, et al. *Blood* 2025;146(Supplement 1):4042.

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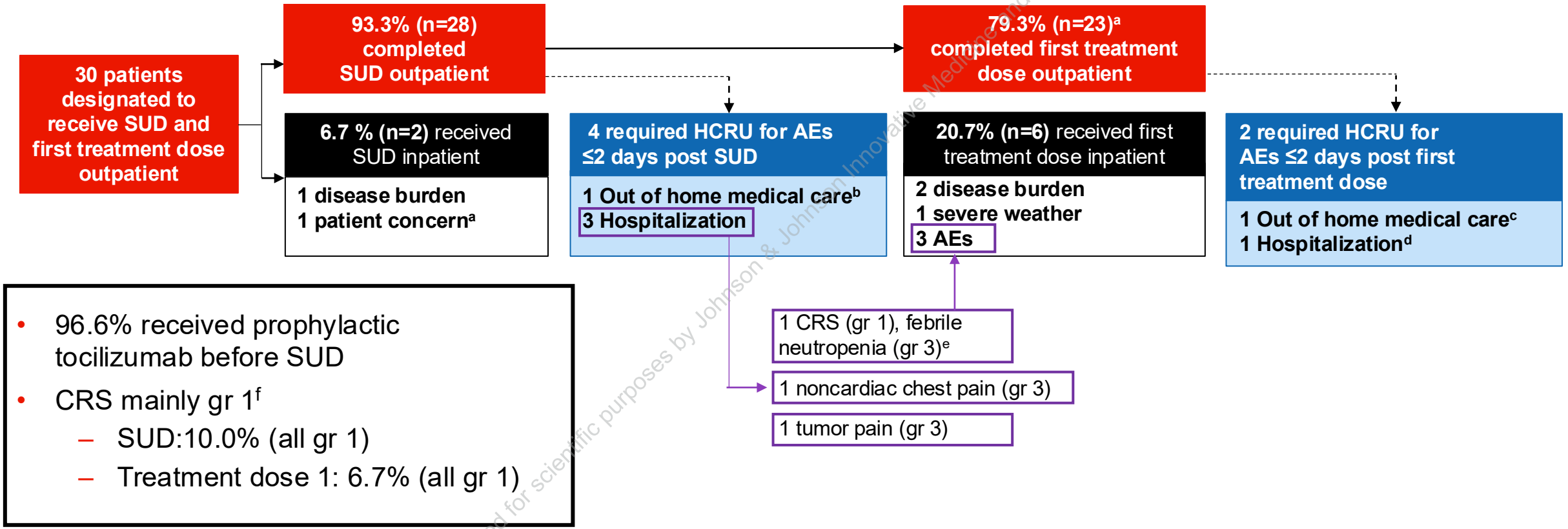
TRIlogy-1 Update: Outpatient Dosing of Ram Was Feasible with No New Safety Concerns



- 96.6% received prophylactic tocilizumab before SUD
- CRS mainly gr 1[f]
  - SUD:10.0% (all gr 1)
  - Treatment dose 1: 6.7% (all gr 1)

With prophylactic tocilizumab, CRS at SUD and first treatment dose was infrequent and all grade 1

Patients with events leading to hospitalization at SUD denoted with purple boxes did not receive the first treatment dose outpatient due to the same or related events. [a]One patient died due to refractory disease after SUD and did not receive the first treatment dose; the percentage receiving the first treatment dose is calculated using n=29 as the denominator. [b]Due to grade 1 CRS. [c]Due to grade 1 CRS, grade 2 diarrhea, and grade 1 headache. [d]Due to grade 2 bone pain. [e]Patient received the first treatment dose inpatient due to grade 3 neutropenia. [f]One grade 3 event occurred at dose 2 in a nonresponder with PD.
AE, adverse event; CRS, cytokine release syndrome; HCRU, healthcare resource utilization; PD, progressive disease; Ram, ramantamig; SUD, step-up dose.

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TRIlogy-1 Update: Conclusions

- Dual-antigen targeting of BCMAxGPRC5D in a single molecule with Ram using a single SUD followed by 100 mg monthly dosing (RP2D) continues to demonstrate deep, durable responses
  - **2-year PFS >80%** in patients with BCMA/GPRC5D-naïve TCE RRMM
- Responses maintained or deepened with switch to less frequent Q8W dosing
- Novel binding domains and Q4W→Q8W dosing may offer a favorable safety profile vs Tec and Tal[1,2]
  - Low rates of CRS and severe infections, with taste changes, skin, and nail AEs mostly grade 1
- Dedicated phase 1 outpatient cohort with Ram's single SUD with Q4W→Q8W dosing schedule and prophylactic tocilizumab demonstrates safe, feasible administration of Ram in a fully outpatient setting from start of treatment
  - Outpatient dosing implemented across ongoing phase 2 and 3 studies (>500 patients treated to date)
  - Randomized phase 2 TRI-Pro study: prophylactic tocilizumab for CRS mitigation (NCT07589634)

Robust efficacy, manageable safety and convenient schedule support use of Ram, a novel trispecific antibody, for triple-class exposed RRMM across all practice settings

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AE, adverse event; BCMA, B-cell maturation antigen; CRS, cytokine release syndrome;GPRC5D, G protein–coupled receptor class C group 5 member D; PFS, progression-free survival; Q8W, every 8 weeks; Ram, ramantamig; RP2D, recommended phase 2 dose; RRMM, relapsed/refractory multiple myeloma; SUD, step-up dose; Tal, talquetamab; Tec, teclistamab.

1. Moreau P, et al. *N Engl J Med* 2022;387:495-505. 2. Chari A, et al. *N Engl J Med* 2022;387:2232-44.

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