# Talquetamab + Daratumumab + Pomalidomide in Patients With Relapsed/Refractory Multiple Myeloma: Results From the Phase 1b TRIMM-2 Study

**Nizar Bahlis[1], Niels W.C.J. van de Donk[2], Donna Reece[3], Manisha Bhutani[4], Bhagirathbhai Dholaria[5], Anita D'Souza[6], Thomas G Martin[7], John McKay[8], Alfred Garfall[9], Amrita Krishnan[10], Kalpana Bakshi[11], Lijuan Kang[11], Lien Vandenberk[12], Thomas Prior[11], Jaszianne Tolbert[11], Ajai Chari[13]**

[1]Arnie Charbonneau Cancer Institute, University of Calgary, Calgary, AB, Canada; [2]Amsterdam University Medical Center, Vrije Universiteit Amsterdam, Amsterdam, Netherlands; [3]Princess Margaret Cancer Centre, Toronto, ON, Canada; [4]Levine Cancer Institute / Wake Forest School of Medicine, Charlotte, NC, USA; [5]Vanderbilt University Medical Center, Nashville, TN, USA; [6]Medical College of Wisconsin, Milwaukee, WI, USA; [7]Helen Diller Family Comprehensive Cancer Center, San Francisco Medical Center, University of California, San Francisco, CA, USA; [8]Wake Forest University School of Medicine, Winston-Salem, NC, USA; [9]Abramson Cancer Center, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA, USA; [10]City of Hope Comprehensive Cancer Center, Duarte, CA, USA; [11]Janssen Research & Development, Spring House, PA, USA; [12]Janssen Research & Development, Antwerp, Belgium; [13]University of California, San Francisco, San Francisco, CA, USA





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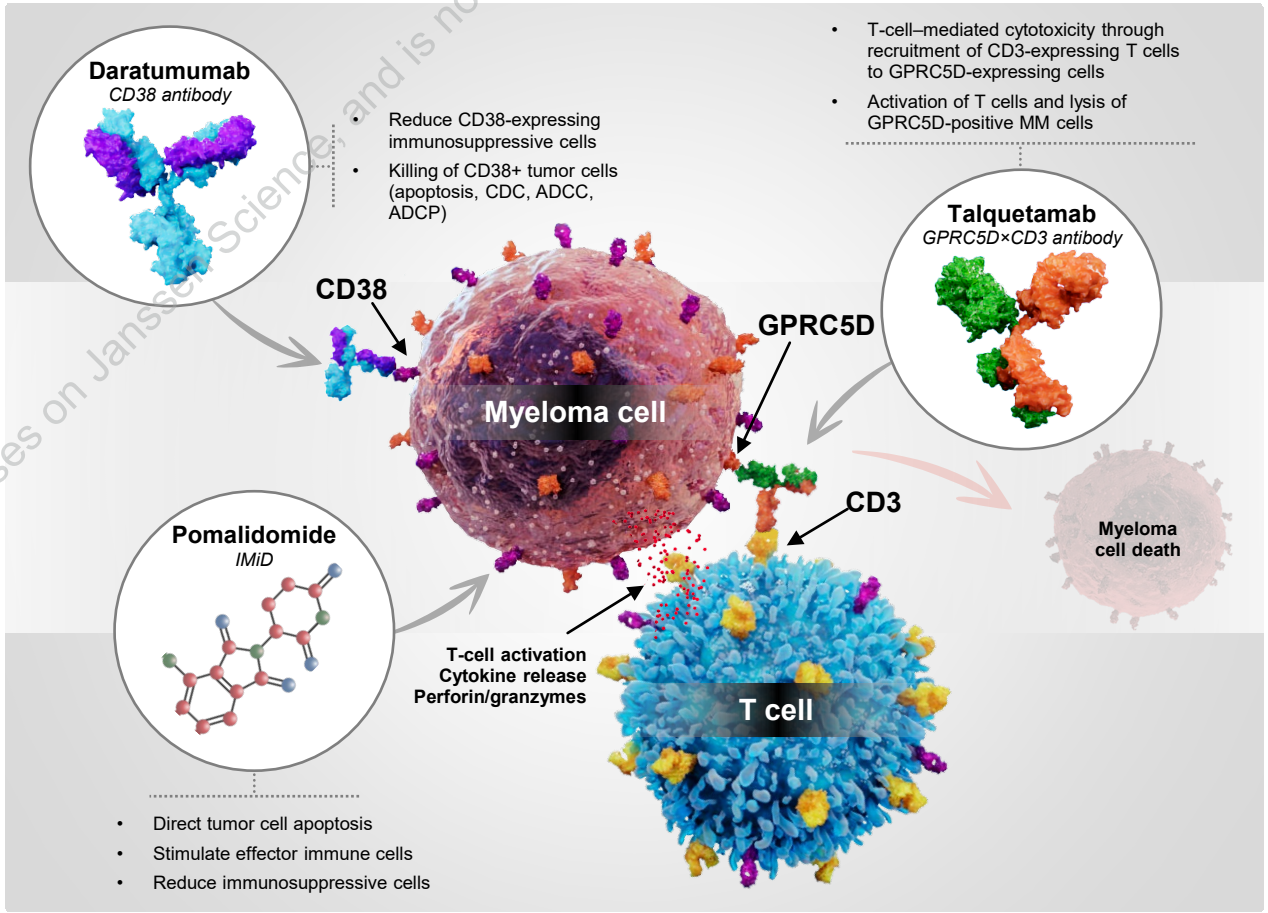
# TRIMM-2 Tal + Dara + Pom Cohort: Background

- Talquetamab (tal) is the first approved GPRC5D-targeting bispecific antibody for TCE RRMM[1-3]
  - ORRs of ≥70% in MonumenTAL-1 study[1]
- Daratumumab (dara) is a foundational therapy in MM with direct on-tumor and immunomodulatory actions[4]
- Pomalidomide (pom) is a third-generation IMiD used in multiple regimens for RRMM[5]
- Preclinical data suggest that the immunomodulatory effects of dara + pom potentiate the efficacy of tal[6]
- We present first results from the tal + dara + pom cohort of TRIMM-2






TRIMM-2 ClinicalTrials.gov identifier: NCT04108195.
ADCC, antibody-dependent cellular cytotoxicity; ADCP, antibody-dependent cellular phagocytosis; CDC, complement-dependent cytotoxicity; GPRC5D, G protein–coupled receptor family C group 5 member D; IMiD, immunomodulatory drug; MM, multiple myeloma; ORR, overall response rate; RRMM, relapsed/refractory multiple myeloma; TCE, triple-class exposed.

1. Rasche L, et al. Presented at EHA; June 13–16, 2024; Madrid, Spain. 2. TALVEY (talquetamab). Summary of product characteristics. Horsham, PA: Janssen Biotech, Inc; 2023. 3. TALVEY (talquetamab-tgvs). Prescribing information. Horsham, PA: Janssen Biotech, Inc; 2023. 4. DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj) injection, for subcutaneous use. Package insert. Horsham, PA: Janssen Biotech, Inc; 2022. 5. POMALYST® (pomalidomide) capsules, for oral use. Package insert. Utrecht, Netherlands; Celene; 2017. 6. Verkleij CPM, et al. *Blood Adv* 2021;5:2196-215.



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# TRIMM-2 Study Design: Tal + Dara + Pom Cohort

**Key eligibility criteria**

- MM per IMWG
- ≥3 prior LOT[a] or double refractory to PI and IMiD
- Permitted:
  - Anti-CD38 mAb >90 days and IMiD >7 days prior
  - Refractory to anti-CD38 mAb
  - Prior bispecific antibody or CAR-T exposure

| Tal[b] | + | Dara[c] 1800 mg SC | + | Pom 2 mg PO |
|---|---|---|---|---|
| SUD followed by 0.4 mg/kg SC QW or 0.8 mg/kg SC Q2W<br>*May change schedule from QW to Q2W after cycle 4 if in PR and from Q2W to Q4W after cycle 8 if in VGPR* | | QW cycles 1–2<br>Q2W cycles 3–6<br>Q4W cycles ≥7 | | Starting cycle 2<br>*May be reduced in response to hematologic AEs* |

**Key objectives**

- Safety and antitumor activity



[a]Including a PI and an IMiD. [b]2–3 step-up doses before first full dose. Premedication including glucocorticoid, antihistamine, and antipyretic at step-up and first full dose. [c]Given with 2-week corticosteroid taper (steroid-free administration after first full treatment dose). AE, adverse event; CAR, chimeric antigen receptor; dara, daratumumab; IMiD, immunomodulatory drug; IMWG, International Myeloma Working Group; LOT, line of therapy; mAb, monoclonal antibody; MM, multiple myeloma; PI, proteasome inhibitor; PO, orally; pom, pomalidomide; PR, partial response; Q2W, every other week; Q4W, every 4 weeks; QW, weekly; SC, subcutaneous; tal, talquetamab; VGPR, very good partial response.

# TRIMM-2 Tal + Dara + Pom Cohort: Majority of Patients Dara And Pom Refractory

| Characteristic | Tal 0.4 mg/kg QW + dara + pom (n=18) | Tal 0.8 mg/kg Q2W + dara + pom (n=59) |
|---|---|---|
| Age (years), median (range) | 62 (42–75) | 64 (33–81) |
| Male, n (%) | 12 (66.7) | 31 (52.5) |
| Race, n (%) | | |
| White | 12 (66.7) | 51 (86.4) |
| Black/African American | 4 (22.2) | 4 (6.8) |
| Asian | 1 (5.6) | 1 (1.7) |
| American Indian/Alaska Native | 0 (0) | 1 (1.7) |
| Not reported | 1 (5.6) | 2 (3.4) |
| Soft tissue plasmacytoma(s),[a] n (%) | 4 (22.2) | 14 (23.7) |
| High cytogenetic risk,[b] n (%) | 4 (22.2) | 13 (27.7) |
| ISS stage,[c] n (%) | | |
| I | 8 (50.0) | 29 (52.7) |
| II | 3 (18.8) | 15 (27.3) |
| III | 5 (31.3) | 11 (20.0) |
| Time since diagnosis (years), median (range) | 5.7 (0.3–18.3) | 7.2 (0.7–17.5) |

| Characteristic | Tal 0.4 mg/kg QW + dara + pom (n=18) | Tal 0.8 mg/kg Q2W + dara + pom (n=59) |
|---|---|---|
| Prior LOT (n), median (range) | 6 (3–11) | 6 (1–17) |
| Prior stem cell transplantation, n (%) | 16 (88.9) | 50 (84.7) |
| Prior therapies, n (%) | | |
| Anti-CD38 | 17 (94.4) | 55 (93.2) |
| IMiD | 18 (100.0) | 59 (100.0) |
| Triple class[d] | 17 (94.4) | 55 (93.2) |
| Penta drug[e] | 12 (66.7) | 41 (69.5) |
| BCMA-targeted therapy | 13 (72.2) | 40 (67.8) |
| CAR-T | 5 (27.8) | 19 (32.2) |
| Bispecific antibody[f] | 6 (33.3) | 17 (28.8) |
| ADC | 3 (16.7) | 12 (20.3) |
| Refractory status, n (%) | | |
| Anti-CD38[g] | 15 (83.3) | 49 (83.1) |
| Pom | 13 (72.2) | 45 (76.3) |
| Triple class[d] | 15 (83.3) | 45 (76.3) |
| Penta drug[e] | 4 (22.2) | 20 (33.9) |
| Any prior bispecific antibody | 7 (38.9) | 22 (37.3) |
| To last line of therapy | 17 (94.4) | 53 (89.8) |

Data cut-off: July 29, 2024. [a]Soft tissue plasmacytomas not associated with the bone were included. [b]del(17p), t(4;14), and/or t(14;16); percentages calculated from n=18 for tal QW and n=47 for tal Q2W. [c]Percentages calculated from n=16 for tal QW and n=55 for tal Q2W. [d]≥1 PI, ≥1 IMiD, and ≥1 anti-CD38 mAb. [e]≥2 PIs, ≥2 IMiDs, and ≥1 anti-CD38 mAb. [f]6 patients received non-BCMA–directed bispecific antibodies. [g]All patients in the tal QW cohort received dara; in the tal Q2W cohort, 89.8% received dara, 13.6% received isatuximab, and 1.7% received other anti-CD38 therapies. ADC, antibody-drug conjugate; BCMA, B-cell maturation antigen; CAR, chimeric antigen receptor; dara, daratumumab; IMiD, immunomodulatory drug; ISS, International Staging System; LOT, line of therapy; mAb, monoclonal antibody; PI, proteasome inhibitor; pom, pomalidomide; Q2W, every other week; QW, weekly; tal, talquetamab.





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# TRIMM-2 Tal + Dara + Pom Cohort: CRS/ICANS Consistent With Tal Monotherapy

| Characteristic | Tal 0.4 mg/kg QW + dara + pom (n=18) | Tal 0.8 mg/kg Q2W + dara + pom (n=59) |
|---|---|---|
| Patients with CRS,[a] n (%) | 10 (55.6) | 47 (79.7) |
| Grade 1 | 7 (38.9) | 32 (54.2) |
| Grade 2 | 3 (16.7) | 15 (25.4) |
| Time to onset (days),[b] median (range) | 3 (1–5) | 2 (1–7) |
| Duration (days), median (range) | 2 (1–6) | 2 (1–7) |
| Received supportive measures,[c] n (%) | 10 (55.6) | 42 (71.2) |
| Tocilizumab | 7 (38.9) | 34 (57.6) |
| Acetaminophen | 7 (38.9) | 27 (45.8) |
| Corticosteroids | 0 (0) | 8 (13.6) |
| Oxygen | 0 (0) | 2 (3.4) |
| Other | 8 (44.4) | 30 (50.8) |

- CRS mostly confined to step-up and cycle 1 dosing
  - No grade ≥3 CRS
  - All events recovered
- ICANS[a] in 3 patients (all Q2W)
  - 1 grade 4 ICANS led to discontinuation



Data cut-off: July 29, 2024.

[a]CRS and ICANS were graded per ASTCT criteria. [b]Relative to most recent dose (day of most recent dose = day 1). [c]A patient could receive >1 supportive therapy. ASTCT, American Society for Transplantation and Cellular Therapy; CRS, cytokine release syndrome; dara, daratumumab; ICANS, immune effector cell-associated neurotoxicity syndrome; pom, pomalidomide; Q2W, every other week; QW, weekly; tal, talquetamab.



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# TRIMM-2 Tal + Dara + Pom Cohort: Hematologic AEs Consistent With Addition of Dara + Pom to Tal

| Most common AEs,[a] n (%) | Tal 0.4 mg/kg QW + dara + pom (n=18) | | Tal 0.8 mg/kg Q2W + dara + pom (n=59) | |
|---|---|---|---|---|
| | Any grade | Grade 3/4 | Any grade | Grade 3/4 |
| Neutropenia | 15 (83.3) | 14 (77.8) | 47 (79.7) | 42 (71.2) |
| Anemia | 9 (50.0) | 6 (33.3) | 30 (50.8) | 22 (37.3) |
| Thrombocytopenia | 6 (33.3) | 4 (22.2) | 31 (52.5) | 20 (33.9) |
| Leukopenia | 4 (22.2) | 4 (22.2) | 22 (37.3) | 19 (32.2) |
| Lymphopenia | 9 (50.0) | 9 (50.0) | 16 (27.1) | 16 (27.1) |

- 4 (5.2%) patients had febrile neutropenia (all Q2W)



Data cut-off: July 29, 2024.
[a]AEs were graded by CTCAE v5.0. AEs are listed in descending order by frequency in the total population (N=77); only AEs occurring in ≥30% are included. AE, adverse event; CTCAE, Common Terminology Criteria for Adverse Events; dara, daratumumab; pom, pomalidomide; Q2W, every other week; QW, weekly; tal, talquetamab.



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# TRIMM-2 Tal + Dara + Pom Cohort: Grade 3/4 Infection Rate Generally Low Despite Neutropenia Being Common

| AEs,[a] n (%) | Tal 0.4 mg/kg QW + dara + pom (n=18) | | Tal 0.8 mg/kg Q2W + dara + pom (n=59) | |
|---|---|---|---|---|
| | Any grade | Grade 3/4 | Any grade | Grade 3/4 |
| Infections | 13 (72.2) | 3 (16.7) | 46 (78.0) | 22 (37.3) |
| COVID-19 | 7 (38.9) | 0 (0) | 16 (27.1) | 0 (0) |
| Upper respiratory tract infection (undefined) | 2 (11.1) | 0 (0) | 15 (25.4) | 1 (1.7) |
| Pneumonia | 0 (0) | 0 (0) | 10 (16.9) | 4 (6.8) |
| Viral upper respiratory tract infection | 3 (16.7) | 0 (0) | 6 (10.2) | 0 (0) |
| Sinusitis | 4 (22.2) | 0 (0) | 4 (6.8) | 3 (5.1) |

- Of patients with grade 3/4 infections, 84.0% had onset within first 6 months
- 2 patients with opportunistic infections
  - Adenovirus infection
  - Cytomegalovirus viremia
- Baseline and posttreatment IgG <400 mg/dL observed in 33.8% and 72.7% of patients, respectively
- 53.2% received ≥1 dose of IVIG

Data cut-off: July 29, 2024.

[a]AEs were graded by CTCAE v5.0. AEs are listed in descending order by frequency in the total population (N = 77); only AEs occurring in ≥10% are included. AE, adverse event; CTCAE, Common Terminology Criteria for Adverse Events; dara, daratumumab; IgG, immunoglobulin G; IVIG, intravenous immunoglobulin; pom, pomalidomide; Q2W, every other week; QW, weekly; tal, talquetamab.





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# TRIMM-2 Tal + Dara + Pom Cohort: Nonhematologic AEs Consistent With Profile of Individual Agents

| Most common AEs,[a] n (%) | Tal 0.4 mg/kg QW + dara + pom (n=18) | | Tal 0.8 mg/kg Q2W + dara + pom (n=59) | |
|---|---|---|---|---|
| | Any grade | Grade 3/4 | Any grade | Grade 3/4 |
| Oral events[b] | 18 (100.0) | 0 (0) | 50 (84.7) | 4 (6.8) |
| CRS | 10 (55.6) | 0 (0) | 47 (79.7) | 0 (0) |
| Nonrash skin events[c] | 16 (88.9) | 0 (0) | 40 (67.8) | 0 (0) |
| Nail events[d] | 15 (83.3) | 0 (0) | 33 (55.9) | 0 (0) |
| Fatigue | 11 (61.1) | 0 (0) | 34 (57.6) | 4 (6.8) |
| Weight decrease ≥10% | 12 (66.7) | 2 (11.1) | 29 (49.2) | 10 (16.9) |
| Pyrexia | 7 (38.9) | 0 (0) | 28 (47.5) | 0 (0) |
| Cough | 7 (38.9) | 0 (0) | 26 (44.1) | 2 (3.4) |

- Median duration of treatment (mo): 13.6 (tal); 13.6 (dara); 6.7 (pom)
- No DLTs
- Dose reduction of tal due to AEs
  - 33.3% (QW) and 52.5% (Q2W)
- Discontinuation of ≥1 drug due to AEs
  - 27.8% (QW) and 47.5% (Q2W)
- 2 deaths[e] due to AEs
- Taste, skin, and nail AEs mostly low grade; no discontinuations
  - Rash[f] in 27.8% (QW) and 25.4% (Q2W) of patients

Data cut-off: July 29, 2024. [a]AEs were graded by CTCAE v5.0, except for CRS, which was graded per ASTCT criteria. AEs are listed in descending order by frequency in the total population (N=77); only AEs occurring in ≥40% are included. [b]Oral AEs include dysgeusia, ageusia, taste disorder, hypogeusia, dry mouth, dysphagia, cheilitis, glossitis, glossodynia, mouth ulceration, oral discomfort, oral mucosal erythema, oral pain, stomatitis, swollen tongue, tongue discomfort, tongue erythema, tongue edema, and tongue ulceration. Per CTCAE, the maximum grade for dysgeusia (part of oral AEs) is 2. [c]Skin AEs include skin exfoliation, dry skin, pruritus, and palmar-plantar erythrodysaesthesia syndrome. [d]Nail AEs include nail discoloration, nail disorder, onycholysis, onychomadesis, onychoclasis, nail dystrophy, nail toxicity, and nail ridging. [e]Hemorrhagic transformation stroke and pseudomonal sepsis.[f]Rash includes rash, maculopapular rash, erythematous rash, and erythema. AE, adverse event; ASTCT, American Society for Transplantation and Cellular Therapy; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; dara, daratumumab; DLT, dose-limiting toxicity; mo, month; pom, pomalidomide; Q2W, every other week; QW, weekly; tal, talquetamab.





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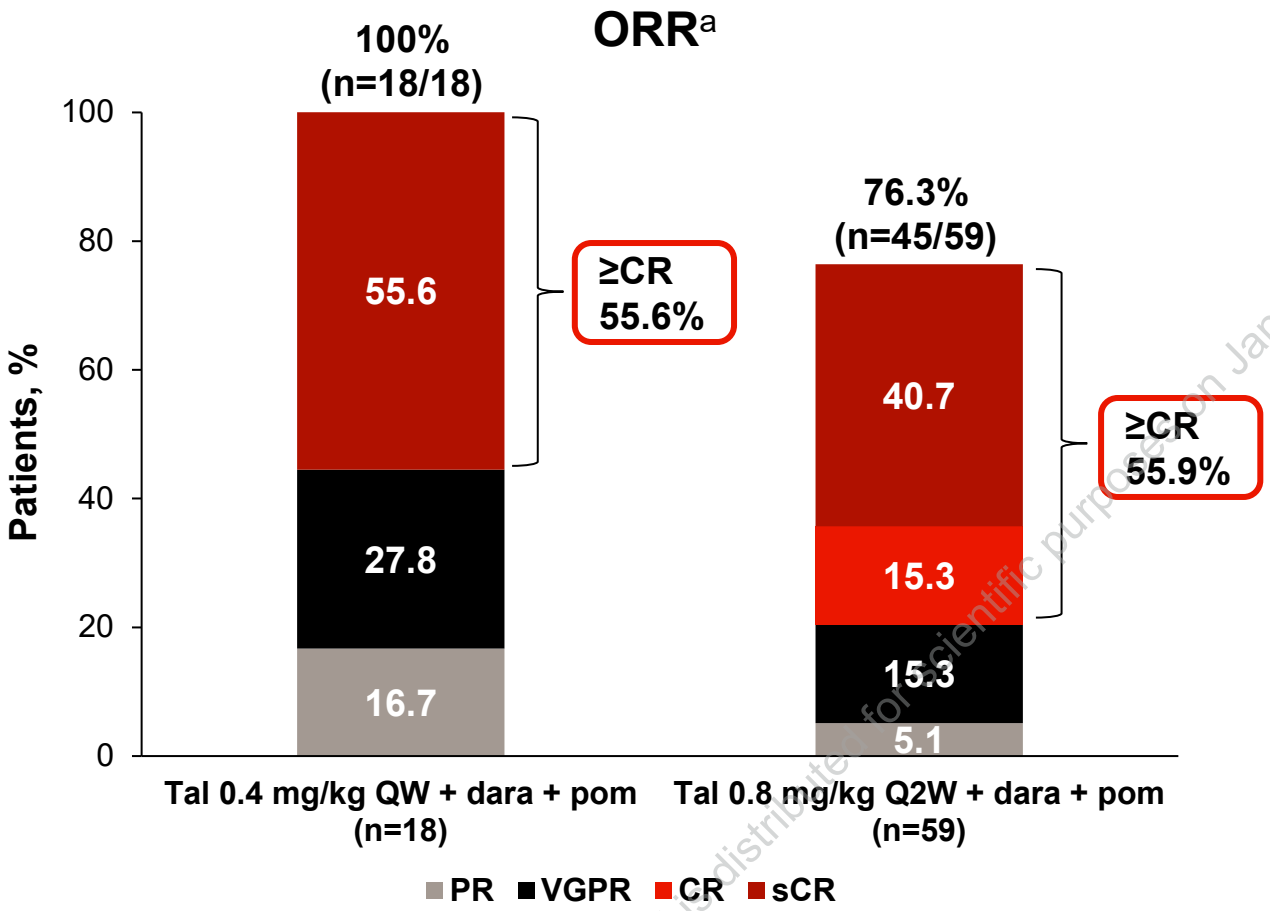
# TRIMM-2 Tal + Dara + Pom Cohort: Combined ORR 82% and ≥CR rate 56%




| | Tal 0.4 mg/kg QW + dara + pom (n=18) | Tal 0.8 mg/kg Q2W + dara + pom (n=59) |
|---|---|---|
| Median (range) follow-up, months | 15.8 (3.2–37.9) | 17.5 (0.2–37.7) |
| Median (range) time to first response, months | 1.0 (0.9–3.6) | 1.0 (0.9–6.7) |
| Combined ORR, % (n/N) | 81.8 (63/77) | |
| Combined ≥CR, % (n/N) | 55.8 (43/77) | |



Data cut-off: July 29, 2024.

[a]Response was assessed by investigators, based on IMWG criteria. Percentages are calculated with the number of patients in each group as denominator. CR, complete response; dara, daratumumab; IMWG, International Myeloma Working Group; ORR, overall response rate; pom, pomalidomide; PR, partial response; Q2W, every other week; QW, weekly; sCR, stringent complete response; tal, talquetamab; VGPR, very good partial response.



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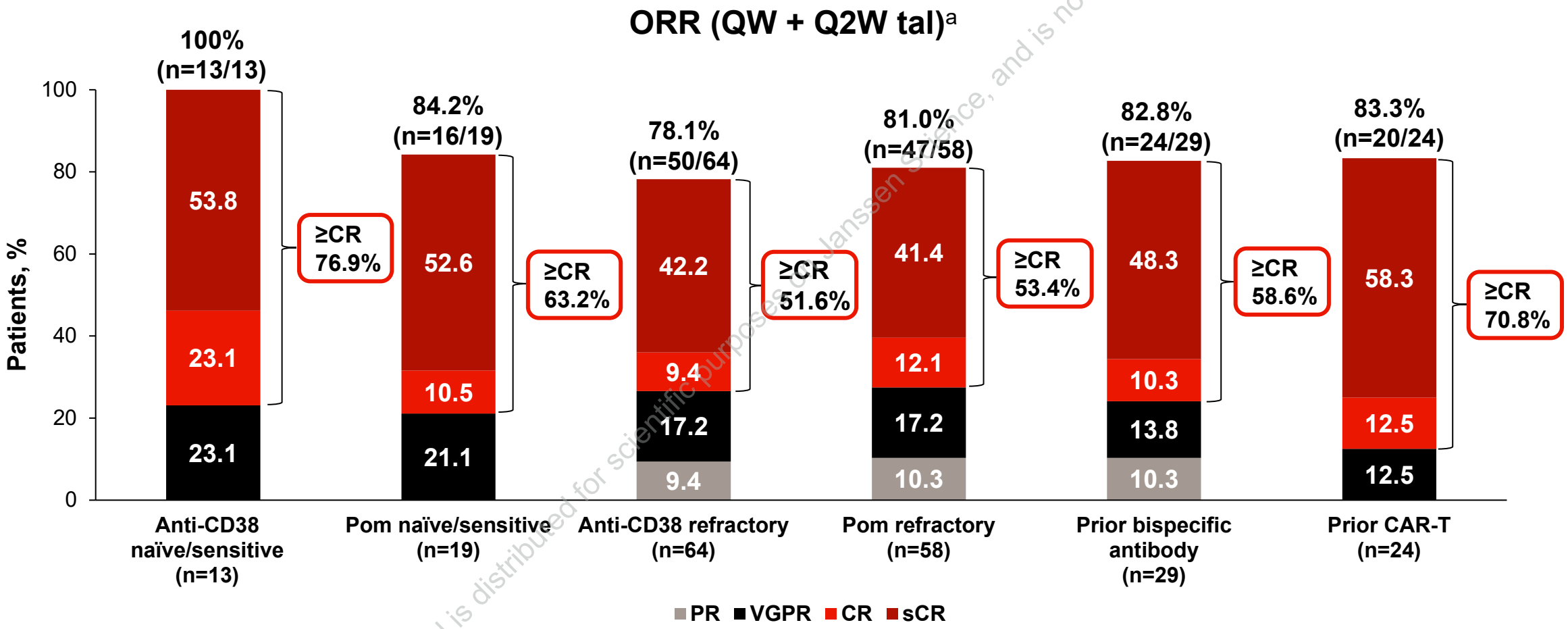
# TRIMM-2 Tal + Dara + Pom Cohort: High ORRs in Prior Exposure Subgroups




Data cut-off: July 29, 2024.

Anti-CD38 naïve = never received anti-CD38 therapy; anti-CD38 sensitive = minimal response or better during treatment; anti-CD38 refractory = best response of SD or PD during treatment or within 60 days of completing anti-CD38 therapy. [a]Response was assessed by investigators, based on IMWG criteria. Percentages are calculated with the number of patients in each group as denominator. CAR, chimeric antigen receptor; CR, complete response; dara, daratumumab; IMWG, International Myeloma Working Group; ORR, overall response rate; pom, pomalidomide; PD, progressive disease; PR, partial response; Q2W, every other week; QW, weekly; sCR, stringent complete response; SD, stable disease; tal, talquetamab; VGPR, very good partial response.





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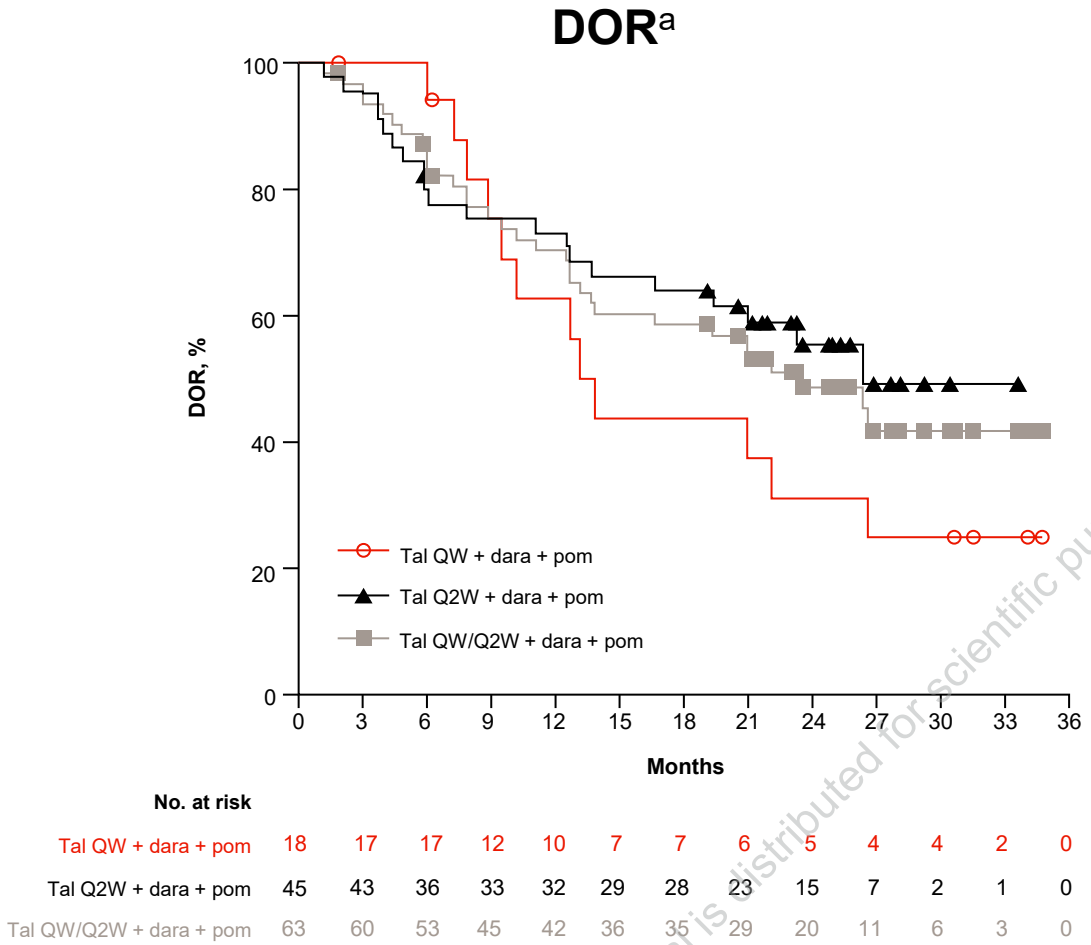
# TRIMM-2 Tal + Dara + Pom Cohort: Durable responses, Including in Key Exposure Subgroups




| Parameter | Tal 0.4 mg/kg QW + dara + pom (n=18) | Tal 0.8 mg/kg Q2W + dara + pom (n=45) |
|---|---|---|
| Median (range) follow-up, months | 15.8 (3.2–37.9) | 17.5 (0.2–37.7) |
| Median DOR, months (95% CI) | 13.8 (8.8–26.6) | 26.4 (16.7–NE) |
| 12-month DOR, % (95% CI) | 62.7 (35.1–81.3) | 73.1 (57.5–83.7) |

**12-month DOR (QW + Q2W tal)**

- Anti-CD38 naïve/sensitive (n=13): 83.9%
- Pom naïve/sensitive (n=16): 80.8%
- Anti-CD38 refractory (n=50): 67.0%
- Pom refractory (n=47): 67.0%
- Prior bispecific antibody (n=24): 70.2%
- Prior CAR-T (n=20): 84.4%

Data cut-off: July 29, 2024.
Anti-CD38 naïve = never received anti-CD38 therapy; anti-CD38 sensitive = minimal response or better during treatment; anti-CD38 refractory = best response of SD or PD during treatment or within 60 days of completing anti-CD38 therapy. [a]Response and progression were assessed by investigators, based on IMWG criteria. CAR, chimeric antigen receptor; dara, daratumumab; DOR, duration of response; IMWG, International Myeloma Working Group; NE, not evaluable; PD, progressive disease; pom, pomalidomide; Q2W, every other week; QW, weekly; SD, stable disease; tal, talquetamab.





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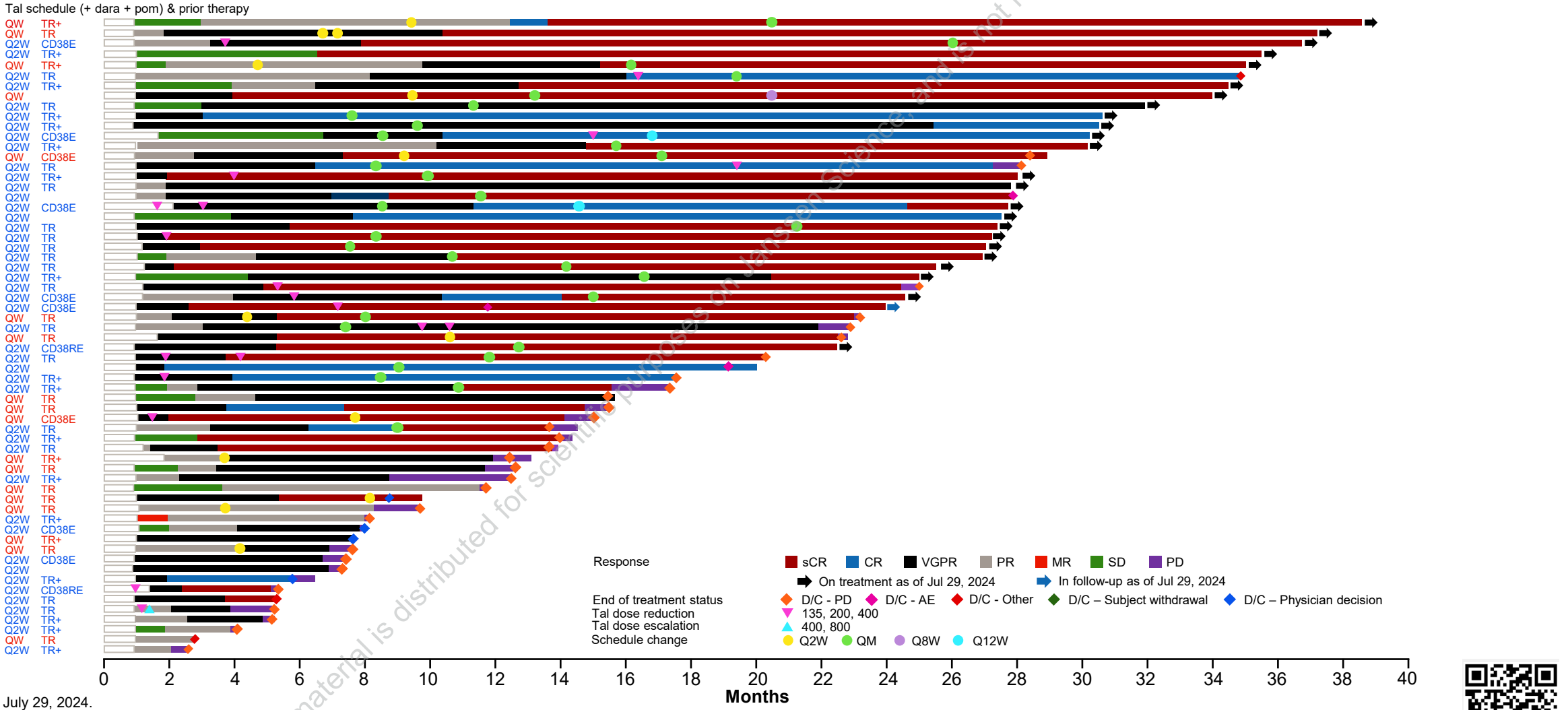
# TRIMM-2 Tal + Dara + Pom Cohort: Responses Deepened Over Time, Including With Reduced Dose Intensity




Data cut-off: July 29, 2024.

+, penta-drug refractory; AE, adverse event; CD38E, anti-CD38 therapy exposed; CD38RE, anti-CD38 therapy refractory; CR, complete response; D/C, discontinuation; MR, minimal response; Q2W, every other week; Q8W, every 8 weeks; Q12W, every 12 weeks; QM, monthly; QW, weekly; PD, progressive disease; PR, partial response; sCR, stringent complete response; SD, stable disease; TR, triple-class refractory; VGPR, very good partial response.





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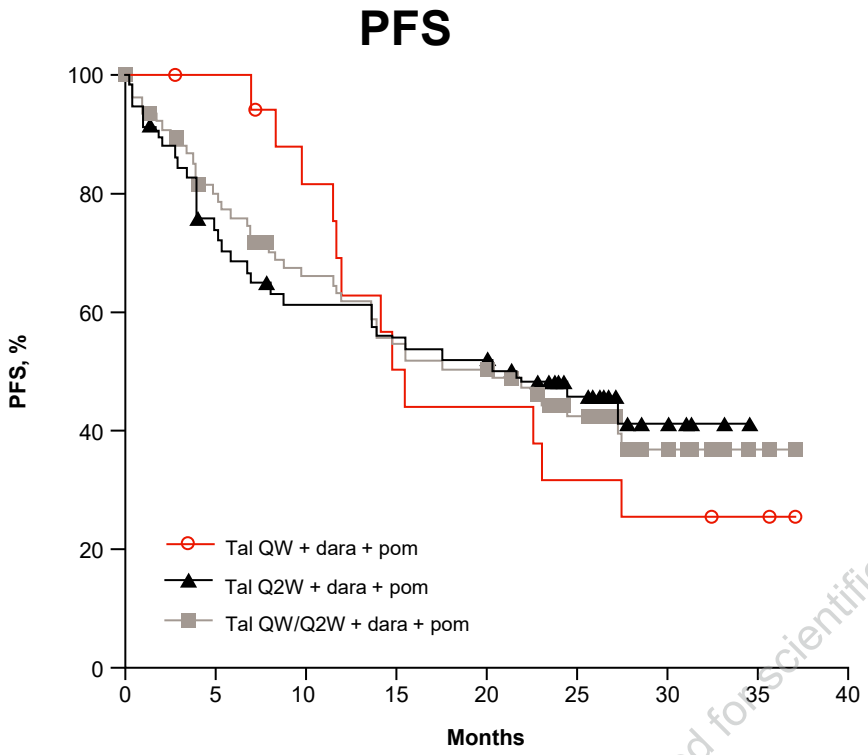
# TRIMM-2 Tal + Dara + Pom Cohort: Promising PFS, Including in Key Exposure Subgroups




| No. at risk | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Tal QW + dara + pom | 18 | 17 | 13 | 8 | 7 | 5 | 4 | 2 | 0 |
| Tal Q2W + dara + pom | 59 | 41 | 33 | 30 | 28 | 18 | 6 | 0 | 0 |
| Tal QW/Q2W + dara + pom | 77 | 58 | 46 | 38 | 35 | 23 | 10 | 2 | 0 |

| Parameter | Tal 0.4 mg/kg QW + dara + pom (n=18) | Tal 0.8 mg/kg Q2W + dara + pom (n=59) |
|---|---|---|
| Median (range) follow-up, months | 15.8 (3.2–37.9) | 17.5 (0.2–37.7) |
| Median PFS, months (95% CI) | 15.4 (11.5–27.5) | 20.3 (7.9–NE) |
| 12-month PFS, % (95% CI) | 62.7 (35.1–81.3) | 61.1 (47.1–72.4) |

**12-month PFS (QW + Q2W tal)**

- Anti-CD38 naïve/sensitive (n=13): 84.6%
- Pom naïve/sensitive (n=19): 68.4%
- Anti-CD38 refractory (n=64): 56.9%
- Pom refractory (n=58): 59.4%
- Prior bispecific antibody (n=29): 69.2%
- Prior CAR-T (n=24): 73.9%

Data cut-off: July 29, 2024.
Anti-CD38 naïve = never received anti-CD38 therapy; anti-CD38 sensitive = minimal response or better during treatment; anti-CD38 refractory = best response of SD or PD during treatment or within 60 days of completing anti-CD38 therapy. CAR, chimeric antigen receptor; dara, daratumumab; NE, not evaluable; PD, progressive disease; pom, pomalidomide; PFS, progression-free survival; Q2W, every other week; QW, weekly; SD, stable disease; tal, talquetamab.





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# TRIMM-2 Tal + Dara + Pom Cohort: Conclusions

- **Novel tal + dara + pom triplet showed deep and durable responses in patients with RRMM, particularly those with prior bispecific antibody exposure and CD38- and/or pom-refractory disease**
  - ORR 82% and ≥CR 56% overall
  - ORR 78–83% and ≥CR 52–71% across key exposure or refractory subgroups
  - With Q2W tal dosing, 76% ORR, median DOR 26 months, and median PFS 20 months
- **Safety of triplet consistent with known profiles of individual agents, supporting combinability of tal**
  - Despite high rate of neutropenia, grade 3/4 infections consistent with addition of dara and pom to tal
  - Taste, skin, and nail AEs were low grade, with no discontinuations of tal
- **Novel triplet combination with Q2W tal warrants further investigation**
  - Phase 3 MonumenTAL-3 trial of tal + dara ± pom vs dara + pom + dex in patients with RRMM and ≥1 prior LOT (NCT05455320)



AE, adverse event; CR, complete response; dara, daratumumab; dex, dexamethasone; DOR, duration of response; LOT, line of therapy; ORR, overall response rate; PFS, progression-free survival; pom, pomalidomide; Q2W, every other week; QW, weekly; RRMM, relapsed/refractory multiple myeloma; tal, talquetamab.



Presented by N Bahlis at 21st International Myeloma Society (IMS) Annual Meeting; September 25–28, 2024; Rio de Janeiro, Brazil

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