Phase 2 Study of Teclistamab-based Induction Regimens in Patients With Transplant-eligible Newly Diagnosed Multiple Myeloma: Results From the GMMG-HD10/DSMM-XX (MajesTEC-5) Trial*

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https://www.congresshub.com/ASH2024/Oncology/Teclistamab/Raab

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GMMG-HD10/DSMM-XX/MajesTEC-5: Introduction

- Teclistamab (Tec), a first-in-class BCMA × CD3 BsAb with weight-based dosing, is approved in TCE RRMM and is being evaluated as monotherapy in early-line RRMM and in daratumumab (Dara)-based combinations in early-line RRMM and NDMM[1-7]
- Dara-based triplet and quadruplet therapies (DRd, DVRd) have extended survival in NDMM[8-10]
  - MRD negativity (10^{-5}) of 57.5% post-consolidation with DVRd in TE NDMM in the PERSEUS study[11]
- Rationale for Tec-DR or Tec-DVR in transplant-eligible NDMM:
  - Target treatment-naive T cells for potential early eradication of all myeloma subclones to further improve rates of MRD-negativity and long-term outcomes
  - Potentially further augment T-cell cytotoxic activity and enhance efficacy by combining Tec with Dara and Len[12,13]
  - Improve patient outcomes with a steroid-sparing regimen
- MajesTEC-5 is the first study to evaluate the efficacy and safety of Tec-DR[a] and Tec-DVR[a] induction in patients with TE NDMM; here, we present initial outcomes from 3 induction cohorts in our phase 2 study

[a]Dexamethasone was also administered in C1 and C2.

BCMA, B-cell maturation antigen; BsAb, bispecific antibody; C, Cycle; D, daratumumab; d, dexamethasone; GMMG/DSMM, German-speaking Myeloma Multicenter Group/Deutsche Studiengruppe Multiples Myelom; MRD, minimal residual disease; NDMM, newly diagnosed multiple myeloma; R, lenalidomide; RRMM, relapsed/refractory multiple myeloma; TCE, triple-class–exposed; TE, transplant-eligible; Tec, teclistamab; V, bortezomib.

1. TECVAYLI® (teclistamab). Summary of product characteristics. Janssen Biologics BV; 2024. 2. TECVAYLI® (teclistamab-cqyv) injection [package insert]. Janssen Biotech, Inc.; 2024. 3. Moreau P, et al. *N Engl J Med*. 2022;387(6):495-505. 4. Garfall AL, et al. *J Clin Oncol*. 2024;42(16 suppl). Abstract 7540. 5. Touzeau C, et al. *J Clin Oncol*. 2024;42(16 suppl). Abstract 7506. 6. Searle E, et al. *Blood*. 2022;140(suppl 1):394-396. 7. Rodriguez-Otero P, et al. *Blood*. 2021;138(suppl 1):1647. 8. Facon T, et al. *Lancet Oncol*. 2021;22(11):1582-1596. 9. Sonneveld P, et al. *N Engl J Med*. 2024;390(4):301-313. 10. Facon T, et al. *N Engl J Med*. 2019;380(22):2104-2115. 11. Rodriguez-Otero P, et al. Presented at: American Society of Clinical Oncology (ASCO) Annual Meeting; May 31-June 4, 2024; Chicago, IL, USA. Abstract 7502. 12. Frerichs KA, et al. *Clin Cancer Res*. 2020:26(9):2203-2215.13. Cho SF, et al. *Blood Adv.* 2020;4(17):4195-4207.

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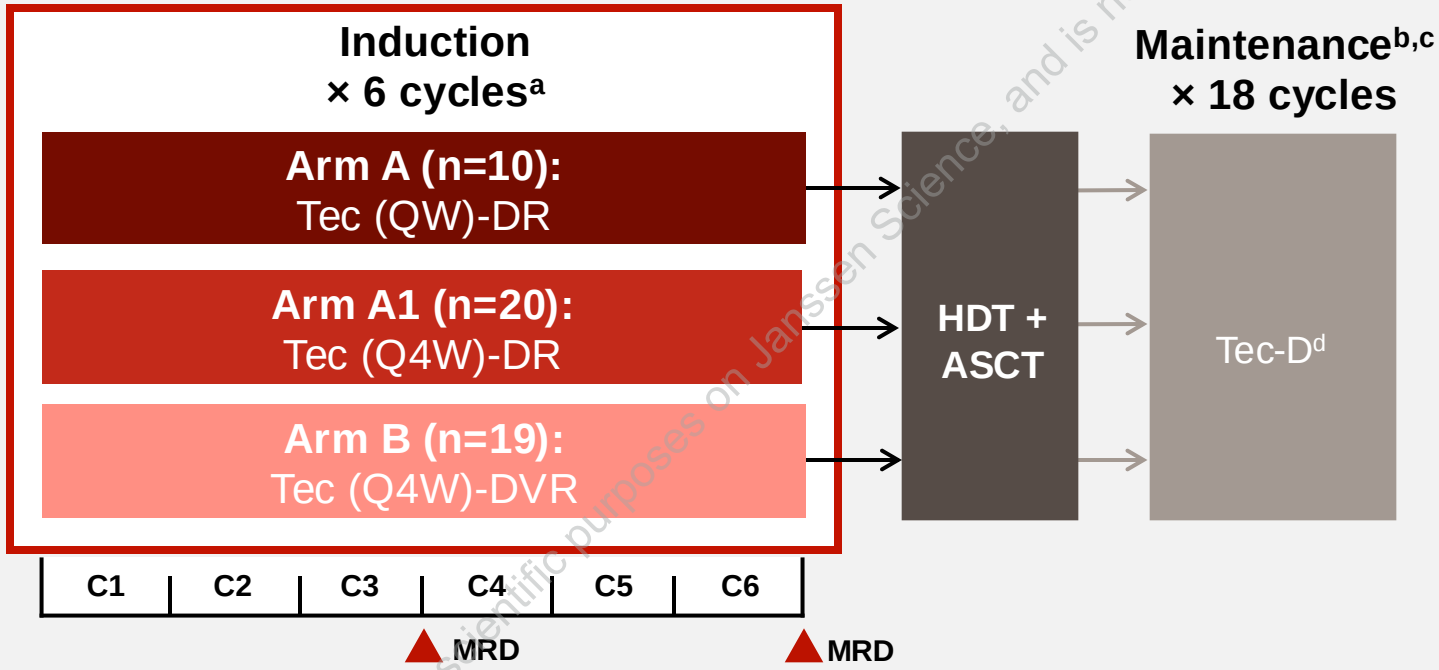
GMMG-HD10/DSMM-XX/MajesTEC-5: Study Design

Key eligibility criteria:

- TE NDMM
- ECOG PS score of 0-2
- Aged 18-70 years



Primary endpoint:
- AEs, SAEs

Select secondary endpoints:
- MRD negativity (10^{-5})
- ORR
- ≥CR
- ≥VGPR
- Stem cell yield

- Per protocol, MRD assessments by NGF were planned following completion of C3 and C6 in all patients
- Additional cohorts evaluating Tal and Tec/Tal combinations are also being investigated as part of this study

[a]Each cycle is 28 days. Dexamethasone was also administered in C1 and C2. Stem cell collection was planned after 3 cycles of induction. [b]Following maintenance therapy, patients could receive additional SoC maintenance treatment per institutional standard and local investigator decision. [c]Maintenance treatment can be discontinued when 12 months of sustained MRD negativity (10^{-5}) have been observed, beginning in induction. [d]Planned maintenance treatment in Arm A was Tec-DR. A protocol amendment permitted patients initially assigned to Tec-DR maintenance to receive Tec-D maintenance per investigator's choice (patients who started Tec-DR may have discontinued Len to receive Tec-D per investigator's choice).
AE, adverse event; ASCT, autologous stem cell transplant; C, Cycle; CR, complete response; D, daratumumab; ECOG PS, Eastern Cooperative Oncology Group performance status; GMMG/DSMM, German-speaking Myeloma Multicenter Group/Deutsche Studiengruppe Multiples Myelom; HDT, high-dose therapy; Len, lenalidomide; MRD, minimal residual disease; NDMM, newly diagnosed multiple myeloma; NGF, next-generation flow cytometry; ORR, overall response rate; QW, weekly; Q4W, every 4 weeks; R, lenalidomide; SAE, serious adverse event; SoC, standard-of-care; Tal, talquetamab; TE, transplant-eligible; Tec, teclistamab; V, bortezomib; VGPR, very good partial response.

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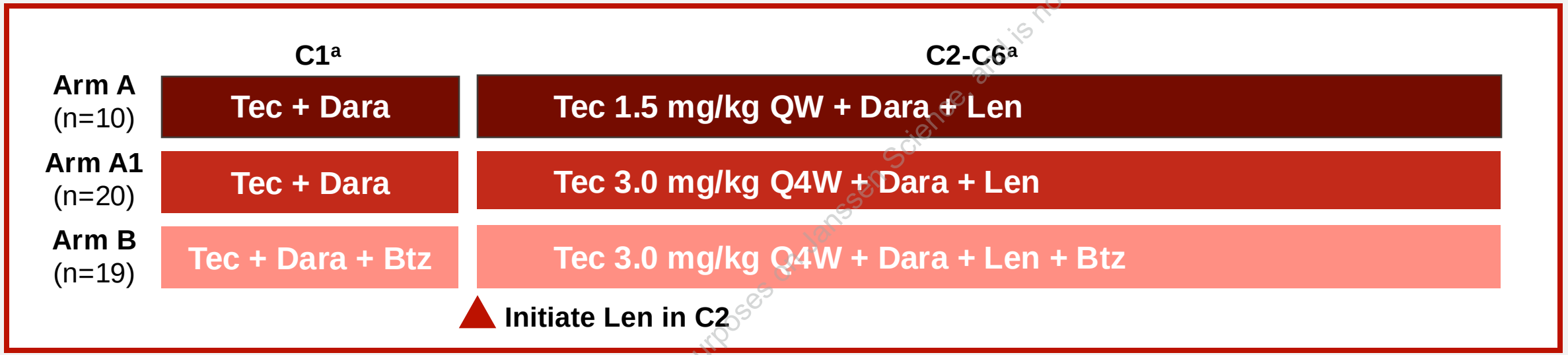
GMMG-HD10/DSMM-XX/MajesTEC-5: Dosing Schedule



- **Tec in C1:** Tec step up[a] + 1.5 mg/kg on Days 8 and 15[b]
- **Dara:** 1800 mg SC per label (QW for C1 and C2; Q2W for C3-C6)
- **Btz:** 1.3 mg/m^2 SC QW
- **Len:** 25 mg PO daily starting in C2 (Days 1-21)
- **Dex:** 20 mg (PO or IV) in C1 and C2[c]

[a]Patients received step-up doses of 0.06 and 0.3 mg/kg on Day 2 and 4. [b]Patients in Arm A received an additional dose of Tec 1.5 mg/kg on Day 22.[c]Days 1-2, 8-9, 15-16, and 22-23.
Btz, bortezomib; C, Cycle; Dara, daratumumab; Dex, dexamethasone; GMMG/DSMM, German-speaking Myeloma Multicenter Group/Deutsche Studiengruppe Multiples Myelom; IV, intravenously; Len, lenalidomide; PO, orally; QW, weekly; Q2W, every 2 weeks; Q4W, every 4 weeks; SC, subcutaneously; Tec, teclistamab.

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GMMG-HD10/DSMM-XX/MajesTEC-5: Patients With High-risk Disease Were Well Represented

	Arm A: Tec (QW)-DR (n=10)	Arm A1: Tec (Q4W)-DR (n=20)	Arm B: Tec (Q4W)-DVR (n=19)	Total (N=49)
Median age, years (range)	63.0 (54-66)	57.5 (36-65)	56.0 (30-68)	58.0 (30-68)
≥65, n (%)	3 (30)	2 (10)	3 (15.8)	8 (16.3)
Male, n (%)	6 (60)	13 (65)	12 (63.2)	31 (63.3)
Ethnicity, n (%)				
Caucasian	10 (100)	20 (100)	19 (100)	49 (100)
ECOG PS score, n (%)				
≤1	9 (90)	20 (100)	18 (94.7)	47 (95.9)
2	1 (10)	0	1 (5.3)	2 (4.1)
≥60% BMPCs, n (%)	4 (40)	10 (50)	8 (42.1)	22 (44.9)
≥1 soft tissue plasmacytoma,[a] n (%)	0	5 (25)	3 (15.8)	8 (16.3)
ISS disease stage, n (%)				
I	8 (80)	10 (50)	10 (52.6)	28 (57.1)
II	1 (10)	7 (35)	7 (36.8)	15 (30.6)
III	1 (10)	3 (15)	2 (10.5)	6 (12.2)
High cytogenetic risk,[b] n (%)	1 (10)	5 (25)	4 (21.1)	10 (20.4)

Data cutoff: September 30, 2024. [a]All bone-related soft tissue plasmacytomas; no extramedullary soft tissue plasmacytomas. [b]Cytogenetic risk is based on central FISH or local FISH and karyotype testing if central FISH is unavailable. High cytogenetic risk is defined as the presence of ≥1 of the following abnormalities: del(17p), t(4;14), or t(14;16).
BMPC, bone marrow plasma cell; D, daratumumab; ECOG PS, Eastern Cooperative Oncology Group performance status; FISH, fluorescence in situ hybridization; GMMG/DSMM, German-speaking Myeloma Multicenter Group/Deutsche Studiengruppe Multiples Myelom; ISS, International Staging System; QW, weekly; Q4W, every 4 weeks; R, lenalidomide; Tec, teclistamab; V, bortezomib.

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GMMG-HD10/DSMM-XX/MajesTEC-5: Disposition

	Arm A: Tec (QW)-DR	Arm A1: Tec (Q4W)-DR	Arm B: Tec (Q4W)-DVR	Total
Patients starting induction, n	10	20	19	49
Ongoing induction, n (%)	0	14 (70)	10 (52.6)	24 (49)
Discontinued study treatment during induction, n (%)	0	1 (5)	1 (5.3)	2 (4.1)[a]

- Stem cell mobilization was feasible with Tec-DR and Tec-DVR, yielding a median number of CD34-positive cells of 8.4 × 10^6/kg across arms

Data cutoff: September 30, 2024. [a]Both discontinuations were due to patient refusal of further study treatment.
D, daratumumab; GMMG/DSMM, German-speaking Myeloma Multicenter Group/Deutsche Studiengruppe Multiples Myelom; QW, weekly; Q4W, every 4 weeks; R, lenalidomide; Tec, teclistamab; V, bortezomib.

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GMMG-HD10/DSMM-XX/MajesTEC-5: Hematologic TEAEs

TEAEs, n (%)[a]	Arm A: Tec (QW)-DR (n=10)		Arm A1: Tec (Q4W)-DR (n=20)		Arm B: Tec (Q4W)-DVR (n=19)		Total (N=49)	
	All grade	Grade 3/4	All grade	Grade 3/4	All grade	Grade 3/4	All grade	Grade 3/4
Hematologic								
Neutropenia	4 (40)	3 (30)	13 (65)	13 (65)	14 (73.7)	12 (63.2)	31 (63.3)	28 (57.1)
Lymphopenia	8 (80)	7 (70)	7 (35)	7 (35)	7 (36.8)	7 (36.8)	22 (44.9)	21 (42.9)
Thrombocytopenia	3 (30)	1 (10)	7 (35)	2 (10)	7 (36.8)	1 (5.3)	17 (34.7)	4 (8.2)
Anemia	5 (50)	0	6 (30)	4 (20)	5 (26.3)	0	16 (32.7)	4 (8.2)
Leukopenia	5 (50)	2 (20)	3 (15)	2 (10)	6 (31.6)	5 (26.3)	14 (28.6)	9 (18.4)

- The most common hematologic TEAE was neutropenia
- Weekly bortezomib did not increase the frequency of thrombocytopenia

Data cutoff: September 30, 2024. [a]TEAEs reported in ≥25% of patients in any arm. AEs are graded according to the NCI-CTCAE Version 5.0.
AE, adverse event; D, daratumumab; GMMG/DSMM, German-speaking Myeloma Multicenter Group/Deutsche Studiengruppe Multiples Myelom; NCI-CTCAE, National Cancer Institute Common Terminology Criteria for Adverse Events; QW, weekly; Q4W, every 4 weeks; R, lenalidomide; TEAE, treatment-emergent adverse event; Tec, teclistamab; V, bortezomib.

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GMMG-HD10/DSMM-XX/MajesTEC-5: Nonhematologic TEAEs

TEAEs, n (%)[a]	Arm A: Tec (QW)-DR (n=10)		Arm A1: Tec (Q4W)-DR (n=20)		Arm B: Tec (Q4W)-DVR (n=19)		Total (N=49)	
	All grade	Grade 3/4	All grade	Grade 3/4	All grade	Grade 3/4	All grade	Grade 3/4
Nonhematologic[b]								
CRS	6 (60)	0	14 (70)	0	12 (63.2)	0	32 (65.3)	0
Pyrexia	6 (60)	1 (10)	9 (45)	2 (10)	7 (36.8)	0	22 (44.9)	3 (6.1)
URTI	6 (60)	0	8 (40)	1 (5)	6 (31.6)	0	20 (40.8)	1 (2)
Rash	5 (50)	2 (20)	5 (25)	0	7 (36.8)	0	17 (34.7)	2 (4.1)
GGT increased	3 (30)	0	6 (30)	3 (15)	5 (26.3)	3 (15.8)	14 (28.6)	6 (12.2)
Diarrhea	6 (60)	0	4 (20)	1 (5)	4 (21.1)	0	14 (28.6)	1 (2)
Hypokalemia	1 (10)	0	8 (40)	2 (10)	4 (21.1)	0	13 (26.5)	2 (4.1)
Nausea	1 (10)	0	4 (20)	0	7 (36.8)	0	12 (24.5)	0
Peripheral sensory neuropathy	1 (10)	0	5 (25)	0	4 (21.1)	0	10 (20.4)	0
BAP increased	4 (40)	0	1 (5)	0	3 (15.8)	1 (5.3)	8 (16.3)	1 (2)
ALT increased	3 (30)	0	2 (10)	1 (5)	2 (10.5)	2 (10.5)	7 (14.3)	3 (6.1)
Nasopharyngitis	3 (30)	0	2 (10)	0	2 (10.5)	0	7 (14.3)	0
Lipase increased	1 (10)	1 (10)	5 (25)	3 (15)	1 (5.3)	1 (5.3)	7 (14.3)	5 (10.2)
Hyperglycemia	3 (30)	0	3 (15)	1 (5)	0	0	6 (12.2)	1 (2)
Constipation	0	0	1 (5)	0	5 (26.3)	0	6 (12.2)	0

- Among the most common nonhematologic TEAEs, rates of grade 3/4 events were low
- All CRS events were grade 1/2
  - Most occurred in C1
  - All resolved; no discontinuations due to CRS
- No ICANS
- No grade 5 TEAEs

Data cutoff: September 30, 2024. [a]TEAEs reported in ≥25% of patients in any arm. AEs are graded according to the NCI-CTCAE Version 5.0. [b]Hypogammaglobulinemia based on TEAE reporting also met the ≥25% threshold and is reported separately.
AE, adverse event; ALT, alanine aminotransferase; BAP, blood alkaline phosphatase; CRS, cytokine release syndrome; D, daratumumab; GGT, gamma-glutamyltransferase; GMMG/DSMM, German-speaking Myeloma Multicenter Group/Deutsche Studiengruppe Multiples Myelom; ICANS, immune effector cell–associated neurotoxicity syndrome; NCI-CTCAE, National Cancer Institute Common Terminology Criteria for Adverse Events; QW, weekly; Q4W, every 4 weeks; R, lenalidomide; TEAE, treatment-emergent adverse event; Tec, teclistamab; URTI, upper respiratory tract infection; V, bortezomib.

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GMMG-HD10/DSMM-XX/MajesTEC-5: Infections

TEAE, n (%)[a]	Arm A: Tec (QW)-DR (n=10)		Arm A1: Tec (Q4W)-DR (n=20)		Arm B: Tec (Q4W)-DVR (n=19)		Total (N=49)	
	All grade	Grade 3/4	All grade	Grade 3/4	All grade	Grade 3/4	All grade	Grade 3/4
Any infection	10 (100)	4 (40)	18 (90)	9 (45)	11 (57.9)	4 (21.1)	39 (79.6)	17 (34.7)
Infections[b]								
URTI	6 (60)	0	8 (40)	1 (5)	6 (31.6)	0	20 (40.8)	1 (2)
COVID-19	2 (20)	0	4 (20)	1 (5)	3 (15.8)	3 (15.8)	9 (18.4)	4 (8.2)
Nasopharyngitis	3 (30)	0	2 (10)	0	2 (10.5)	0	7 (14.3)	0
Bronchitis	2 (20)	0	0	0	0	0	2 (4.1)	0
Infection (NOS)	0	0	1 (5)	1 (5)	2 (10.5)	1 (5.3)	3 (6.1)	2 (4.1)
Pneumonia	1 (10)	1 (10)	1 (5)	0	2 (10.5)	2 (10.5)	4 (8.2)	3 (6.1)

- 17 (34.7%) patients had grade 3/4 infections
  - URTI and COVID-19 were the most common all grade
  - No discontinuations due to infection
  - No grade 5 infections
- Hypogammaglobulinemia[c] was reported in 45 (91.8%) patients
  - 44 (89.8%) received ≥1 dose of IVIg[d]
- Infection prophylaxis, including Ig replacement, was strongly recommended[e]

Data cutoff: September 30, 2024. [a]AEs are graded according to the NCI-CTCAE Version 5.0. [b]Infections reported in >10% of patients in any arm. [c]Includes patients with ≥1 TEAE of hypogammaglobulinemia or post-baseline IgG value <400 mg/dL. [d]Includes patients who started IVIg prior to Tec. [e]Prophylaxis for *Pneumocystis jirovecii* pneumonia and herpes zoster reactivation was also recommended, as well as routine antibiotic prophylaxis.
D, daratumumab; GMMG/DSMM, German-speaking Myeloma Multicenter Group/Deutsche Studiengruppe Multiples Myelom; Ig, immunoglobulin; IgG, immunoglobulin G; IVIg, intravenous immunoglobulin; NCI-CTCAE, National Cancer Institute Common Terminology Criteria for Adverse Events; NOS, not otherwise specified; QW, weekly; Q4W, every 4 weeks; R, lenalidomide; TEAE, treatment-emergent adverse event; Tec, teclistamab; URTI, upper respiratory tract infection; V, bortezomib.

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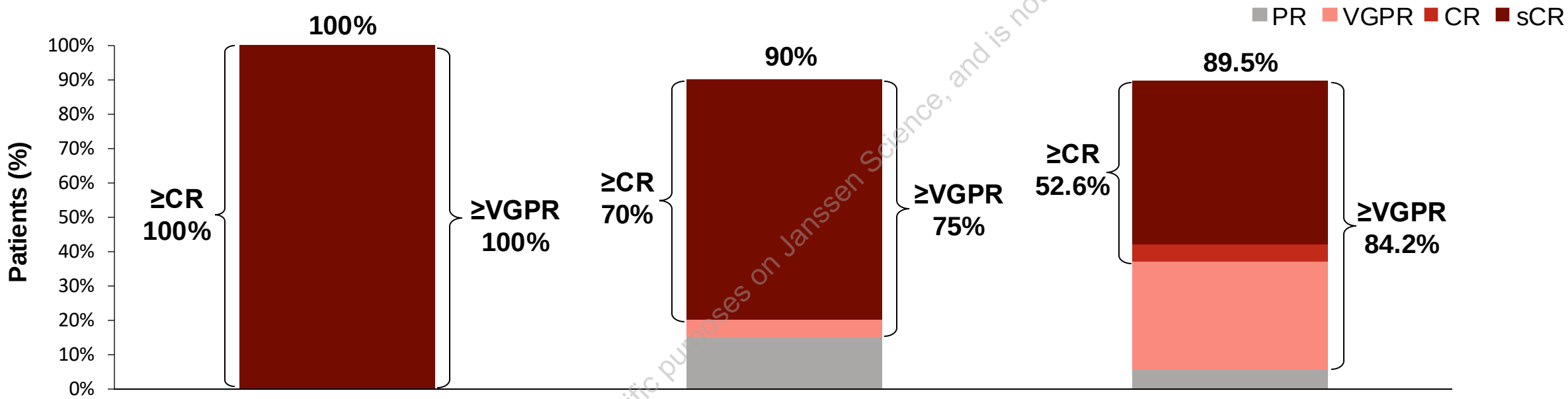
GMMG-HD10/DSMM-XX/MajesTEC-5: Response Rates[a]



	Arm A: Tec (QW)-DR n=10	Arm A1[b]: Tec (Q4W)-DR n=20	Arm B[c]: Tec (Q4W)-DVR n=19
Induction complete, n	10	5[d]	8[e]
Induction ongoing, n	0	14	10

100% sCR observed in Arm A, with deepening responses in maturing cohorts

Data cutoff: September 30, 2024. [a]Response was assessed by investigators based on IMWG criteria. Confirmed response required ≥2 consecutive identical responseassessments. Response rates are presented during induction only. [b]2 (10.0%) patients had stable disease. [c]2 (10.5%) patients had stable disease. [d]1 patient discontinued due to refusal of further treatment. [e]1 patient discontinued due to refusal of further treatment.
CR, complete response; D, daratumumab; GMMG/DSMM, German-speaking Myeloma Multicenter Group/Deutsche Studiengruppe Multiples Myelom; IMWG, International Myeloma Working Group; PR, partial response; QW, weekly; Q4W, every 4 weeks; R, lenalidomide; sCR, stringent complete response; Tec, teclistamab; V, bortezomib; VGPR, very good partial response.

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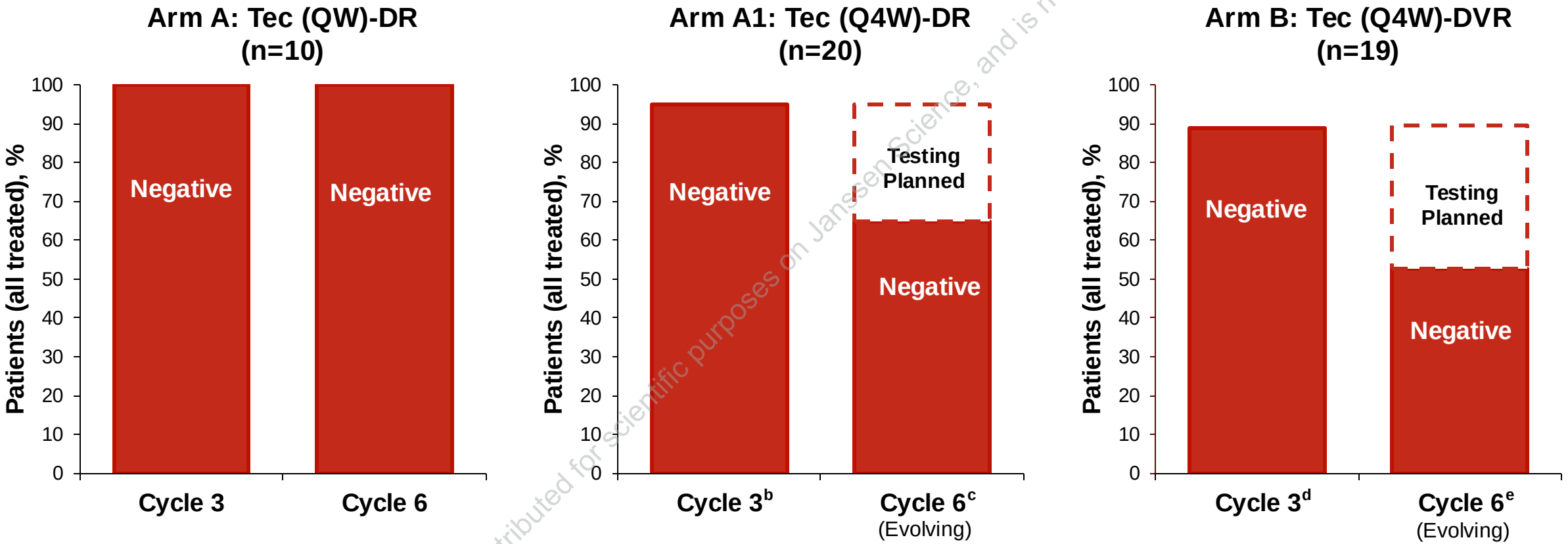
GMMG-HD10/DSMM-XX/MajesTEC-5: MRD Negativity (10^{-5})[a]



100% of evaluable patients achieved MRD negativity by C3; no patients were MRD positive

Data cutoff: September 30, 2024. [a]MRD-negativity rate was defined as the proportion of patients who achieved MRD negativity (10^{-5}), regardless of response. MRD was determined by NGF testing. [b]In Arm A1, 1 patient did not have bone marrow collected after C3. [c]In Arm A1, 1 patient did not have MRD testing (10^{-5}) after C6. [d]In Arm B, 1 patient was not tested at C3, but was MRD-negative at C6; 1 patient discontinued before C3 and had no on-study MRD testing. [e]In Arm B, 1 patient was MRD negative at 10^{-4} after C6 and was considered indeterminate and without available MRD testing (10^{-5}); 1 patient discontinued before C3 and had no on-study MRD testing.

C, Cycle; D, daratumumab; GMMG/DSMM, German-speaking Myeloma Multicenter Group/Deutsche Studiengruppe Multiples Myelom; MRD, minimal residual disease; NGF, next-generation flow cytometry; QW, weekly; Q4W, every 4 weeks; R, lenalidomide; Tec, teclistamab; V, bortezomib.

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GMMG-HD10/DSMM-XX/MajesTEC-5: Conclusions

- Tec-DR[a] and Tec-DVR[a] induction was feasible, with very high and early clinical efficacy in patients with TE NDMM
- MRD negativity (10^{-5}) was achieved in 100% of MRD-evaluable patients after C3 and maintained in evaluable patients through C6
- No TEAE-related discontinuations and no new safety signals compared with individual regimen components
- Infections were common, 34.7% of patients had grade 3/4 infections, and no grade 5 events were reported
  - Infection prophylaxis, including Ig replacement, was adopted
- Stem cell mobilization was feasible with Tec-D(V)R[a]

Teclistamab in combination with daratumumab-based standard of care in patients with transplant-eligible NDMM demonstrates promising efficacy with unprecedented early MRD-negativity rates

[a]Dexamethasone was also administered in C1 and C2.
C, Cycle; D, daratumumab; d, dexamethasone; GMMG/DSMM, German-speaking Myeloma Multicenter Group/Deutsche Studiengruppe Multiples Myelom; Ig, immunoglobulin; MRD, minimal residual disease; NDMM, newly diagnosed multiple myeloma; R, lenalidomide; TE, transplant-eligible; Tec, teclistamab; TEAE, treatment-emergent adverse event; V, bortezomib.

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- Data and safety monitoring committee
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- Leo Rasche is a co-principal investigator of this study

- This study was sponsored by the Heidelberg University Hospital

GMMG/DSMM, German-speaking Myeloma Multicenter Group/Deutsche Studiengruppe.
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https://www.congresshub.com/ASH2024/Oncology/Teclistamab/Raab

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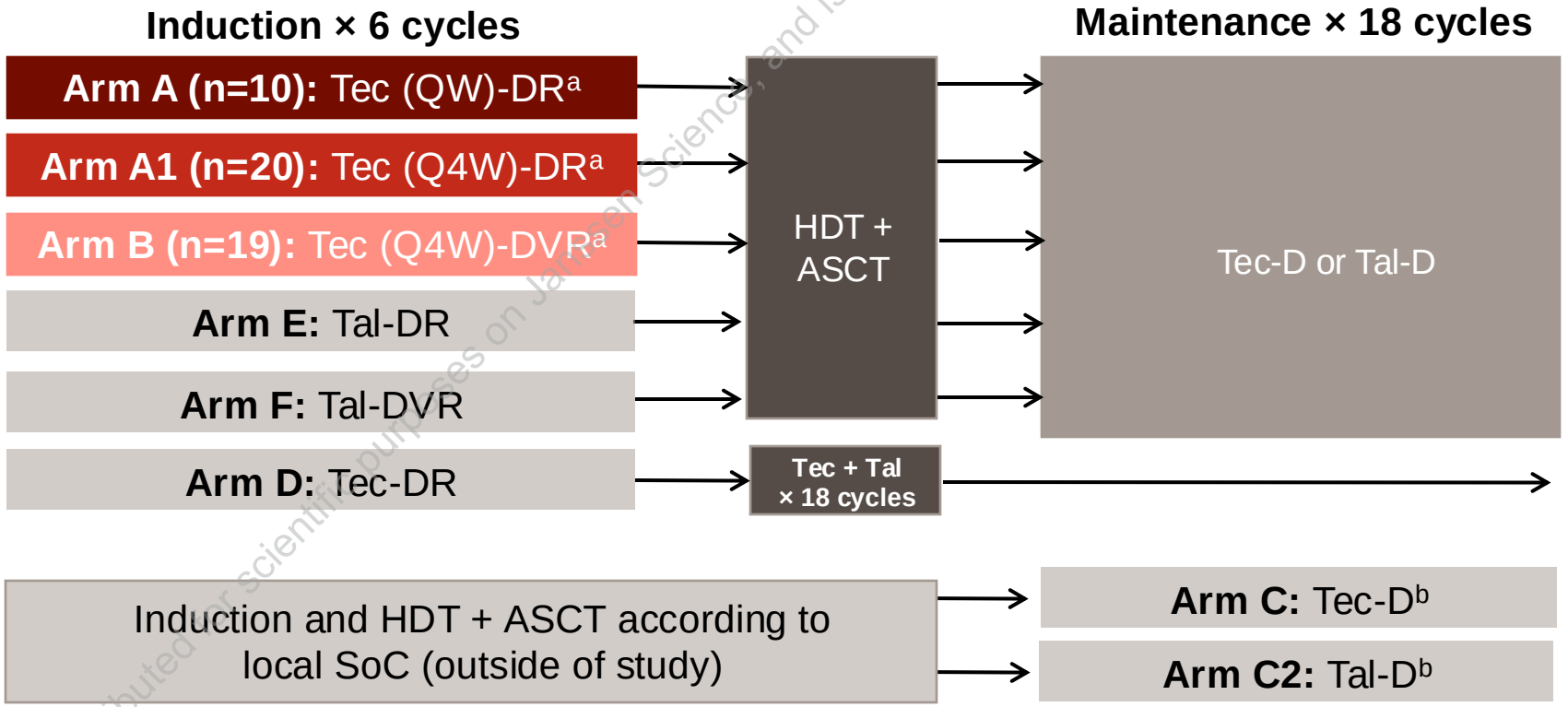
GMMG-HD10/DSMM-XX/MajesTEC-5: Future Directions

- Patients in Arms A, A1, and B who complete induction and receive transplant are progressing on to Tec-D maintenance therapy
- Additional cohorts evaluating Tal and Tec/Tal combinations are also being investigated as part of this study



[a]Dexamethasone was also administered in C1 and C2. [b]Arms C and C2 include patients who are post-induction and HDT + ASCT according to local SoC (outside of the study) with ≥PR.
ASCT, autologous stem cell transplant; C, Cycle; D, daratumumab; GMMG/DSMM, German-speaking Myeloma Multicenter Group/Deutsche Studiengruppe Multiples Myelom; HDT, high-dose therapy; PR, partial response; QW, weekly; Q4W, every 4 weeks; R, lenalidomide; SoC, standard of care; Tal, talquetamab; Tec, teclistamab; V, bortezomib.
ClinicalTrials.gov Identifier: NCT05695508. Accessed November 18, 2024. https://clinicaltrials.gov/study/NCT05695508.

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