Post-Induction Outcomes and Updated Minimal Residual Disease Analysis From GMMG-HD10/DSMM-XX (MajesTEC-5): a Study of Teclistamab-Based Induction Regimens in Newly Diagnosed Multiple Myeloma (NDMM)*



deutsche studiengruppe multiples myelom



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

- Teclistamab (Tec), the first-in-class BCMA × CD3 BsAb with weight-based dosing,^{1,2} has demonstrated high response rates and a favorable safety profile in heavily pretreated RRMM³
- Dara-based frontline SoC regimens have led to notable efficacy in NDMM, as shown in PERSEUS
 (D-VRd) with a post-consolidation MRD-negative (10⁻⁵) ≥CR rate of 57.5%, which deepened over time⁴
- The demonstrated association between deep MRD-negativity rates and improved long-term survival outcomes highlights the need for novel therapies to further enhance the depth of response^{5,6}
- Tec-Dara—based immunotherapy combinations may enhance overall antimyeloma effects
 - Dara depletes immunosuppressive T cells, creating a sensitive immune microenvironment for Tec-mediated cytotoxicty,⁷ resulting in durable and sustained antimyeloma activity
 - Efficacy may be further potentiated with an IMiD ± PI, without the need for continuous steroid use



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

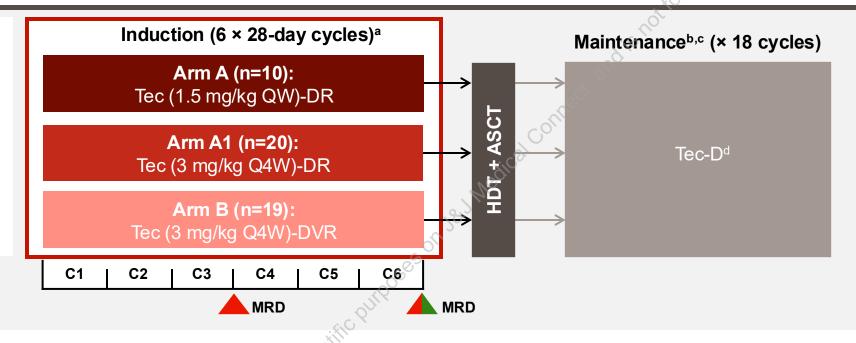
- MajesTEC-5 is the first study to evaluate Tec-Dara—based induction regimens in TE NDMM
- As presented at ASH 2024, Tec-D(V)R induction showed unprecedented efficacy and manageable safety in 49 patients from 3 cohorts in MajesTEC-5¹
 - 100% MRD negativity (10⁻⁵) was achieved in MRD-evaluable patients after induction Cycle 3
 - No TEAE-related discontinuations or new safety signals were observed
- Here, we present updated results for these 49 patients following completion of induction, which includes:
 - Additional MRD testing, including MRD at 10⁻⁶ data after induction Cycle 6
 - Additional stem cell mobilization data
 - A comprehensive safety dataset within induction phase



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

Key eligibility criteria:

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



- **Primary endpoints:**
- AEs, SAEs

Select secondary endpoints:

- MRD negativity (10⁻⁵ and 10⁻⁶)
- ORR
- ≥CR
- ≥VGPR
- · Stem cell yield



- Tec (Cycle 1): Tec step-up dosing (0.06 and 0.3 mg/kg on Days 2 and 4) + 1.5 mg/kg on Days 8 and 15e
 - Tec (Cycles 2-6): 1.5 mg/kg QW on Day 1 (Arm A); 3 mg/kg Q4W on Day 1 (Arm A1 and B)
- **D:** 1800 mg SC per label (QW for Cycles 1-2; Q2W for Cycles 3-6)
- V: 1.3 mg/m² SC QW
- R: 25 mg PO daily starting in Cycle 2 (Days 1-21)
- d: 20 mg (PO or IV) in Cycles 1-4 (Arm A) or Cycles 1-2 (Arm A1/B) only

aStem cell collection was planned after 3 cycles of induction. ^bFollowing maintenance therapy, patients could receive additional SoC maintenance treatment per institutional standard and loc al investigator decision. ^cMaintenance treatment can be discontinued when 12 months of sustained MRD negativity (10⁻⁵) have been observed, beginning in induction. ^dPlanned 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 R to receive Tec-D per investigator's choice. Patients in Arm A received an additional dose of Tec 1.5 mg/kg on Day 22. AE, adverse event; ASCT, autologous stem cell transplant; CR, complete response; D, daratumumab; d, dexamethasone; DSMM, Deutsche Studiengruppe Multiples Myelom; ECOG PS, Eastern Cooperative Oncology Group performance status; GMMG, German-speaking Myeloma Multicenter Group; HDT, high-dose therapy; MRD, minimal residual disease; NDMM, newly diagnosed multiple myeloma; NGF, next-generation flow cytometry; NGS, next-generation flow cytometry; NGS, next-generation flow cytometry; NGS, next-generation flow cytometry; NGPR, very quencing; ORR, overall response rate; QW, weekly; Q2W, every 2 weeks; Q4W, every 4 weeks; R, lenalidomide; SAE, serious adverse event; SoC, standard of care; TE, transplant-eligible; Tec, teclistamab; V, bortezomib; VGPR, very open partial response.



GMMG-HD10/DSMM-XX/MajesTEC-5: Baseline Demographics and Disease Characteristics

- Patients were representative of the TE NDMM population¹⁻³
- Patients with high-risk disease were well represented

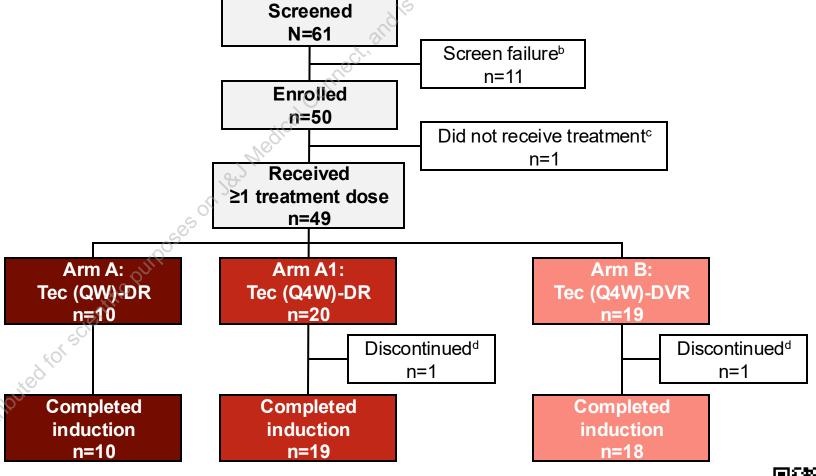
	Arm A: Tec (QW)-DR (n=10)	Arm A1: Tec (Q4W)-DR (n=20)	Arm B: Tec (Q4W)-DVR (n=19)	Total (N=49)
Median age, years (range)	63.0 (54-66)	57.5 (36-65)	56.0 (30-68)	58.0 (30-68)
≥65, n (%)	3 (30)	2 (10)	3 (15.8)	8 (16.3)
Male, n (%)	6 (60)	13 (65)	12 (63.2)	31 (63.3)
Ethnicity, n (%)	70			
Caucasian	10 (100)	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 paraskeletal soft tissue plasmacytoma,ª n (%)	0	5 (25)	4 (21.1)	9 (18.4)
ISS disease stage, n (%)	, ot			
	8 (80)	10 (50)	10 (52.6)	28 (57.1)
	1 (10)	7 (35)	7 (36.8)	15 (30.6)
III "is ^{itti} "	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)

^aAll soft tissue plasmacytomas reported were paraskeletal in nature, whereas no extramedullary soft tissue plasmacytomas were reported. ^bCytogenetic risk is based on central FISH or local FISH 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; DSMM, Deutsche Studiengruppe Multiples Myelom; ECOG PS, Eastern Cooperative Oncology Group performance status; FISH, fluorescence in situ hybridization; GMMG, German-speaking Myeloma Multicenter Group; ISS, International Staging System; NDMM, newly diagnosed multiple myeloma; QW, weekly; Q4W, every 4 weeks; R, lenalidomide; TE, transplant-eligible; Tec, teclistamab; V, bortezomib. 1. Liu X, et al. *Sci Rep.* 2025;15(1):13595. 2. Abildgaard N, et al. *Eur J Cancer*. 2024;201:113921. 3. Martínez-Lopez J, et al. *Future Oncol.* 2023;19(31):2103-2121.



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

- 47 of 49 (95.9%) patients completed induction^a
- Median (range) induction treatment duration:
 7.0 (2.5-13.2) months
- Median (range) follow-up:7.3 (3.1-14.5) months
- No new study discontinuations since prior analysis,¹ with 7 months of additional follow-up



^aOne patient in Arm B skipped Cycle 6 of induction due to neutropenia but proceeded to receive ASCT and maintenance and therefore was considered as having completed induction. A total of 46 patients completed 6 cycles of induction. Not meeting inclusion criteria, n=9; "other" reasons, n=2. "Upon further review, 1 patient did not meet inclusion criteria. Both patients (Arm A1, n=1; Arm B, n=1) discontinued induction after Cycle 3 due to refusal of further study treatment. ASCT, autologous stem cell treatment; D, daratumumab; DSMM, Deutsche Studiengruppe Multiples Myelom; GMMG, German-speaking Myeloma Multicenter Group; QW, weekly; Q4W, every 4 weeks; R, lenalidomide; Tec, teclistamab; V, bortezomib. 1. Raab MS, et al. Presented at ASH 2024. Oral 493.



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

	Tec (C	rm A: Arm A1: (QW)-DR Tec (Q4W)-DR n=10) (n=20)		Arm B: Tec (Q4W)-DVR (n=19)		Total (N=49)		
TEAEs, n (%)ª	All grade	Grade 3/4	All grade	Grade 3/4	All grade	Grade 3/4	All grade	Grade 3/4
Hematologic				ical Co				
Neutropenia	4 (40)	3 (30)	13 (65)	13 (65)	14 (73.7)	12 (63.2)	31 (63.3)	28 (57.1)
Lymphopenia	9 (90)	8 (80)	9 (45)	9 (45)	12 (63.2)	12 (63.2)	30 (61.2)	29 (59.2)
Anemia	5 (50)	0	8 (40)	4 (20)	7 (36.8)	1 (5.3)	20 (40.8)	5 (10.2)
Thrombocytopenia	3 (30)	1 (10)	7 (35)	2 (10)	7 (36.8)	1 (5.3)	17 (34.7)	4 (8.2)
Leukopenia	5 (50)	2 (20)	3 (15)	2 (10)	6 (31.6)	5 (26.3)	14 (28.6)	9 (18.4)

Neutropenia was the most common all grade hematologic TEAE.

The addition of weekly bortezomib did not increase the rate of thrombocytopenia



aTEAEs reported in ≥25% of patients in any arm. AEs are graded according to the NCI-CTCAE Version 5.0. The median follow-up was 7.3 (3.1-14.5) months.

AE, adverse event; D, daratumumab; DSMM, Deutsche Studiengruppe Multiples Myelom; GMMG, German-speaking Myeloma Multicenter Group; 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.

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

	Tec (Q	n A: \W)-DR =10)	Tec (Q4	1 A1: 4W)-DR =20)	Tec (Q4	n B: W)-DVR :19)	To (N=	tal :49)	•
TEAEs, n (%)ª	All grade	Grade 3/4	All grade	Grade 3/4	All grade	Grade 3/4	All grade	Grade 3/4	
Nonhematologic ^b	-					. C	,0`		_
CRS	6 (60)	0	14 (70)	0	12 (63.2)	0.00	32 (65.3)	0	•
Pyrexia	7 (70)	1 (10)	10 (50)	2 (10)	8 (42.1)	10	25 (51.0)	3 (6.1)	
URTI	6 (60)	0	8 (40)	1 (5)	6 (31.6)	20	20 (40.8)	1 (2)	
Rash	6 (60)	2 (20)	5 (25)	0	8 (42.1)	0	19 (38.8)	2 (4.1)	
GGT increased	3 (30)	0	6 (30)	3 (15)	5 (26.3)	4 (21.1)	14 (28.6)	7 (14.3)	
Hypokalemia	1 (10)	0	9 (45)	2 (10)	4 (21.1)	0	14 (28.6)	2 (4.1)	,
Diarrhea	6 (60)	0	4 (20)	1 (5)	4 (21.1)	0	14 (28.6)	1 (2)	
Nausea	1 (10)	0	4 (20)	0 490	8 (42.1)	0	13 (26.5)	0	_
PN	1 (10)	0	5 (25)	0	4 (21.1)	0	10 (20.4)	0	•
BAP increased	4 (40)	0	1 (5)	(S) 0	3 (15.8)	1 (5.3)	8 (16.3)	1 (2)	•
Lipase increased	1 (10)	1 (10)	5 (25)	3 (15)	1 (5.3)	1 (5.3)	7 (14.3)	5 (10.2)	
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	
Hyperglycemia	3 (30)	0	<i>-</i> 3 (15)	1 (5)	0	0	6 (12.2)	1 (2)	-

- Safety consistent with individual treatment components
- All CRS events were grade 1/2 and resolved
 - 10 (20.4%) were grade 2
 - Most occurred in Cycle 1
 - No discontinuations due to CRS
- No ICANS reported
- No grade 5 TEAEs
- No increase in PN with bortezomib



^aTEAEs reported in ≥25% of patients in any arm. AEs are graded according to the NCI-CTCAE Version 5.0. The median follow-up was 7.3 (3.1-14.5) months. ^bConstipation and hypogammaglobulinemia based on TEAE reporting also met the ≥25% threshold. Hypogammaglobulinemia is reported separately. AE, adverse event; ALT, alanine aminotransferase; BAP, blood alkaline phosphatase; CRS, cytokine release syndrome; D, daratumumab; DSMM, Deutsche Studiengruppe Multiples Myelom; GGT, gamma-glutamyl transferase; GMMG, German-speaking Myeloma Multicenter Group; ICANS, immune effector cell–associated neurotoxicity syndrome; NCI-CTCAE, National Cancer Institute Common Terminology Criteria for Adverse Events; PN, peripheral sensory neuropathy; QW, weekly; Q4W, every 4 weeks; R, lenalidomide; TEAE, treatment-emergent adverse event; Tec, teclistamab; URTI, upper respiratory tract infection: V. bortezomib.

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

	Arn Tec (Q (n=	W)-DR	Arm A1: Tec (Q4W)-DR (n=20)		Arm B: Tec (Q4W)-DVR (n=19)		Total (N=49)	
TEAE, n (%)ª	All grade	Grade 3/4	All grade	Grade 3/4	All grade	Grade 3/4	Ail grade	Grade 3/4
Any infection	10 (100)	4 (40)	18 (90)	10 (50)	11 (57.9)	4 (21.1)b	39 (79.6)	18 (36.7) ^b
Infections	Infections ^c							
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)	2 (10.5)	9 (18.4)	3 (6.1)
Nasopharyngitis	3 (30)	0	2 (10)	0	2 (10.5)	0	7 (14.3)	0
Pneumonia	1 (10)	1 (10)	0	0101	2 (10.5)	2 (10.5)	3 (6.1)	3 (6.1)
RTI	0	0	1 (5)	0	2 (10.5)	0	3 (6.1)	0
Bronchitis	2 (20)	0	0/0/1/2	0	0	0	2 (4.1)	0

- 18 (36.7%) patients had grade 3/4 infections^b
 - No discontinuations due to infection
 - No grade 5 infections
- Hypogammaglobulinemia^d reported in 45 (91.8%) patients
 - 44 (89.8%) patients received ≥1 dose of IVIg
- Stringent infection prophylaxis was strongly recommended,^e including lg replacement
- Low patient numbers and relatively short follow-up time may account for differing infection rates across arms



^aAEs are graded according to the NCI-CTCAE Version 5.0. The median follow-up was 7.3 (3.1-14.5) months. ^bOne patient had a grade 3 "unknown" infection that was reported under the "uncoded" category. ^cInfections reported in >10% of patients in any arm. ^dIncludes patients with ≥1 TEAE of hypogammaglobulinemia or a post-baseline IgG value <400 mg/dL. ^eAdditional recommended measures included prophylaxis for Pneumocystis jirovecii pneumonia and herpes zoster reactivation as well as routine antibiotic prophylaxis. D, daratumumab; DSMM, Deutsche Studiengruppe Multiples Myelom; GMMG, German-speaking Myeloma Multicenter Group; Ig, immunoglobulin; IVIg, intravenous immunoglobulin; NCI-CTCAE, National Cancer Institute Common Terminology Criteria for Adverse Events; QW, weekly; Q4W, every 4 weeks; R, Ienalidomide; RTI, respiratory tract infection; TEAE, treatment-emergent adverse event; Tec, teclistamab; URTI, upper respiratory tract infection; V, bortezomib.

GMMG-HD10/DSMM-XX/MajesTEC-5: Stem Cell Mobilization^a

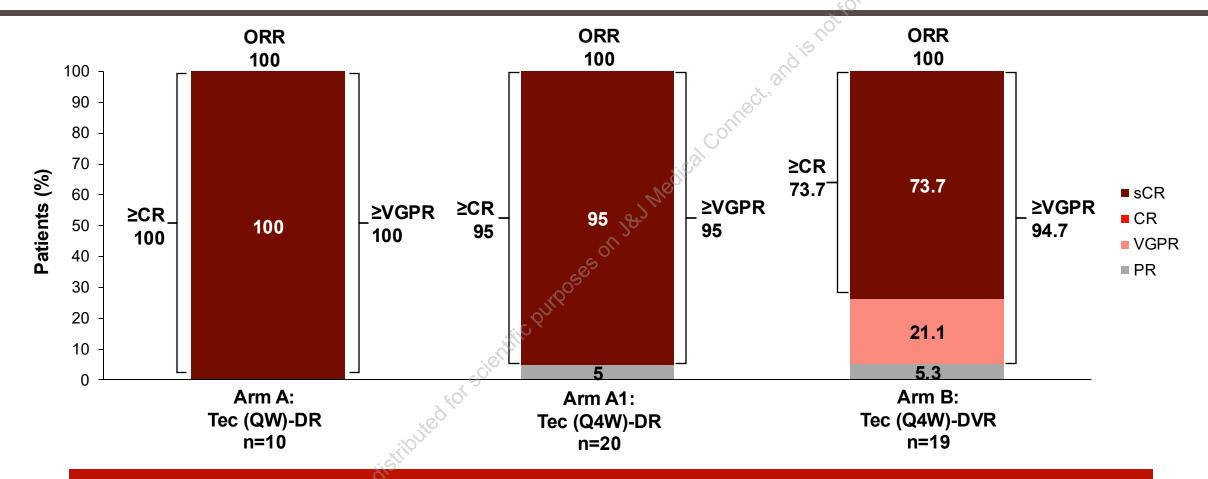
	Arm A: Tec (QW)-DR (n=10)	Arm A1: Tec (Q4W)-DR (n=20)	Arm B: Tec (Q4W)-DVR (n=19)	Total (N=49)			
Undergone stem cell mobilization, ^b n (%)	10 (100)	20 (100)	17 (89.5) ^c	47 (95.9)			
Received plerixaford	2 (20)	11 (55)	7 (41.2)	20 (42.6)			
Received cyclophosphamide and G-CSF ^d	10 (100)	15 (75)	14 (82.4)	39 (83)			
Stem cell yield (10 ⁶ CD34 cells/kg)	S						
Median (range)	8.6 (5.7-14.9)	7.7 (2.6-15.1)	7.5 (2.9-15.9)	8.1 (2.6-15.9)			

Tec-D(V)R enabled successful stem cell mobilization (~96% of patients) with total median stem cell yield surpassing minimum protocol requirements^e

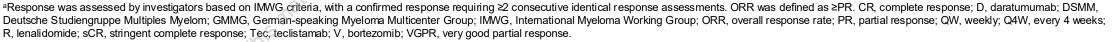


^aStem cell collection was planned after 3 cycles of induction. ^bPercentages are calculated based on the number of patients in each treatment group as the denominator. ^c2 patients in the Tec-DVR group did not undergo mobilization; 1 patient withdrew consent after Cycle 3 and 1 patient failed to proceed to mobilization due to cytopenia and insufficient circulation of CD34+ cells. ^dPercentages are calculated based on the number of patients who underwent stem cell mobilization as the denominator. ^ePer protocol minimum, defined as 2.5×10^e/kg CD34+ cells. In addition, an ideal target was also identified as a yield of 5×10^e/kg CD34+ cells. D, daratumumab; DSMM, Deutsche Studiengruppe Multiples Myelom; G-CSF, granulocyte-colony stimulating factor; GMMG, German-speaking Myeloma Multicenter Group; QW, weekly; Q4W, every 4 weeks; R, lenalidomide; Tec. teclistamab; V, bortezomib.

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



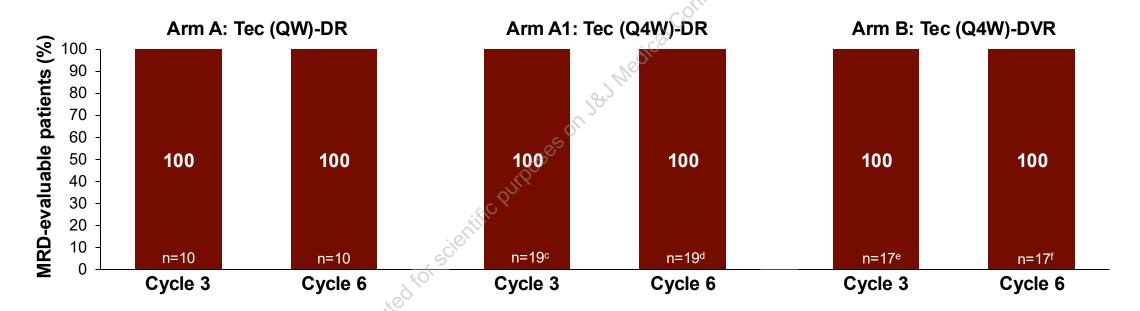
100% of patients responded by the end of induction





GMMG-HD10/DSMM-XX/MajesTEC-5: MRD Negativity (10⁻⁵)^a in the MRD-Evaluable Analysis Set

- MRD-evaluable population: all patients with an available MRD test (positive or negative)
 - Only 1 patient was not evaluable for MRD throughout induction (Cycle 3 or 6) due to discontinuation before Cycle 3

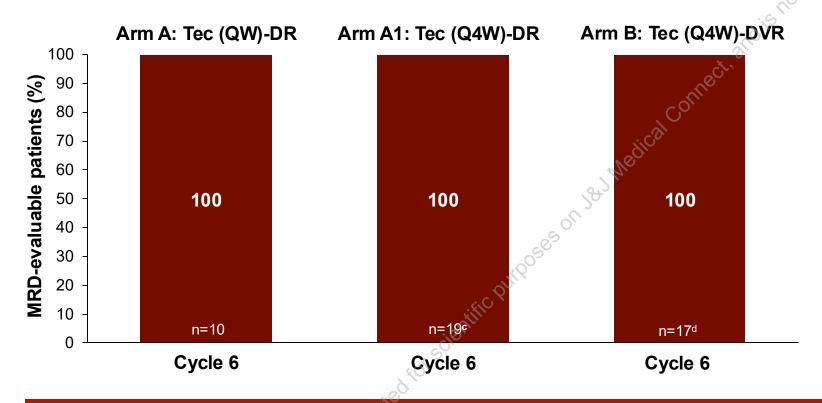


With completion of induction, 100% MRD negativity (10⁻⁵) continues to be observed in MRD-evaluable patients, regardless of depth of response

aMRD-negativity rate was defined as the proportion of patients who achieved MRD negativity (10⁻⁵) per NGF, regardless of response (ie, not all patients achieved CR). bExcluding those who were not tested, indeterminate, or had no baseline clone detected (NGS). Cone patient was not tested. One patient had discontinued after completing Cycle 3. One patient was not tested, and 1 had discontinued before completing Cycle 3. Indeterminate result. CR, complete response; D, daratumumab; DSMM, Deutsche Studiengruppe Multiples Myelom; GMMG, German-speaking Myeloma Multicenter Group; MRD, minimal residual disease; NGF, next-generation flow cytometry; NGS, next-generation sequencing; QW, weekly; Q4W, every 4 weeks; R, lenalidomide; Tec, teclistamab; V, bortezomib.



GMMG-HD10/DSMM-XX/MajesTEC-5: MRD Negativity (10⁻⁶)^a in the MRD-Evaluable Analysis Set^b



- When combining all patients across all arms (n=49), cumulative MRD-negativity rate by end of induction in the efficacy analysis set was 98.0%
- 85.7% (42/49) of patients achieved ≥CR and MRD negativity at Cycle 6 (≤10⁻⁵)

100% of patients in the MRD-evaluable population,^b regardless of depth of response, achieved MRD negativity (10⁻⁶) at Cycle 6

^aMRD-negativity rate was defined as the proportion of patients who achieved MRD negativity (10⁻⁶), regardless of response. ^bMRD-evaluable population defined as those patients with an available MRD test with a positive or negative result (excluding those who were not tested, were indeterminate, or had no baseline clone detected [NGS]). ^cOne patient had discontinued after completing Cycle 3. ^dOne patient had discontinued before completing Cycle 3, and 1 had no baseline clone detected for NGS. ^ePatients who achieved MRD negativity at 10⁻⁵ or 10⁻⁶ at any time on study (post-induction cycle 3 or cycle 6). D, daratumumab; DSMM, Deutsche Studiengruppe Multiples Myelom; GMMG, German-speaking Myeloma Multicenter Group; MRD, minimal residual disease; NGF, next-generation flow cytometry; NGS, next-generation sequencing; QW, weekly; Q4W, every 4 weeks; R, lenalidomide; Tec, teclistamab; V, bortezomib.



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

- Tec-Dara—based immunotherapy induction was well managed, with no discontinuations of all study drugs due to TEAEs, confirming its combinability
- Infections are common (grade 3/4, 36.7%); however, no infections led to discontinuation of all study drugs, and no grade 5 infections were reported
 - Infection prophylaxis, including Ig replacement, was adopted and is strongly recommended.
- 96% of patients were able to complete successful stem cell mobilization with Tec-D(V)R,^a with a median total stem cell yield surpassing minimum protocol requirements
- Unprecedented levels of 100% ORR and MRD negativity at Cycle 3 (10⁻⁵) and maintained through Cycle 6 (10⁻⁵ and 10⁻⁶)^b seen with Tec-Dara–based immunotherapy induction
- Results build confidence in Tec-Dara—based regimens as we await results of the first phase 3 study with this immunotherapy doublet in the setting of 1-3 prior LOT (MajesTEC-3)¹

Tec-Dara—based immunotherapy induction is manageable with unprecedented MRD negativity in TE NDMM



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- · Leo Rasche is a co-principal investigator of this study
- This study was sponsored by the Heidelberg University Hospital









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