POST-ORLANDO 2025
Novità dal Meeting della Società Americana di Ematologia

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Torino
Centro Congressi Lingotto
19-21 febbraio 2026

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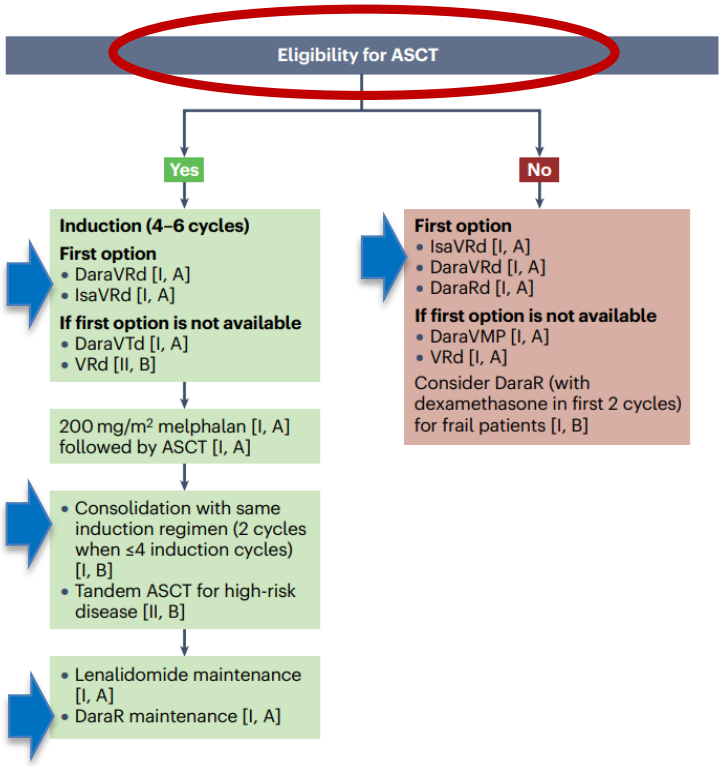
GlaskoSmithKline					x	x	
Amgen					x	x	
Oncopeptides					x		
Menarini					x		

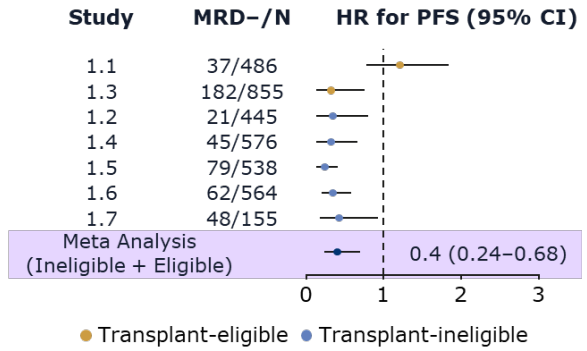
EHA–EMN 2025 Evidence-Based Guidelines for NDMM



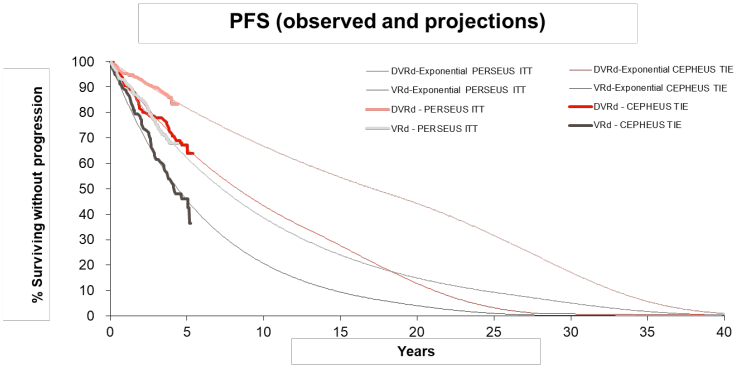
MRD as an early endpoint for accelerated approval

EVIDENCE meta-analysis[1]
N=4,907

Individual-level association between MRD at 12 months and PFS



Significantly Longer Projected PFS With DVRd vs VRd For the Best-Fit Distribution



Estimated PFS, DVRd vs VRd
PERSEUS: **205 months (17.1 years)** vs 87 months (7.3 years)
CEPHEUS: **100 months (8.3 years)** vs 53 months (4.4 years)

Dimopoulos MA et al. Nature Reviews Clinical Oncology 2025; Shi Q et al. J Clin Oncol 2025; Sonneveld P et al. EMN 2025

ASH 2025

- **Quadruplet-based induction therapy and doublet maintenance**
  - IsaVRd in NDTIMM, the BENEFIT study adjourned results (Bobin A et al, Abs 368; Schavgoulidze A et al, Abs 497)
  - DaraR maintenance, the AURIGA study adjourned results (Chung A et al, Abs 97)

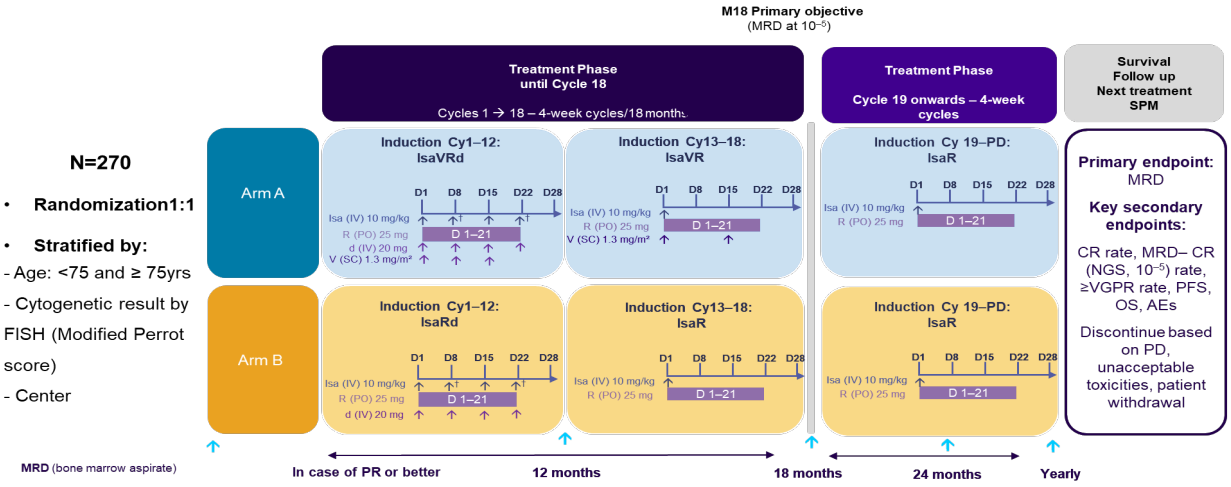
- **Induction regimen including second generation PI**
  - KRD vs VRD, COBRA trial (Dytfeld D et al, Abs 99)

- **Early incorporation of T-cell redirecting therapy**
  - TecDara for NDTIMM, IFM2021-01 TecLille trial cohort A (Manier S et al, Abs 367)
  - Linvoseltamab monotherapy for NDTIMM, LINKER-MM4 study (Orlowski R, Abs 697)
  - Fixed-duration Linvoseltamab immuno-consolidation, IMMUNOPLANT study (Kazandjian D et al, Abs 248)

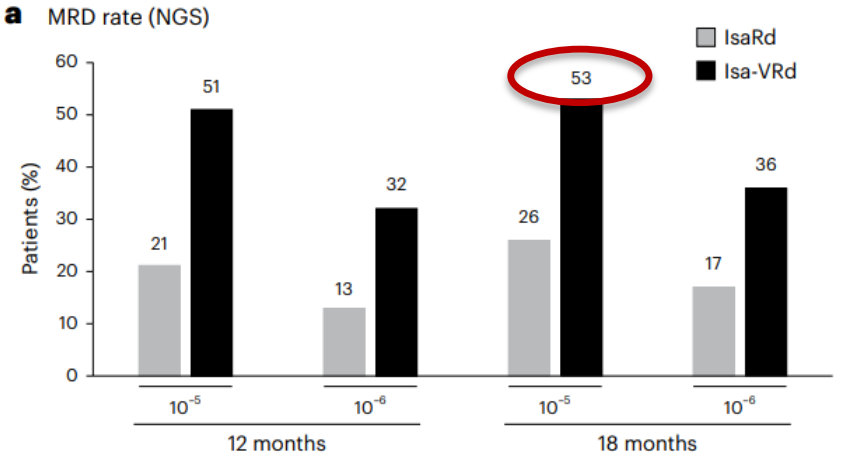
Isa-VRd versus Isa-Rd in NDTI MM: the BENEFIT (IFM 2020-05) study

Isa-VRd and Dara-VRd have emerged as new SOC in ND TI MM patients based on the BENEFIT, IMROZ and CEPHEUS studies

270 pts with NDMM, TI and aged 65–79 years



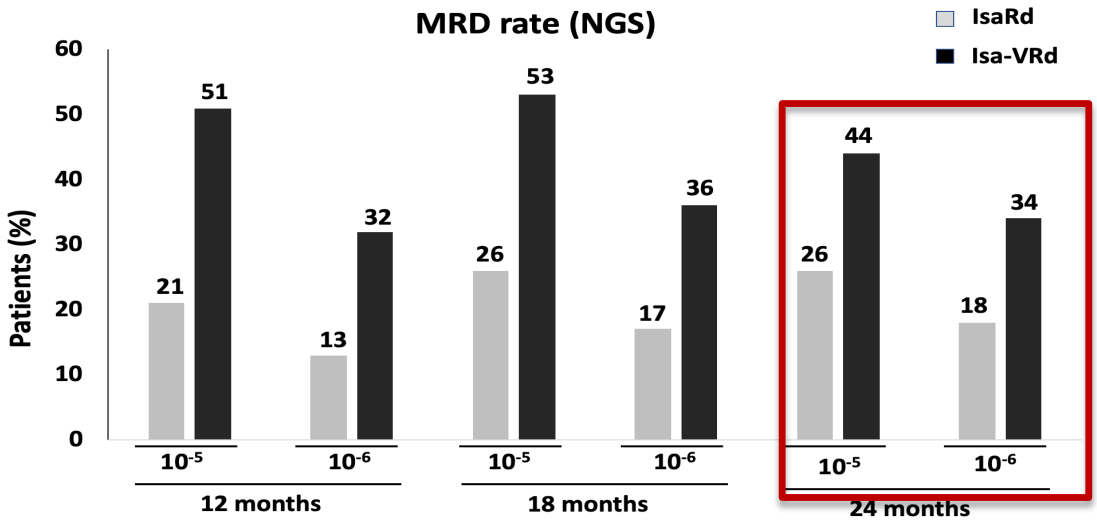
Primary end-point: MRD negativity rate at 10^{-5} (NGS) at 18 mo from randomization



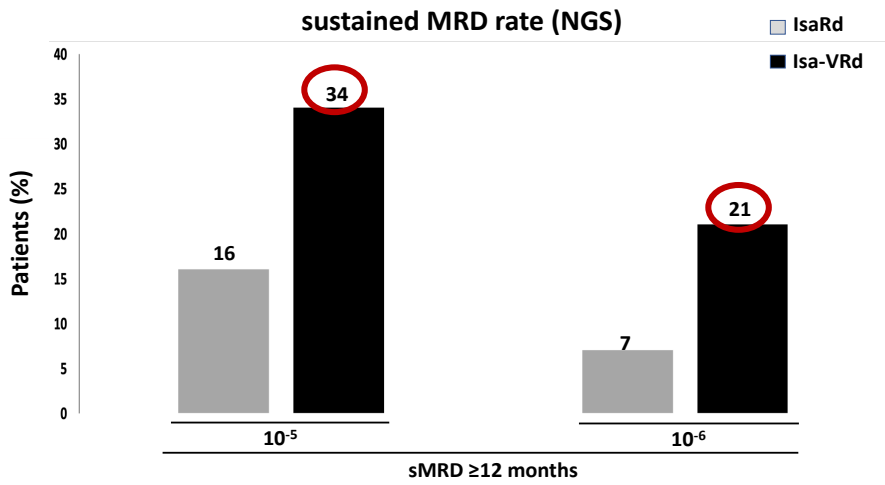
Leleu X et al. Nature Medicine 2024; Facon T et al. NEJM 2024 and ASCO 2024; Usmani S et a. Nature medicine 2025; Bobin A et al. ASH 2025, Abs 368; Schavgoulidze A et al. ASH 2025, Abs 497

MRD and sustained MRD

Median follow-up: **33.4 months** [95%CI, 33–34]

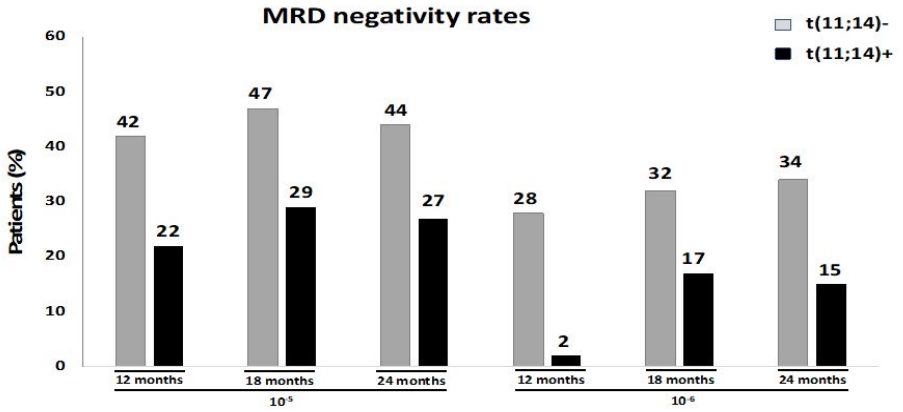


Isa-VRd resulted in a significant improvement in the MRD at 24 months at 10^{-5} and 10^{-6} in the ITT population



Isa-VRd resulted in a significant improvement in the sMRD ≥12 months at 10^{-5} and 10^{-6} in the ITT population

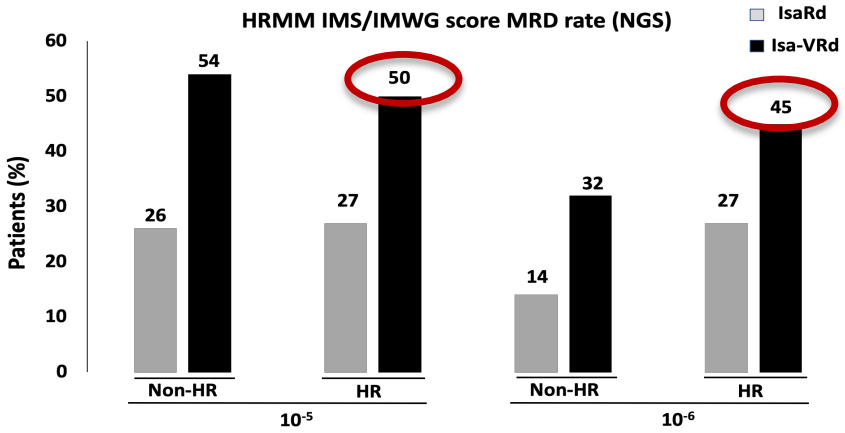
MRD– Rate at 12, 18 and 24 Months According to t(11;14) – ITT Population



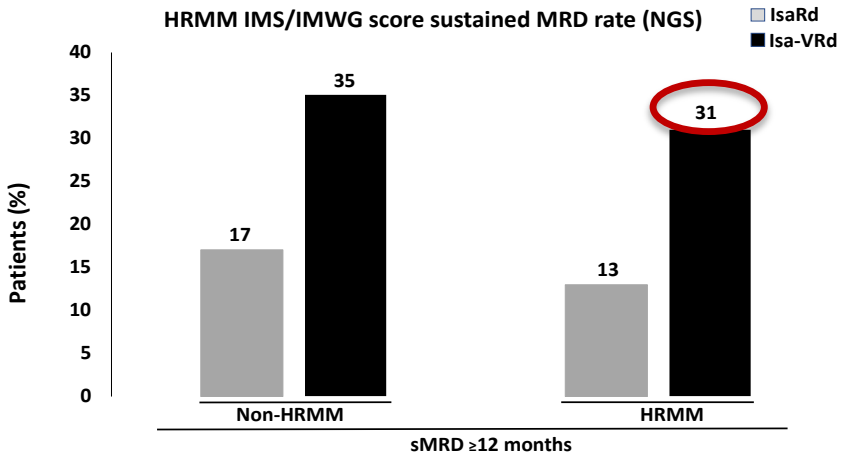
Bobin A et al. ASH 2025, Abs 368

MRD in High-Risk patients

	Isa-Rd (N=135)	Isa-VRd (N=135)
Cytogenetic risk at baseline CGS score – no. (%)*		
Non-high	111 (82)	102 (76)
High	24 (18)	33 (24)



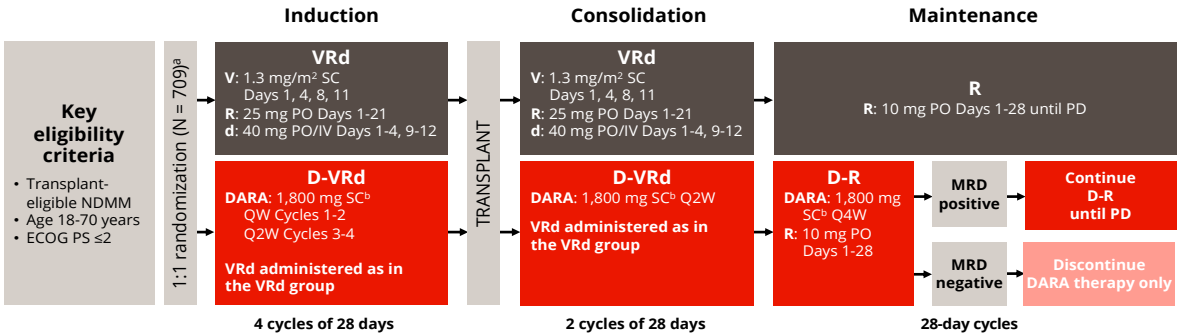
Isa-VRd improved the MRD at 18 months at 10^{-5} and 10^{-6} in the ITT population with HRMM



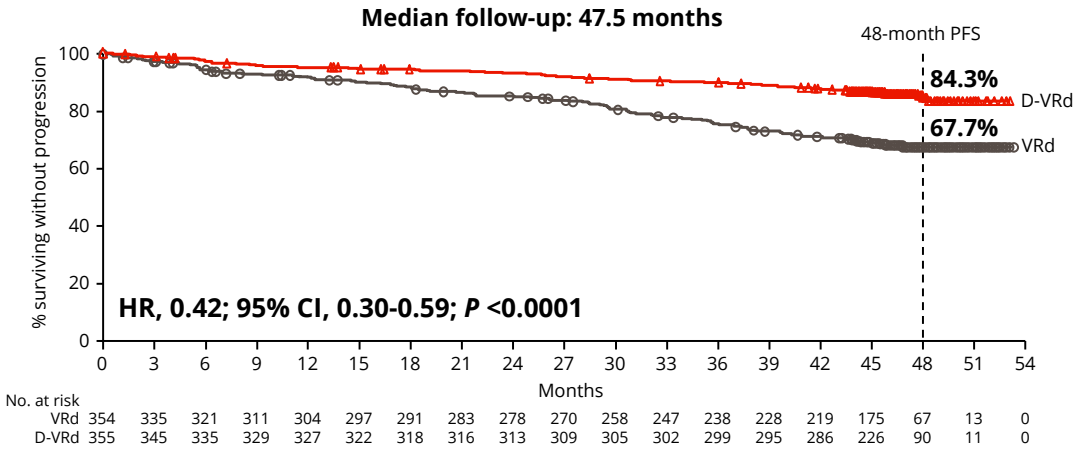
Isa-VRd improved the sMRD ≥12 months at 10^{-5} in HRMM

Schavgoulidze A et al. ASH 2025, Abs 497

Dara-VRd induction and Consolidation followed by Dara-R maintenance: PERSEUS phase 3 trial



NDMM, newly diagnosed multiple myeloma; ISS, International Staging System stage; V, bortezomib; D, Daratumumab; R, lenalidomide; d, dexamethasone; IV intravenous; PO, orally; SC subcutaneous; PFS, progression-free survival. HR, hazard ratio; CI, confidence interval, MRD measurable residual disease, PD progressive disease, yr year; QW,weekly; Q2W, every 2 weeks.



Sonneveld et al NEJM 2024 and ASH 2023; Rodriguez P et al ASCO 2024

MRD dynamics in post-transplant pts with NDMM who received Dara plus Lena vs Lena alone as maintenance therapy in the AURIGA Study

Median follow-up: **40.3** months

Key eligibility criteria
- 18-79 years of age
- NDMM with ≥4 cycles of induction therapy and underwent ASCT within 12 months of the start of induction
- ≥VGPR at screening[a]
- MRD[b] positive (10^{-5}) after ASCT
- No prior anti-CD38
- Randomization within 6 months of the ASCT date

Stratification factor
- Cytogenetic risk[c] at diagnosis (standard/unknown vs high risk)

1:1 RANDOMIZATION (N = 200)

Maintenance: up to 36 cycles[d] (28-day cycles)

D-R
DARA: 1,800 mg SC[e] QW Cycles 1-2, Q2W Cycles 3-6, Q4W Cycles 7+
R: 10 mg PO daily Days 1-28
(after Cycle 3, 15 mg PO daily if tolerated)

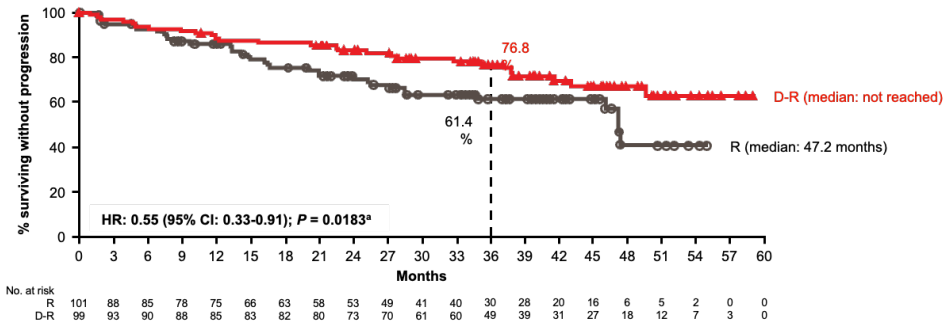
R
R: 10 mg PO daily Days 1-28
(after Cycle 3, 15 mg PO daily if tolerated)

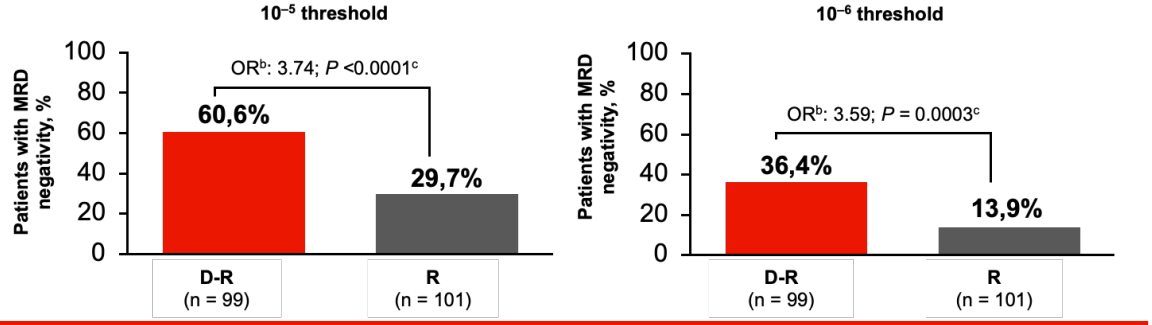
Primary endpoint
- MRD-negative (10^{-5}) conversion rate from baseline to 12 months after maintenance treatment

Secondary endpoints
- Overall MRD-negative conversion rate, sustained MRD-negative rate, PFS, response rate, duration of ≥CR, OS, safety

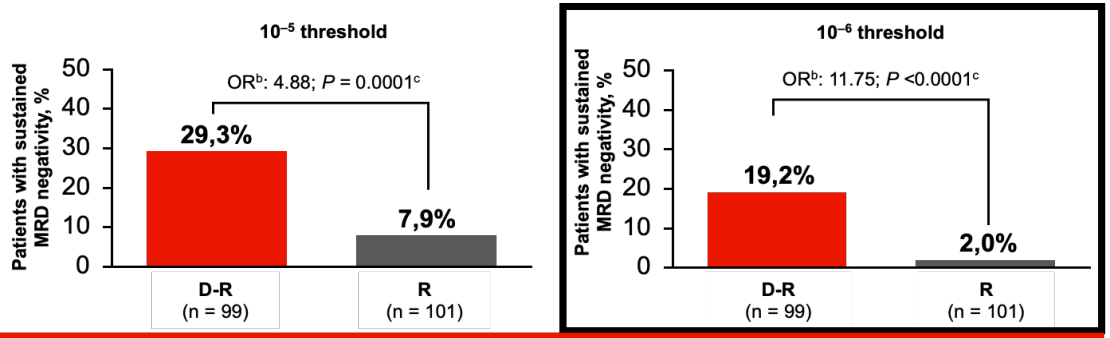
MRD[b] obtained after 12, 18, 24, and 36 cycles, enabling analysis of *MRD dynamics*

PFS





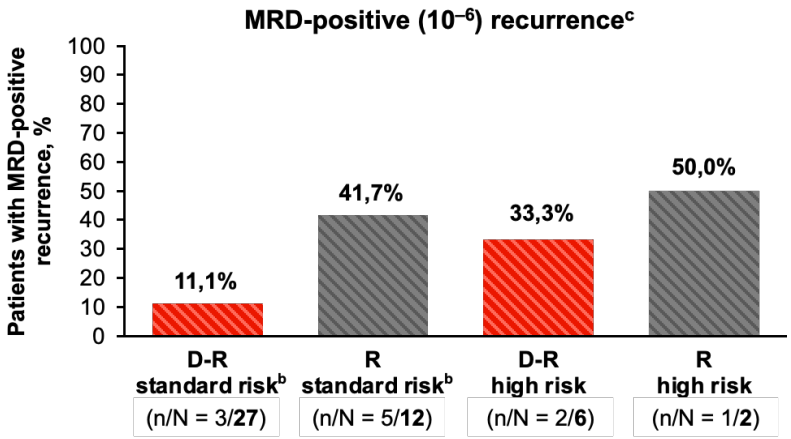
At a median follow-up of 40.3 months, MRD-negative conversion rates continued to be more than double with D-R at both the 10^{-5} and 10^{-6} thresholds compared with R alone



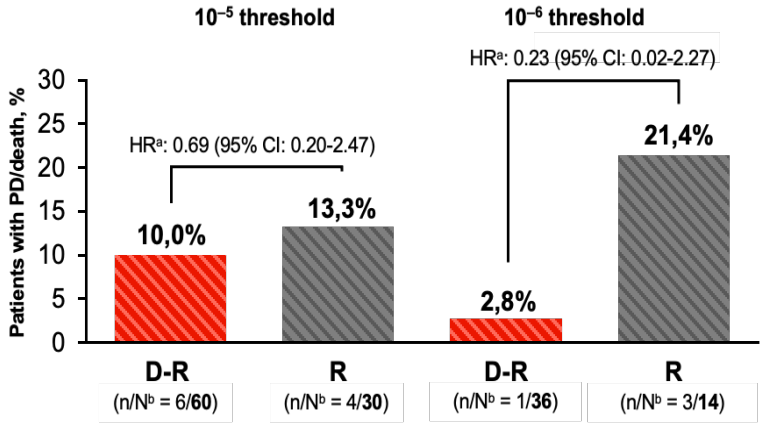
Rates of sustained MRD negativity lasting ≥12 months for D-R maintenance versus R alone were >3.5-fold at the 10^{-5} threshold and ~10-fold at the 10^{-6} threshold

Chung A et al. ASH 2025, Abs 97

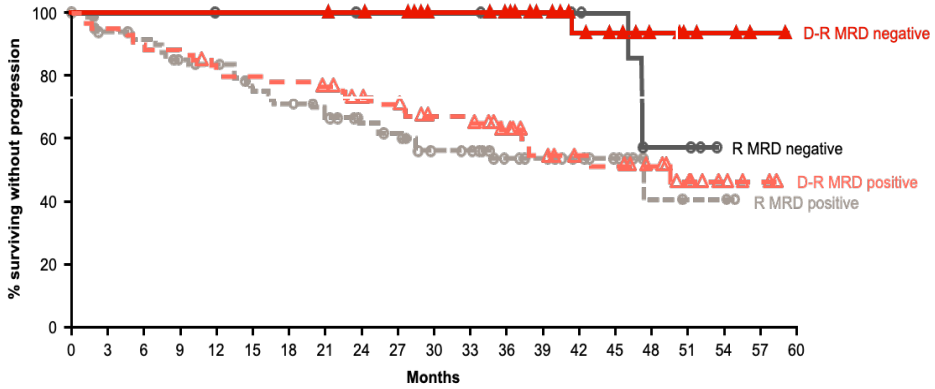
MRD-Positive (10^{-6}) Recurrence Among Patients Who Achieved MRD Negativity (10^{-6})



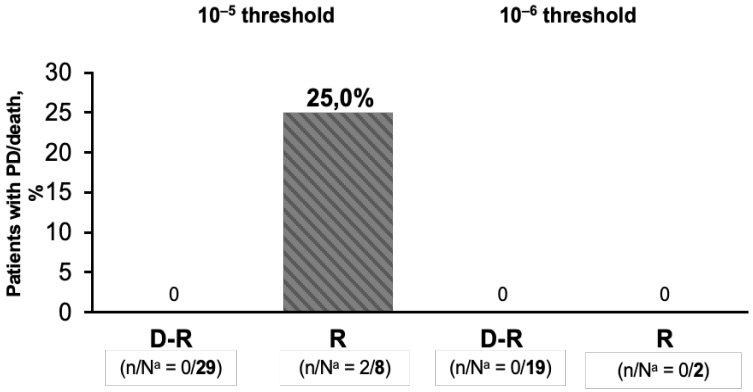
PFS Events in Pts Achieving MRD-Negative Conversion



PFS by MRD (10^{-6}) status



PFS Events in Pts Achieving Sustained MRD Negativity



Chung A et al. ASH 2025, Abs 97

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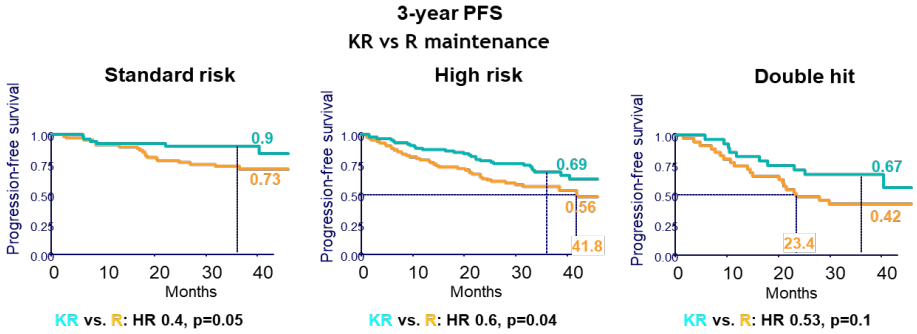
First-line treatment deserves a risk-stratified approach
Anti-CD38 Mo Abs + KRd: the treatment for HR patients?

FORTE phase III trial:
KRd vs KRD+ASCT vs KCd + ASCT

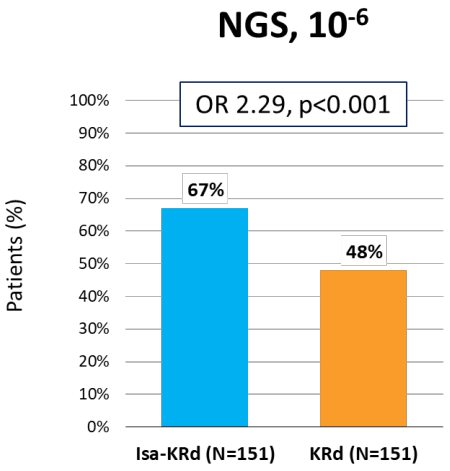
Carfilzomib with cyclophosphamide and dexamethasone or lenalidomide and dexamethasone plus autologous transplantation or carfilzomib plus lenalidomide and dexamethasone, followed by maintenance with carfilzomib plus lenalidomide or lenalidomide alone for patients with newly diagnosed multiple myeloma (FORTE): a randomised, open-label, phase 2 trial

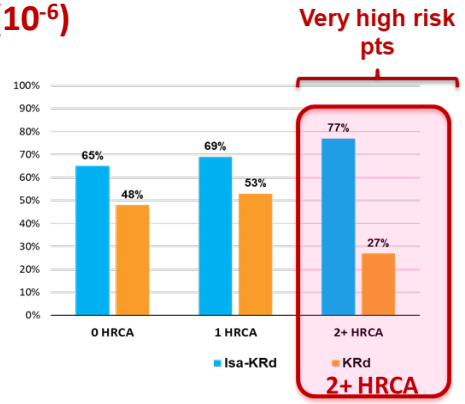
Francesca Gay, Pellegrino Musto*, Delia Rota-Scalabrini, Luca Bertamini, Angelo Belotti, Monica Galli, Massimo Offidani, Elena Zamagni, Antonio Ledda, Mariella Grasso, Stelvio Ballanti, Antonio Spadano, Michele Cea, Francesca Patriarca, Mattia D'Agostino, Andrea Capra, Nicola Giuliani, Paolo de Fabritiis, Sara Aquino, Angelo Palmas, Barbara Gamberi, Renato Zambello, Maria Teresa Petrucci, Paolo Corradini, Michele Cavo, Mario Boccadoro*



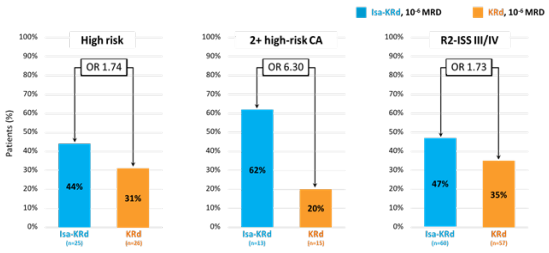
EMN24/ISKIA phase III trial: Isa-KRd vs KRd + ASCT

Post-consolidation MRD negativity by NGS (10^{-6})



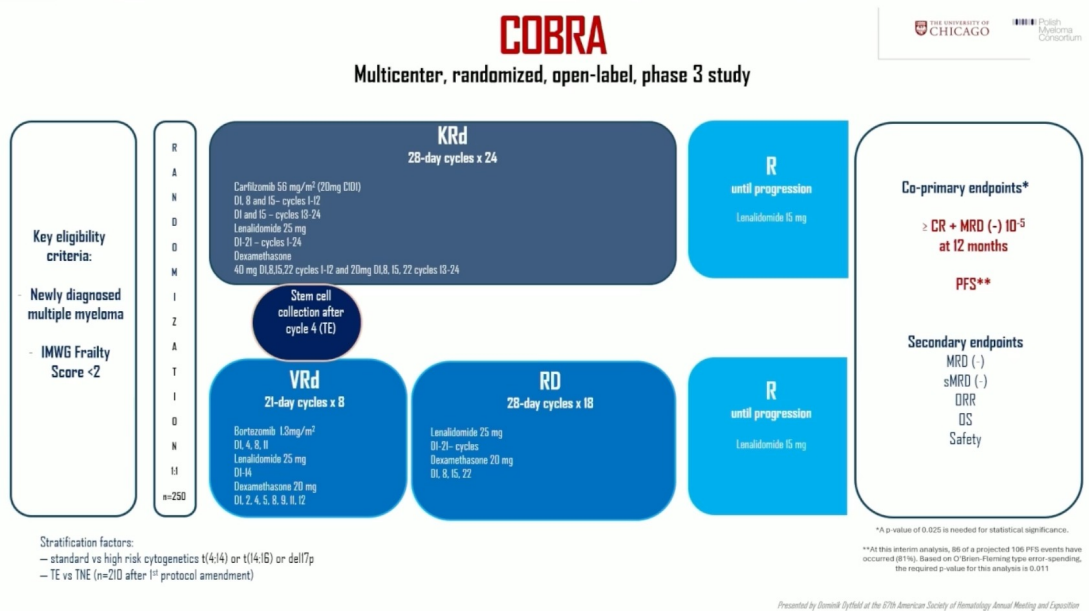


1-yr sustained MRD negativity rates (10^{-6})



Gay F et al, Lancet Oncology 2021; Mina R et al, Lancet Oncology 2023; Gay F et al, ASH 2023; Gay F et al, SIE 2025

KRd vs VRd in patients with NDMM: results of the randomized phase III COBRA trial



Baseline Patient Characteristics

	KRd n=126	VRd n=124
age median (range)	66 (33-78)	67 (31-80)
female/male	70 (56%) / 56 (44%)	73 (59%) / 51 (41%)
white/black/asian/other	117 (93%) / 3 (2%) / 2 (2%) / 4 (3%)	120 (97%) / 3 (2%) / 0 / 1 (1%)
TE/TNE (n=210)*	65 (59%) / 40 (41%)	65 (59%) / 40 (41%)
ECOG 0/1/2	31 (25%) / 89 (70%) / 6 (5%)	31 (25%) / 91 (74%) / 2 (1%)
ISS I/II/III	43 (35%) / 47 (38%) / 33 (27%)	50 (40%) / 47 (38%) / 27 (22%)
standard risk	97 (77%)	96 (77%)
high risk del17p/t (4;14)/t (14;16)/more than 1	29 (23%) 14 (48%) / 15 (51%) / 8 (27%) / 8 (27%)	28 (23%) 15 (53%) / 11 (39%) / 4 (14%) / 2 (7%)

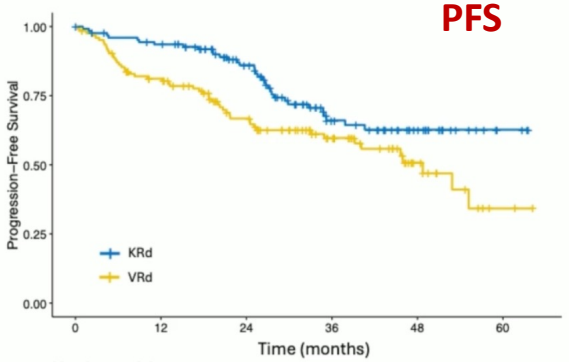
*Data collected after 1st amendment

Presented by Dominik Dytfeld at the 67th American Society of Hematology Annual Meeting and Exposition

Median follow-up: 35 months (range: 0-66)

Dytfeld D et al. ASH 2025, Abs 99

PFS



intent-to-treat

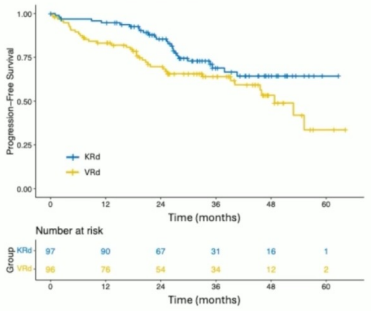
Median follow up: 53 months
HR 0.57 (95% CI: 0.37-0.88) p=0.0095

Progression or death KRd 35 (28%)
Median PFS KRd: NR

Progression or death VRd 51 (41%)
Median PFS VRd: 48.8 m

Presented by Dominik Dytfeld at the 67th American Society of Hematology Annual M

Standard risk

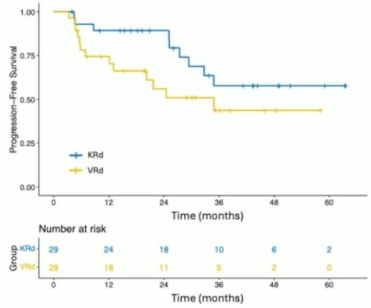


HR 0.59 (95% CI: 0.36-0.98) p=0.04

Progression or death KRd 26 (27%)
Median PFS KRd: NR

Progression or death VRd 38 (40%)
Median PFS VRd: 48.8 m

High risk



HR 0.52 (95% CI: 0.22-1.22) p=0.12

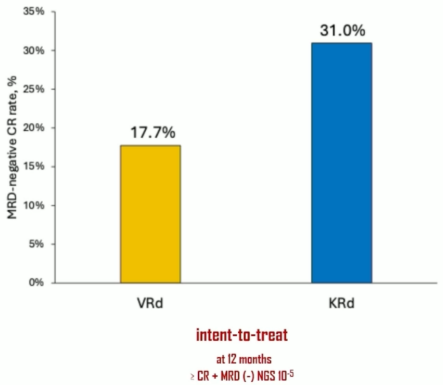
Progression or death KRd 9 (31%)
Median PFS KRd: NR

Progression or death VRd 13 (48%)
Median PFS VRd: 34.9 m

Presented by Dominik Dytfeld at the 67th American Society of Hematology Annual Meeting and Exposition

MRD 10^{-5}

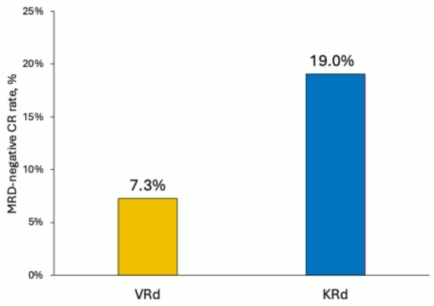
OR=2.02
95%CI: 1.15-3.77; p 0.016



intent-to-treat
at 12 months
› CR + MRD (-) NGS 10^{-5}

MRD 10^{-6}

OR=3.01
95%CI: 1.34-6.77; p 0.008



intent-to-treat
at 12 months
› CR + MRD (-) NGS 10^{-6}

	KRd n=126	VRd n=124
any AEs grade/≥G3	96% / 73%	94% / 62%
any AE s leading to treatment discontinuation	11%	8%
any AEs grade 5*	5 (4%)	7 (6%)
neutropenia any grade/≥G3	29% / 21%	17% / 11%
neuropathy any grade/≥G3	17% / 2%	56% / 2%
cardiac any grade/≥G3	18% / 6%	10% / 2%
infection any grade/≥G3	75% / 25%	60% / 23%

* KRd: 1 x COVID, 1 x stroke , 1 x pneumonia, 1 x sepsis, 1 x acute kidney failure
VRd - 3 x COVID, 1 x pneumonia, 1 x respiratory failure, 2 x unknown

Dytfeld D et al. ASH 2025, Abs 99

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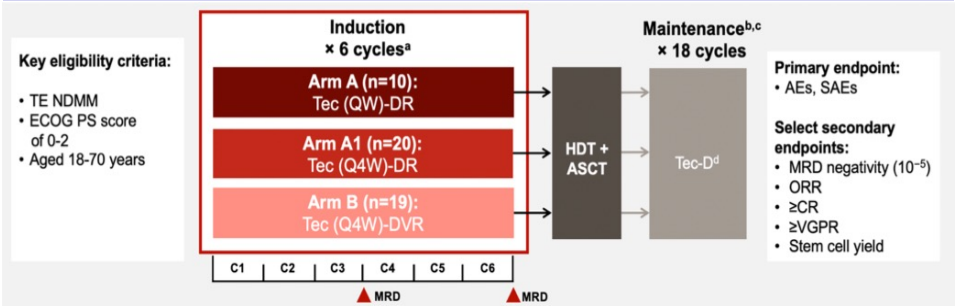
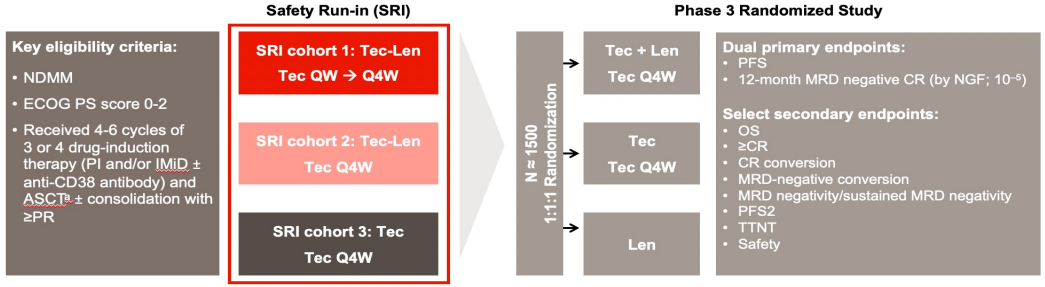
BsAb induction and maintenance for transplant-eligible patients

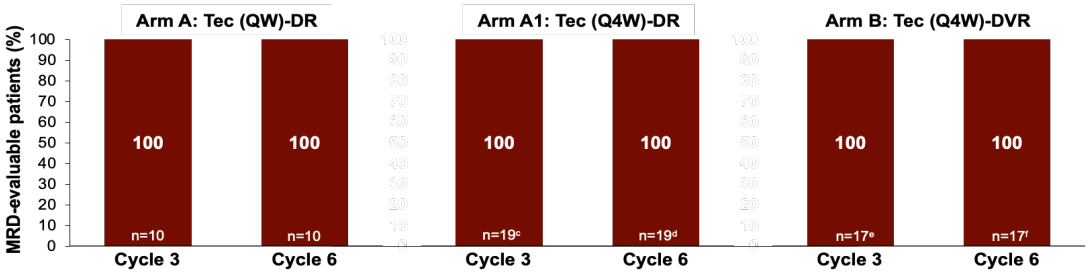
Teclistamab induction in TE patients GMMG-HD10/DSMM-XX (MajesTEC-5) Trial

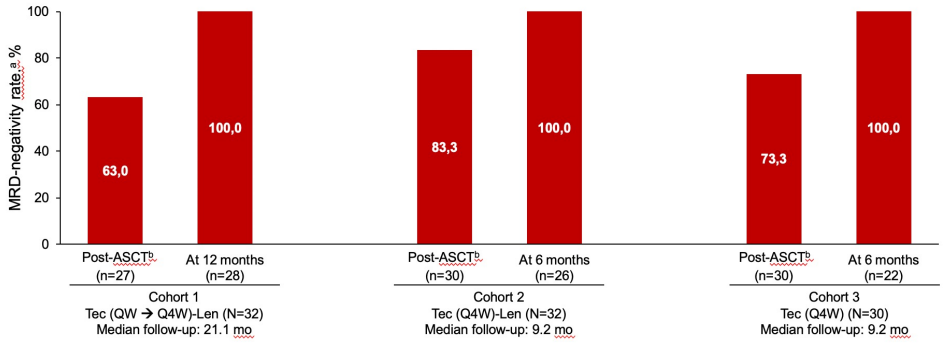


Teclistamab maintenance in NDMM after ASCT: Phase 3 EMN30/MajesTEC-4 study (SRI data)



Pre-Post-maintenance MRD rates (10^{-5})



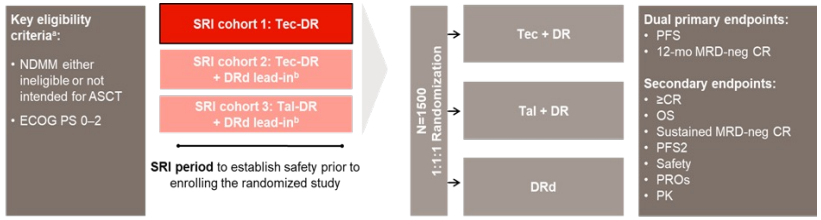


With completion of induction, 100% MRD negativity (10^{-5}) continues to be observed in MRD-evaluable patients, regardless of depth of response

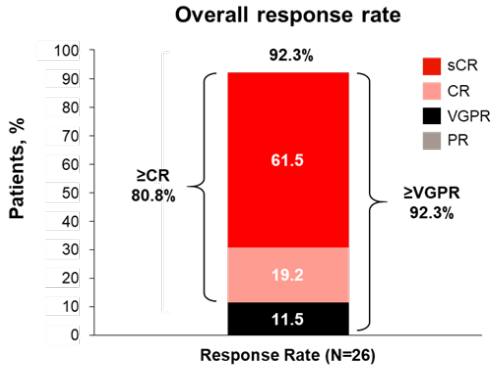
Raab M. et al ASH24; IMS 2025; Zamagni E. et al ASH24

BsAb combinations for transplant-ineligible patients

TecDaraR in TI patients
Safety Run-In Cohort 1 of the Phase 3 MajesTEC-7

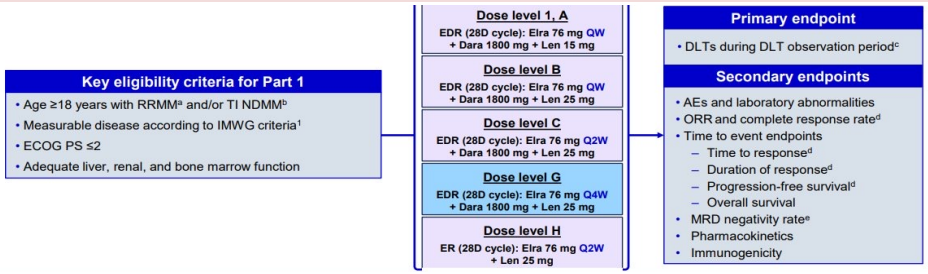


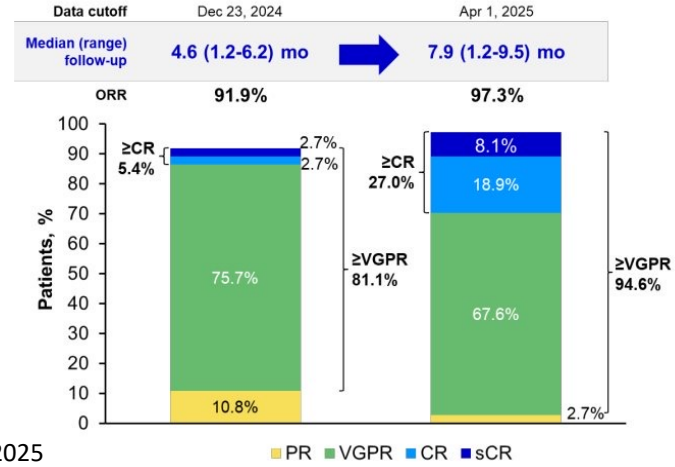
SRI cohort 1: Tec-DR	mFU	Cycle 1	Cycle 2	Cycle 3–6	Cycle 7+ until PD
	13.8 mo (range, 2.0–15.4)	Tec step-up[c] + D	Tec 1.5 mg/kg QW + DR	Tec 3 mg/kg Q2W + DR	Tec 3 mg/kg Q4W + DR



- 92.3% ORR (80.8% ≥CR); all responses were ≥VGPR
- No disease progressions

ElraDaraR in TI patients
Initial results from MagnetisMM-6 Part 1

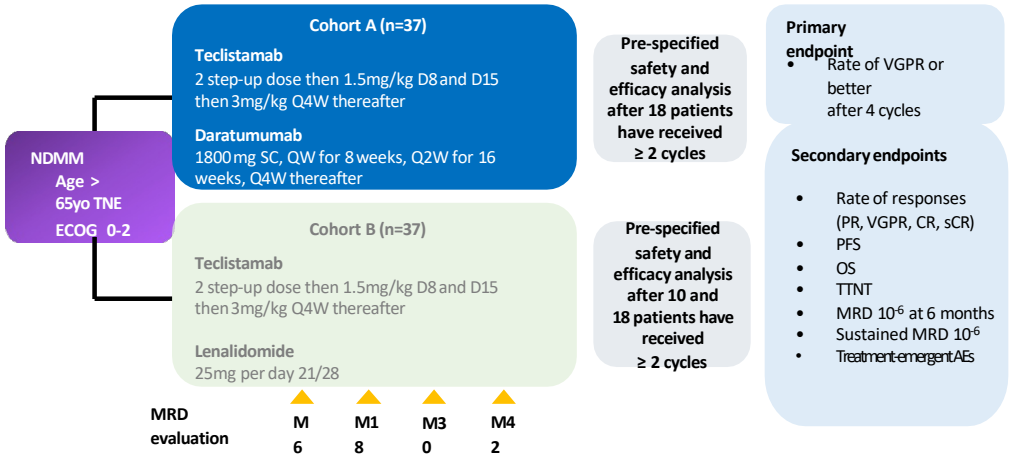




Touzeau C et al. ASCO 2024; Dimopoulos MA et al. EHA 2025

A Phase 2 Study of Teclistamab in Combination with Daratumumab in Elderly Patients with Newly Diagnosed Multiple Myeloma: The IFM2021-01 TecLille trial, cohort A

Phase 2 study of Tec-Dara and Tec-Len in TNE NDMM (n = 74)



Current amendment:
Teclistamab 3mg/kg Q8W after C13 if CR or better and treatment interruption if 2-years sustained MRD -

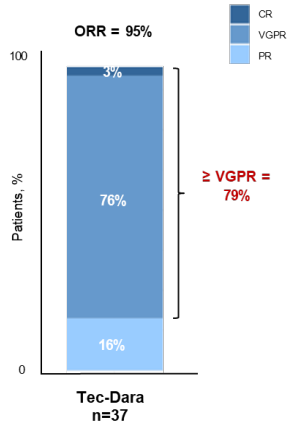
Median follow-up of 10.3 months

Patients characteristics	Tec-Dara (n=37)
Median age (range) - yr	73 (66-87)
Age category – no. (%)	
65 to < 70 yr	7 (19%)
70 to < 75 yr	18 (49%)
≥ 75 yr	12 (32%)
Sex - no. (%)	
Female	20 (54%)
Male	17 (46%)
ECOG – no. (%)	
0	9 (24%)
1	24 (65%)
2	4 (11%)
Frailty score (IMWG) – no. (%)	
Fit	16 (44%)
Intermediate	12 (33%)
Frail	8 (22%)
Creatinine clearance – no. (%)	
30 to < 60mL/min	14 (38%)
≥ 60 mL/min	23 (62%)

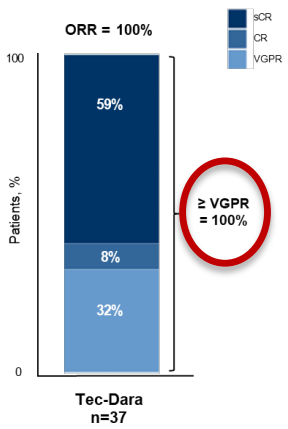
Disease characteristics	Tec-Dara (n=37)
Type of measurable disease – no (%)	
IgG	22 (59%)
IgA	8 (22%)
SFLC only	7 (19%)
ISS disease stage – no. (%)	
I	13 (35%)
II	19 (51%)
III	5 (14%)
Cytogenetic risk (IMWG/IMS) – no (%)	
Standard risk	25 (68%)
High risk	12 (32%)
del17p	4 (14%)
TP53 mutation	3 (10%)
t(4;14)	1 (3%)
t(14;16)	1 (3%)
t(14;20)	1 (3%)
gain 1q	11 (38%)
del1p32	2 (7%)
Extramedullary disease – no (%)	
No	35 (95%)
Yes	2 (5%)

Patients were representative of the TNE NDMM population

VGPR rate after 4 cycles*

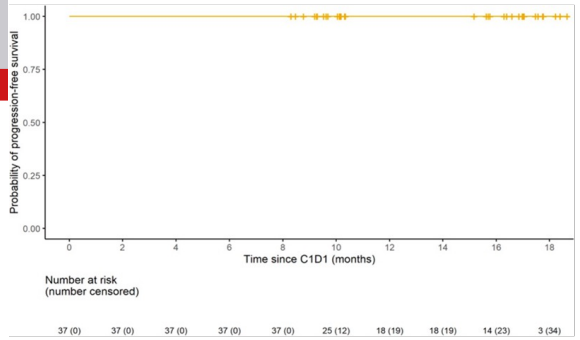


Best response rate

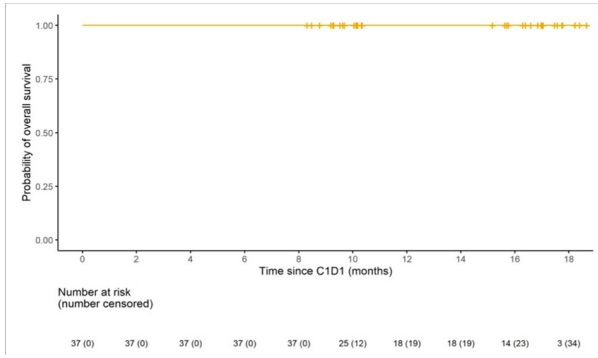


All patients achieved VGPR or better at best response

PFS

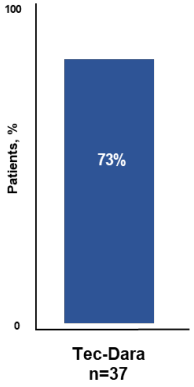


OS

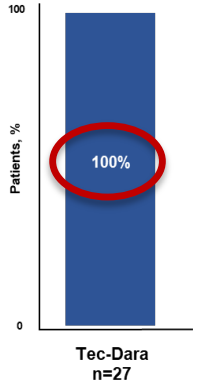


No event of progression or death occurred

MRD by NGS 10^{-6} at 6 months ITT



MRD by NGS 10^{-6} at 6 months Evaluable samples



All evaluable samples were MRD negative at 10^{-6} by NGS at 6 mo

Grade ≥ 3 AEs

AEs, n(%)	Tec-Dara (n=37) Grade ≥ 3
All grade ≥ 3 AEs	29 (78%)
All grade ≥ 3 SAEs	10 (27%)
Grade 5	-
Hematologic AEs	26 (70%)
Lymphopenia	21 (57%)
Neutropenia	16 (43%)
Anemia	2 (5%)
Thrombocytopenia	1 (3%)
Non-hematologic AEs	10 (27%)
Infection	5 (14%)
Hepatic cytolysis	2 (5%)
Skin rash	2 (5%)

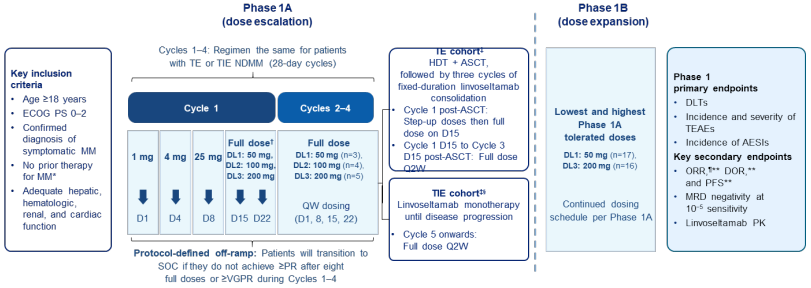
All grade AESI

AESI, n(%)	Tec-Dara (n=37) All grade	Grade 1-2	Grade ≥ 3
Infections	24 (65%)	19 (52%)	5 (14%)
Bronchitis	6 (16%)	6 (16%)	-
COVID-19	5 (14%)	4 (11%)	1 (3%)
Urinary tract infection	5 (14%)	5 (14%)	-
Sinusitis	4 (11%)	4 (11%)	-
Pneumonia	3 (8%)	2 (5%)	1 (3%)
GI salmonella	1 (3%)	-	1 (3%)
Peritonitis	1 (3%)	-	1 (3%)
HHV6 infection	1 (3%)	-	1 (3%)
CRS	22 (59%)	G1: 13 (35%) G2: 9 (24%)	-
ICANS	-	-	-
Injection site reaction	7 (19%)	7 (19%)	-
Second primary malignancy	1 (3%)	1 (3%)	-

	Tec-Dara (n=37)
Treatment discontinuation due to AE*, n (%)	1 (3%)

Manier S et al. ASH 2025, Abs 367

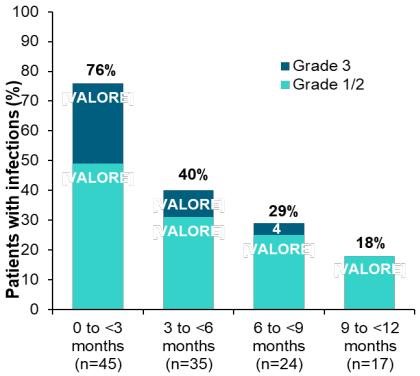
Safety and efficacy of linvoseltamab as a simplified monotherapy first-line regimen in NDMM: Initial results from the window of opportunity Phase from the window of opportunity Phase 1/2 LINKER-MM4 trial

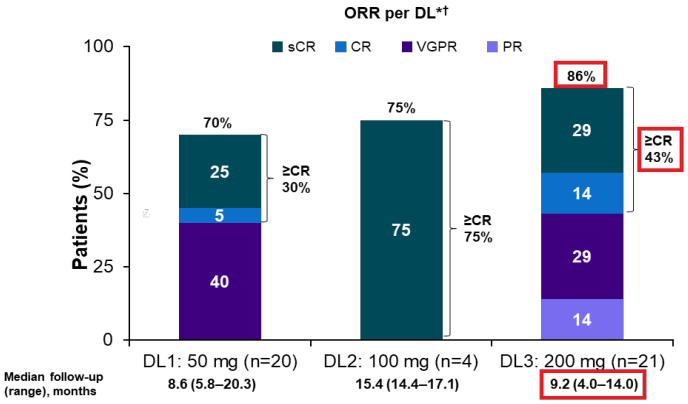


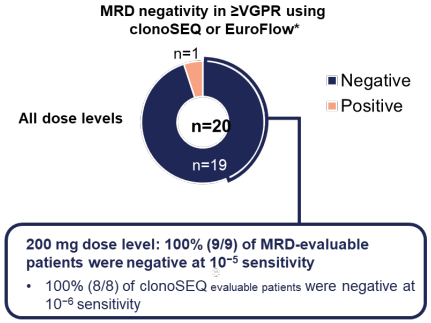
- Phase 1A and Phase 1B data will inform the RP2D

Characteristic	DL1: 50 mg (n=20)	DL2: 100 mg (n=4)	DL3: 200 mg (n=21)	All doses: Phase 1 total (N=45)
Median follow-up (range), months	8.6 (5.8–20.3)	15.4 (14.4–17.1)	9.2 (4.0–14.0)	9.2 (4.0–20.3)
Transplant eligibility, n (%)				
TE	12 (60.0)	3 (75.0)	13 (61.9)	28 (62.2)
TIE	8 (40.0)	1 (25.0)	8 (38.1)	17 (37.8)
Median age (range), years	67.0 (43–84)	66.5 (63–71)	66.0 (46–83)	67.0 (43–84)
Male, n (%)	11 (55.0)	3 (75.0)	13 (61.9)	27 (60.0)
Race, n (%)				
White	12 (60.0)	3 (75.0)	15 (71.4)	30 (66.7)
Black or African American	4 (20.0)	1 (25.0)	3 (14.3)	8 (17.8)
Asian	1 (5.0)	0	1 (4.8)	2 (4.4)
Not reported	3 (15.0)	0	2 (9.5)	5 (11.1)
ECOG PS, n (%)				
0	11 (55.0)	1 (25.0)	11 (52.4)	23 (51.1)
1	6 (30.0)	3 (75.0)	9 (42.9)	18 (40.0)
2	3 (15.0)	0	1 (4.8)	4 (8.9)
BMPCs ≥50%, n (%)	13 (65.0)	4 (100)	13 (61.9)	30 (66.7)
sBCMA ≥400 ng/mL, n (%)	8 (40.0)	3 (75.0)	10 (47.6)	21 (46.7)
R-ISS score at study entry*, n (%)				
I	10 (50.0)	2 (50.0)	9 (42.9)	21 (46.7)
II	9 (45.0)	2 (50.0)	10 (47.6)	21 (46.7)
III	1 (5.0)	0	1 (4.8)	2 (4.4)
Unknown	0	0	1 (4.8)	1 (2.2)
High cytogenetic risk by R-ISS†, n (%)	2 (10.0)	1 (25.0)	2 (9.5)	5 (11.1)

Event, n (%)	All doses: Phase 1 total (N=45)	
	Any grade	Grade 3/4
Patients with any TEAE	45 (100)	39 (86.7)
Serious TEAE	30 (66.7)	23 (51.1)
TEAE leading to treatment discontinuation	1 (2.2)*	1 (2.2)*
Treatment-related TEAE	41 (91.1)	30 (66.7)
Infections†	38 (84.4)	15 (33.3)
Most common‡ hematologic TEAE		
Neutropenia§	17 (37.8)	15 (33.3)
Anemia§	12 (26.7)	8 (17.8)
Most common‡ non-hematologic TEAE		
CRS	20 (44.4)	0
Transaminase elevation§	14 (31.1)	6 (13.3)
Hypophosphatemia	14 (31.1)	3 (6.7)
Nausea	14 (31.1)	0
Diarrhea	13 (28.9)	4 (8.9)
Hypogammaglobulinemia	13 (28.9)	0
Infusion-related reactions	12 (26.7)	0







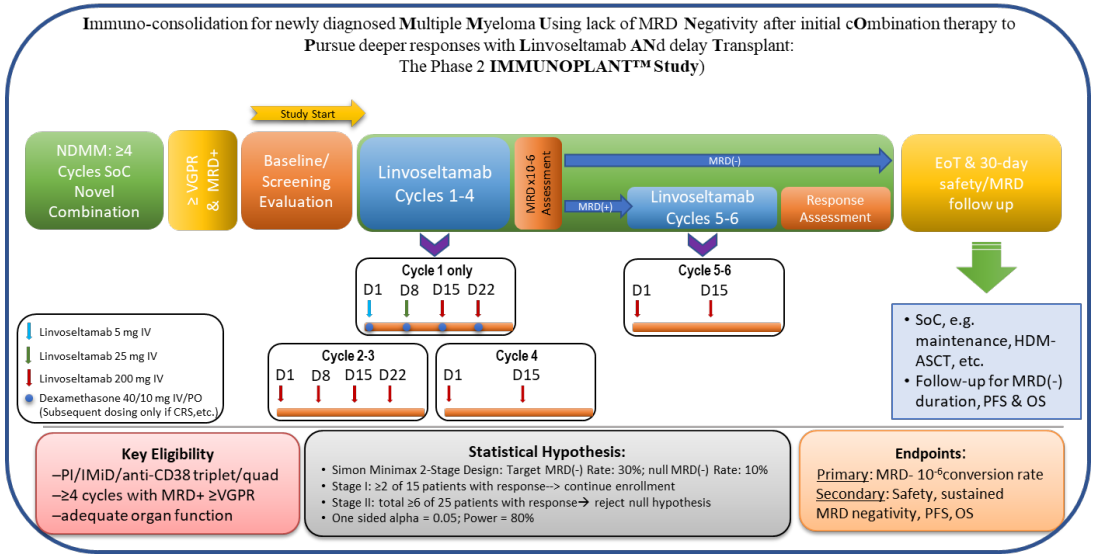
200 mg dose level: 100% (9/9) of MRD-evaluable patients were negative at 10^{-5} sensitivity

- 100% (8/8) of clonoSEQ evaluable patients were negative at 10^{-6} sensitivity

Orlowski R et al. ASH 2025, Abs 697

A Phase 2 Trial of Abbreviated Fixed-Duration (Default 4 Cycles) Linvoseltamab Immuno-Consolidation to Deepen Responses Post NDMM Combination Therapy for Minimal Residual Disease Positivity (NCT06376526): The IMMUNOPLANT™ Study

Study Design: Schema

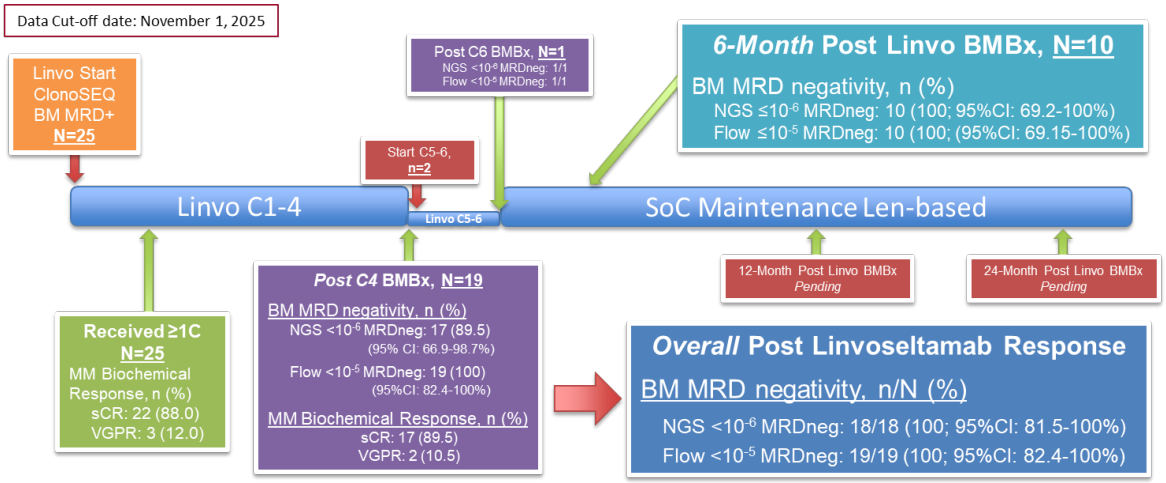


Primary Objective: Determine MRD conversion rate (ClonoSEQ) with fixed short duration linvoseltamab consolidation

Patient Demographics	N=25
Median age, years (range)	62 (40-77)
≥65, n (%)	8 (32)
FISH/Cytogenetics, n (%)	
High-Risk	7 (28)
Standard	14 (56)
Unknown	4 (16)
Median # of Initial Induction Cycles (range)	8 (6-13)
Initial NDMM Regimens, n (%)	
D-VRd	8 (32)
KRd	8 (32)
D-KRd	7 (28)
DRd	1 (4)
Isa-VRd	1 (4)
MRD+ ClonoSEQ at Study Start, n (%)	25 (100)
sCR	4 (16)
VGPR	21 (84)

Kazandjian D et al. ASH 2025, Abs 248

IMMUNOPLANT™ Study: Efficacy Timeline and Safety



The IMMUNOPLANT™ Study using short/fixed (4-6cycles) duration bispecific T cell redirecting antibody, linvoseltamab, for immunoconsolidation of patients with MRD+ after initial combination induction appears to successfully convert patients to deep and potentially durable responses

- **MRD-negativity (<10^{-6}) rate of 100%** (17 of 19 requiring only 4 linvoseltamab cycles)
- **6-Month durable MRD negativity of 100%**; 12 and 24 –month MRD evaluations upcoming

Common (>1 patient), Grade 3, Treatment-Related Adverse Events (N=25)

TEAEs, n (%)	All grade	Grade 3
Neutropenia	5 (20)	2 (8)
Infection, Other (peritonsillar abscess)	1 (4)	1 (4)
Upper Respiratory Infection	7 (28)	–
ALT/AST Elevation	4 (16)	–
Diarrhea	4 (16)	–
Bone Pain	3 (12)	–
Cough	3 (12)	–
Fatigue	3 (12)	–
Nausea	3 (12)	–
Rash	3 (12)	–
Thrombocytopenia	3 (12)	–
Arthralgia	2 (8)	–
Hyperphosphatemia	2 (8)	–

- Generally, manageable safety profile with expected toxicities and no new safety signals
- No CRS/ICANS; prophylactic one-time use of tocilizumab

Kazandjian D et al. ASH 2025, Abs 248

Conclusion

- **New quadruplet-based induction** regimens are confirmed as SOC for newly NDMM patients
- **Doublet maintenance** (D-R) can deepen and sustain MRD negativity
- **KRd-based induction** regimens may represent a new option to be further evaluated
- **BsAbs** may **move to first-line treatment**
- **MRD** will be increasingly used **to guide decisions**
- **Potential for fixed-duration therapies** based on sustained MRD negativity

Acknowledgments

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