Memorial Sloan Kettering Cancer Center

Managing Newly Diagnosed, Transplant-Eligible Multiple Myeloma in 2024

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NDMM: Principles of Therapy

- Picking the right strategy that gives the highest likelihood of the best depth of response in the first year of diagnosis is extremely important for survival outcomes.
  - MRD 10^{-5} >> MRD 10^{-6} >> Sustained MRD 10^{-6}
- Optimize induction, consolidation and maintenance based on:
  - Disease biology (what kind?).
  - Disease burden (how much?).
  - Patient characteristics (PS, co-morbidities, frailty).
  - Patient preference.
- Never under-treat, put your best foot forward!
  - Especially true for high risk NDMM (HR-NDMM)
- Do not forget supportive care measures: bone health, infection prevention, pain management, physical therapy and rehabilitation, mental health.

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Staging and Cytogenetic Risk-Assessment

Stage[1]	R-ISS[1]
I	Serum albumin ≥3.5 g/dL^{-1} Serum β2M <3.5 mg/L^{-1} No high-risk cytogenetics Normal LDH level
II	Not stage I or III
III	Serum β2M >5.5 mg/L^{-1} High-risk cytogenetics: t(4;14), t(4;16), or del(17p) or elevated LDH

Risk[2]	Features
Standard	Trisomies t(11;14) t(6;14)
High	t(4;14) t(14;16) t(14;20) Del(17p) *p53* mutation Gain/Amp 1q High plasma cell S-phase GEP high-risk signatures Circulating Plasma Cells Elevated LDH/EMD
Ultra-High Risk	2 or more features

Stage[1]	R2-ISS[3]
I	0 Points (Low Risk, 19% pts)
II	0.5-1 Points (Low-Intermediate Risk, 31% pts)
III	1.5-2.5 Points (Intermediate-High Risk, 41% pts)
IV	3-5 Points (High Risk, 9 % pts)
POINTS: ISS III= 1.5, ISS-II = 1, Del17p =1, elevated LDH =1, Chromosome 1q21+ = 0.5	

High-Risk Consensus Definition for Trials[4]

- R-ISS III
- R-ISS II with 1q21+, Del17p, t(14;16), t(14;20)
- Circulating PCs ≥5%
- Extramedullary disease

1. Palumbo A, et al. *J Clin Oncol*. 2015;33:2863-2869; 2. Costa LJ, Usmani SZ. J Natl Compr Canc Netw. 2020;18(12):1730-1737;
2. 3. D'Agostino et al. *J Clin Oncol* 2022 ;40(29):3406-3418; 4; Davies F et al. Blood Cancer Discovery 2022

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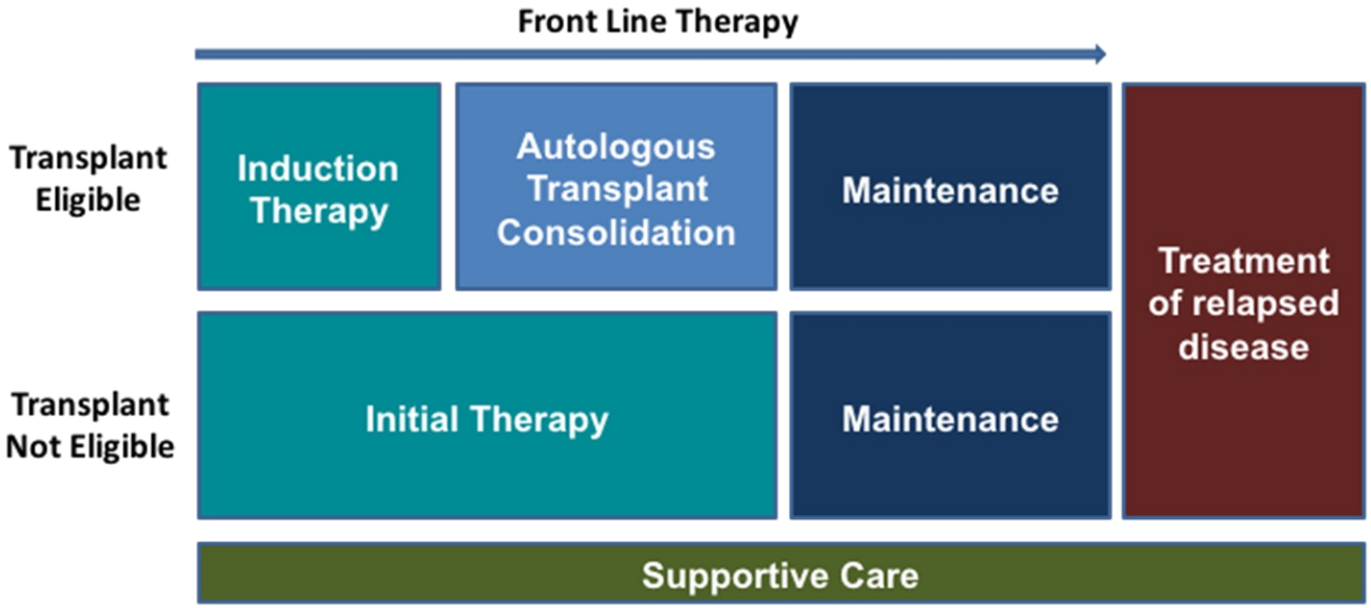
Treatment Paradigm For Newly Diagnosed Multiple Myeloma



Standard-Risk NDMM OS: ~ 13 years
High-Risk NDMM OS: ~ 7 years

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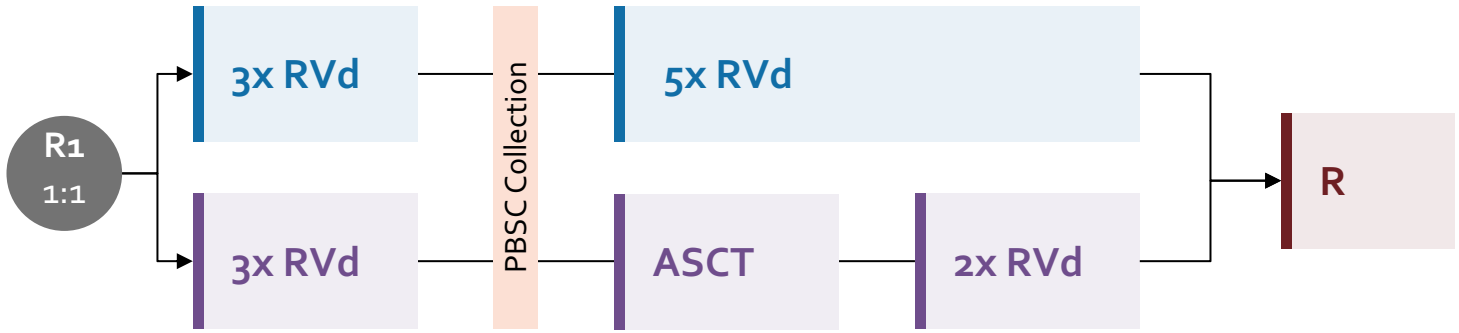
IFM 2009 Study: Early vs Late ASCT



RVd 21-day Cycles
R: 25 mg d 1 – 14
V: 1.3 mg/m² d 1, 4, 8, 11
d: 20 mg d 1, 2, 4, 5, 8, 9, 11, 12

R Maintenance
R: 10-15 mg/d for 13 cycles

Primary endpoint: PFS
Secondary endpoints:
ORR, MRD, TTP, OS, safety

Attal M, et al. N Engl J Med. 2017;376:1311-1320.

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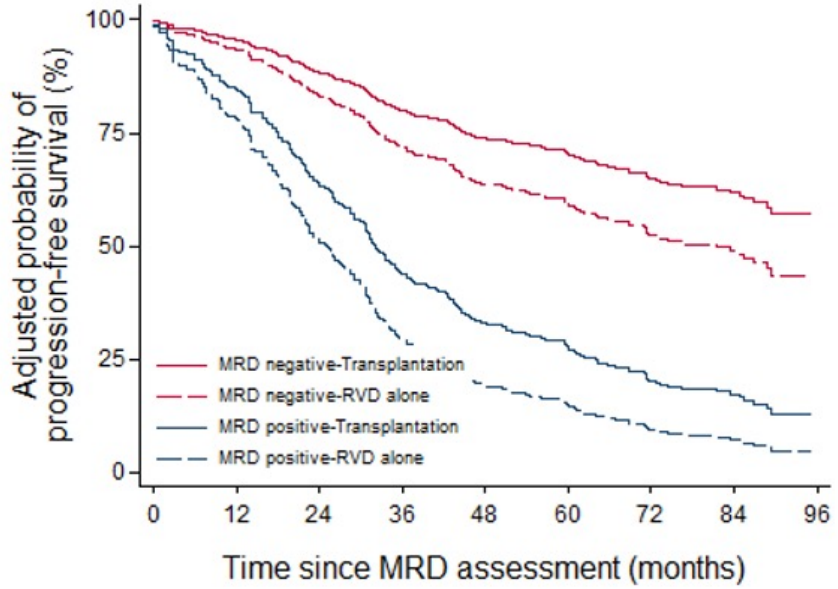
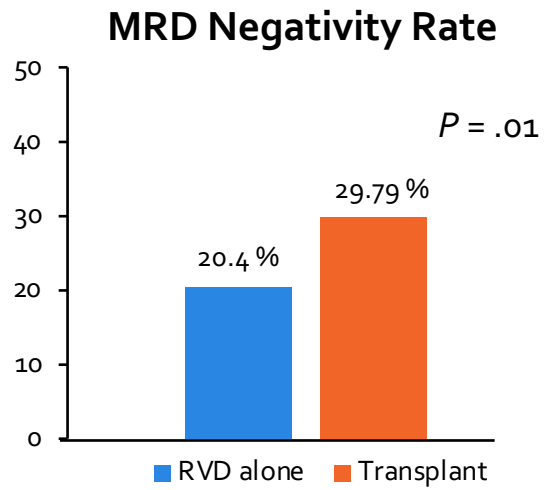
Superior PFS With ASCT vs RVd Alone





RVd + transplant was superior to RVd alone, even with undetectable MRD at 10^{-6}

MRD, minimal residual disease.
Perrot A. Presented at: 62nd ASH Annual Meeting and Exposition; December 5-8, 2020; Abstract 143.

Presented by: Saad Z. Usmani, MD MBA FACP, @szusmani

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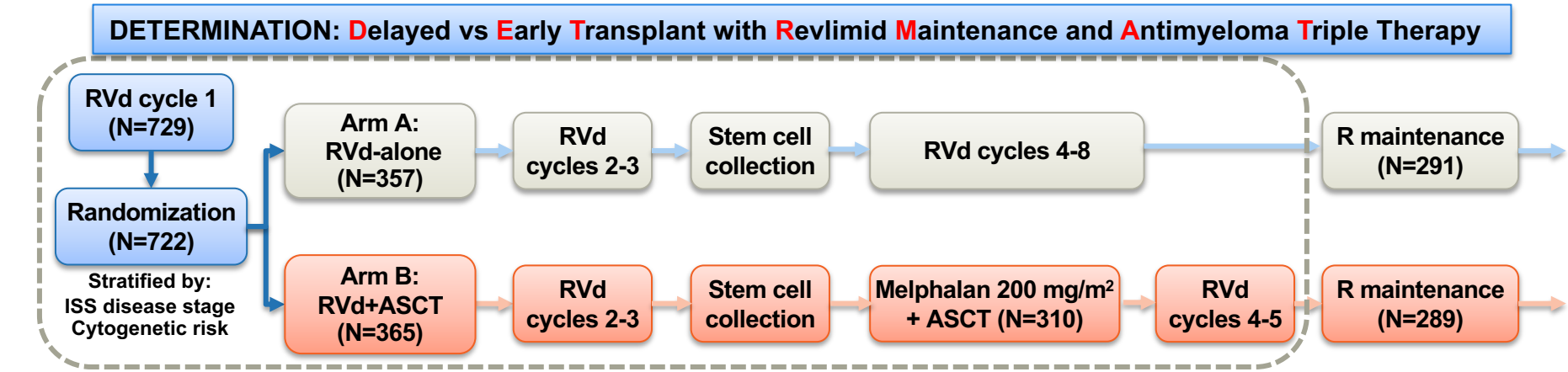
DETERMINATION: study design and patient disposition



Primary endpoint: PFS

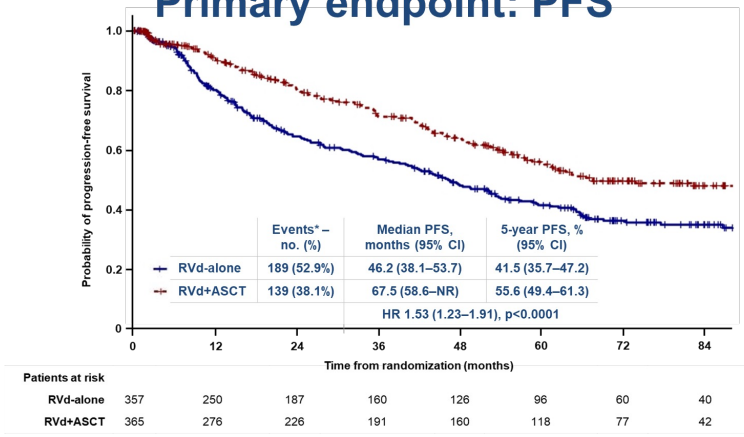
Secondary endpoints: response rates; DOR; TTP; OS; QoL; safety

- d/Dex, dexamethasone; DOR, duration of response; ISS, International Staging System; IV, intravenous; PO, orally; R, lenalidomide; SC, subcutaneous; TTP, time to progression; V, bortezomib

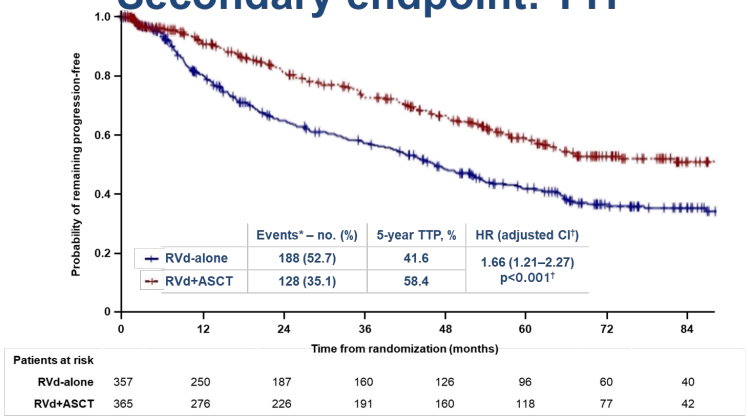
Richardson PG, et al. N Engl J Med. 2022 Jun 5. doi: 10.1056/NEJMoa2204925

DETERMINATION: Endpoint Readouts
(Median follow-up 70 months)

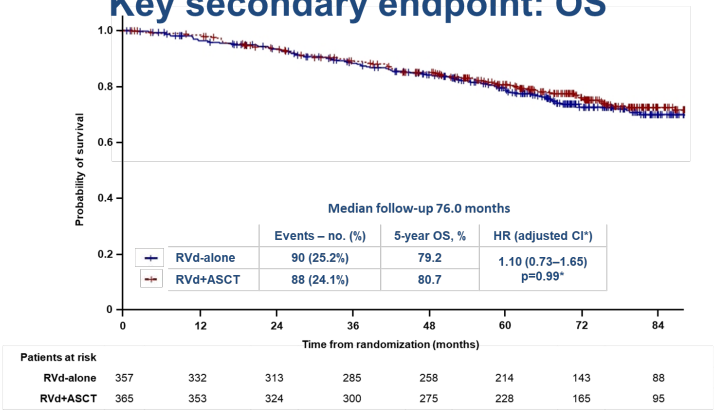
Primary endpoint: PFS



Secondary endpoint: TTP



Key secondary endpoint: OS



Second primary malignancies

5-year cumulative incidence of SPMs (RVd-alone vs RVd+ASCT):

- All : 9.7% vs 10.8%
- Invasive: 4.9% vs 6.5%
- Hematologic: 1.59% vs 3.52%

At time of data cutoff, among patients on the RVd-alone and RVd+ASCT arms who had hematologic SPMs, respectively:

- 6/7 vs 2/3 patients with ALL alive
- 6/10 patients with AML/MDS alive
- 1/2 patients with CLL/CML alive
- Overall, 7/9 RVd-alone vs 8/13 RVd+ASCT alive

SPMs	RVd-alone (N=357)	RVd+ASCT (N=365)
Any, %	10.4	10.7
Any invasive SPM, %	5.3	6.8
Any hematologic SPM, %	2.5	3.6
ALL, n	7	3
AML/MDS, n	0	10
CLL/CML, n	2	0
Any solid tumor SPM, %	3.4	3.3
Any non-invasive solid tumor SPM, %	0	0.5
Any non-melanoma skin cancer, %	5.9	4.1

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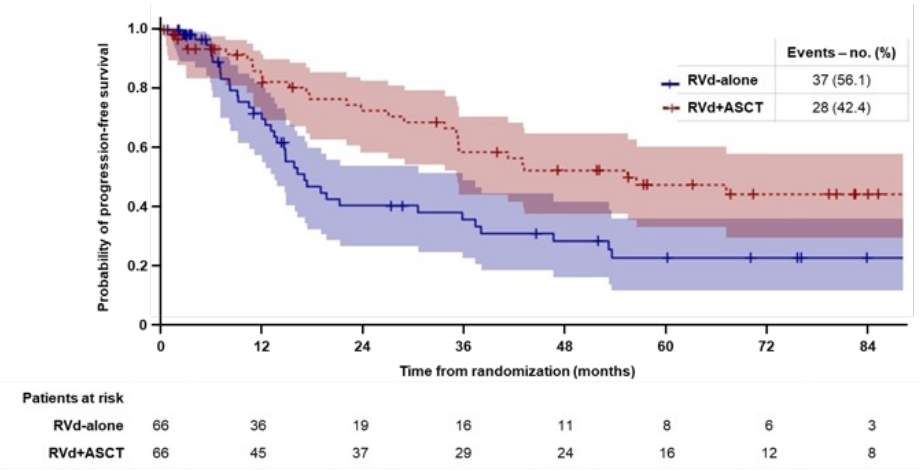
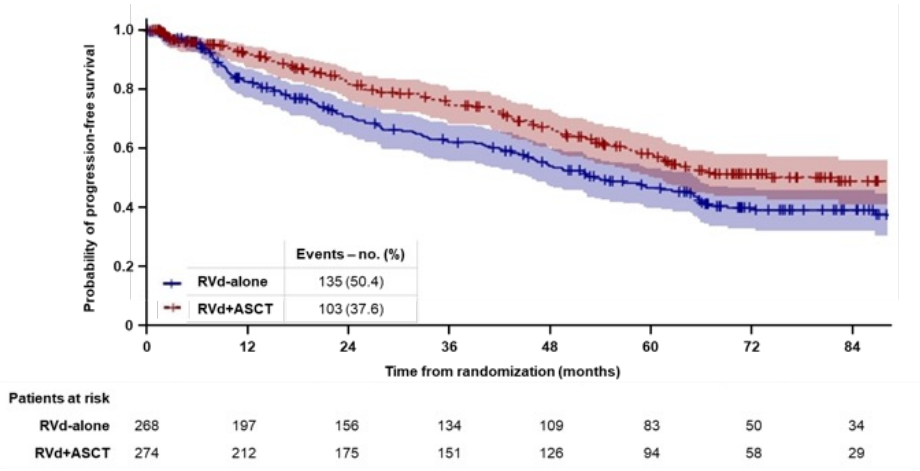
DETERMINATION Trial: PFS by Risk





Median PFS, months	RVd-alone	RVd+ASCT
High-risk	17.1	55.5
	HR 1.99 (95% CI 1.21–3.26)	

Median PFS, months	RVd-alone	RVd+ASCT
Standard-risk	53.2	82.3
	HR 1.38 (95% CI 1.07–1.79)	

Richardson PG, et al. N Engl J Med. 2022 Jun 5. doi: 10.1056/NEJMoa2204925

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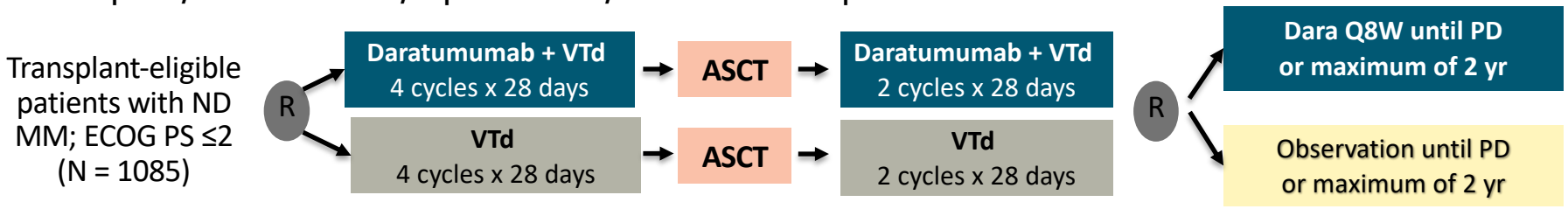
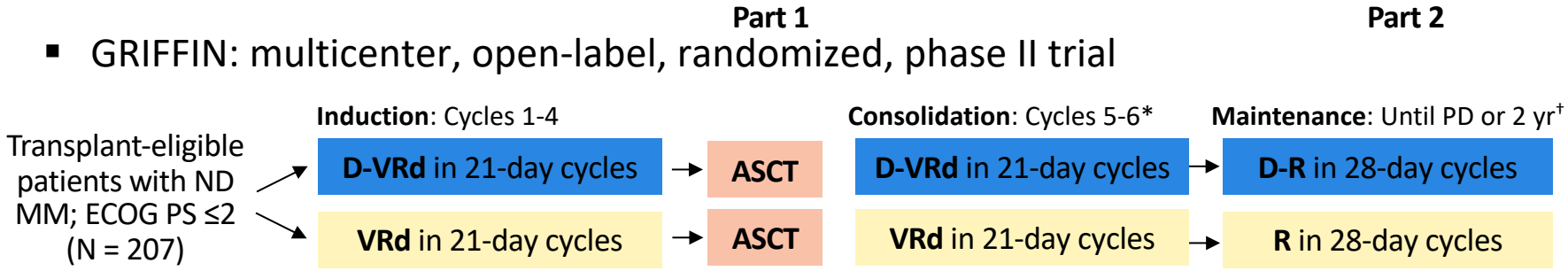
Trials With Daratumumab Quad Therapy in NDMM

- CASSIOPEIA: 2-part, multicenter, open-label, randomized phase III trial



- GRIFFIN: multicenter, open-label, randomized, phase II trial



*Consolidation began 60-100 days after ASCT. †Patients completing maintenance were permitted to continue single-agent lenalidomide.

Moreau. Lancet. 2019;394:29. Voorhees. Blood. 2020;136:936.

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Daratumumab-Based Quads: Depth of Response

Trial	Regimen	N	Depth of Response, %						
			Post Induction		Post ASCT		Post Consolidation		
			sCR	VGPR	sCR	VGPR	sCR	VGPR	MRD-
CASSIOPEIA	VTd	542	6.5	47.2	9.4	52.8	20.3	52.0	44
	Dara-VTd	543	7.4	50.5	13.4	54.1	28.9	44.6	64

Trial	Regimen	N	Depth of Response, %						
			Post Induction		Post Consolidation		Final Analysis		
			sCR	VGPR	sCR	VGPR	sCR	VGPR	MRD-
GRIFFIN	VRd	97	7.2	43.3	32	31	48	17	30
	Dara-VRd	99	12.1	52.5	42.4	39	67	13	64

Moreau. Lancet. 2019;394:29. Voorhees. Blood. 2020;136:936. Voorhees. Lancet Haematol. 2023;10:e825.

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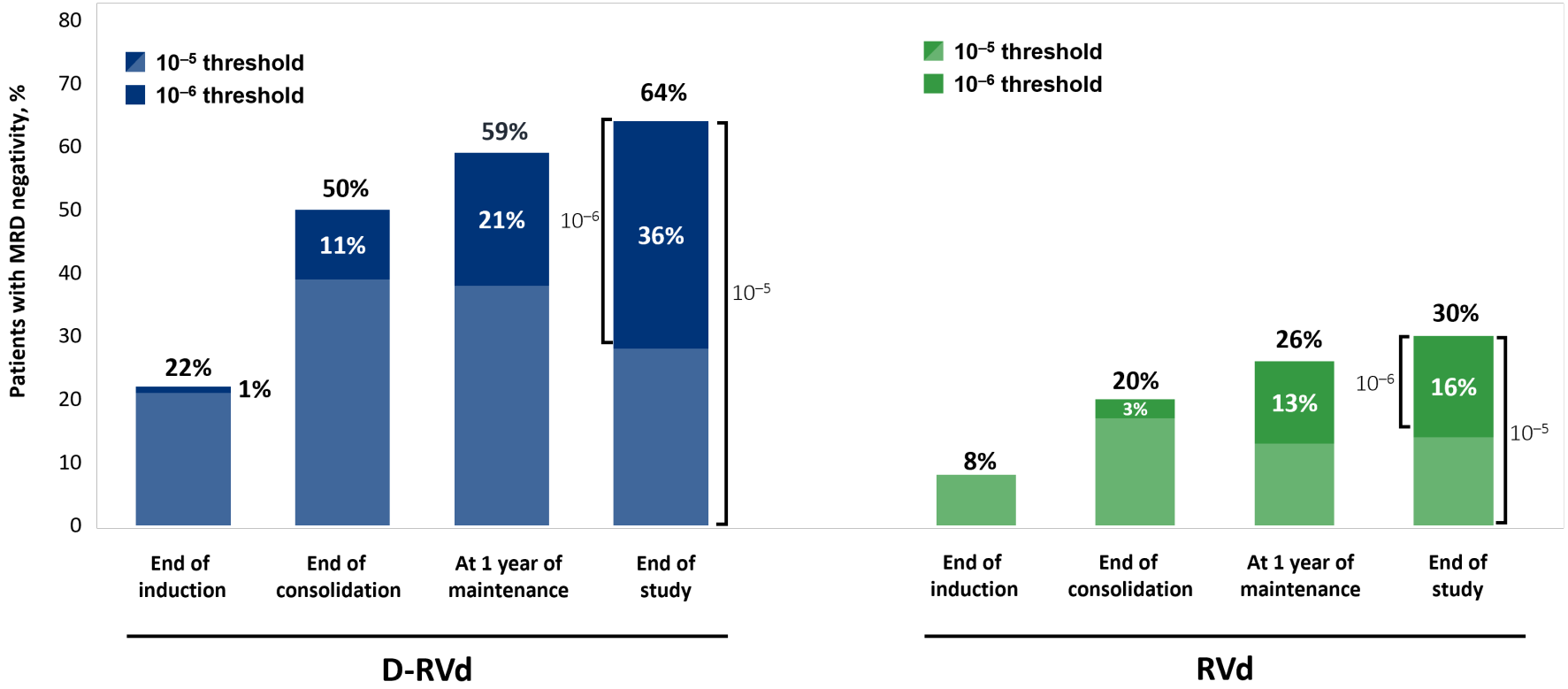
GRIFFIN: Daratumumab Plus Lenalidomide, Bortezomib, and Dexamethasone in Transplant-Eligible NDMM – 24 Months of Maintenance

RVd ± Daratumumab x 6 cycles (4 pre- and 2 post ASCT) → ASCT → R ± Daratumumab maintenance x 2 years → optional R maintenance



MRD assessed in the ITT population

Voorhees PM et al. Lancet Haematology 2023.

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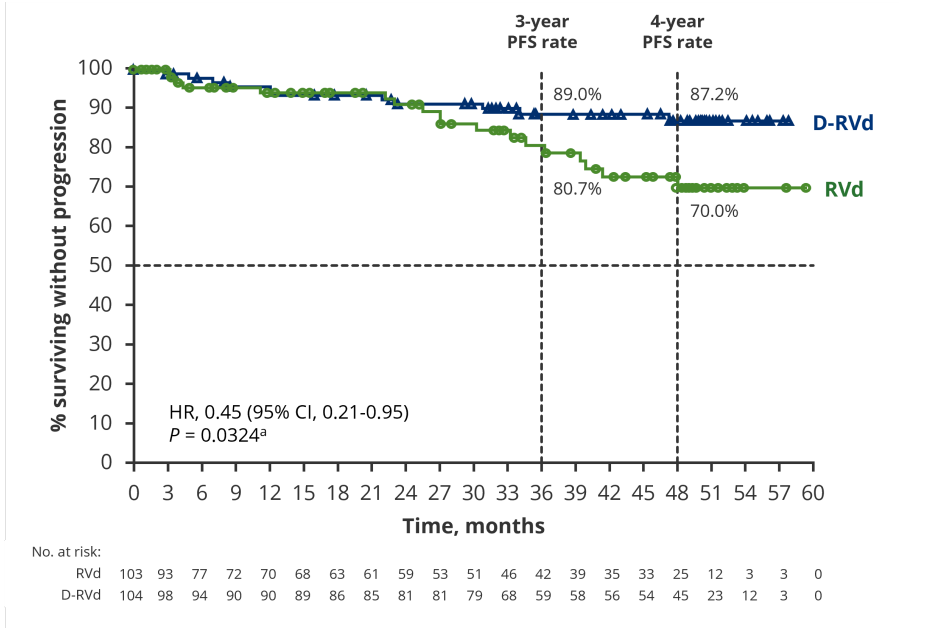
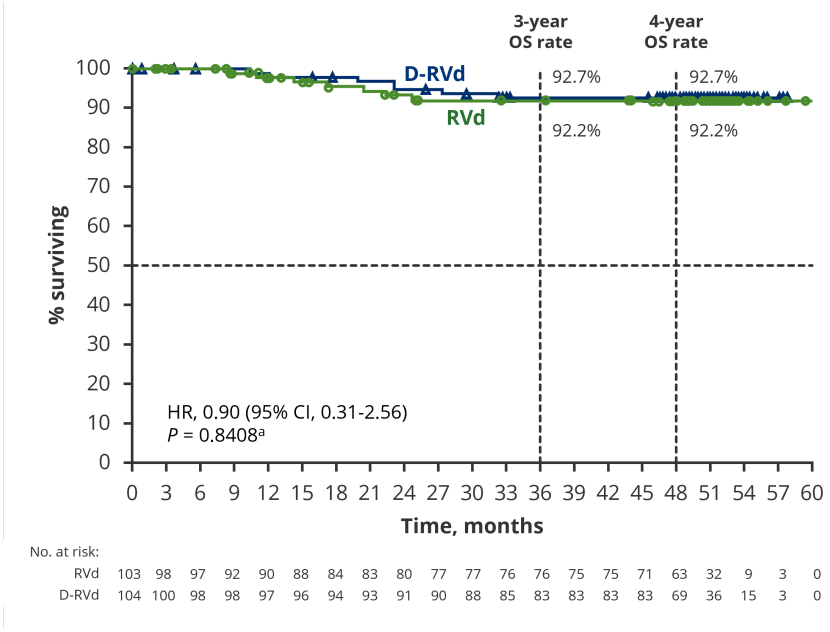
GRIFFIN: Longitudinal Outcomes





Voorhees PM et al. Lancet Haematology 2023.

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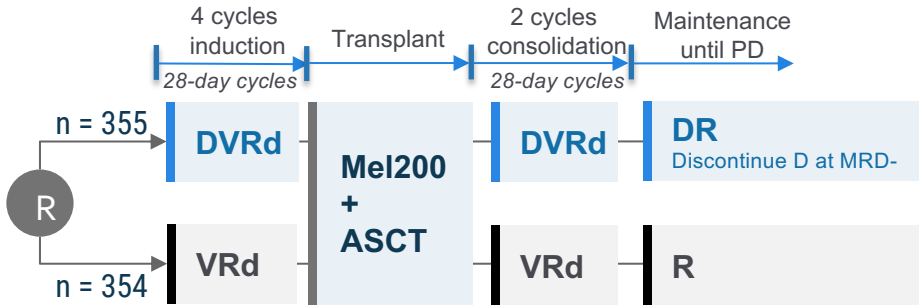
PERSEUS: *DVRd vs VRd in Transplant-Eligible NDMM*

Eligibility

- Transplant-eligible NDMM
- Age 18 – 70
- ECOG PS 0 – 2



Induction/Consolidation Schedule
D: 1800 mg SC days 1, 8, 15, 22 in cycles 1-2, days 1, 15 in cycles 3-6
V: 1.3 mg/m² days 1, 4, 8, 11
R: 25 mg PO days 1 – 21
d: 40 mg PO/IV days 1-4, 9-12

Key Baseline Characteristics	DVRd n = 355	VRd n = 354
Median age (range), y	61 (32 – 70)	59 (31 – 70)
High risk cytogenetics, n (%)	76 (21.4)	78 (22.0)
Extramedullary disease, n (%)	15 (4.2)	16 (4.5)
ISS stage, n (%)		
I	186 (52.4)	178 (50.4)
II	114 (32.1)	125 (35.4)
III	55 (15.5)	50 (14.2)

Primary endpoint: PFS

Key secondary endpoints: CR rate, MRD, OS

- ASCT, autologous stem cell transplant; CR, complete response; DVRd, daratumumab, bortezomib, lenalidomide, and dexamethasone; DR, daratumumab and lenalidomide; ECOG, Eastern Cooperative Oncology Group; ISS, International Staging System; IV, intravenous; MRD, minimal residual disease; NDMM, newly diagnosed multiple myeloma; PFS, progression-free survival; PS, performance status; OS, overall survival; PO, by mouth; R, lenalidomide; SC, subcutaneous; VRd, bortezomib, lenalidomide, and dexamethasone.

Sonneveld P, et al. NEJM 2023

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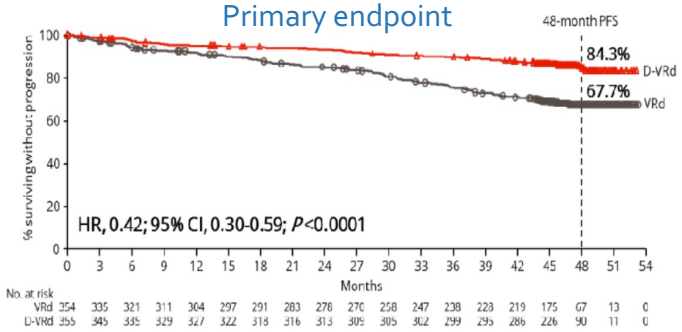
PERSEUS: *PFS and OS*

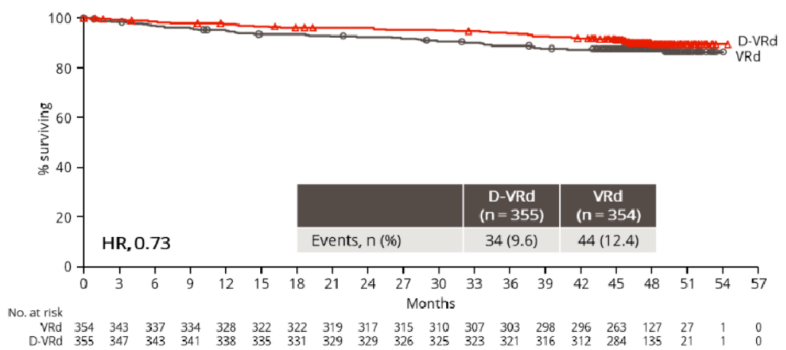
Median follow-up 47.5 mo

PFS

Primary endpoint



OS



Sonneveld P, et al. NEJM 2023

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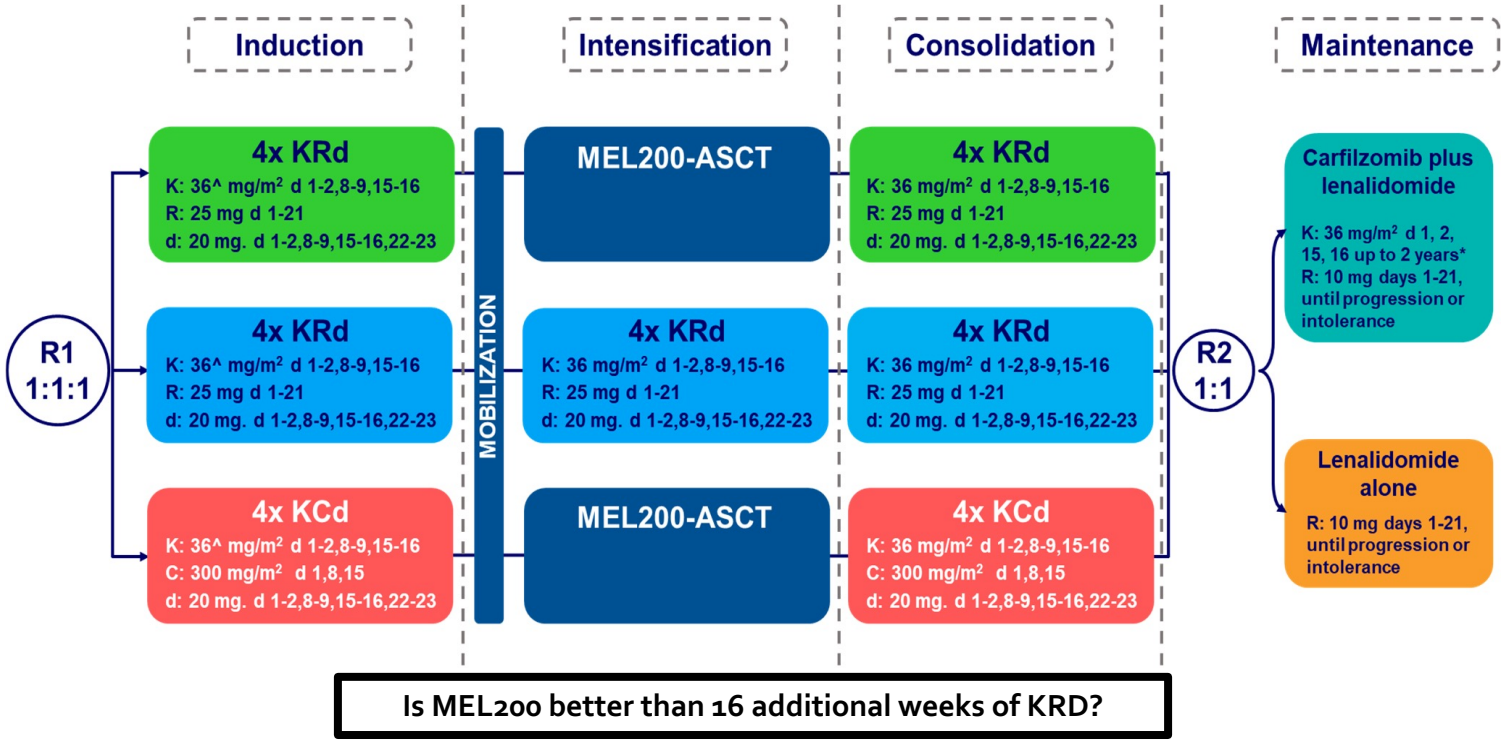
The FORTE Trial

Multicenter, Randomized (1:1), Open-Label, Phase 2 Study



FORTE. Updated November 3, 2022. https://classic.clinicaltrials.gov/ct2/show/NCT02203643

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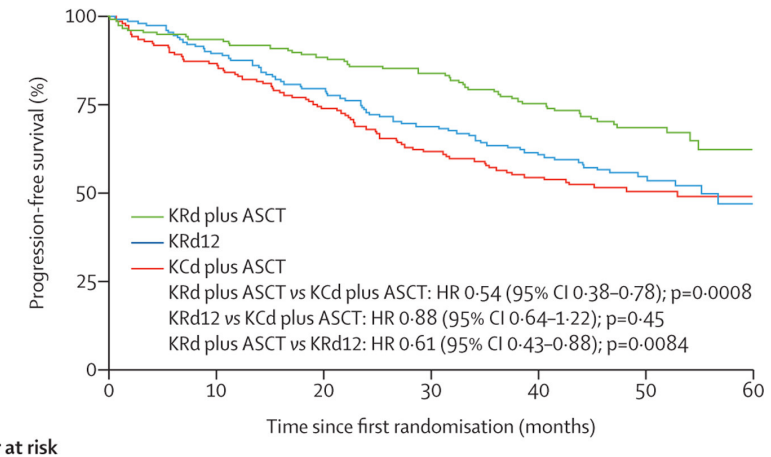
FORTE: Depth of Response and PFS

Progression-Free Survival



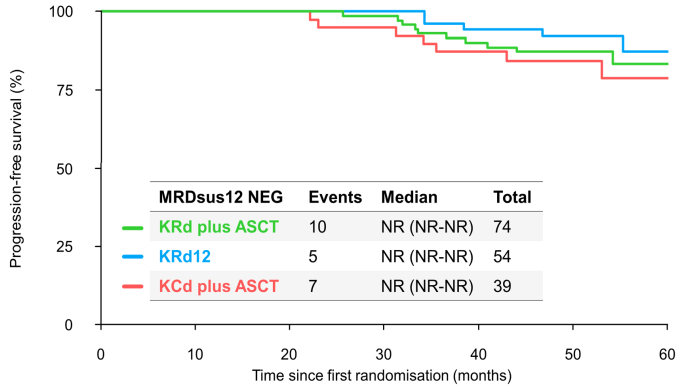
Number at risk (number censored)							
KRd plus ASCT	158 (0)	147 (1)	137 (3)	129 (4)	111 (9)	61 (51)	5 (103)
KRd12	157 (0)	135 (6)	120 (6)	103 (7)	90 (9)	51 (39)	5 (81)
KCd plus ASCT	159 (0)	137 (1)	115 (3)	94 (5)	80 (8)	46 (37)	6 (76)

The quality of MRD negativity was superior in the KRd → ASCT arm

MRD Negativity		
Treatment Arm	**Pre-Maintenance**	**Sustained 1 Year**
KRd → ASCT	62%	47%[†]
KRd 12	58%	35%
KCd → ASCT	43%	25%

[†] OR KRd → ASCT vs KRd 12: 1.69 (95% CI 1.07 – 2.66, *P* = .024).

Progression-Free Survival With Sustained MRD Negativity



MRDsus12 NEG:							
KRd plus ASCT	74 (0)	73 (1)	72 (2)	71 (2)	63 (4)	39 (27)	4 (60)
KRd12	54 (0)	54 (0)	54 (0)	54 (0)	50 (1)	34 (16)	2 (47)
KCd plus ASCT	39 (0)	39 (0)	39 (0)	37 (0)	33 (1)	20 (13)	2 (30)

Number at risk (number censored)

Gay F et al. *Lancet Oncol*. 2021;22(12):1705-1720.

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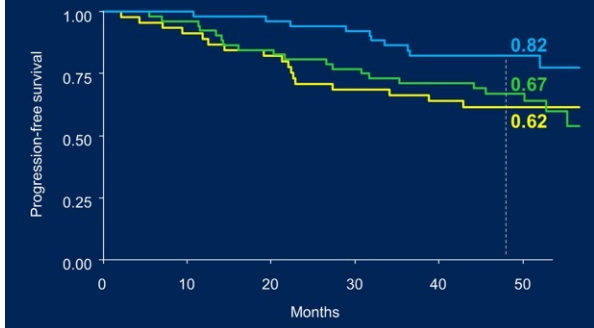
Progression-free survival: Random 1

KRd_ASCT vs. KRd12 vs. KCd_ASCT

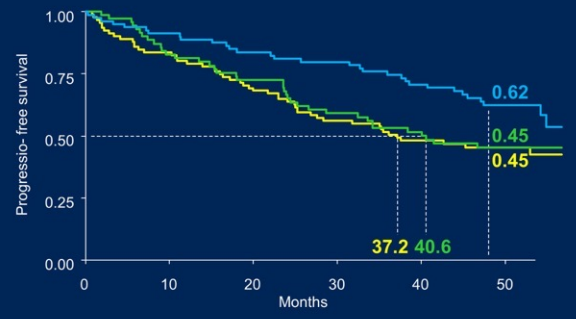
Median follow-up from Random 1: 51 months (IQR 46-55)

Standard risk (N=153)



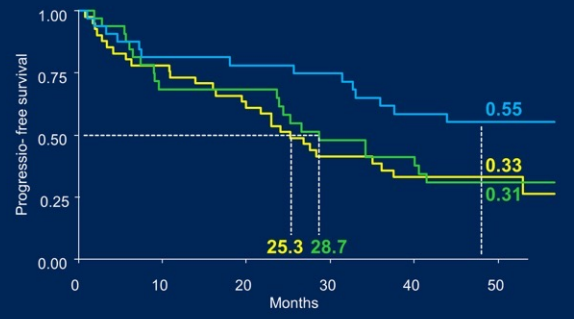
KRd_ASCT vs. KCd_ASCT: HR 0.44, p=0.04
KRd_ASCT vs. KRd12: HR 0.46, p=0.04
KRd12 vs. KCd_ASCT : HR 0.96, p=0.9

High risk (N=243)



KRd_ASCT vs. KCd_ASCT: HR 0.57, p=0.01
KRd_ASCT vs. KRd12: HR 0.6, p=0.04
KRd12 vs. KCd_ASCT: HR 0.95, p=0.8

Double hit (N=105)



KRd_ASCT vs. KCd_ASCT: HR 0.49, p=0.03
KRd_ASCT vs. KRd12: HR 0.53, p=0.07
KRd12 vs. KCd_ASCT: HR 0.91, p=0.75

Random 1, first randomization (induction/consolidation treatment); ASCT, autologous stem-cell trasplantation; K, carfilzomib; R, lenalidomide; C, cyclophosphamide; d, dexamethasone; KCd_ASCT, KCd induction-ASCT-KCd consolidation; KRd_ASCT, KRd induction-ASCT-KRd consolidation; KRd12, 12 cycles of KRd; HR, hazard ratio; CI, confidence interval; p, p-value; iQR, interquartile range.

Presented By: Francesca Gay

2021 ASCO ANNUAL MEETING

Presented by: Saad Z. Usmani, MD MBA FACP, @szusmani

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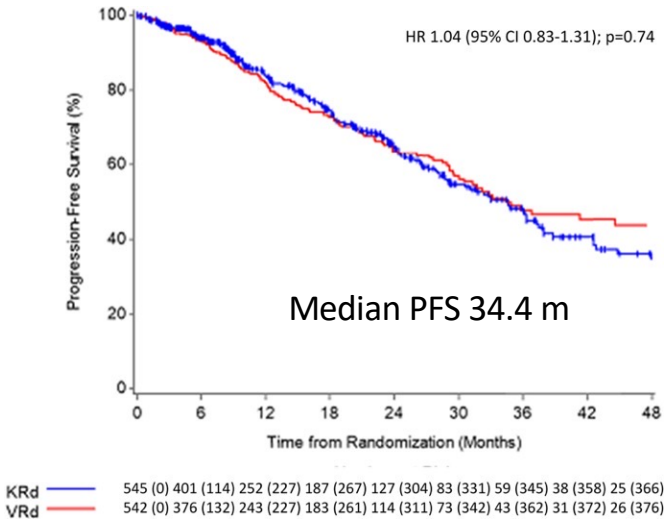
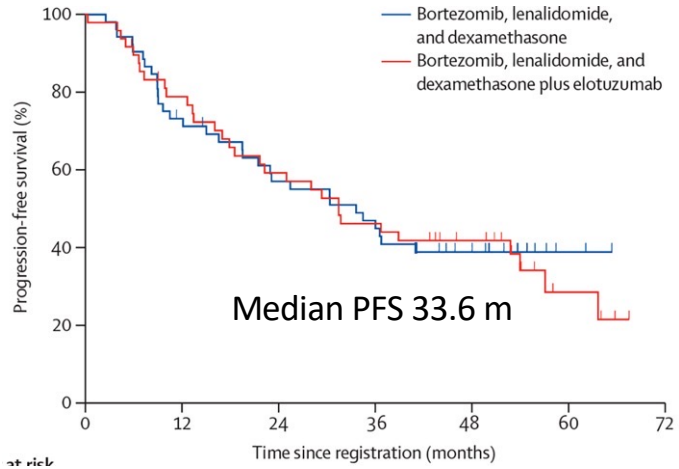
Impact of PI/IMiD Maintenance in High-Risk MM

Standard Risk



ENDURANCE: VRd or KRd with len maintenance
Kumar S et al Lancet Oncol 2021

High Risk



S1211: Elo VRd or VRd with VR maintenance
Usmani SZ et al Lancet Haematol 2021

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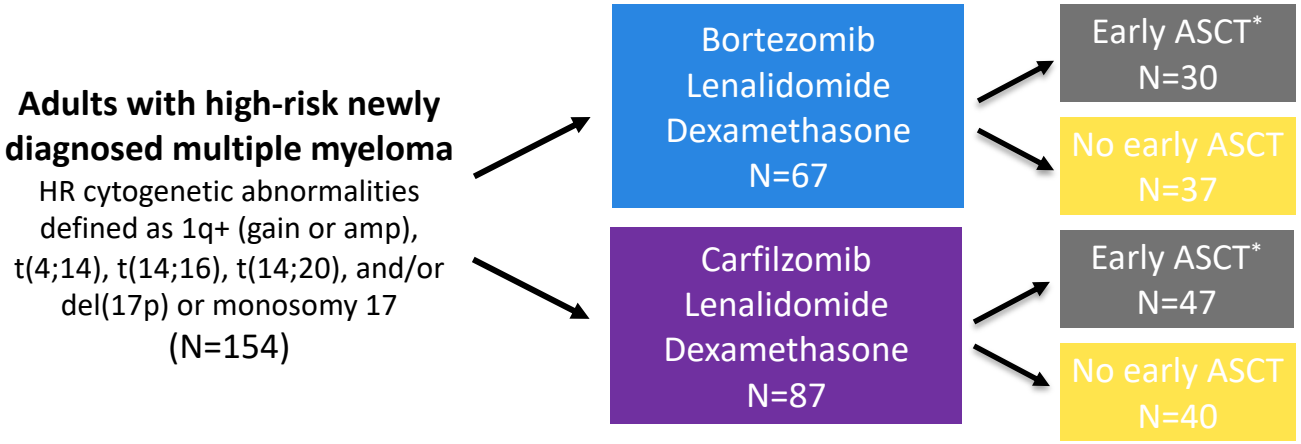
Carfilzomib, Lenalidomide, and Dexamethasone (KRd) vs Bortezomib, Lenalidomide, and Dexamethasone (VRd) as Induction Therapy in Newly Diagnosed HR-NDMM

- **We conducted a retrospective chart review study with 154 consecutive HR-NDMM patients treated with KRd and VRd at Memorial Sloan Kettering Cancer Center.**
- **Time period: January 1, 2015 to December 31, 2019**
- **Date of last follow-up: Sept. 30, 2022**



Primary endpoint:
Progression Free Survival
Secondary endpoints:
- Overall response rate
- MRD negativity rate
- Event Free Survival
- Overall Survival

*Early ASCT: ASCT within 12 months of start of induction therapy without progressive disease
HR: high risk; NDMM: newly diagnosed multiple myeloma; VRd: Bortezomib, lenalidomide, dexamethasone; KRd: Carfilzomib, lenalidomide, dexamethasone; ASCT: Autologous stem cell transplant

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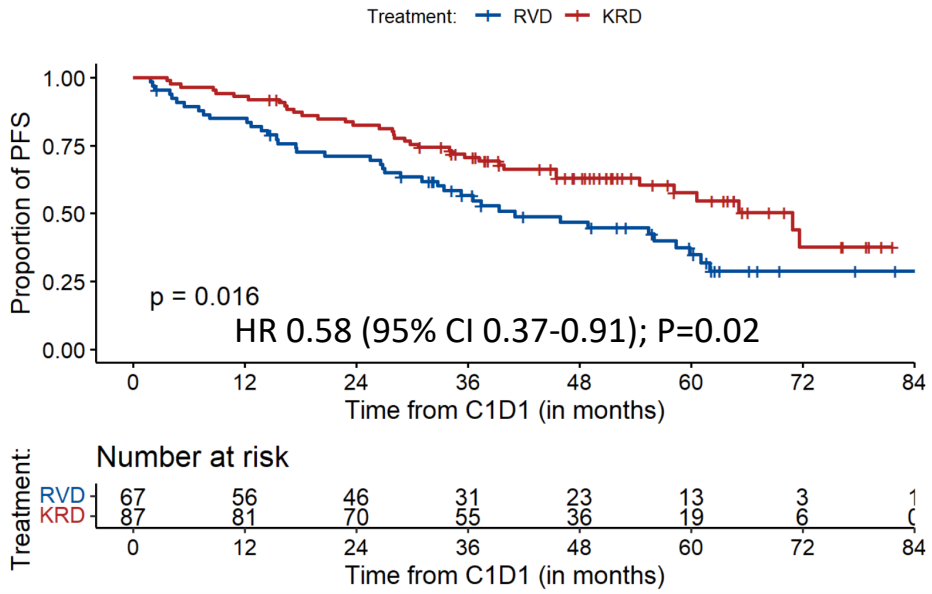
Progression Free Survival



Median f/u for all patients: 55.8 mos (95%CI 50.9-62.6)

Median f/u VRd 61.7 mos (95%CI 53-67.1)

Median f/u KRd 51.6 mos (95%CI 49.1-63.5)

PFS	VRd (N=67)	KRd (N=87)
Median, mo (95%CI)	41 (32.8 – 61.1)	70.9 (58.2 – NR)*
5-yr estimate (95%CI)	35% (24% - 51%)	58% (47% - 71%)

*Median PFS is an estimate

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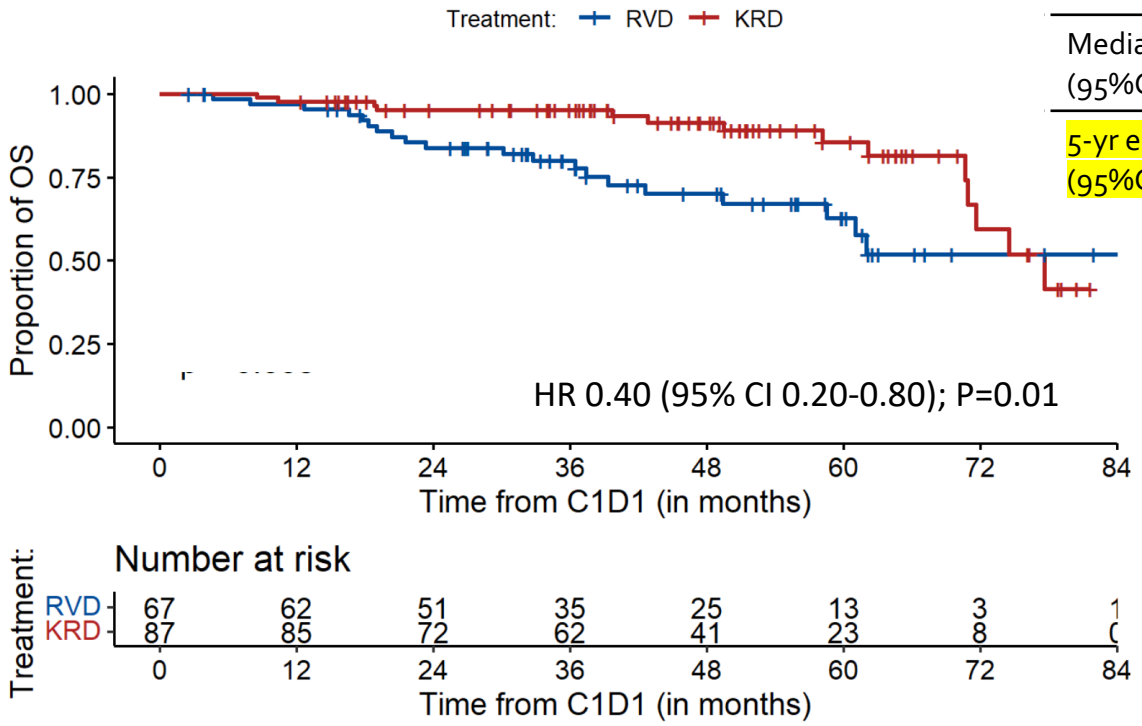
Presented by: Saad Z. Usmani, MD MBA FACP, @szusmani

Overall Survival



OS	VRd (N=67)	KRd (N=87)
Median, mo (95%CI)	NR	77.7 (70.9-NR)
5-yr estimate (95%CI)	63% (49%-80%)	85% (76%-96%)

Median f/u for all patients: 48.9 mos (95%CI 44.9-53)

Median f/u VRd: 49.3 mos (95%CI 36.6-59.8)

Median f/u KRd: 48.6 mos (95%CI 44.9-52.6)

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MRD negativity by cytogenetic risk status* among patients who received D-KRd in MASTER and D-RVd in GRIFFIN

	D-KRd			D-RVd		
	0 HRCA	1 HRCA	≥2 HRCAs	0 HRCA	1 HRCA	≥2 HRCAs
MRD negative						
Evaluable population	n = 50†	n = 44†	n = 24†	n = 67‡	n = 34‡	n = 13‡
10^{-5} sensitivity, %	80.0	86.4	83.3	76.1	55.9	61.5
10^{-6} sensitivity, %	68.0	79.5	66.7	44.8	26.5	15.4
In patients achieving ≥CR	n = 45	n = 39	n = 17	n = 60	n = 26	n = 8
10^{-5} sensitivity, %	84.4	89.7	94.1	74.6	52.9	53.8
Durable MRD negativity lasting ≥12 months						
Evaluable population	n = 50†	n = 44†	n = 24†	n = 67‡	n = 34‡	n = 13‡
10^{-5} sensitivity, %	64.0	72.7	50.0	53.7	38.2	30.8

MRD minimal residual disease, D-KRd daratumumab plus carfilzomib/lenalidomide/dexamethasone, D-RVd daratumumab plus lenalidomide/bortezomib/dexamethasone, HRCA high-risk cytogenetic abnormality, CR complete response, NA not available.

*HRCAs include any of the following genetic abnormalities: del(17p), t(4;14), t(14;16), t(14;20), and gain/amp(1q21) (≥3 copies of chromosome 1q21). Patients were grouped into categories: standard risk (0 HRCA), high risk (1 HRCA), or ultra-high risk (≥2 HRCAs).

†For MASTER, data are for all enrolled patients with available MRD data.

‡For GRIFFIN, the D-RVd group included patients from the randomized phase (n = 104) and the safety run-in phase (n = 16). Patients were grouped by HRCA: 0 HRCA (n = 67), 1 HRCA (n = 34), or ≥2 HRCAs (n = 13). 6 patients were not evaluable for cytogenetic abnormalities.

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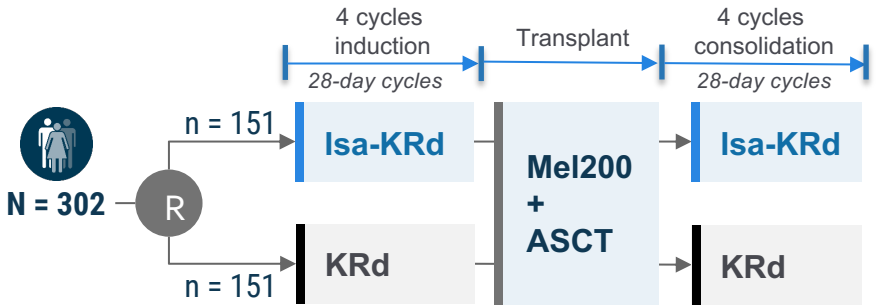
IsKia
Isa-KRd vs KRd in Transplant-Eligible NDMM

Eligibility
- Transplant-eligible NDMM
- Age < 70y



Induction/Consolidation Schedule
Isa: 10 mg/kg IV days 1, 8, 15, 22 in cycle 1,
10 mg/kg IV days 1,15 in cycles 2 – 4
K: 20/56 IV mg/m² days 1, 8, 15
R: 25 mg PO days 1 – 21
d: 40 mg PO days 1, 8, 15, 22

Primary endpoint: rate of post-consolidation MRD-negativity in ITT population

Key secondary endpoints: post-induction MRD-negativity, PFS

Key Baseline Characteristics	Isa-KRd n = 151	KRd n = 151
Median age (range), y	61 (55 – 66)	60 (54 – 63)
High risk by IMWG[a]	25 (18)	26 (19)
# of HRCA[b], n (%)		
0	78 (56)	75 (54)
1	49 (35)	49 (35)
2 or more	13 (9)	15 (11)
Missing	11	12
R-ISS stage, n (%)		
I	50 (35)	48 (34)
II	82 (58)	85 (59)
III	10 (7)	10 (7)
R2-ISS stage, n (%)		
I	34 (24)	35 (25)
II	45 (32)	47 (34)
III	52 (37)	51 (37)
IV	8 (6)	6 (4)

- a. del(17p), t(4;14), and/or t(14;16); b. del(17p), t(4;14), t(14;16), gain or amp(1q).
- Isa, isatuximab; KRd, carfilzomib, lenalidomide, and dexamethasone; R-ISS, Revised International Staging System; Mel200, melphalan 200 mg.

Gay F, et al. Blood. 2023;142(Suppl 1): Plenary Abstract 4.

Presented by: Saad Z. Usmani, MD MBA FACP, @szusmani

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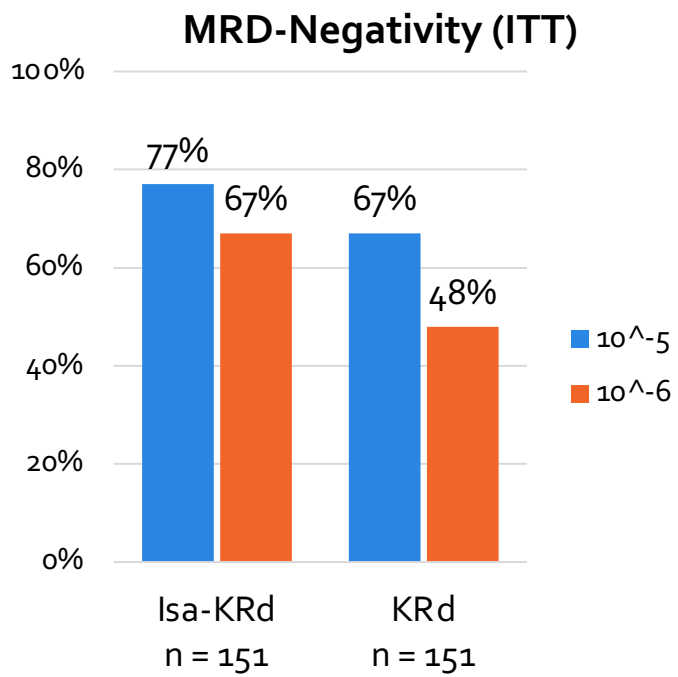
IsKia: Responses

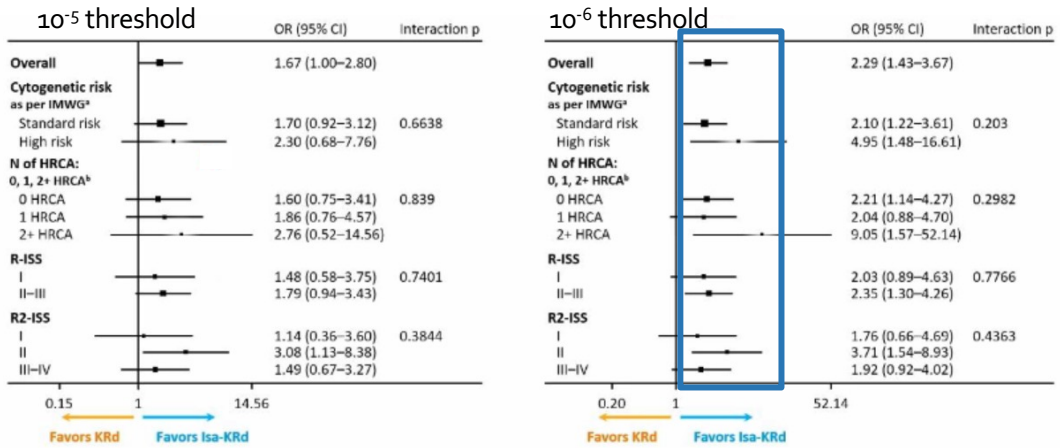
Post-consolidation MRD-Negativity in ITT population

Primary endpoint



MRD advantage with Isa-KRd retained across all subgroups

Subgroup analysis



MRD-Negativity by HRCA	10-5		10-6	
	Isa-KRd	KRd	Isa-KRd	KRd
0 HRCA	79%	72%	65%	48%
1 HRCA	78%	65%	69%	53%
2+ HRCA	**77%**	**53%**	**77%**	**27%**

- Gay F, et al. Blood. 2023;142(Suppl 1): Plenary Abstract 4.

Gay F, et al. Blood. 2023;142(Suppl 1): Plenary Abstract 4.

Presented by: Saad Z. Usmani, MD MBA FACP, @szusmani

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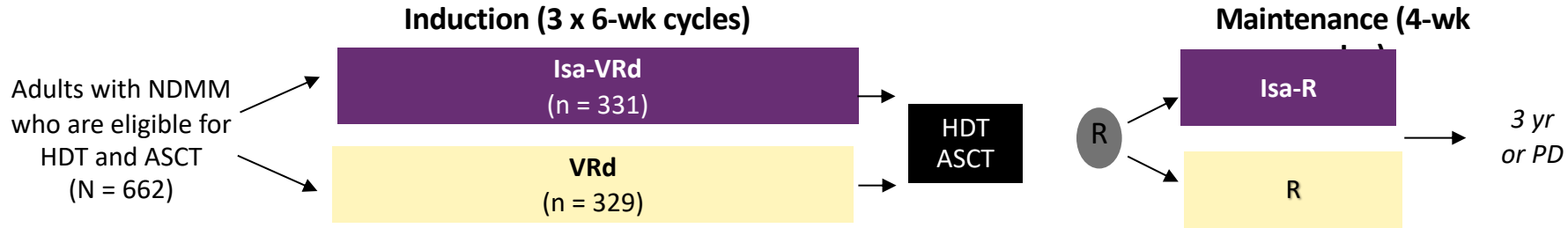
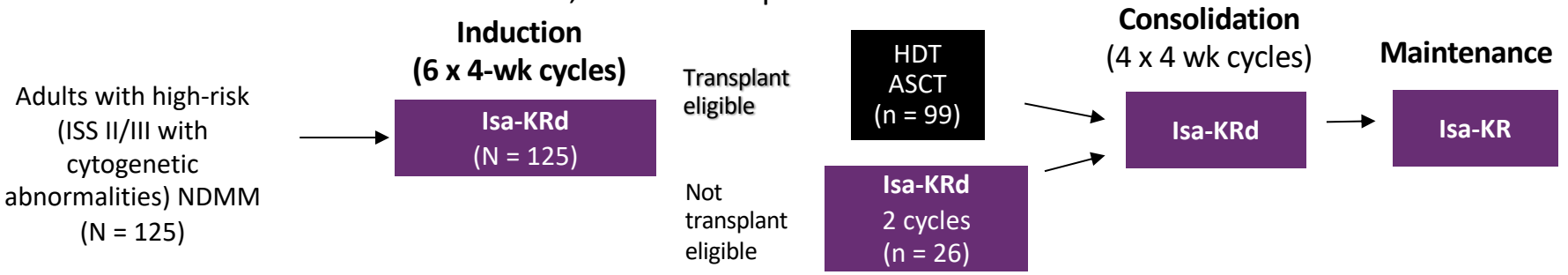
Trials With Isatuximab Quad Therapy in NDMM

- GMMG-HD7: 2-part, multicenter, open-label, randomized phase III study



- GMMG-CONCEPT: nonrandomized, multicenter phase II trial



Goldschmidt. Lancet Haem. 2022;9:e810. Leypoldt. JCO. 2023;[Epub].

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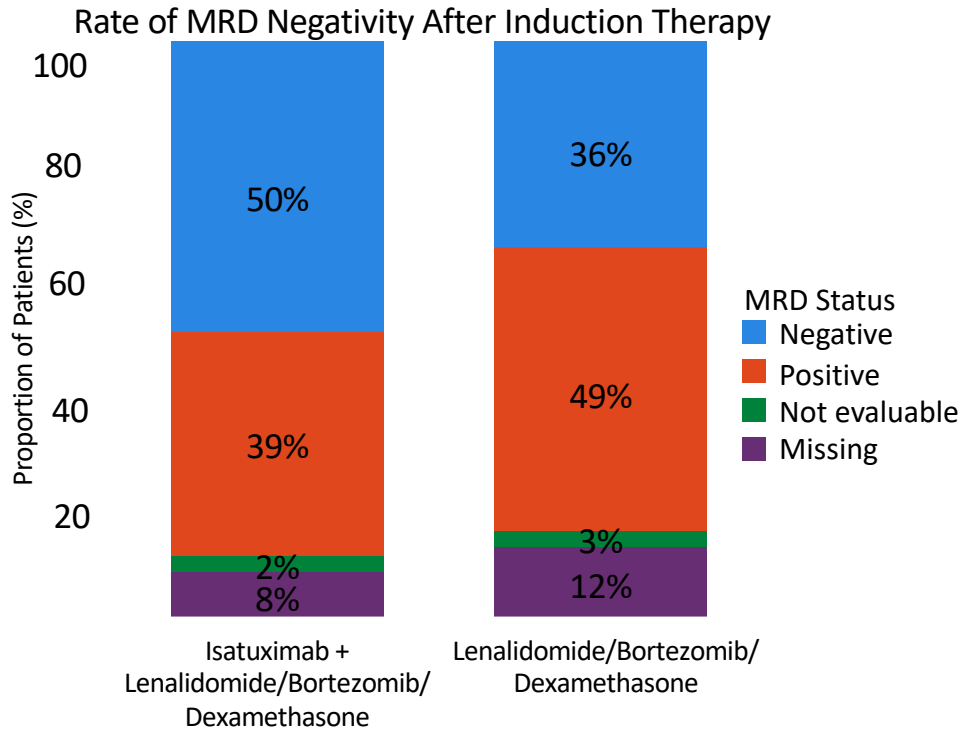
GMMG-HD7: Isatuximab-VRd vs VRd MRD Negativity After Induction (Primary Endpoint)



Parameter	Isa-RVd (n = 331)	Kd (n = 329)
MRD negative (10^{-5}, NGF) after induction, %	50	36
	OR: 1.82; 95% CI: 1.33-2.48; *P* = .00017	
CR, %	24	22
	OR: 1.12; 95% CI: 0.77-1.63; *P*=.58	
≥VGPR, %	77	61
	OR: 2.13; 95% CI:1.5-3.05; *P* <.0001	
≥PR, %	90	84
	OR: 1.6; 95% CI:0.98-2.63; *P* =.049	
≥VGPR + MRD negative, %	47	32
	OR: 1.93; 95% CI:1.39-2.68; *P* <.0001	

Goldschmidt. Lancet Haem. 2022;9:e810. NCT03617731.

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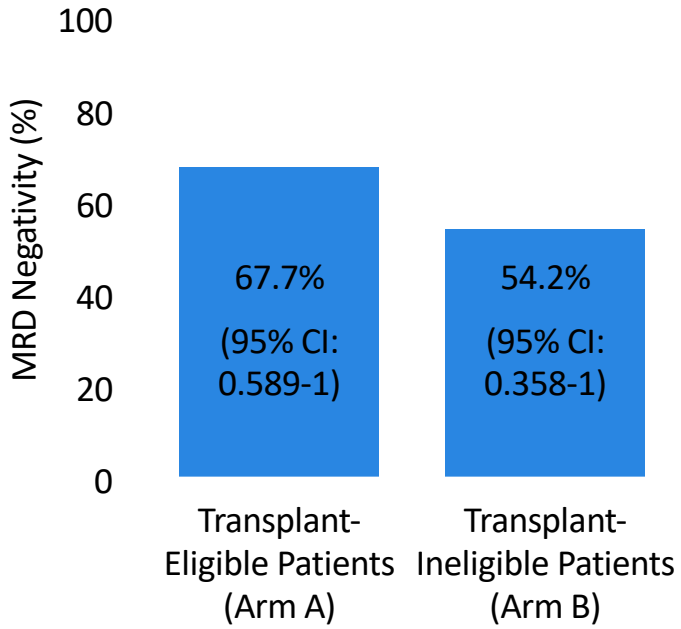
GMMG-CONCEPT: Isatuximab-KRd Negativity After Induction (Primary Endpoint)



Outcome, n (%)	Transplant-Eligible Patients (n = 99)	Transplant-Ineligible Patients (n = 26)
MRD negative (any time point)	81 (81.8)	18 (69.2)
MRD negativity for ≥6 mo	72 (72.7)	14 (53.8)
MRD negativity for ≥12 mo	62 (62.6)	12 (46.2)
CR/sCR	72 (72.8)	15 (57.7)
VGPR	18 (18.2)	8 (30.8)
ORR, %	94.9	88.5

- After median follow-up of 44 mo in transplant-eligible patients and 33 mo in transplant-ineligible patients, median PFS not reached

Leypoldt. JCO. 2023;[Epub].

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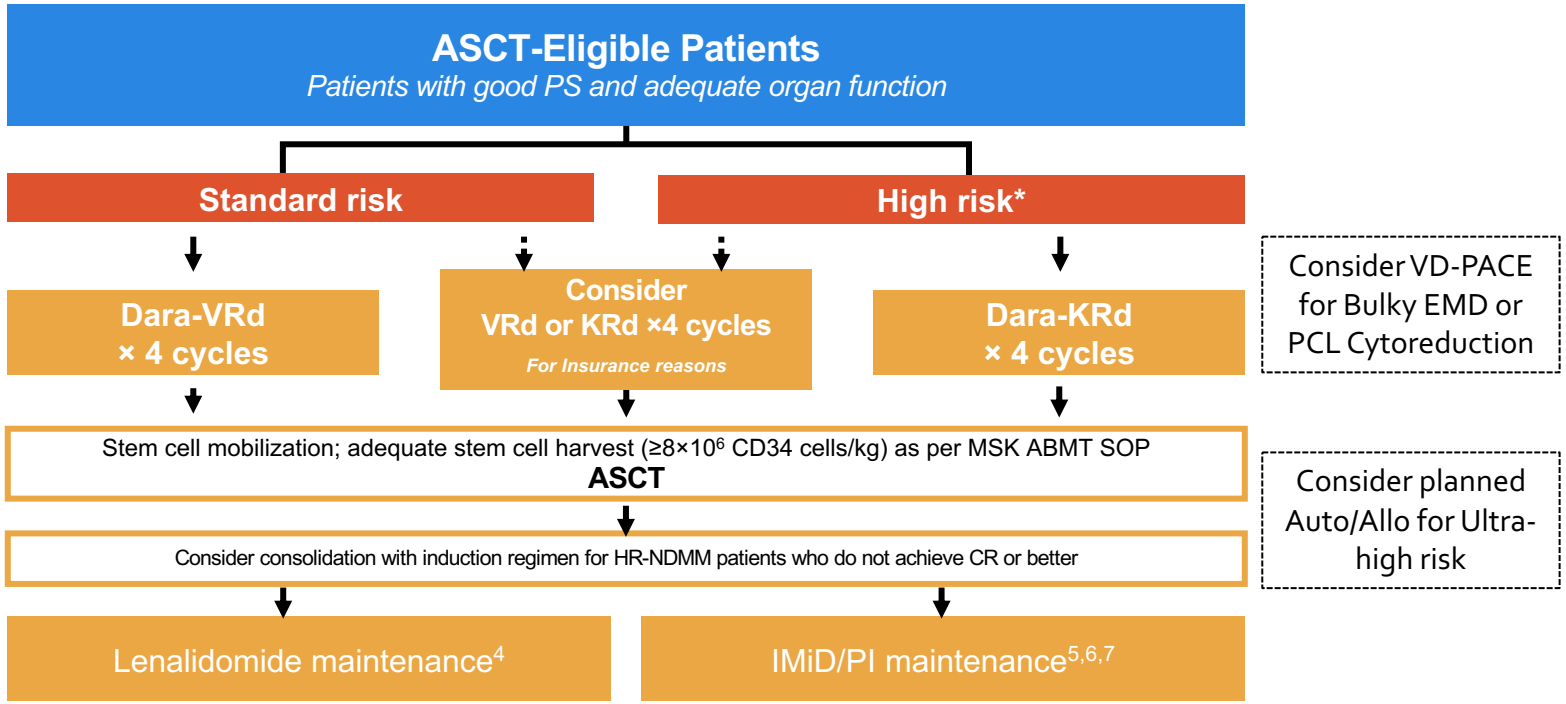
MSK Approach to Transplant Eligible NDMM



ASCT, autologous stem cell transplant; CR, complete response; DVRd, daratumumab, bortezomib, lenalidomide, and dexamethasone; IMiD, immunomodulatory drug; PI, proteasome inhibitor; PS, performance status; Tx, treatment.

*By R-ISS staging (R-ISS II/III) and/or cytogenetics (t[4;14], t[14;16], or del[17p]), elevated LDH, primary plasma cell leukemia

1. Attal. *NEJM*. 2017;376:1311. 2. Voorhees PM. Blood 2020. Gay. ASH 2020. Abstr 294. 4. McCarthy. *J Clin Oncol*. 2017;35:3279. 5. Nooka. *Leukemia*. 2014;28:690. 6. Dimopoulos. ASH 2018. Abstr 301. 7. Usmani. *Lancet Haematol*. 2021 Jan;8(1):e45-e54.

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Conclusions

- Picking the right strategy that gives the highest likelihood of the best depth of response in the first year of diagnosis is extremely important for survival outcomes.
- Anti-CD38 monoclonal antibody-based quadruplet induction provide better depth of response, translating into better PFS (GRIFFIN, CASSIOPEIA, GMMG-HD7).
- Future strategies may incorporate BsAb or biomarker directed small molecules into induction.
- Never under-treat, put your best foot forward!
  - Especially true for high risk NDMM (HR-NDMM)

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- Heather Landau (ABMT)
- Kylee Maclachlan
- Sham Mailankody (Research Director)
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- Sridevi Rajeeve
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- Gunjan Shah (ABMT)
- Urvi Shah
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