



Sagar Lonial, MD

Department Chair and Professor of Hematology and Medical Oncology
Multiple Myeloma

Dr. Sagar Lonial earned his medical degree from the University of Louisville School of Medicine. He completed his internship and residency at Baylor College of Medicine in Houston, Texas, followed by a fellowship in hematology and oncology at Emory University School of Medicine in Atlanta, Georgia. His previous laboratory work has focused on evaluating the impact of purified dendritic cell subsets on the nature of immune responses against antigen, and he has completed several trials evaluating the impact of cytokines on dendritic cell content and post-transplant immune recovery. More recently, Dr. Lonial has focused on combinations of novel agents as therapy for myeloma

He serves as Vice Chair of the Myeloma Committee in the Eastern Cooperative Oncology Group and as Myeloma editor for Clinical Lymphoma, Myeloma and Leukemia. He has received the Celgene Young Investigator Award, the American Cancer Association (IACA) Life Time Achievement Award, the COMY Multiple Myeloma Excellence Award for Clinical Science, and the Giants of Cancer Care inductee, and currently holds the Anne and Bernard Gray Family Chair in Cancer.



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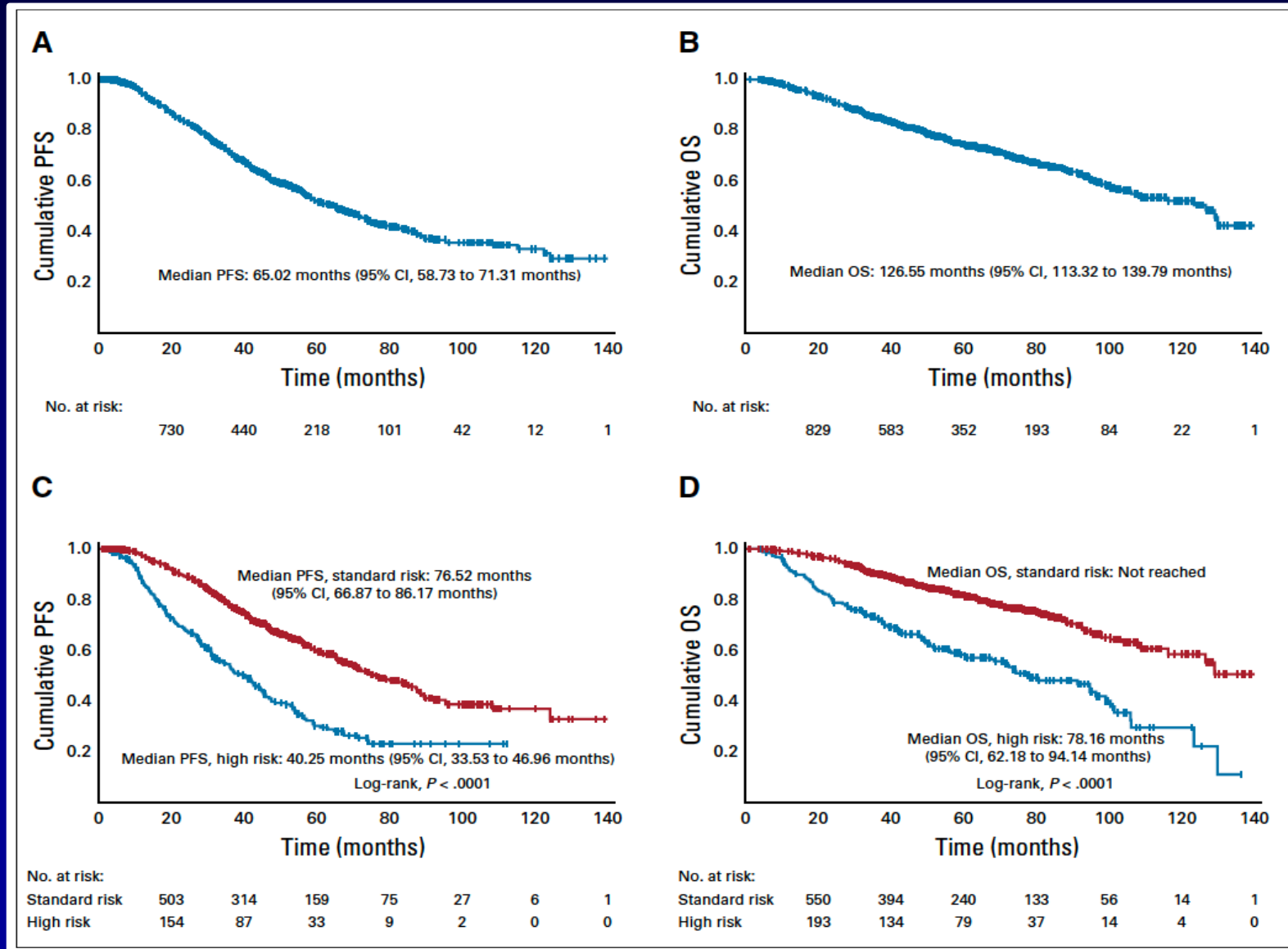


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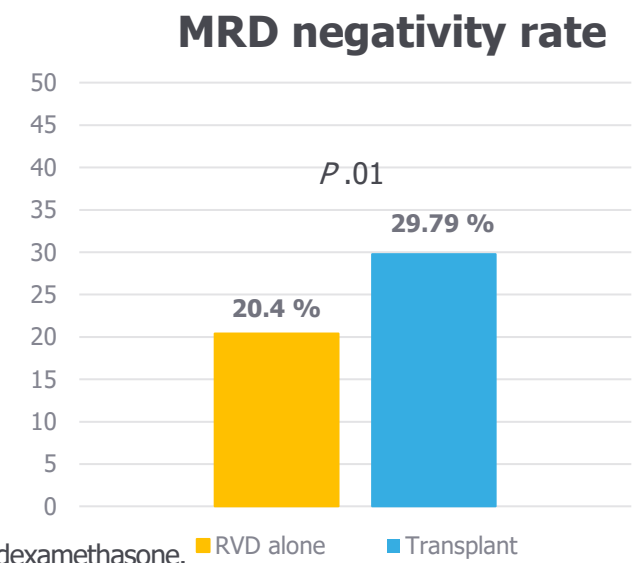
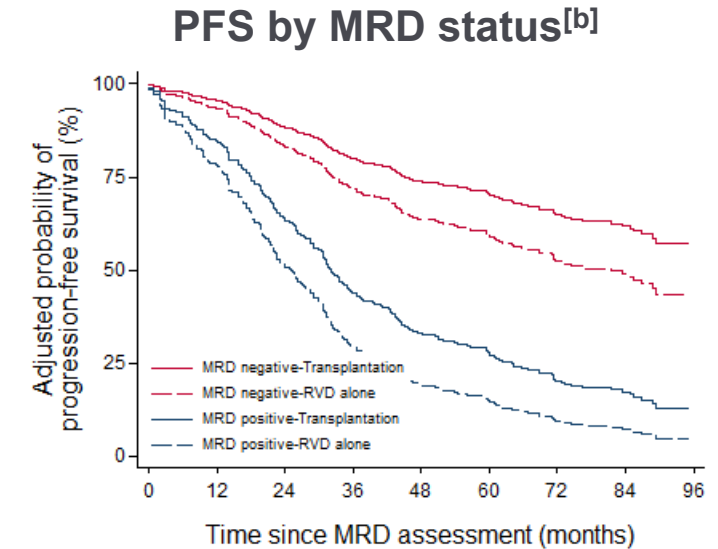
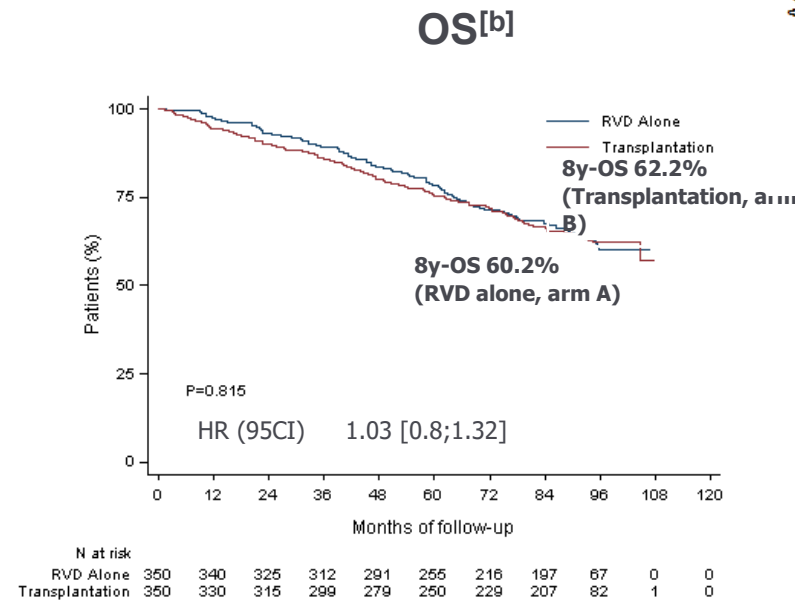
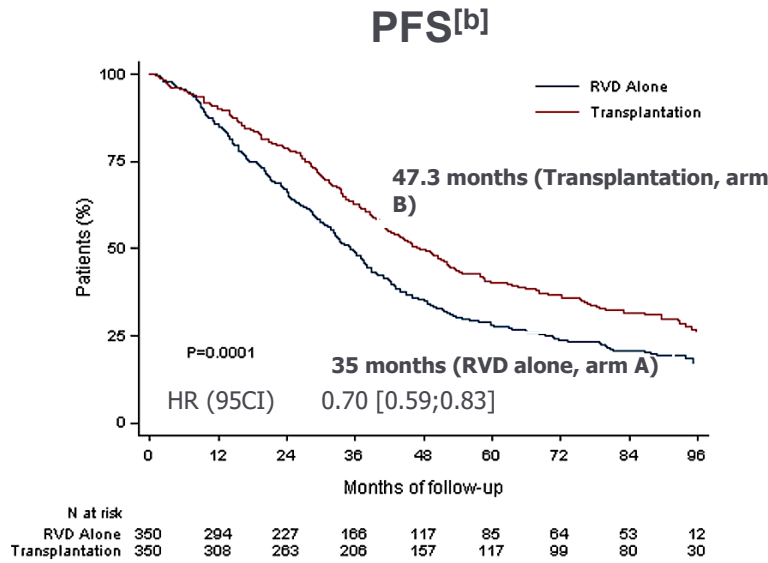
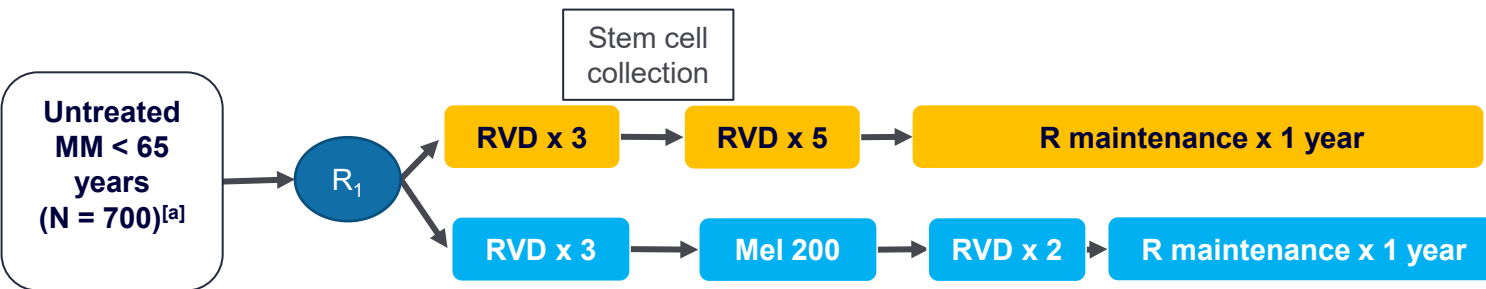
Most Important Advances in Myeloma Cancers

Sagar Lonial, MD
Professor and Chair
Department of Hematology and Medical Oncology
Anne and Bernard Gray Professor in Cancer
Chief Medical Officer, Winship Cancer Institute
Emory University School of Medicine

Outcomes from RVD 1000 Cohort



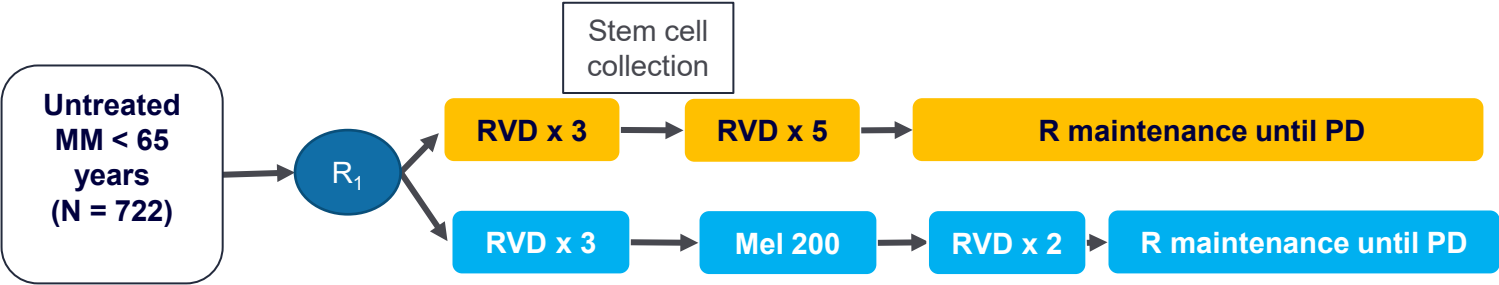
IFM-2009 (N = 700)



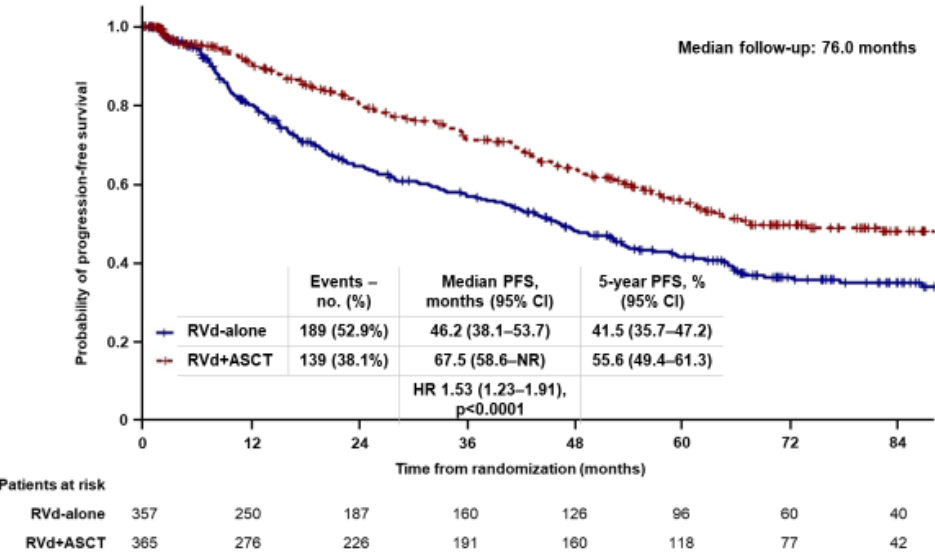
Median follow up 89.8 months

Mel, melphalan; MRD, minimal residual disease; OS, overall survival; PFS, progression-free survival; R, lenalidomide; RVD, lenalidomide/bortezomib/dexamethasone. a. Attal M, et al. N Engl J Med. 2017;376:1311-1320; b. Perrot A, et al. Blood. 2020;136:143.

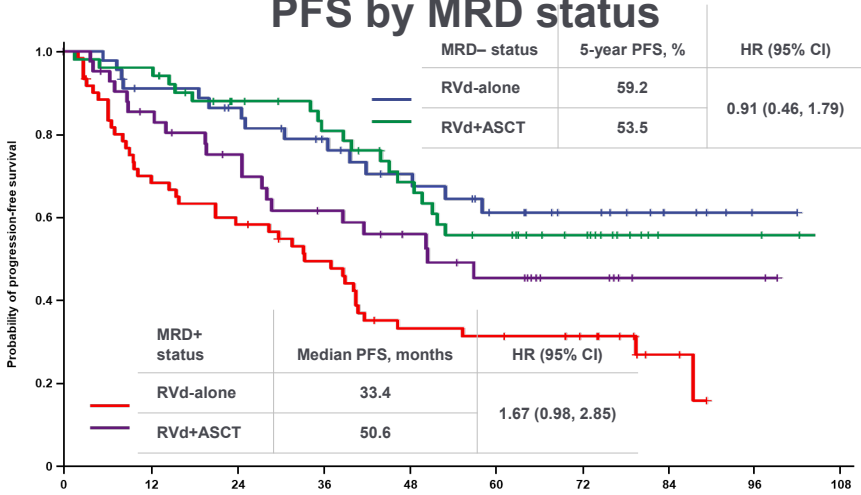
DETERMINATION (N=722)



PFS

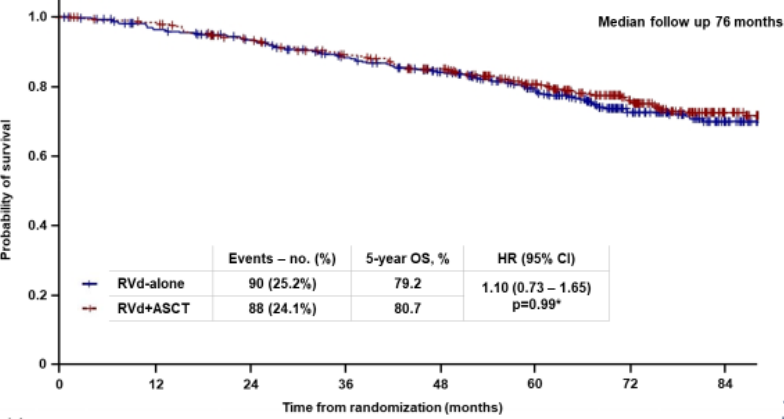


PFS by MRD status



Patients at risk		Time since MRD evaluation at start of maintenance (months)									
		0	12	24	36	48	60	72	84	96	108
RVD-alone, MRD–	43	37	33	28	22	16	11	5	1	0	0
RVD+ASCT, MRD–	49	47	37	32	25	19	13	3	3	0	0
RVD-alone, MRD+	65	39	32	25	15	14	10	3	0	0	0
RVD+ASCT, MRD+	41	32	26	20	15	11	6	2	2	0	0

OS

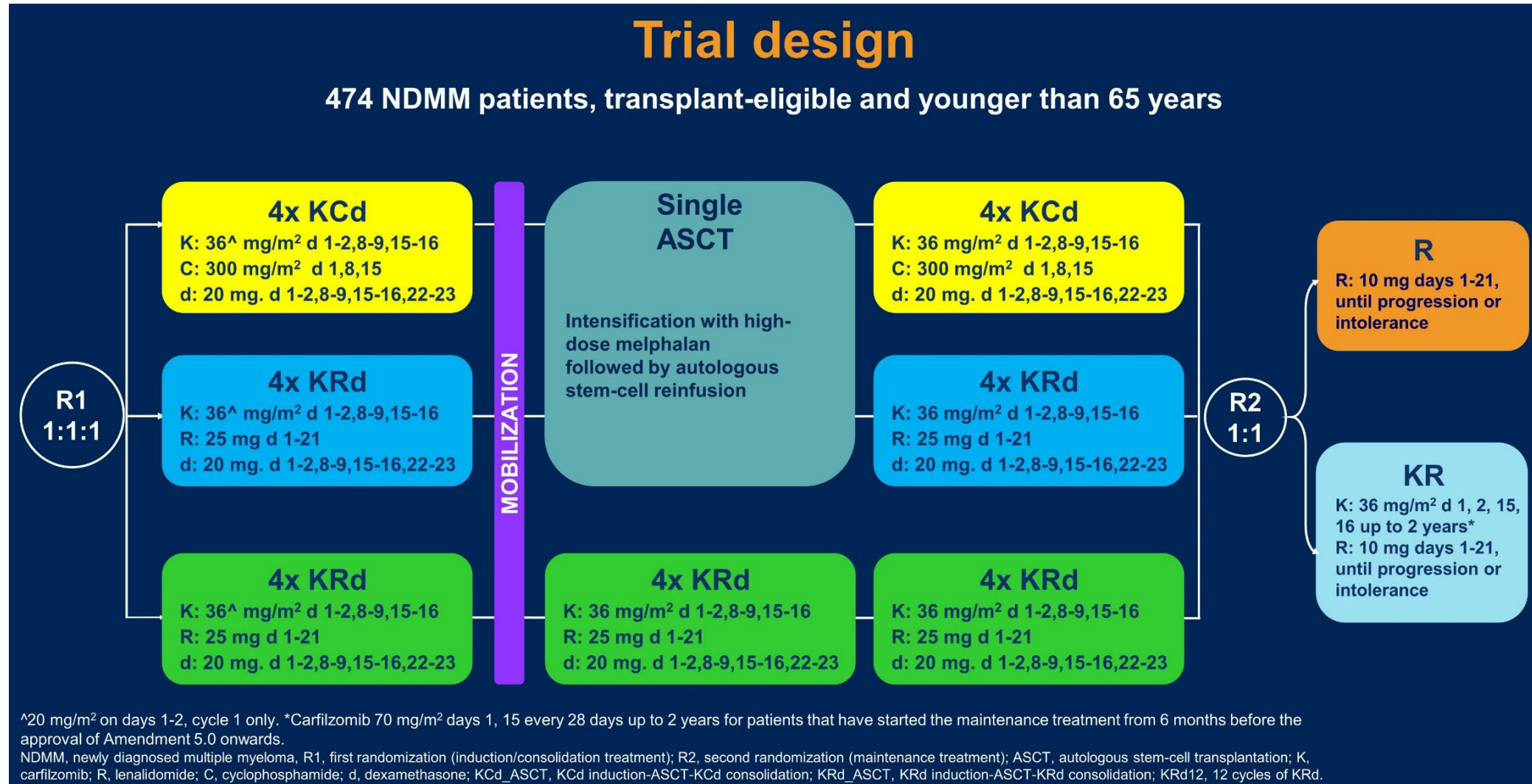


ASCT, autologous stem cell transplant.

Richardson P, et al. J Clin Oncol. 2022;40(17_suppl): LBA4.

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FORTE Trial (N=474)



NDMM, newly diagnosed multiple myeloma; R1, first randomization (induction/consolidation treatment); R2, second randomization (maintenance treatment).
Gay F, et al. J Clin Oncol. 2021;39(suppl 15):8002.

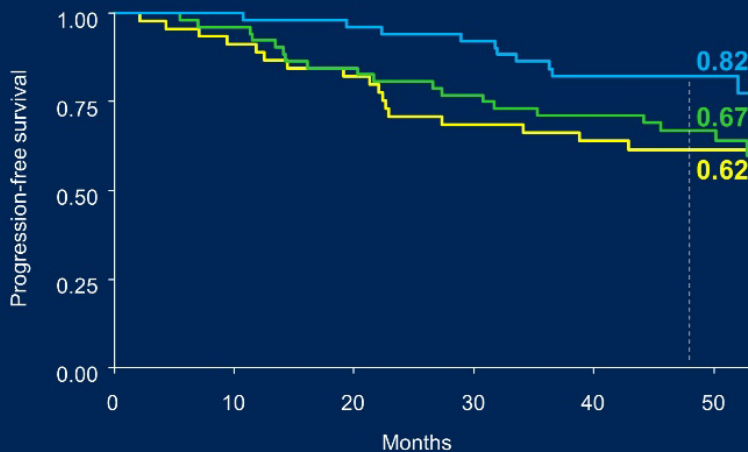
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After R1: PFS Benefit With KRd/ ASCT

PFS benefit observed with KRd/ASCT vs KCd/ASCT or KCd12

Median follow-up from R1: 51 months

Standard risk (N=153)

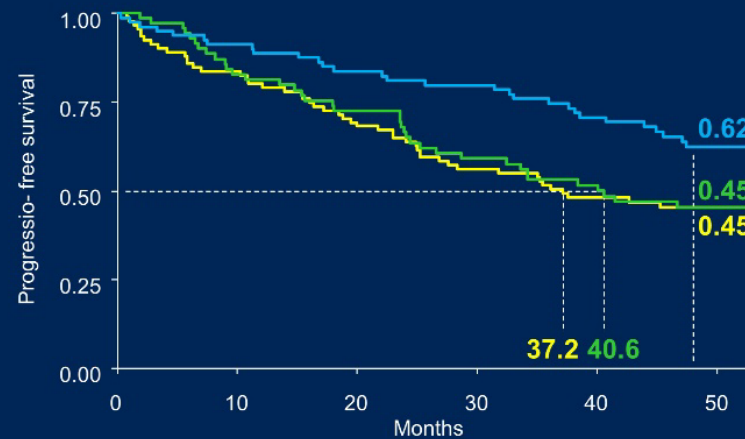


KRd_ASCT vs. KCd_ASCT: HR 0.44, p=0.04

KRd_ASCT vs. KRd12: HR 0.46, p=0.04

KRd12 vs. KCd_ASCT : HR 0.96, p=0.9

High risk (N=243)

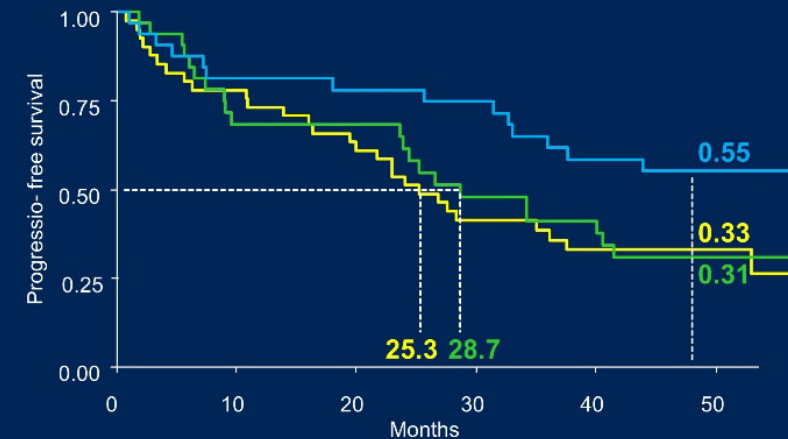


KRd_ASCT vs. KCd_ASCT: HR 0.57, p=0.01

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

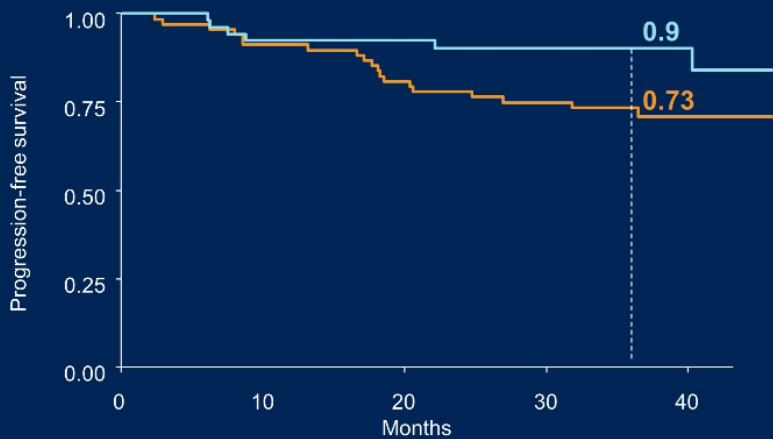
KRd_ASCT vs. KRd12: HR 0.53, p=0.07

KRd12 vs. KCd_ASCT: HR 0.91, p=0.75

After R2: PFS Benefit With KR Maintenance

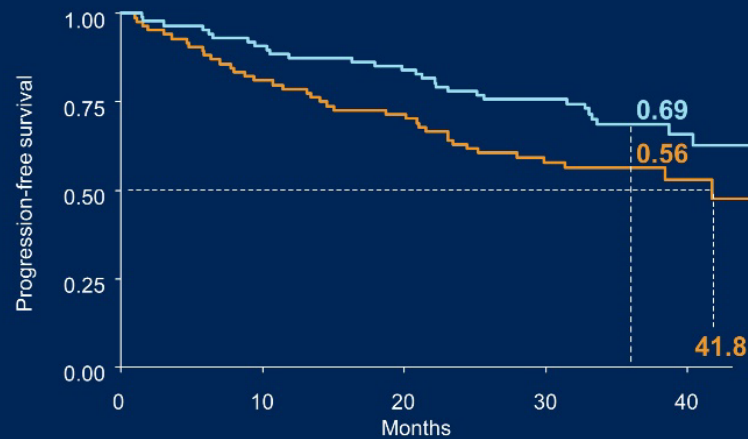
3-Year PFS benefit observed with KR vs R maintenance

**Standard risk
(N=120)**



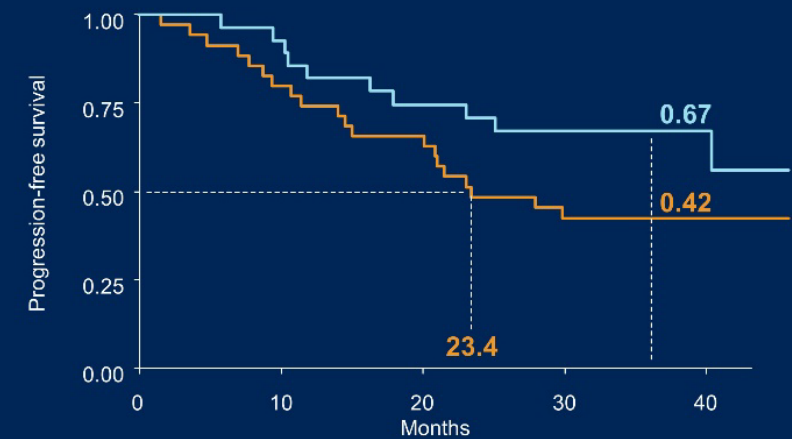
KR vs. R: HR 0.4, p=0.05

**High risk
(N=172)**



KR vs. R: HR 0.6, p=0.04

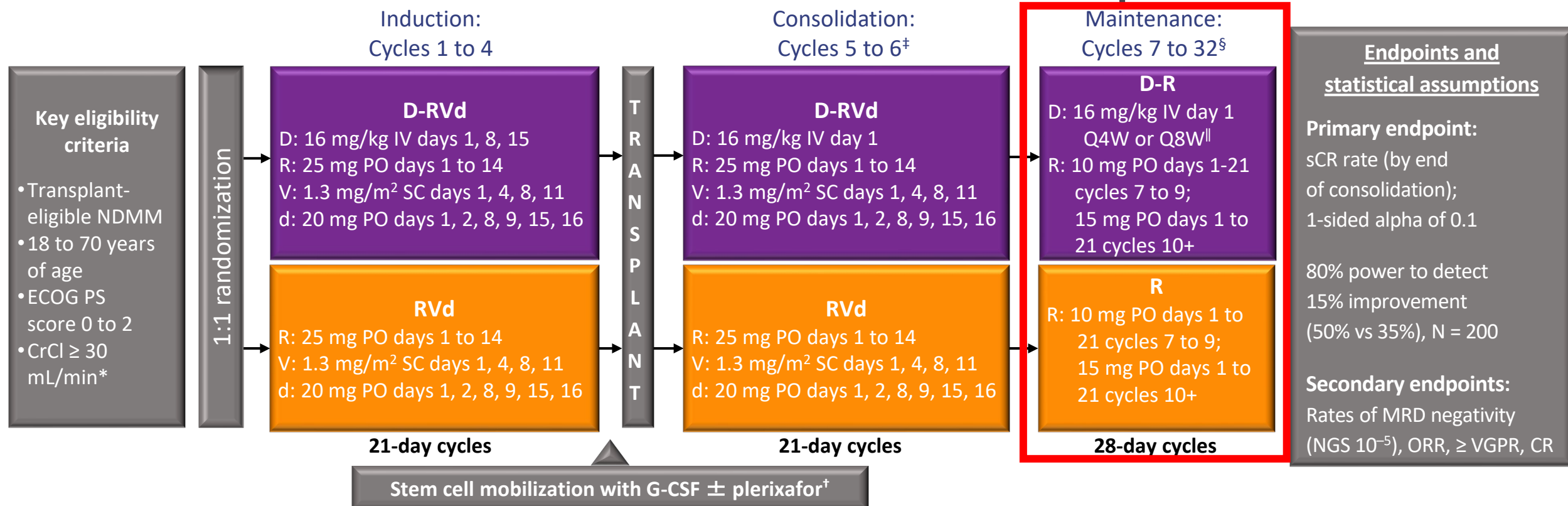
**Double hit
(N=105)**



KR vs. R: HR 0.53, p=0.1

GRIFFIN: Randomized Phase II study

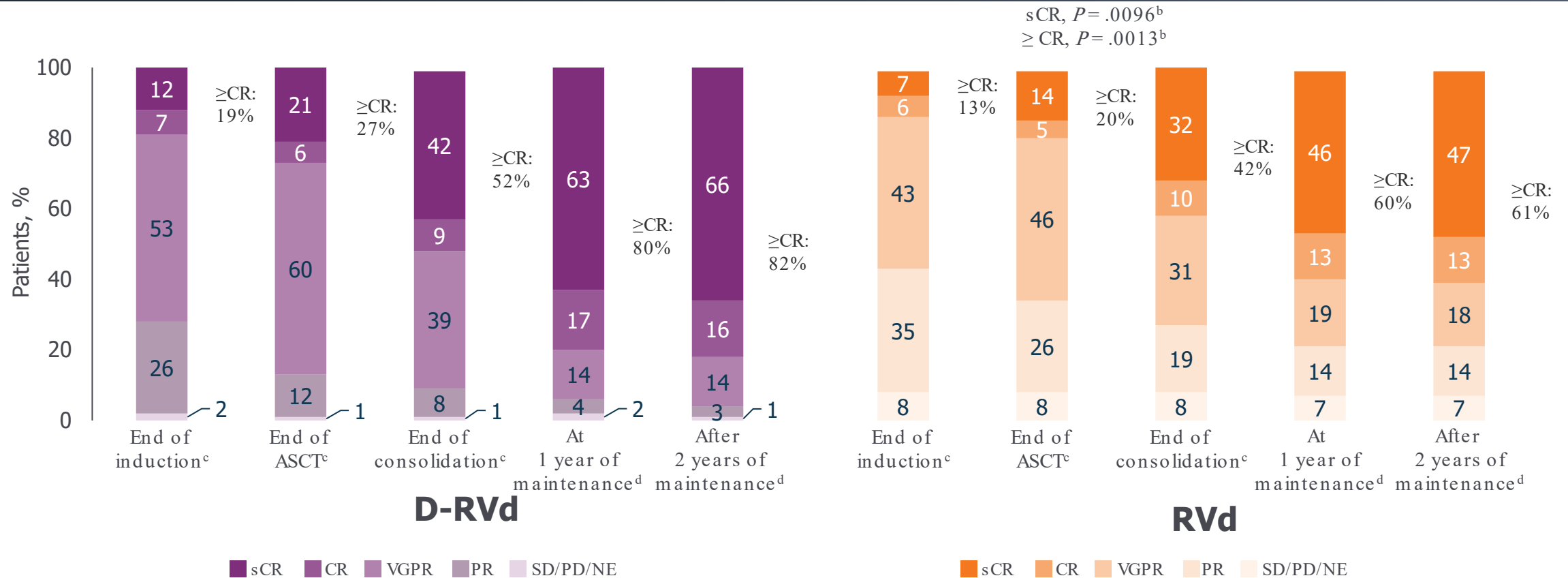
Phase II study of D-RVd vs RVd in transplant-eligible NDMM; 35 sites in the United States with enrollment between December 2016 and April 2018



*Lenalidomide dose adjustments were made for patients with CrCl $\leq$ 50 mL/min. [†]Cyclophosphamide-based mobilization was permitted if unsuccessful. [‡]Consolidation was initiated 60 to 100 days posttransplant. [§]Patients who complete maintenance cycles 7 to 32 may continue single-agent lenalidomide thereafter. ^{||}Protocol amendment 2 allowed for the option to dose daratumumab Q4W, on the basis of pharmacokinetic results from study SMM2001 (NCT02316106).

CrCl, creatinine clearance; ECOG PS, Eastern Cooperative Oncology Group performance status; G-CSF, granulocyte colony-stimulating factor; IV, intravenous; PO, orally; Q4W, every 4 weeks; Q8W, every 8 weeks; VGPR, very good partial response.
Labauch JP, et al. Blood. 2021;138:79.

GRIFFIN: Responses Deepened Over Time



- Response rates for sCR and $\geq CR$ were greater for D-RVd vs RVd at all time points, with the deepest responses occurring after 2 years of maintenance therapy

PD, progressive disease; PR, partial response; SD, stable disease.

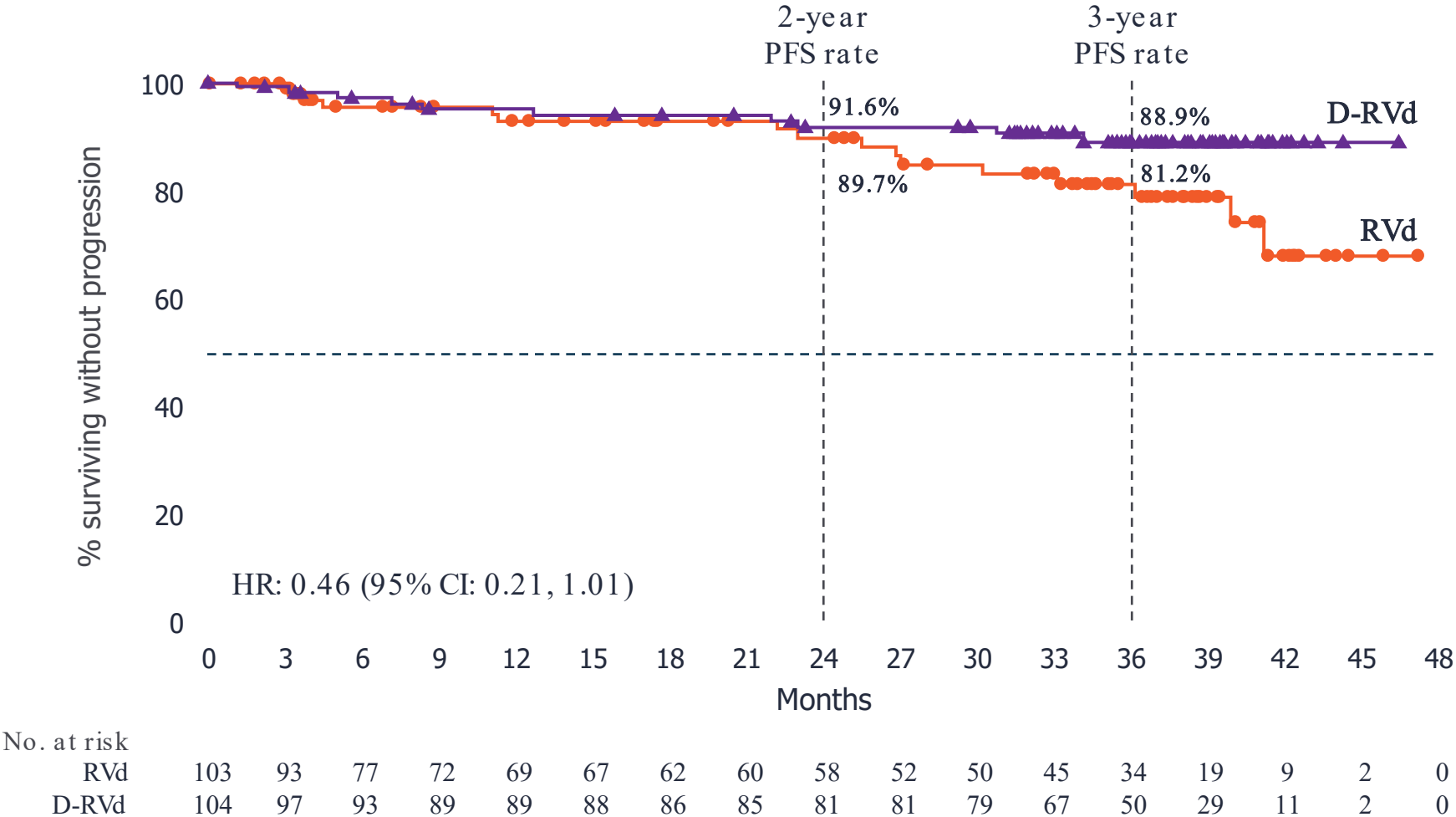
a. Data are shown for the response-evaluable population; b. P values (2-sided) were calculated using the Cochran-Mantel-Haenszel chi-square test; c. Response rates are from the primary analysis cutoff (median follow-up: 13.5 mo), and the response-evaluable population included 196 patients (D-RVd, $n = 99$; RVd, $n = 97$); d. Response rates for the maintenance phase have longer follow-up (median: 38.6 mo), and the response-evaluable population included 197 patients (D-RVd, $n = 100$; RVd, $n = 97$). Percentages may not add up due to rounding.

Laubach JP, et al. Blood. 2021;138:79.

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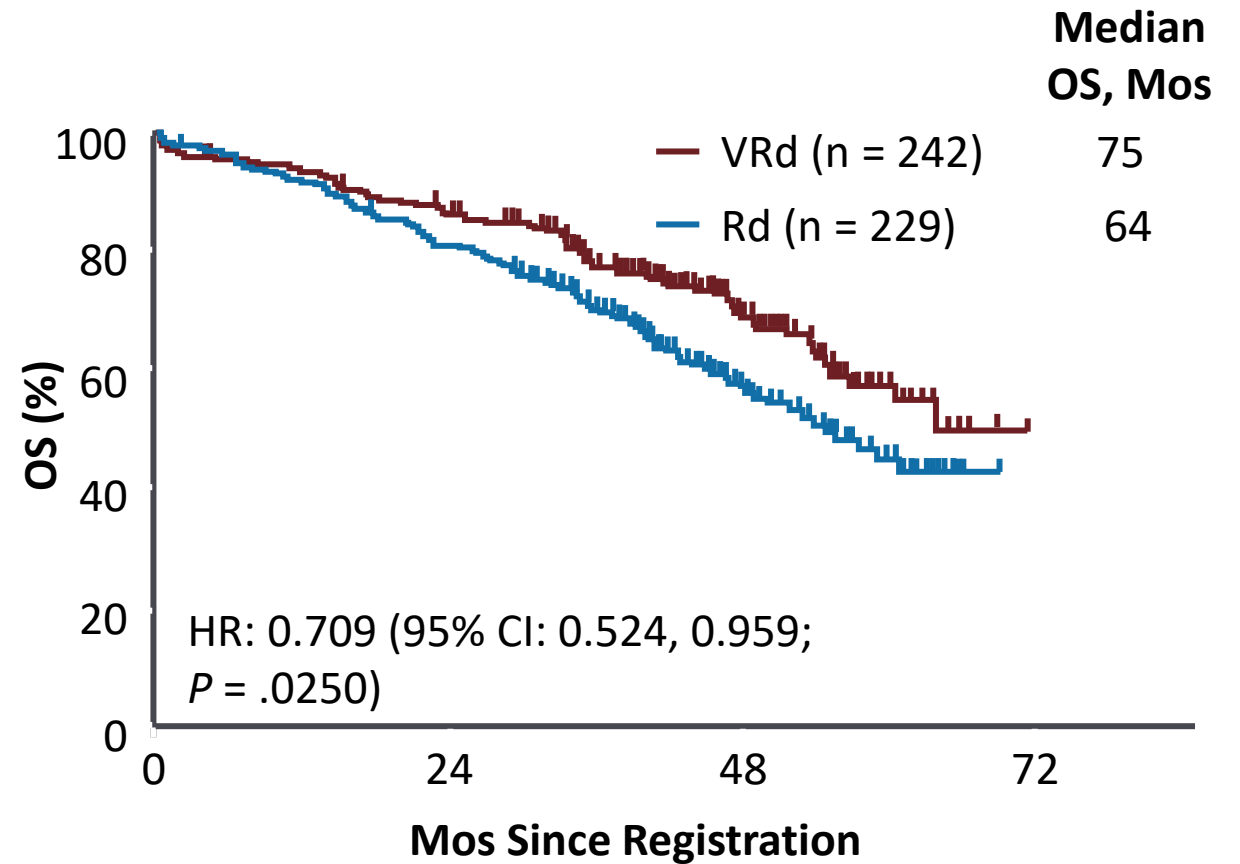
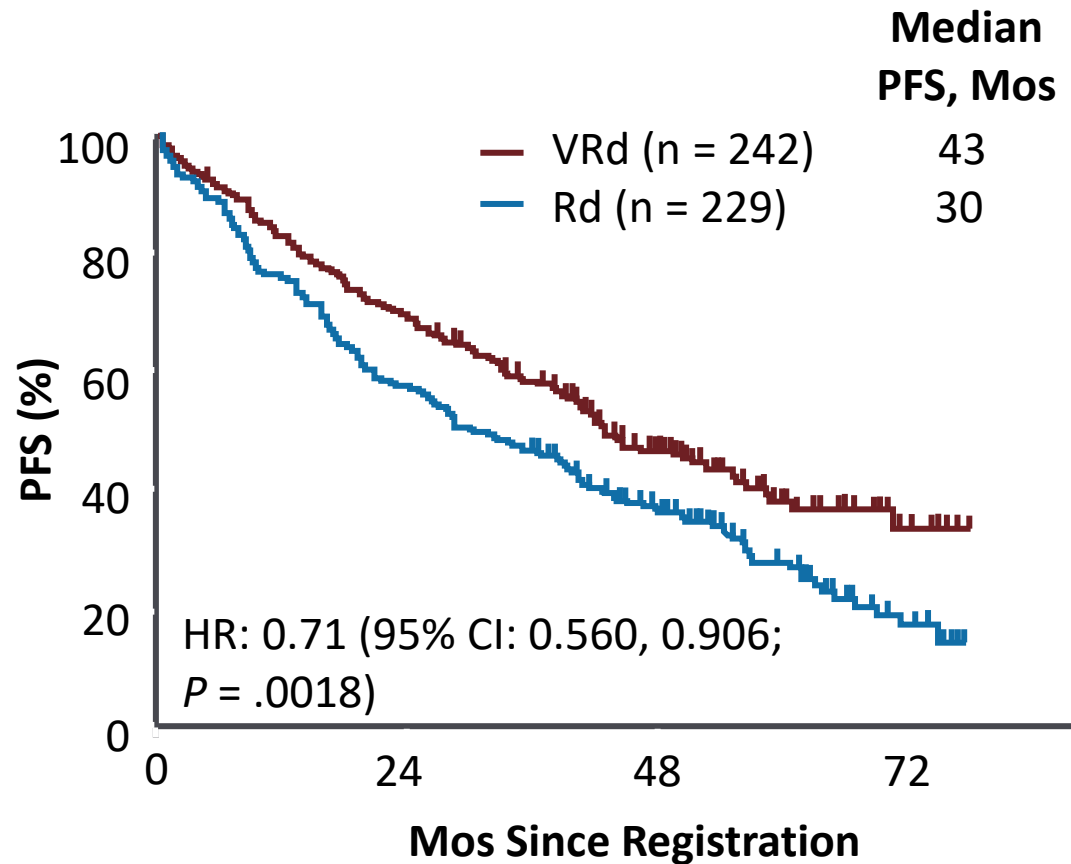
GRIFFIN: PFS in the ITT Population

- Median follow-up: 38.6 months
- Median PFS was not reached in either group
- There is a positive trend toward improved PFS for D-RVd/DR vs RVd/R
- The separation of the PFS curves begins beyond 1 year of maintenance and suggests a benefit of prolonged DR therapy



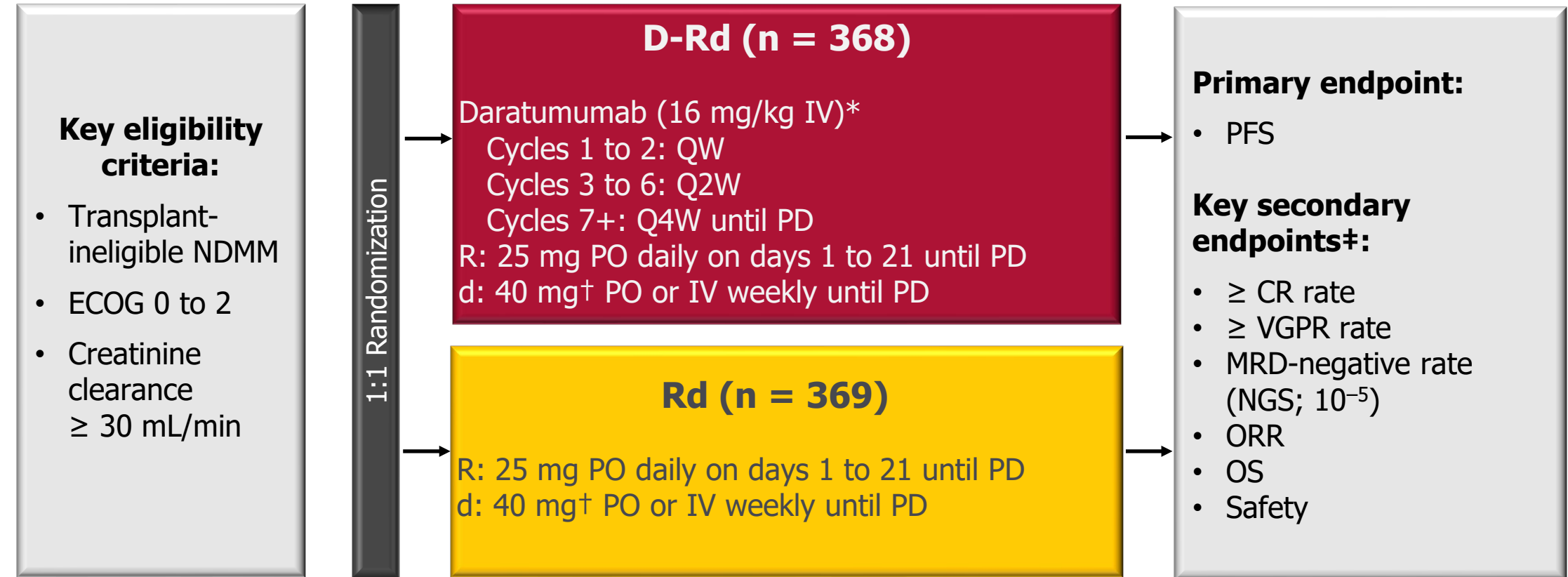
ITT, intent-to-treat.
 Laubach JP, et al. Blood. 2021;138:79.

RVD: SWOG S0777



MAIA Study Design

Phase 3 study of D-Rd vs Rd in transplant-ineligible NDMM (N = 737)



Stratification factors

- ISS (I vs II vs III)
- Region (NA vs other)
- Age (< 75 vs ≥ 75 years)

Cycle: 28 days

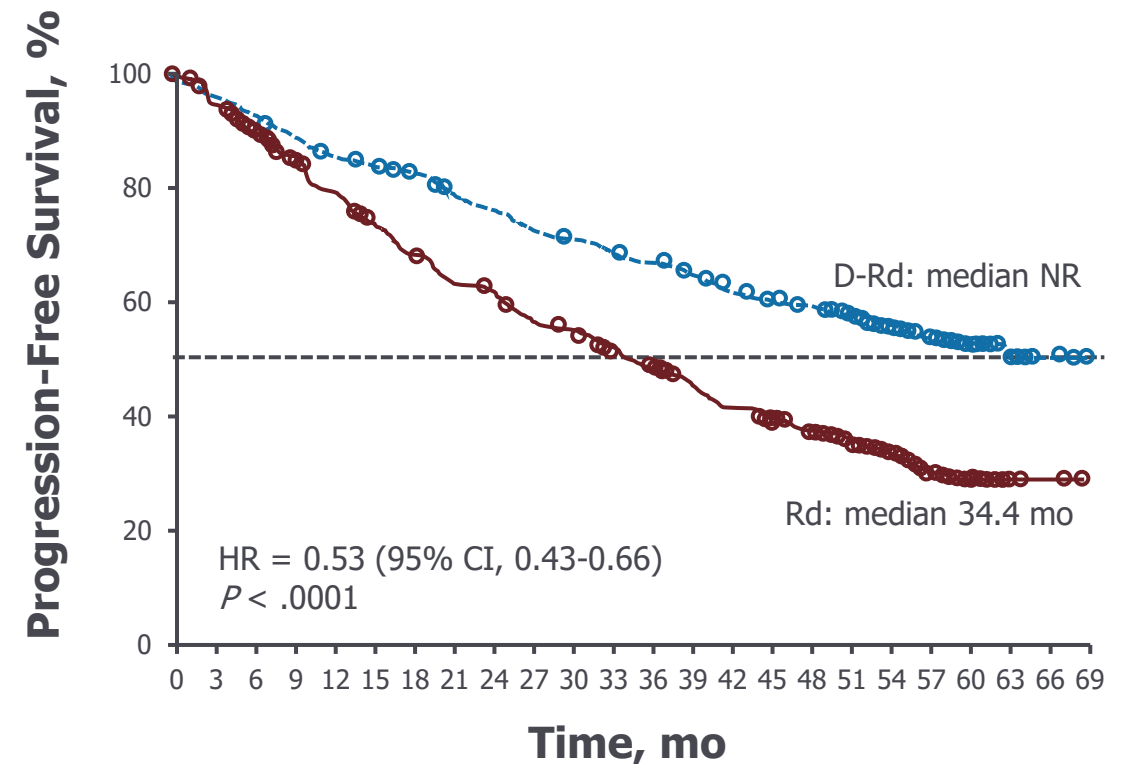
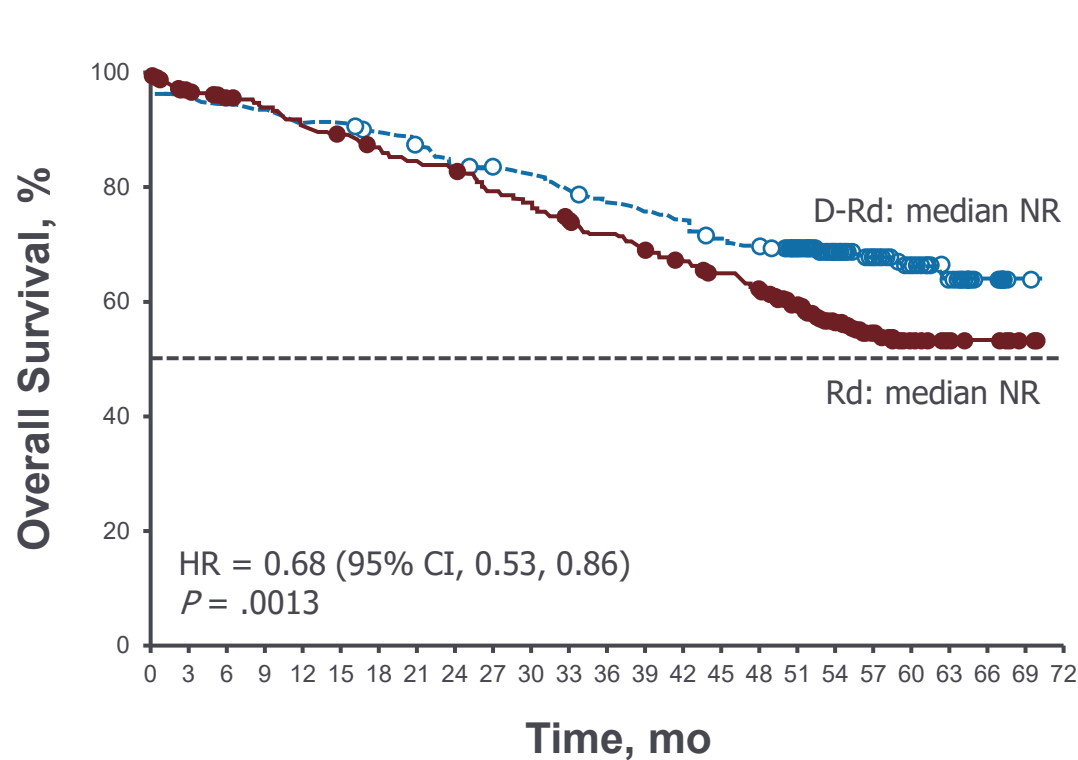
*On days when daratumumab was administered, dexamethasone was administered to patients in the D-Rd arm and served as the treatment dose of steroid for that day, as well as the required pre-infusion medication.

[†]For patients older than 75 years of age or with BMI < 18.5 , dexamethasone was administered at a dose of 20 mg weekly.

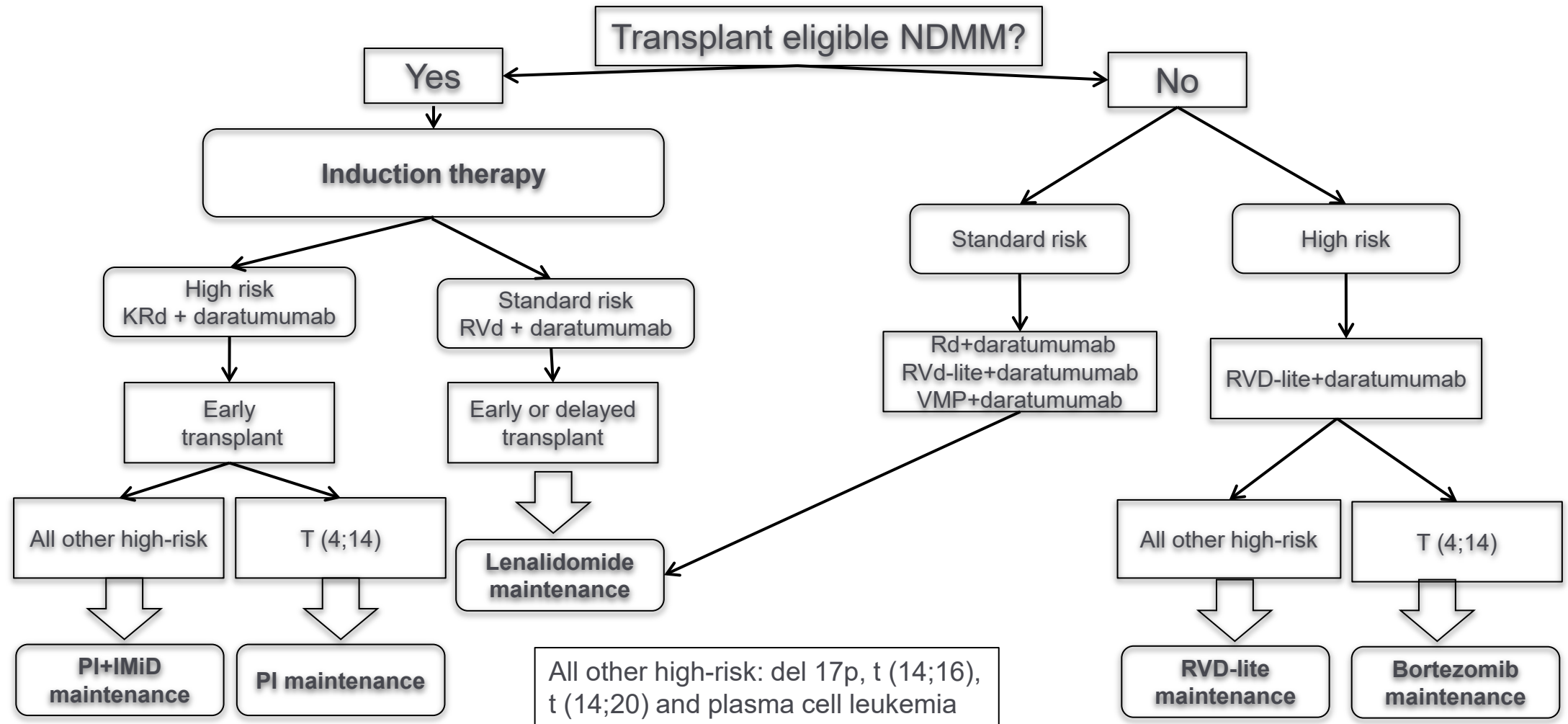
[‡]Efficacy endpoints were sequentially tested in the order shown.

MAIA: Adding Daratumumab to Rd in Non-ASCT Candidates Substantially Improved OS and PFS

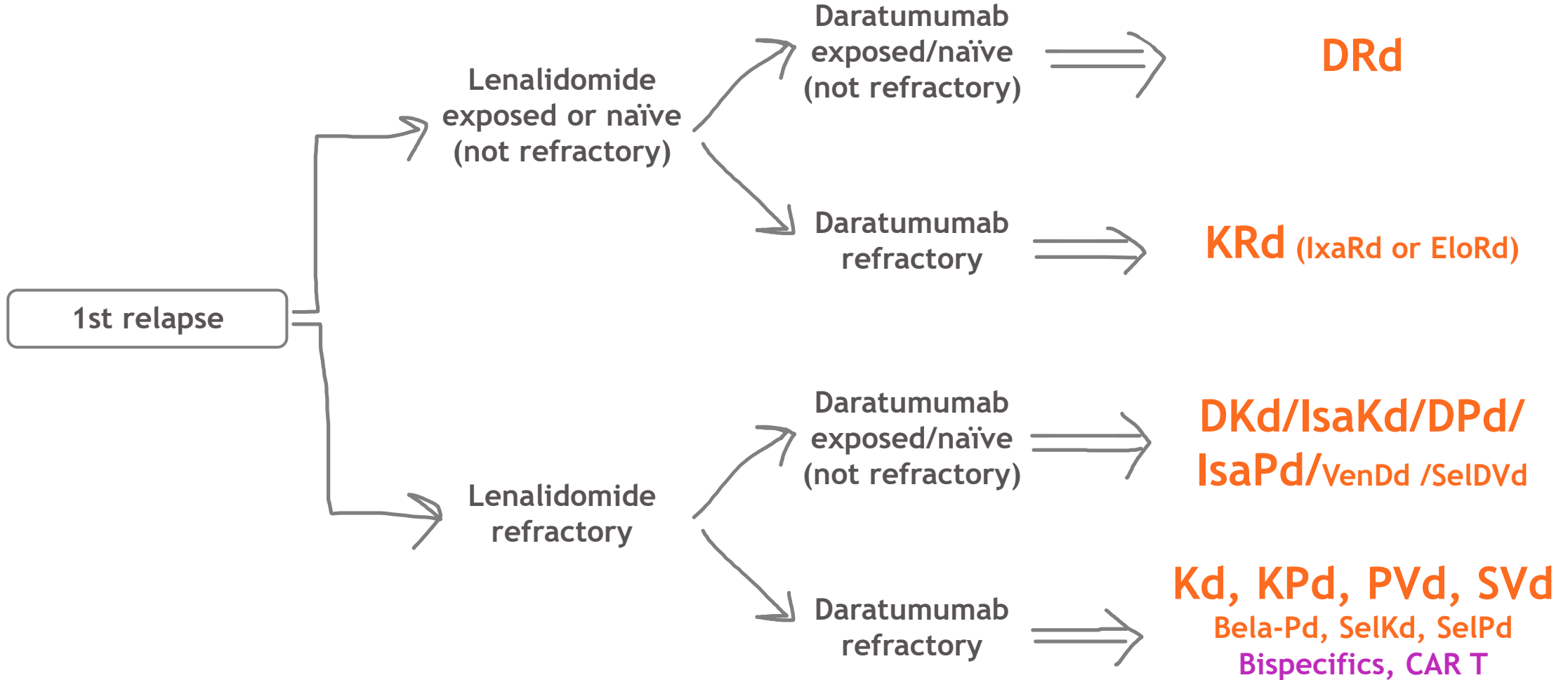
After ~ 5 years of follow-up, a significant and clinically meaningful OS improvement was demonstrated with D-Rd vs Rd, representing a 32% reduction in the risk of death



Emory Algorithm for Newly Diagnosed Patients



Relapsed patient



The data presented are provided for ease of viewing information from multiple trials. Direct comparison between trials is not intended and should not be inferred.

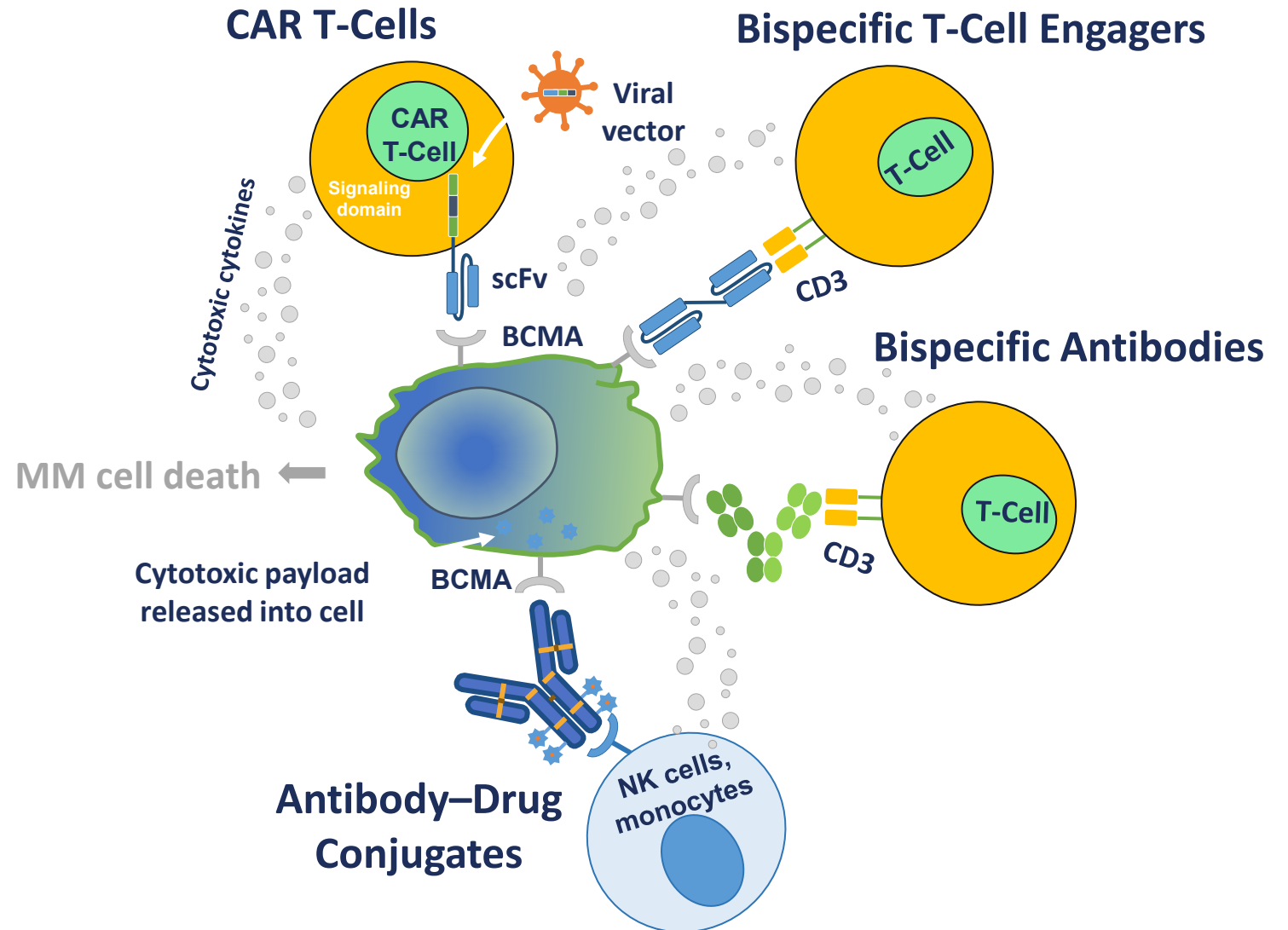
BelaPd, belantamab mafodotin + pomalidomide + dexamethasone; IsaPd, isatuximab + pomalidomide + dexamethasone; KPd, carfilzomib + pomalidomide + dexamethasone; SelDVd, selinexor + daratumumab + bortezomib, + dexamethasone; SelKd, selinexor + carfilzomib + dexamethasone; SelPd, selinexor + pomalidomide + dexamethasone; VenDd, venetoclax + daratumumab + dexamethasone.

Cartoon representation courtesy of Rodriguez P.

Based on: Dimopoulos MA, et al. Ann Oncol. 2021;32:309-22. Kaufman J et al. Blood. 2019;134:abstract 1866. Avet-Loiseau H, et al. Blood Cancer J 2020;10:111. Siegel DS, et al. J Clin Oncol 2018;36:728-34.

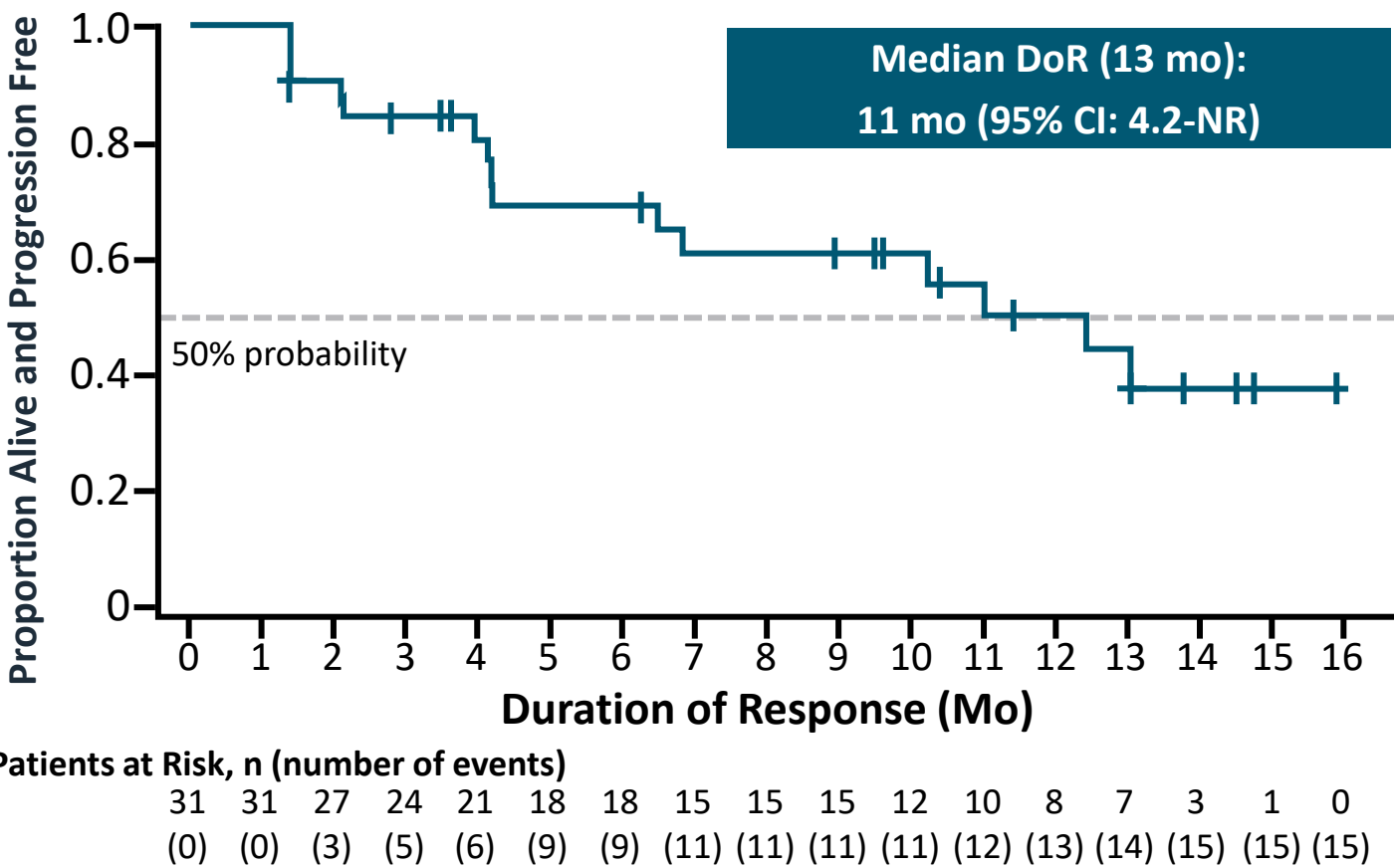
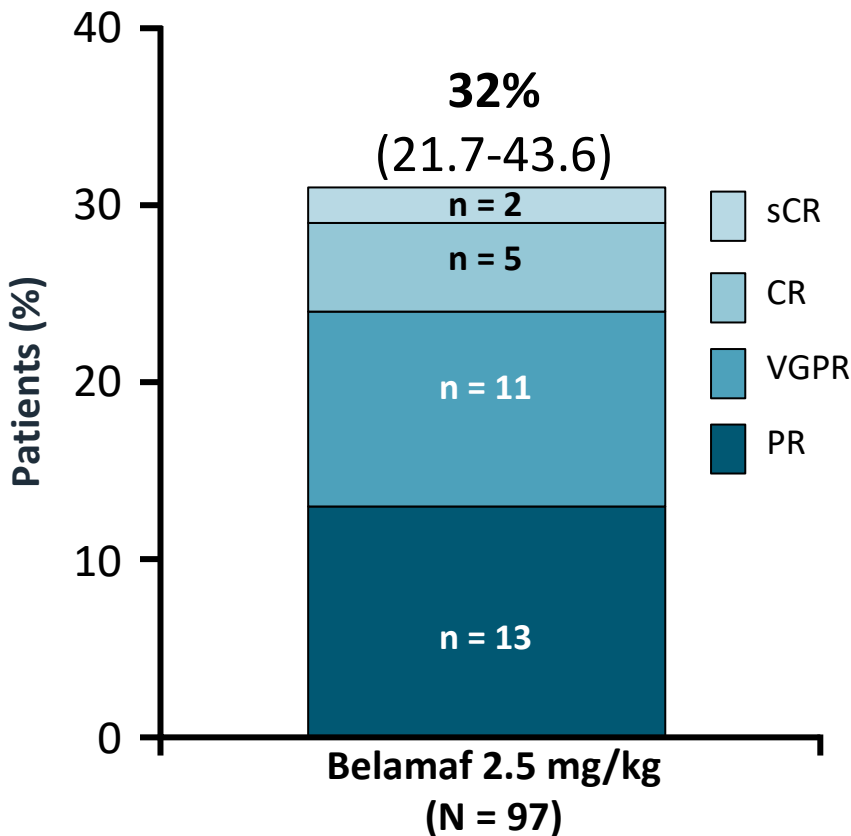
BCMA in Multiple Myeloma

- Expressed on late memory B-cells committed to PC differentiation and PCs
- BCMA plays a role in survival of long-lived PCs
- γ -secretase cleaves BCMA from the cell surface, yielding soluble BCMA

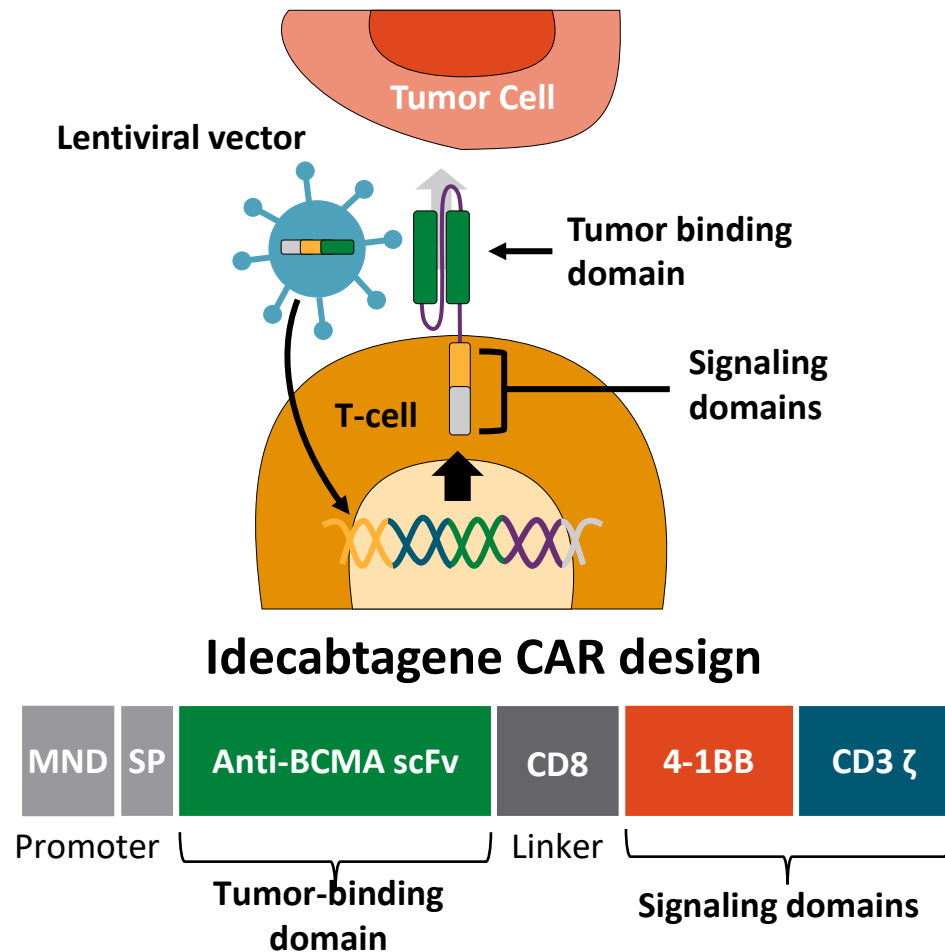


Phase II DREAMM-2: Response and DoR at 13 Mo of Follow-up, Belantamab Mafodotin 2.5 mg/kg

ORR: % of Patients
(95% CI)



Phase II KarMMA: Idecabtagene Vicleucel (Ide-cel) in Relapsed/Refractory MM



Patients with R/R MM and ≥ 3 prior regimens each with ≥ 2 consecutive cycles, prior IMiD, PI, and anti-CD38 mAb, and refractory to last therapy by IMWG criteria (N = 158)

Leukapheresed
n = 140

Idecabtagene vicleucel (n = 128)

150 x 10⁶ CAR T-cells (n = 4)
300 x 10⁶ CAR T-cells (n = 70)
450 x 10⁶ CAR T-cells (n = 54)

Median Follow-Up, mo

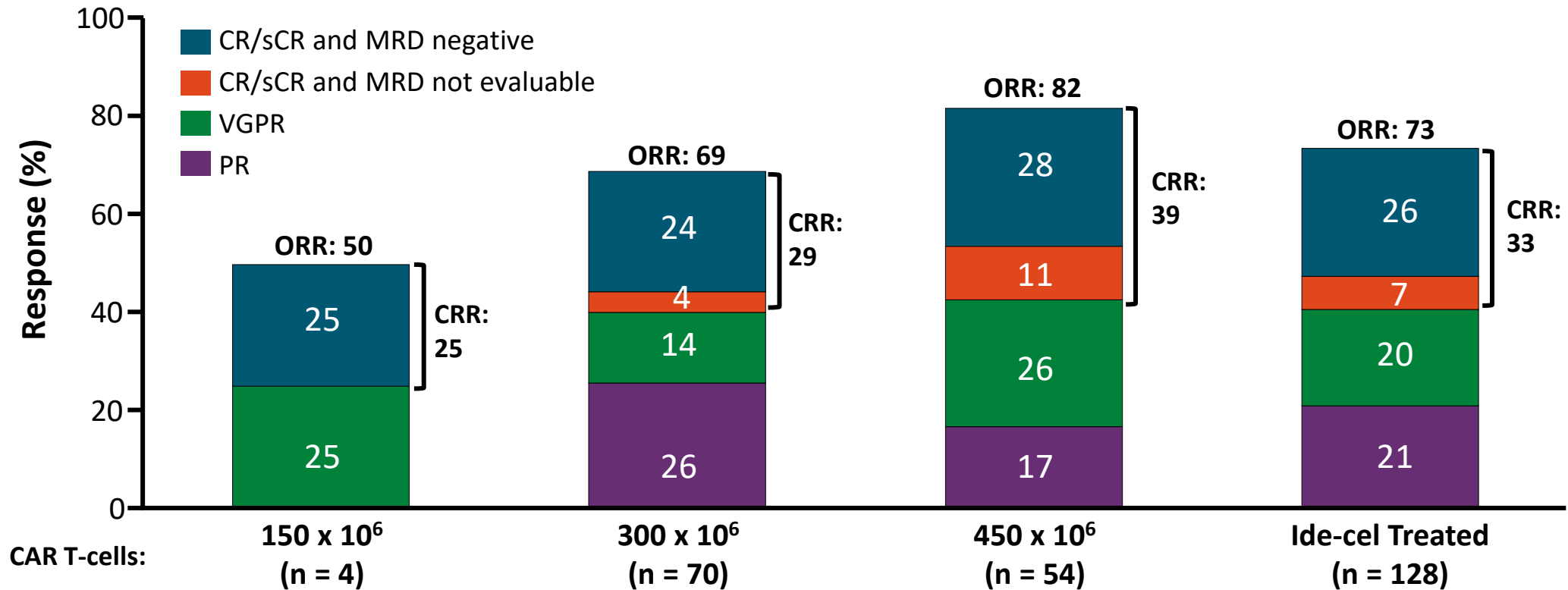
150 x 10⁶ CAR T-cells: 18.0
300 x 10⁶ CAR T-cells: 15.8
450 x 10⁶ CAR T-cells: 12.4
Total: 24.8

- **Primary endpoint:** ORR
- **Secondary endpoints:** CRR, safety, DoR, PFS, OS, PK, MRD, QoL, HEOR
- **Exploratory endpoints:** immunogenicity, BCMA expression/loss, cytokines, T-cell immunophenotype, GEP in BM

Baseline characteristics:

- High-risk cytogenetics: 35%
- Extramedullary disease: 39%
- Median no. of prior therapies: 6 (range: 3-16)
- Triple refractory: 84%

Phase II KarMMa Update: Clinical Response of Idecabtagene Vicleucel in R/R MM



- Median time to first response: 1.0 mo (range: 0.5-8.8); median time to CR: 2.8 mo (range: 1.0-11.8)
- Median follow-up of 13.3 mo across target dose levels
- MRD-negative ($<10^{-5}$) in all treated patients (n = 128) was 26% and 79% in evaluable patients with $\geq$ CR (n = 42)

CAR T Real World Experience

Baseline Characteristics

Characteristic	SOC Ide-cel (N=196)	KarMMa (N=128)
Age, median (range)	64 (36,83)	61 (33,78)
Male Sex, n (%)	113 (58)	76 (59)
Extramedullary disease, n (%)	92 (47)	50 (39)
ECOG PS, n (%)		
0-1	132 (80)	125 (98)
2-4	33 (20)	3 (2)
R-ISS, n (%)		
I	25 (18)	14 (11)
II	73 (54)	90 (70)
III	38 (28)	21 (16)
High-risk cytogenetics, n (%)		
Any high-risk cytogenetics	64 (38)	45 (35)
del (17p)	43 (25)	23 (18)
t(4;14)	25 (15)	23 (18)
t(14;16)	9 (5)	6 (5)
Bridging therapy, n (%)	150 (77)	112 (88)
Prior BCMA therapy, n (%)	43 (22)	0
Prior lines of therapy, median (range)	7 (4,19)	6 (3,16)
Autologous HCT, n (%)	164 (84)	120 (94)
Refractory status, n (%)		
Double-refractory	171 (87)	114 (89)
Triple-refractory	163 (83)	108 (84)
Penta-refractory	86 (44)	33 (26)

Characteristics Differentiating Real-World Patients from KarMMa

77% (N=150) of patients would have been ineligible for participation in the KarMMa clinical trial

KarMMa Exclusion Criteria	N=150 N (%)
Organ dysfunction (renal, cardiac, hepatic)	60 (31)
Prior anti-BCMA therapy	43 (22)
Platelets < 50,000/ μ L	42 (21)
Hemoglobin < 8 g/dL	33 (17)
ECOG Performance status $\geq$ 2	33 (17)
ANC < 1000/ μ L	29 (15)
PCL, POEMS, amyloidosis, non-secretory	26 (13)
CNS pathology	17 (9)
Prior allogeneic SCT	12 (6)
Other malignancies	12 (6)
Chronic immunosuppression	3 (2)

RWE Safety

Safety of Ide-Cel in the Real World

Characteristic	SOC Ide-cel (N=159)	KarMMa ¹ (N=128)
Any CRS*, n (%)	131 (82)	107 (84)
Grade ≥ 3	5 (3)	7 (5)
Any neurotoxicity (NT)*, n (%)	29 (18)	23 (18)
Grade ≥ 3	9 (6)	4 (3)
Tocilizumab use, n (%)	113 (71)	67 (52)
Steroid use, n (%)	42 (26)	19 (15)

Total of 21 (13%) deaths in SOC population:

- N=13 due to myeloma progression
- N=8 due to NRM after SOC ide-cel
 - Toxicity (N=3)
 - Infection (N=3; COVID-19)
 - HLH (N=2)
 - Cardiomyopathy (N=1)

* Concomitant grade 5 CRS/HLH (N=1)

Univariate Analysis by CRS Grade ≥ 3

Selected Characteristics Associated with CRS Grade ≥ 3

Characteristic	CRS Grade < 3, N=154 (97%)	CRS Grade ≥ 3, N=5 (3%)	P
ECOG PS ≥ 2, n (%)	25 (17)	4 (80)	0.004
R-ISS III, n (%)	32 (26)	3 (100)	0.024
High marrow burden, n (%)	33 (23)	3 (75)	0.046

*Patients who did not meet above characteristic criteria or had unknown values for listed variables are not included in table.

**Marrow burden was measured within 30 days of CAR T-cell infusion.

Univariate Analysis by Neurotoxicity Grade ≥ 2

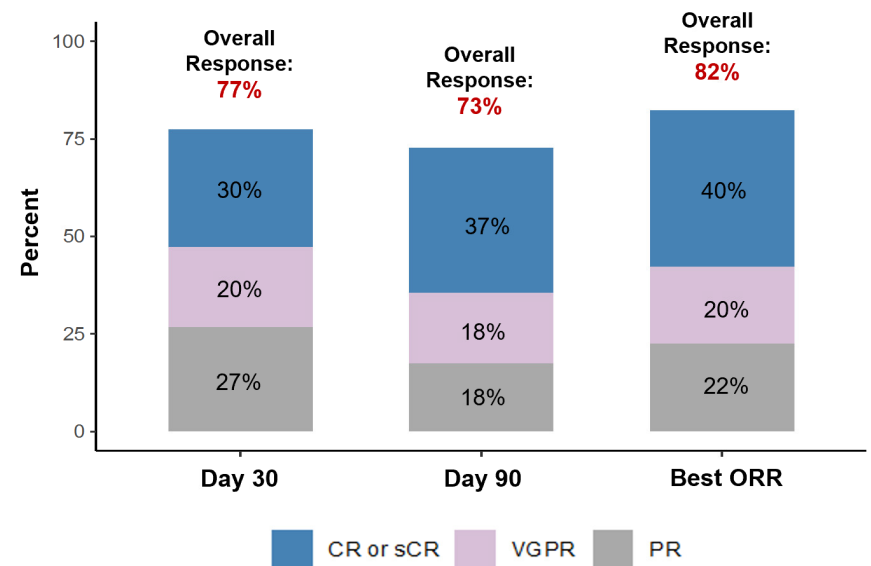
Selected Characteristics Associated with NT Grade ≥ 2

Characteristic	NT Grade < 2, N=142 (89%)	NT Grade ≥ 2, N=17 (11%)	P
ECOG PS ≥ 2, n (%)	21 (15)	8 (47)	0.004
Baseline ferritin ≥ ULN, n (%)	54 (38)	12 (71)	0.010
B2 microglobulin ≥ 5.5 mg/L, n (%)	10 (12)	6 (60)	0.001
Bridging chemotherapy, n (%)	106 (75)	17 (100)	0.014
Cell dose ≥ 400 x 10 ⁶ CAR T cells	77 (56)	14 (82)	0.036

- HLH, hemophagocytic lymphohistiocytosis; NRM, non-relapse mortality; RWE, real-world evidence; SOC, standard of care.
- Hansen, DK. Presented at: 19th International Myeloma Society Annual Meeting; August 25-27, 2022, 2022; Los Angeles, CA. Abstract OAB-004.

RWE Efficacy

Day 30, Day 90, and Best Overall Tumor Responses for SOC Ide-Cel

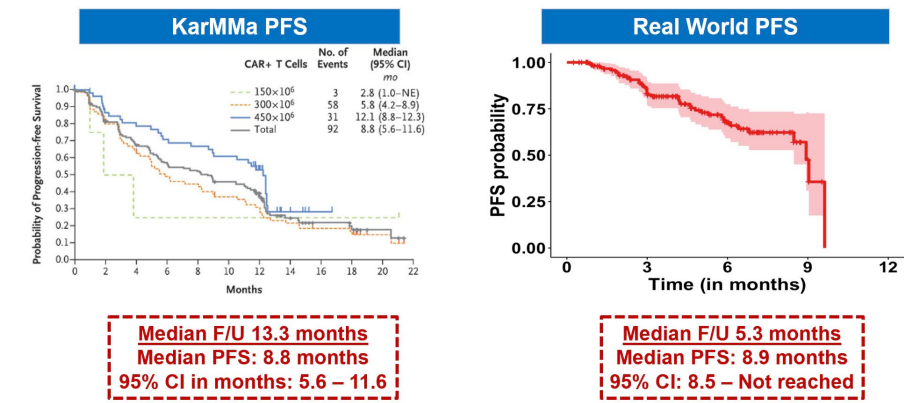


Multivariable Analysis for Efficacy

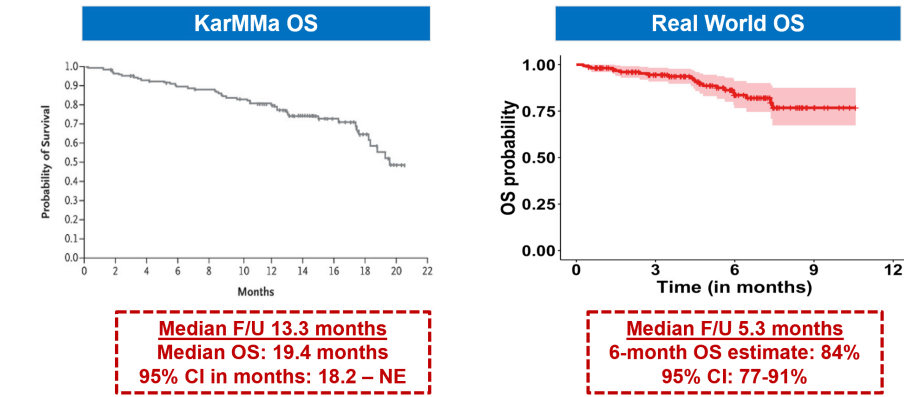
Characteristic	Best Response ≥ CR			Best ORR			PFS		
	OR	95% CI	P	OR	95% CI	P	HR	95% CI	P
Prior anti-BCMA	0.28	0.09, 0.84	0.03	0.36	0.08, 1.63	0.2	3.20	1.35, 7.61	0.008
High-risk cytogenetics	0.79	0.35, 1.75	0.6	0.74	0.19, 3.07	0.7	2.50	1.22, 5.13	0.012

Model also included extramedullary disease, ECOG PS ≥ 2, penta-refractory status, cell dose > 400 x10⁶ CAR T cells, number of prior lines of therapy, and patient age.

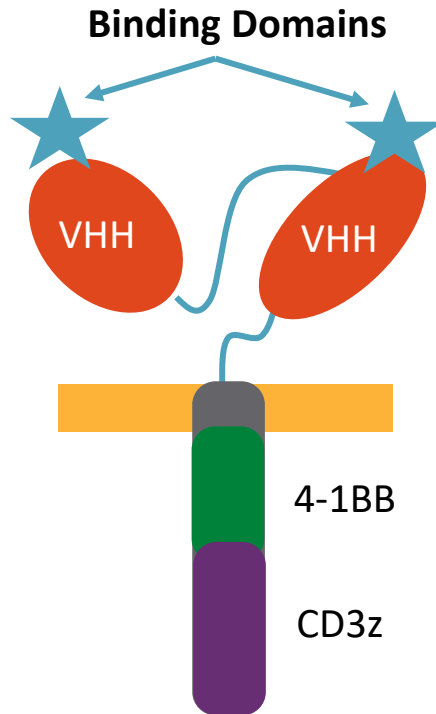
Progression-Free Survival in KarMMa vs the Real World



Overall Survival in KarMMa vs the Real World



CARTITUDE-1: Ciltacabtagene Autoleucel for R/R MM



- Contains 2 BCMA-targeting single-chain antibody designed to confer avidity
- Identical to the CAR construct used in the LEGEND-2 study

- Single-arm, open-label phase Ib/II trial

Patients with R/R MM per IMWG and ≥ 3 prior regimens or double refractory to IMiD and PI and had received IMiD, PI, and anti-CD38 mAb (N = 113)

↓
Lymphodepletion
n = 101

↓
Ciltacabtagene autoleucel (n = 97)
Target 0.75×10^6 CAR T-cells (range $0.5-1 \times 10^6$)

Median administered dose:

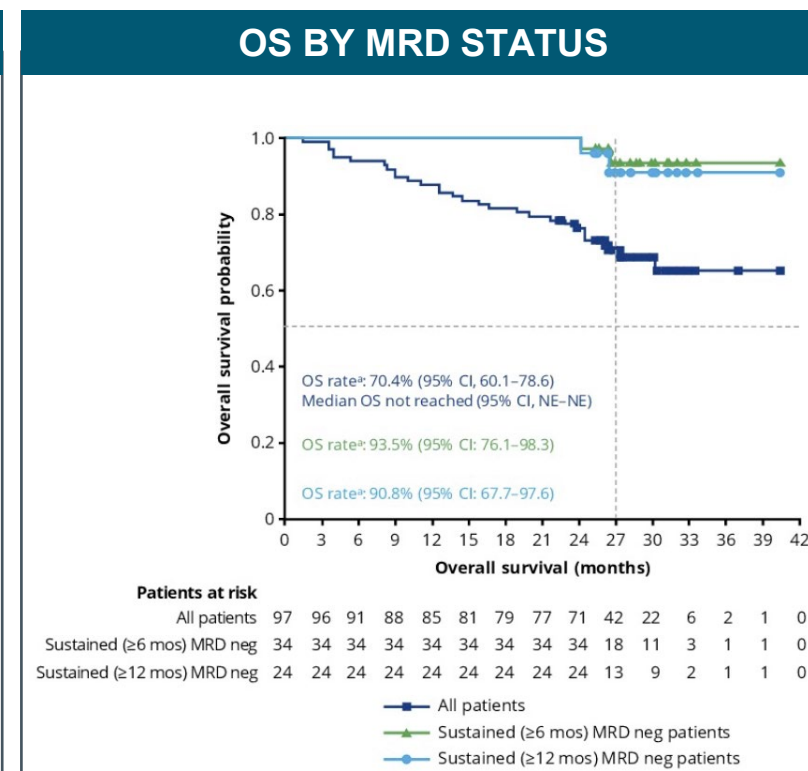
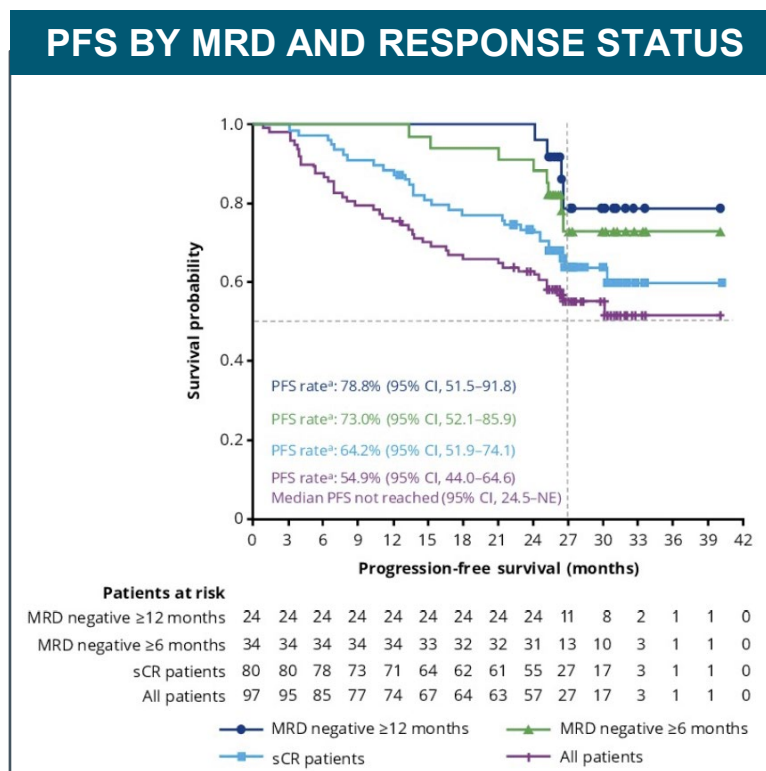
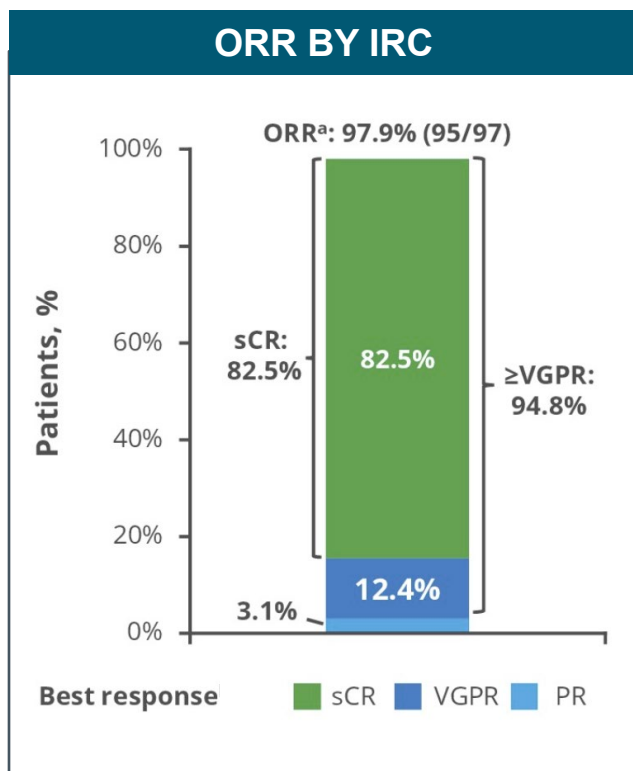
0.71×10^6 ($0.51 - 0.95 \times 10^6$) CAR+ viable T cells/kg

- Primary endpoints: Phase Ib: AEs; phase II: ORR

Baseline characteristics:

- High-risk cytogenetics: 23.7%
- Extramedullary disease: 13.4%
- Median no. of prior therapies: 6 (range 1-12)
- Triple refractory: 87.6%

Landmark 2 Years Post-Last Patient-in Results of the CARTITUDE-1 Phase 1/2 Study of Cilta-Cel in Patients With RRMM: Efficacy^{1,2}



- Median DOR: NE (95% CI, 23.3 months–NE)
- Of 61 patients evaluable, 91.8% were MRD neg (10^{-5})
- DOR, PFS, and/or OS were shorter in subgroups with high-risk cytogenetics, ISS stage III, and high tumor burden, as well as presence of plasmacytomas

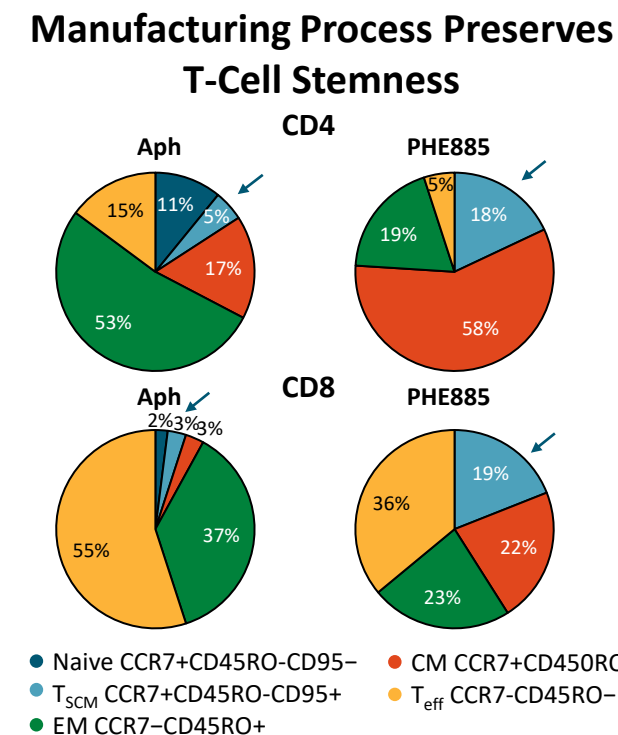
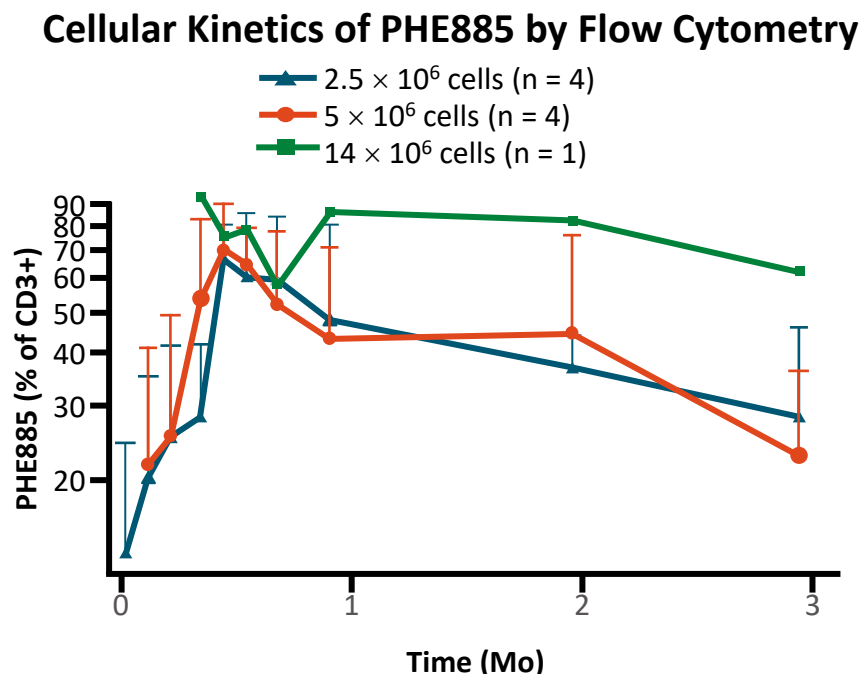
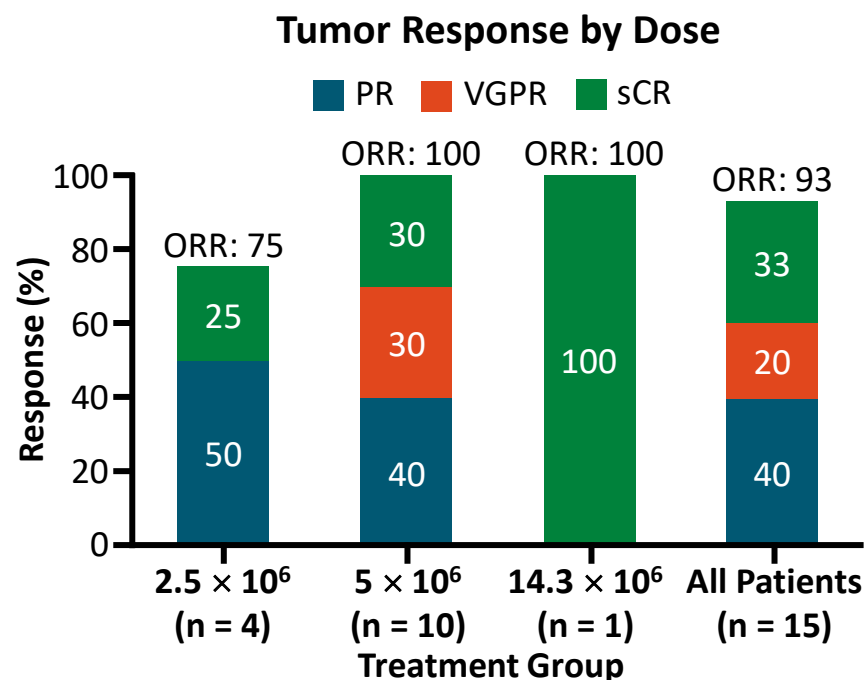
Data cutoff: January 11, 2022. Median follow-up: 27.7 months.

^a 27-month PFS and OS rates.

1. Usmani SZ, et al. ASCO 2022. Abstract 8028. 2. Lin Y, et al. EHA 2022. Abstract P961.

Phase I Trial of PHE885 in R/R MM: Fully Human BCMA CAR T-Cell Therapy

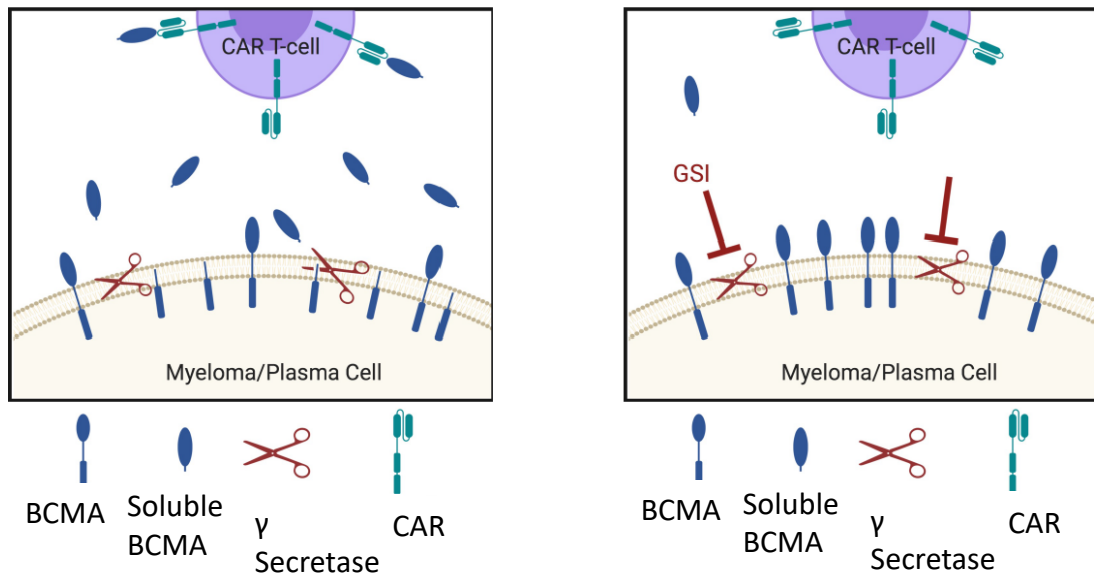
- PHE885: anti-BCMA CAR T-cells manufactured ex vivo with culture time of approximately 24 hr; time to manufacture final product is <2 days, relying entirely on in vivo expansion after CAR T-cell infusion
- Phase I study in heavily pretreated patients with R/R MM



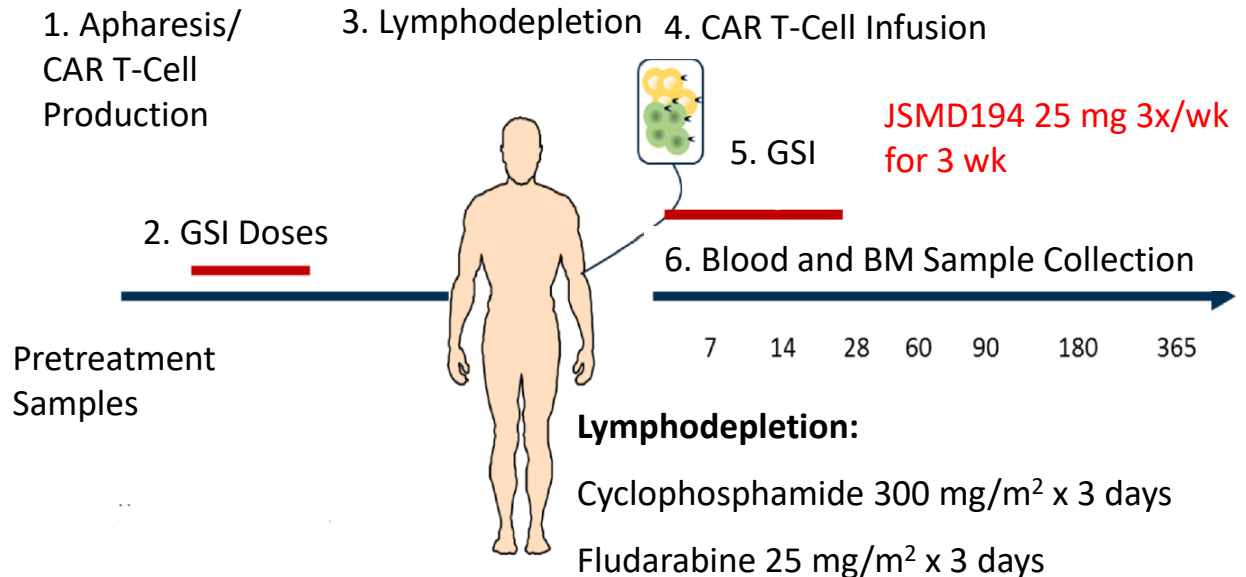
- Following PHE885 treatment, there is a shift toward naive/T_{SCM} phenotype
- Shift to T_{SCM}/T_{naive} population observed in CD4+ and CD8+ T-cells in patients with ≥ VGPR but not wi

Fully Human BCMA CAR T-Cells Combined With γ Secretase Inhibitor to Increase BCMA Expression in R/R MM

γ Secretase Cleaves BCMA From Plasma Cells

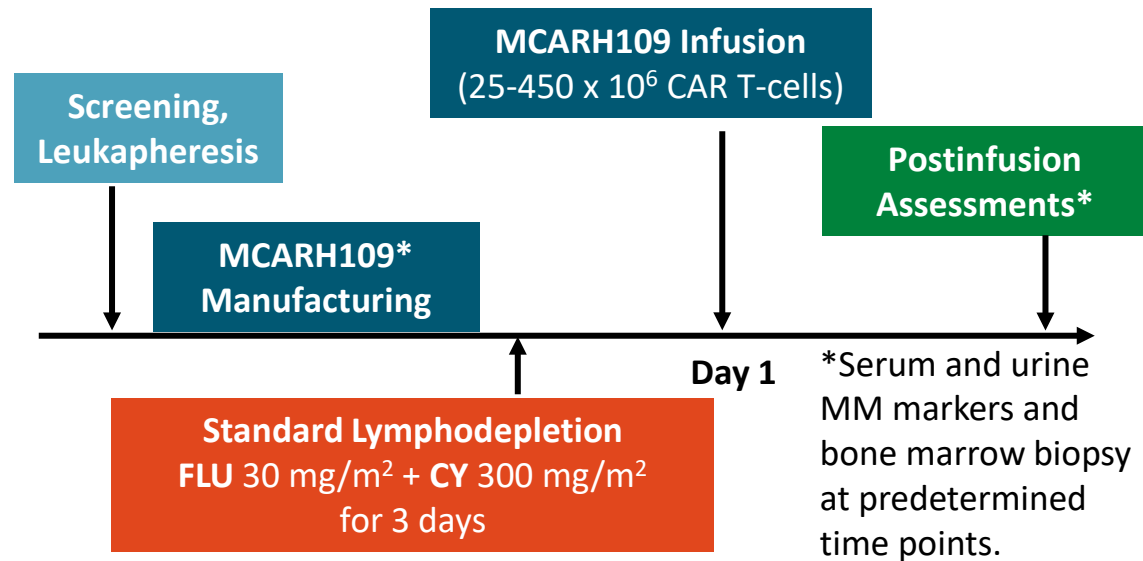


Study Design



GPRC5D-Targeted CAR T-Cell Therapy MCARH109 in R/R MM

- MCARH109: human-derived scFv targeting GPRC₅D with 4-1BB costimulatory domain and lentiviral vector for transduction; production starts with 1:1 ratio of CD4+ and CD8+ cells
- Open-label, 3 + 3 dose-escalation phase I study enrolling adults with R/R MM after ≥3 lines of tx including PI, IMiD, and CD38 Ab
- 16 evaluable patients



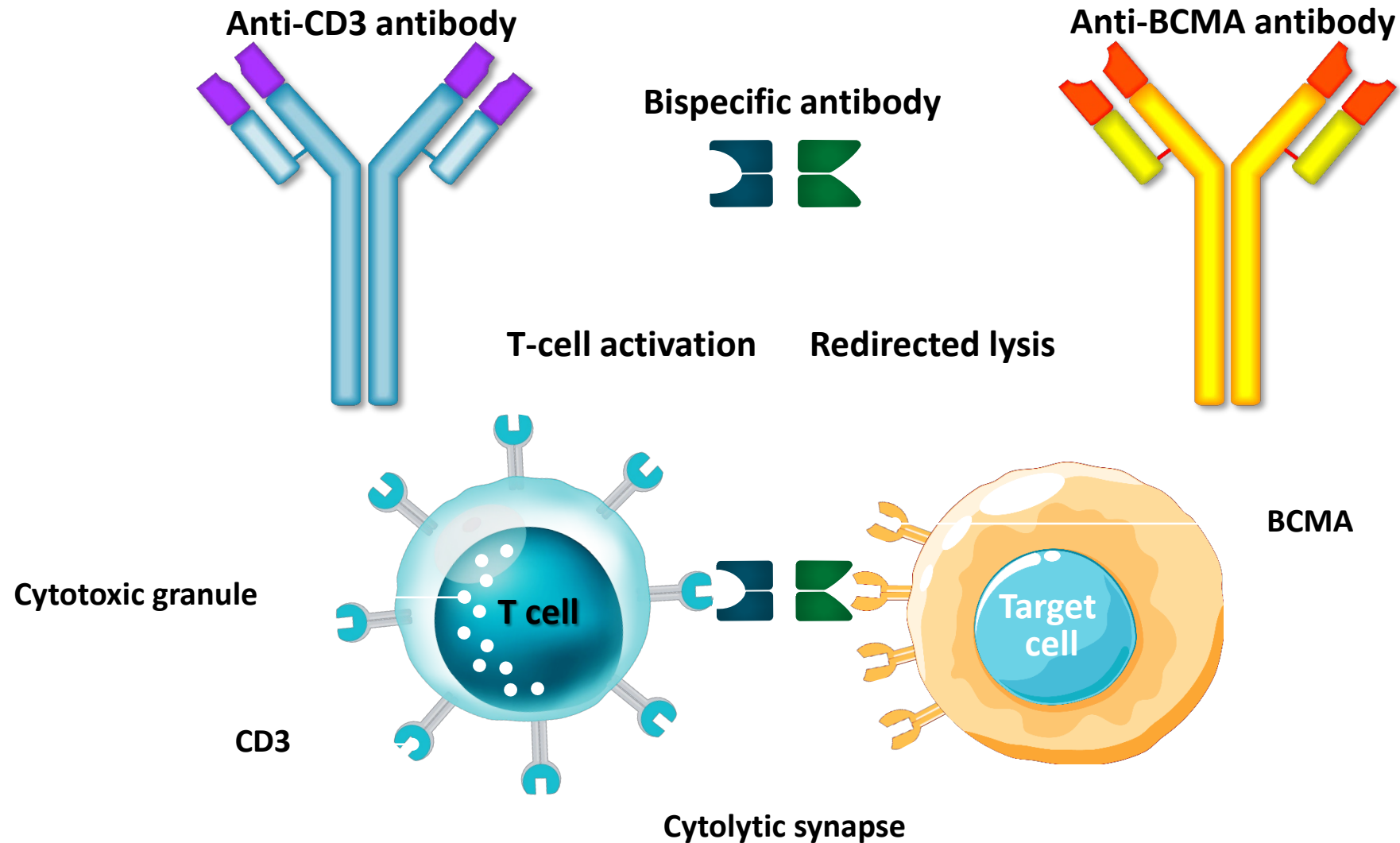
Dose escalation cohorts: 25 x 10⁶ → 50 x 10⁶ → 150 x 10⁶ → 450 x 10⁶ CAR+ T-cells

Response, n (%)	25 x 10 ⁶ CAR+ T-Cells (n = 3)	50 x 10 ⁶ CAR+ T-Cells (n = 3)	150 x 10 ⁶ CAR+ T-Cells (n = 5)	450 x 10 ⁶ CAR+ T-Cells (n = 5)	Total (N = 16)
≥ PR	1 (33)	3 (100)	2 (40)	5 (100)	11 (69)
≥ VGPR	1 (33)	2 (67)	0	4 (80)	7 (44)
≥ CR	0	1 (33)	0	3 (60)	4 (25)
BM MRD negativity	2 (67)	2 (67)	2 (40)	2 (50)	8 (50)

Response, n (%)	Prior BCMA-Targeted Tx (n = 10)	Prior CAR T-Cell Tx (n = 8)
≥ PR	8 (80)	6 (75)
≥ CR	3 (30)	3 (38)
BM MRD negativity [†]	5 (50)	2 (25)

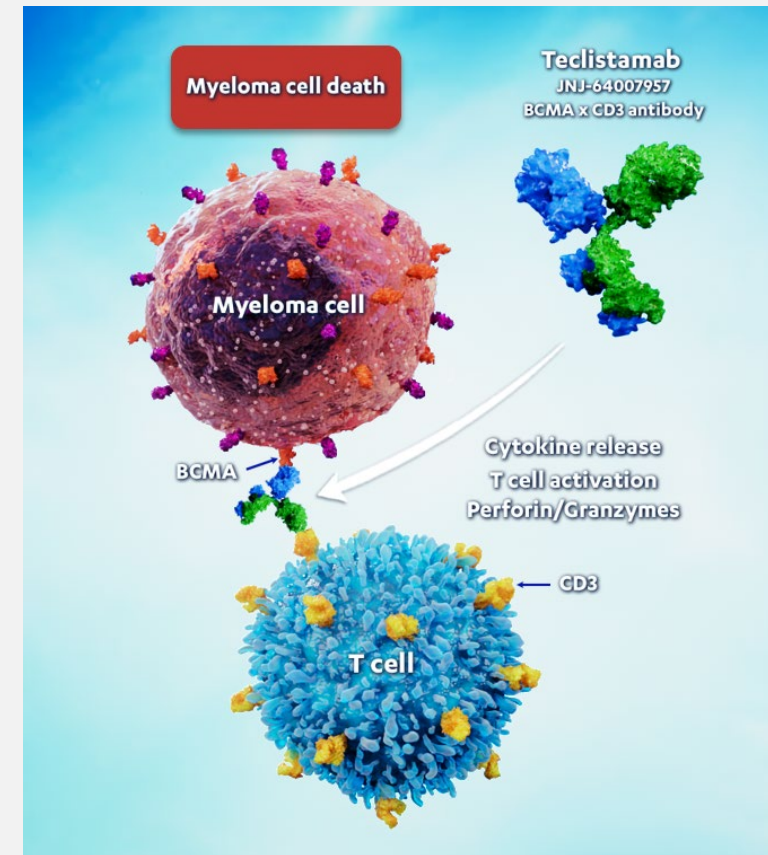
[†]MRD assessment by flow cytometry, sensitivity: 1 in 10⁵.

Bispecific T Cell Engagers



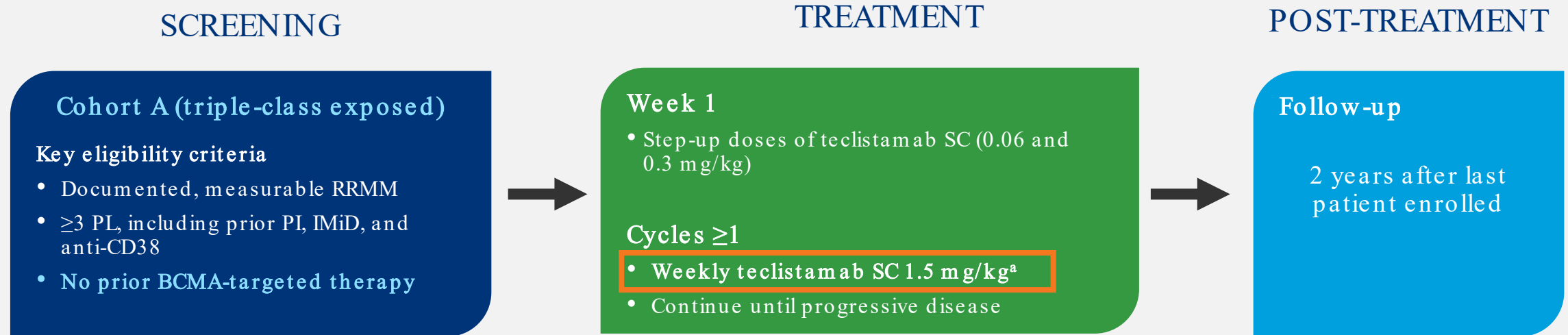
Teclistamab: A Novel BCMA × CD3 T-Cell Redirecting Bispecific Antibody

- Despite newly approved therapies for patients with triple-class exposed RRMM, unmet medical need remains high^{1,2}
- Teclistamab is an off-the-shelf fully humanized IgG4 BCMA x CD3 bispecific antibody based on a validated platform
- Teclistamab redirects CD3+ T cells to mediate T-cell activation and subsequent lysis of BCMA-expressing myeloma cells^{3,4}
- The multicohort, phase 1/2 MajesTEC-1 study is investigating the safety and efficacy of teclistamab in patients with RRMM who previously received ≥ 3 lines of therapy⁵
 - Initial results demonstrated that weekly teclistamab 1.5 mg/kg^a was well tolerated with a high response rate
- Here we present updated results from the all-treated patient population^b with longer follow-up



MajesTEC-1: Study Design

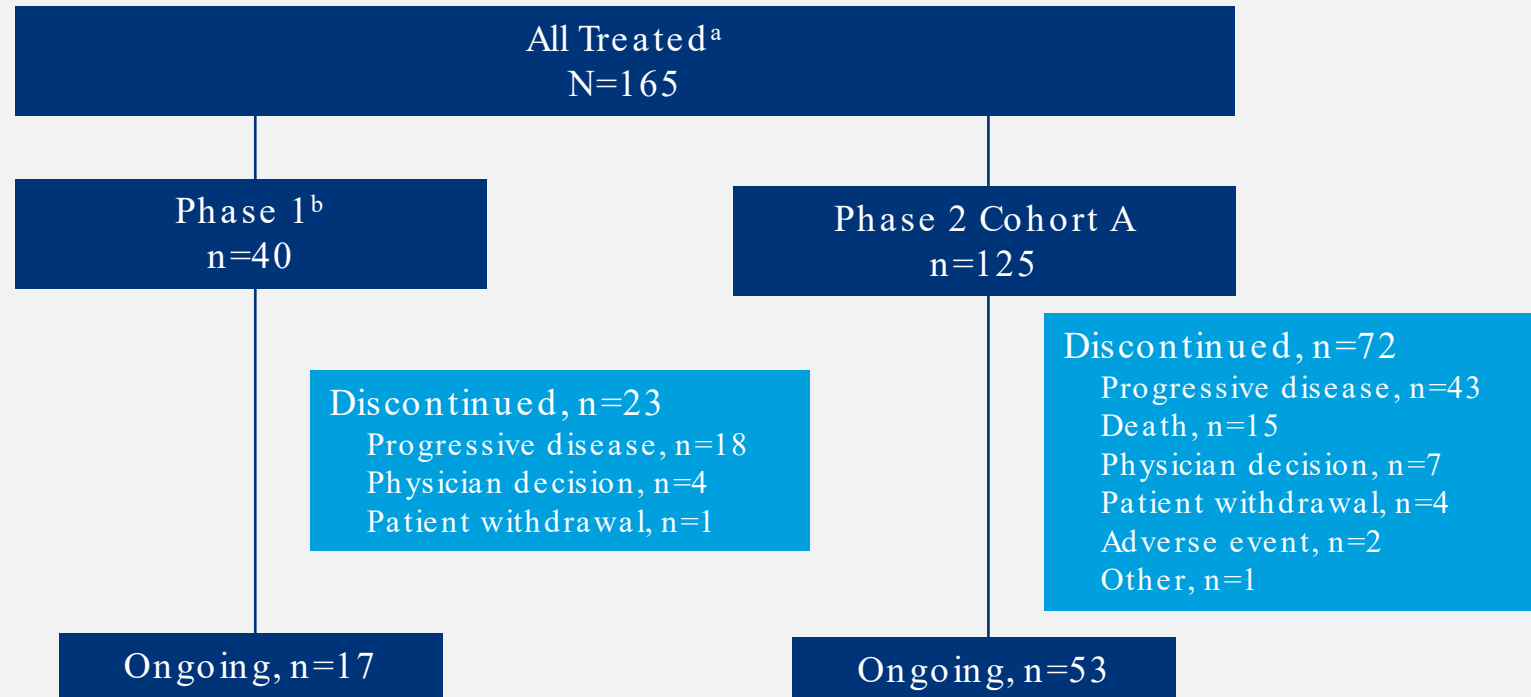
First-in-human, phase 1/2, open-label, multicohort, multicenter, dose-escalation study evaluating teclistamab in patients with RRMM who previously received ≥ 3 lines of therapy (triple-class exposed)



Primary endpoint: ORR

Key secondary endpoints: DOR, $\geq$ VGPR, $\geq$ CR, sCR, TTR, MRD status, PFS, OS, safety, PK, immunogenicity, PROs

MajesTEC-1: Treatment Disposition and Exposure



Median follow-up, months (range)	14.1 (0.26 ⁺ –24.4)
Median treatment duration, months (range)	8.5 (0.2–24.4)
Median relative dose intensity ^c , %	93.7

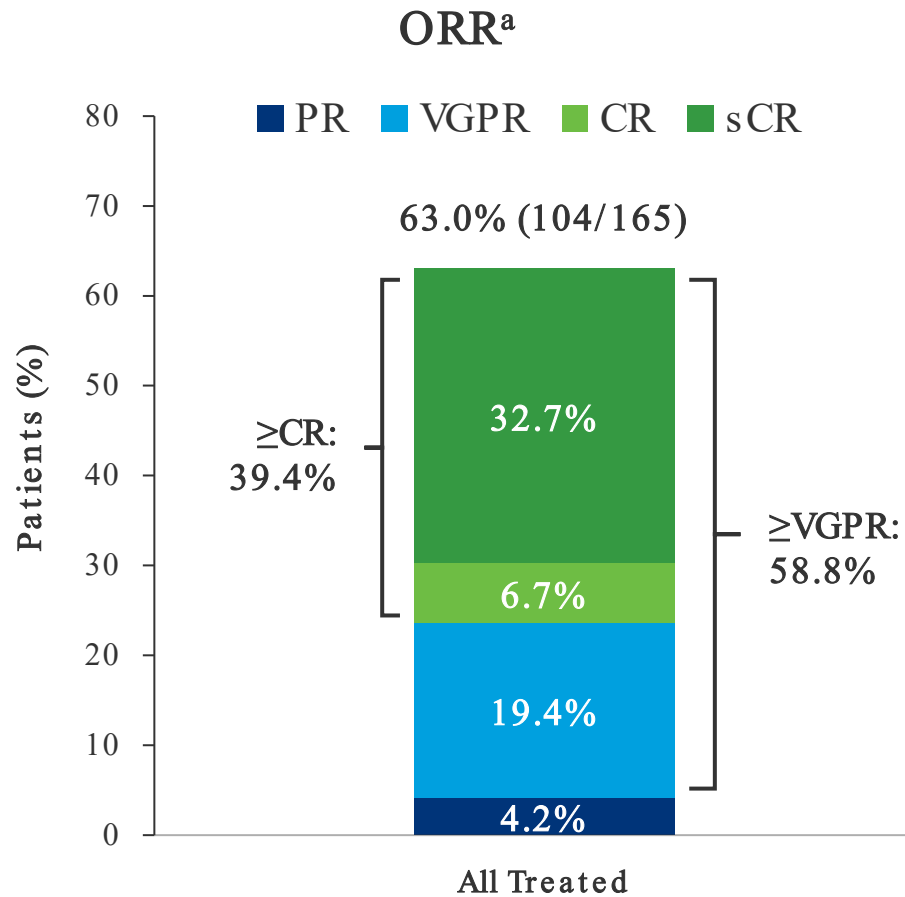
MajesTEC-1:

Patient Demographics and Baseline Characteristics

Characteristic	N=165
Age (years), median (range)	64.0 (33–84)
Age ≥75 years, n (%)	24 (14.5)
Male, n (%)	96 (58.2)
Race, n (%)	
White	134 (81.2)
Black/African American	21 (12.7)
Other ^a	10 (6.1)
Bone marrow plasma cells ≥60% ^b , n (%)	18 (11.3)
Extramedullary plasmacytomas ≥1 ^c , n (%)	28 (17.0)
High-risk cytogenetics ^d , n (%)	38 (25.7)
ISS stage ^e , n (%)	
I	85 (52.5)
II	57 (35.2)
III	20 (12.3)

Characteristic	N=165
Baseline renal function, n (%)	
<60 mL/min/1.73m ²	44 (26.7)
≥60 mL/min/1.73m ²	121 (73.3)
Time since diagnosis (years), median (range)	6.0 (0.8–22.7)
Prior lines of therapy, median (range)	5.0 (2–14)
≥4 prior lines, n (%)	122 (73.9)
Autologous transplantation, n (%)	135 (81.8)
Allogeneic transplantation, n (%)	8 (4.8)
Exposure status, n (%)	
Triple-class ^f	165 (100)
Penta-drug exposed ^g	116 (70.3)
Refractory status, n (%)	
Triple-class ^f	128 (77.6)
Penta-drug ^g	50 (30.3)
To last line of therapy	148 (89.7)

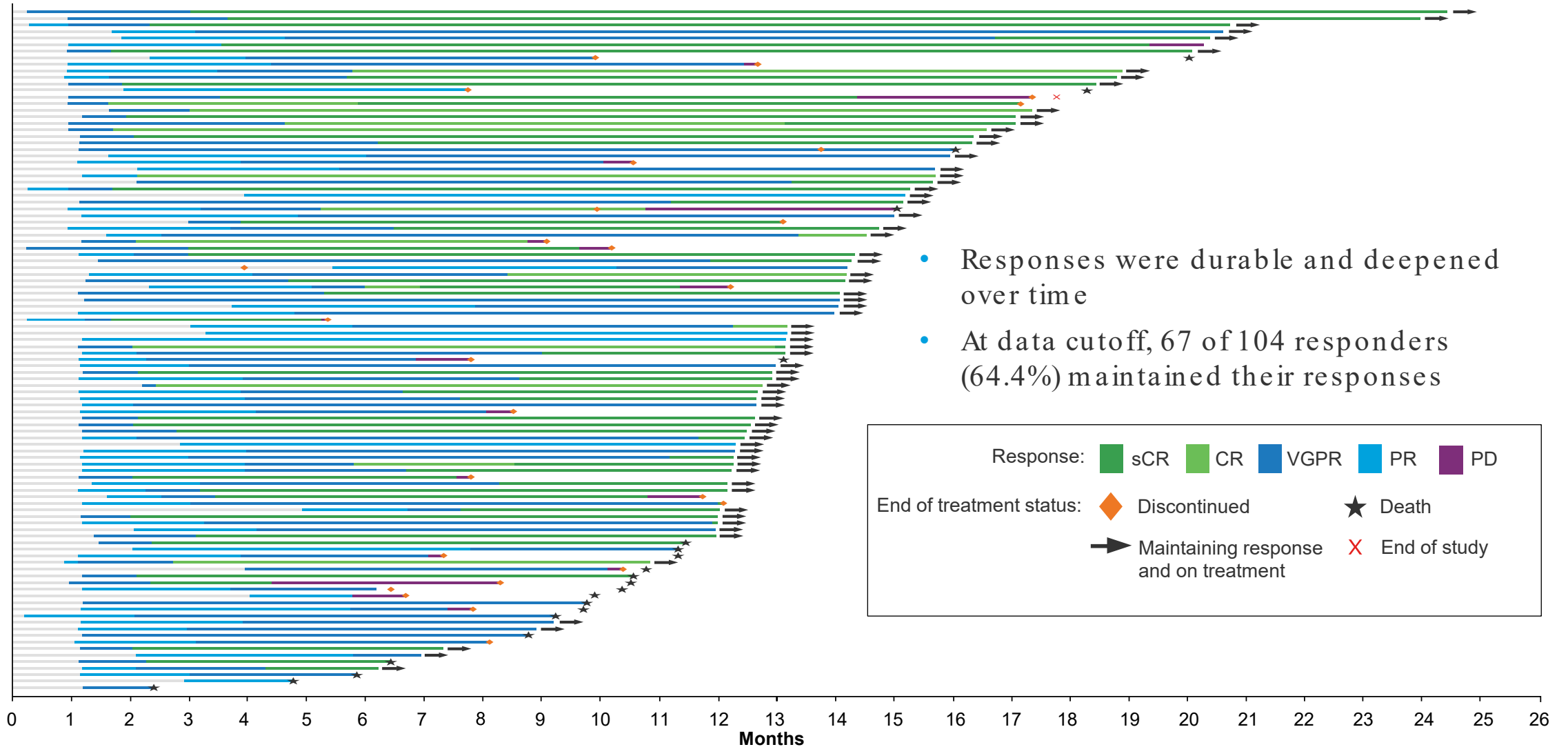
MajesTEC-1: Overall Response to Teclistamab



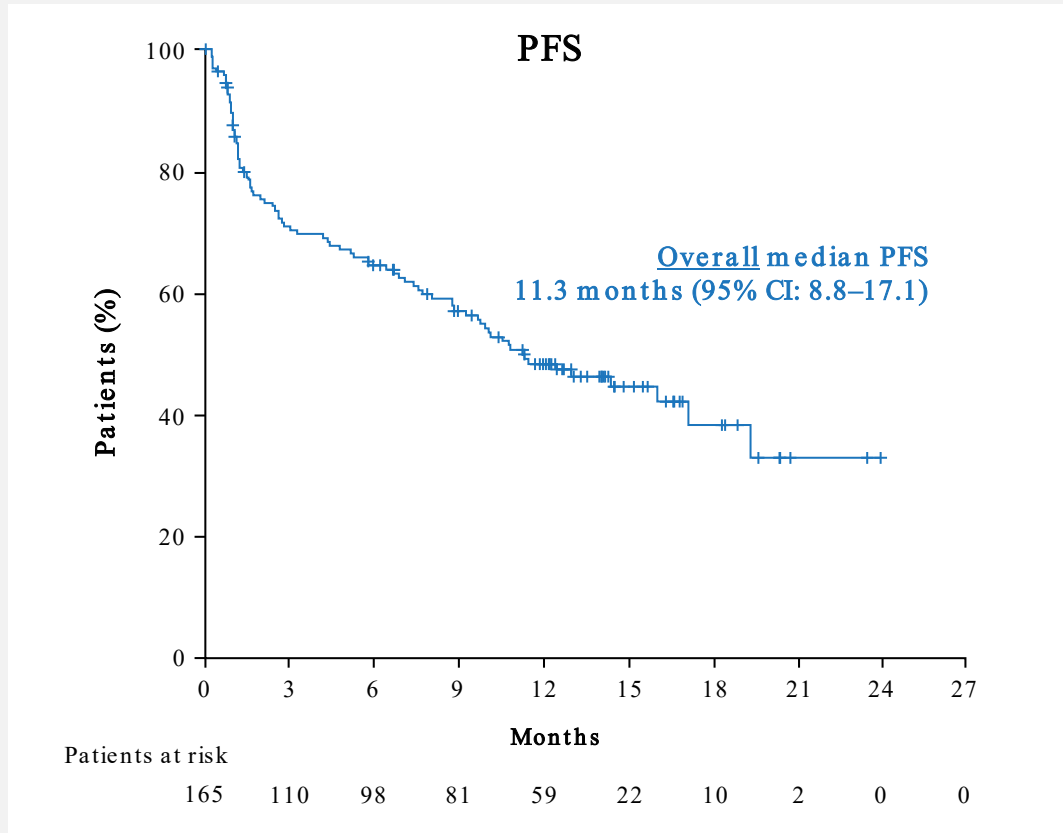
ORR of 63.0% (95% CI: 55.2–70.4) represents a substantial benefit for patients with triple-class exposed disease

- Median time to response (n=104)
 - First response: 1.2 months (range: 0.2–5.5)
 - Best response: 3.8 months (range: 1.1–16.8)
- MRD negativity rate at 10^{-5b}
 - 26.7% in the all-treated (N=165) patient population
 - 81.5% of MRD-evaluable patients (44 of 54) were MRD negative
 - Almost half (46.2%) of patients with $\geq$ CR were MRD negative

MajesTEC-1: Durability of Response



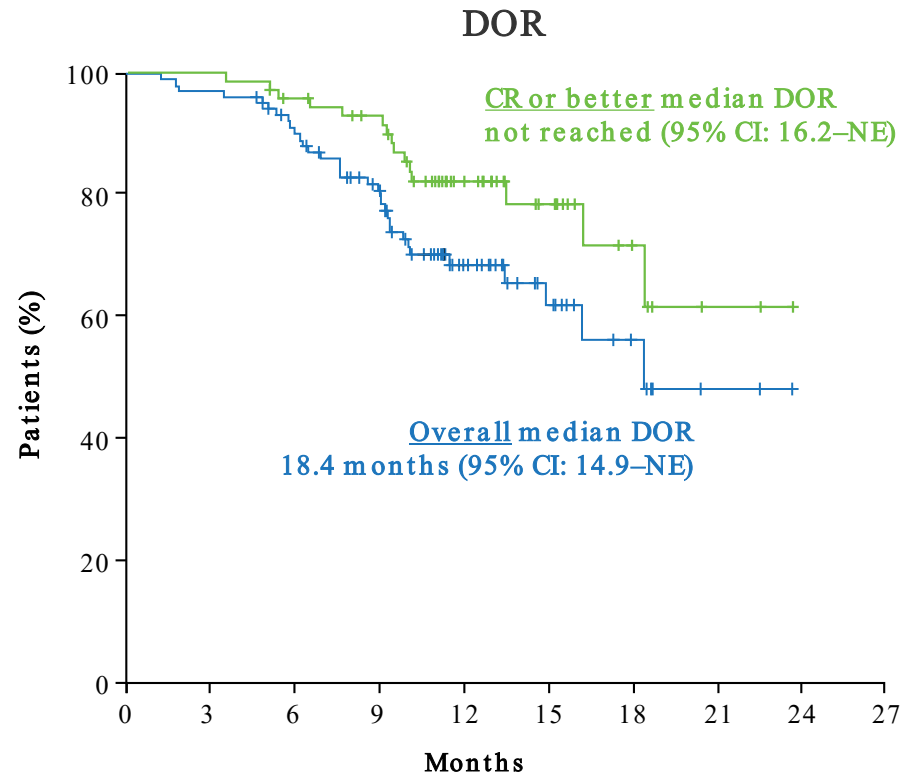
MajesTEC-1: Progression-Free Survival



With a median follow-up of 14.1 months, median PFS was 11.3 months (95% CI: 8.8–17.1)

- Median OS was 18.3 months (95% CI: 15.1–NE) and was not yet mature, with data from 97 patients (58.8%) censored

MajesTEC-1: Duration of Response



Patients at risk

Overall	104	101	89	74	35	17	7	2	0	0
CR or better	65	65	60	55	28	16	6	2	0	0

Overall median DOR of 18.4 months (95% CI: 14.9–NE),
and was not yet mature with data from 71 patients
(68.3%) censored

12-month event-free rate:

- Overall: 68.5% (95% CI: 57.7–77.1)
- Patients with CR or better: 80.1% (95% CI: 67.6–88.2)

MajesTEC-1: Overall Safety Profile

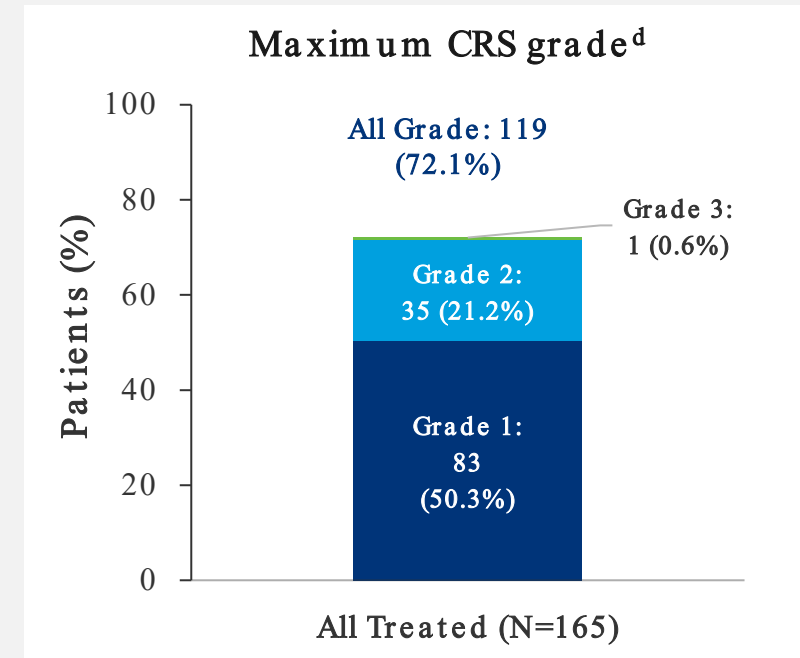
AEs ≥20%, n (%)	Any Grade	Grade 3/4
Hematologic		
Neutropenia	117 (70.9)	106 (64.2)
Anemia	86 (52.1)	61 (37.0)
Thrombocytopenia	66 (40.0)	35 (21.2)
Lymphopenia	57 (34.5)	54 (32.7)
Nonhematologic		
CRS	119 (72.1)	1 (0.6)
Diarrhea	47 (28.5)	6 (3.6)
Fatigue	46 (27.9)	4 (2.4)
Nausea	45 (27.3)	1 (0.6)
Pyrexia	45 (27.3)	1 (0.6)
Injection site erythema	43 (26.1)	0 (0)
Headache	39 (23.6)	1 (0.6)
Arthralgia	36 (21.8)	1 (0.6)
Constipation	34 (20.6)	0 (0)
Cough	33 (20.0)	0 (0)

Teclistamab was well tolerated; discontinuations and dose reductions were infrequent

- 2 patients (1.2%) discontinued due to AEs (grade 3 adenoviral pneumonia; grade 4 PML)
- 1 patient had dose reduction at cycle 21
- The most common AEs were CRS and cytopenias
- Infections occurred in 126 (76.4%) patients (grade 3/4: 44.8%)
- 123 patients (74.5%) had evidence of hypogammaglobulinemia^a
- There were 19 deaths due to AEs, including 12 COVID-19 deaths
 - 5 deaths due to teclistamab-related AEs:
 - COVID-19 (n=2)
 - Pneumonia (n=1)
 - Hepatic failure (n=1)
 - PML (n=1)

MajesTEC-1: Cytokine Release Syndrome

Parameter	N=165
Patients with CRS, n (%)	119 (72.1)
Patients with ≥ 2 CRS events	55 (33.3)
Time to onset ^a (days), median (range)	2 (1–6)
Duration (days), median (range)	2 (1–9)
Received supportive measures ^a for CRS, n (%)	110 (66.7)
Tocilizumab ^b	60 (36.4)
Low-flow oxygen by nasal cannula ^c	21 (12.7)
Corticosteroids	14 (8.5)
Single vasopressor	1 (0.6)



- Most CRS events were confined to step-up and first full treatment doses
- All CRS events were grade 1/2, except for 1 transient-grade 3 CRS event that occurred in the context of concurrent pneumonia (resolved in 2 days)
- All CRS events fully resolved without treatment discontinuation or dose reduction

MajesTEC-1: Neurotoxic Events

Parameter	N=165
Neurotoxic event ^a , n (%)	24 (14.5)
Headache	14 (8.5)
ICANS ^b	5 (3.0)
Dysgeusia	2 (1.2)
Lethargy	2 (1.2)
Tremor	2 (1.2)
Grade ≥ 3 events, n (%)	1 (0.6)
Time to onset, median (range) days	3.0 (1–13)
Duration, median (range) days	7.0 (1–291)
Received supportive measures for neurotoxic events ^c , n (%)	14 (8.5)
Tocilizumab	3 (1.8)
Dexamethasone	3 (1.8)
Levetiracetam	2 (1.2)
Gabapentin	1 (0.6)

- The overall incidence of neurotoxic events was low
- All neurotoxic events were grade 1/2, except for 1 grade 4 seizure (in the context of bacterial meningitis during cycle 7)
- 5 patients (3.0%) had a total of 9 ICANS events
 - 7 events were concurrent with CRS
 - All ICANS events were grade 1/2 and fully resolved
- There were no treatment discontinuations or dose reductions due to neurotoxic events, including ICANS

MajesTEC-1: Conclusions

After a median follow-up of 14 months, teclistamab yields deep and durable responses in patients with highly refractory MM

- Response rate remained high (63.0%) with CR or better achieved in 39.4% of patients
- Median DOR of 18.4 months and in those achieving a CR or better event-free rate was 80.1% at 12 months
- Median PFS of 11.3 months

Teclistamab toxicities were manageable

- CRS was predominantly grade 1/2 and incidence of neurotoxic events was low
- Cytopenias and infections were common but consistent with heavily pretreated RRMM

These data support teclistamab as a promising new, off-the-shelf, T-cell redirecting therapy targeting BCMA for patients with RRMM

- Phase 3 studies are ongoing and early access programs are underway
- Data in patients with prior BCMA exposure was presented by Dr. Touzeau (presentation #8013)



BCMA Bispecific T-Cell Antibodies

Drug	N	Route/Schedule	ORR at RP2D or Higher Doses Tested to-Date	CRS	Comments
AMG 420^[a] (no longer in clinical development)	42	4-week continuous IV	70% (400 ug/day, N = 10)	All grade (38%), grade 3/4 (2%)	Grade 3 peripheral neuropathy (2); 1 death due to hepatic failure (adenovirus)
CC-93269^[b]	30	IV q week	89% (10 mg, N = 9)	All grade (77%), grade 3/4 (0%), grade 5 (3%, 1 patient at 10 mg dose)	2 BCMA binding domains
Teclistamab^[c]	157	SC q week	65%, 58% ≥ VGPR (1.5 mg/kg, N = 150)	All grade (70%), grade 3/4 (1%)	9-month PFS 58.5% Median DOR not reached
TNB-383B (ABBV-383)^[d]	103	IV q3 weeks	60%, 40% ≥ VGPR (≥ 40 mg, N = 60)	All grade (69%), grade 3/4 (4%)	No step-up dosing; 2 BCMA binding domains
REGN5458^[e]	73	IV q week, then q2 weeks starting week 16	75%, 58% ≥ VGPR (200 mg to 800 mg, N = 24)	All grade (38%), grade 2 (4%), grade 3/4 (0%)	
AMG 701^[f]	85	IV q week	83%, 50% ≥ VGPR (18 mg, N = 6)	All grade (65%), grade 3 (9%), grade 4 (0%)	
Elranatamab^[g]	55	SC q week	70% (≥ 215 ug/kg, N = 20)	All grade (87%), grade 3/4 (0%)	7/10 responders in prior BCMA-exposed

Updated Results From the MonumenTAL-1 Phase 1 Study of Talquetamab in Patients With RRMM: Study Design and Patients^{1,2}

Key Eligibility Criteria

- RR or intolerant to established MM therapies
- Prior BCMA-targeted therapy was permitted

Dosing Schedule at RP2D

- Required premedications^a were limited to step-up doses and 1st full dose
- MTD was not reached
- Collective data supported 2 RP2Ds for talquetamab

PHASE 1
(N=130)

SUBQ Talquetamab (n=30)

405 µg/kg SUBQ QW^b for
≥2-3 step-up doses given prior to
1st full dose (21-day cycles)

SUBQ Talquetamab (n=44)

800 µg/kg SUBQ Q2W^b for
≥2-3 step-up doses given prior to
1st full dose (28-day cycles)

Key Objectives: RP2D (Part 1), RP2D safety/tolerability (Part 2), antitumor activity, PK, PD

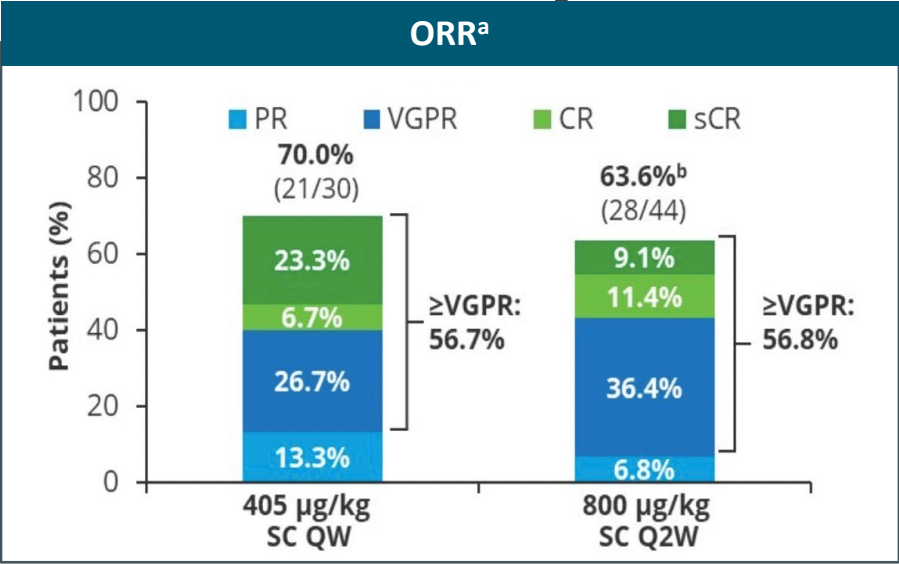
Patient Characteristics		405 µg/kg QW (n=30)	800 µg/kg Q2W (n=44)
Median age, years (range)		61.5 (46-80)	64.0 (47-84)
BM plasma cells ≥60%, n (%)		6 (20.7)	5 (12.2)
Extramedullary plasmacytomas ≥1, n (%)		11 (36.7)	15 (34.1)
High-risk cytogenetics, ^b n (%)		3 (11.1)	9 (22.5)
ISS stage, n (%)	I	12 (41.4)	16 (37.2)
	II	13 (44.8)	18 (41.9)
	III	4 (13.8)	9 (20.9)
Median years since diagnosis (range)		5.6 (1.7-19.6)	6.4 (0.8-21.3)
Median prior lines of therapy (range)		6 (2-14)	5 (2-17)
Prior SCT, n (%)		27 (90.0)	33 (75.0)
Exposure status, n (%)	Triple-class	30 (100)	43 (97.7)
	Penta-drug	24 (80.0)	30 (68.2)
	BCMA	9 (30.0)	12 (27.3)
Refractory status, n (%)	Triple-class	23 (76.7)	34 (77.3)
	Penta-drug	6 (20.0)	12 (27.3)

Data cutoff: April 6, 2022.

^a Glucocorticoid, antihistamine, antipyretic, and steroids. ^b del(17p), t(4;14), and/or t(14;16); calculated from n=27 for 405 µg/kg SUBQ QW and n=40 for 800 µg/kg SUBQ Q2W.

1. Minnema MC, et al. ASCO 2022. Abstract 8015. 2. Minnema MC, et al. EHA 2022. Abstract S182.

Updated Results From the MonumenTAL-1 Phase 1 Study of Talquetamab in Patients With RRMM: Efficacy and Summary^{1,2}



Response	405 µg/kg QW (n=30)	800 µg/kg Q2W (n=44)
Median follow-up, months (range)	13.2 (1.1-24.0)	7.7 (0.7-16.0)
ORR, n (%)	21 (70.0)	28 (63.6)
Triple-class refractory, n/N (%)	15/23 (65.2)	23/34 (67.6)
Penta-drug refractory, n/N (%)	5/6 (83.3)	9/12 (75.0)
Median time to first confirmed response, months, (range)	0.9 (0.2-3.8)	1.2 (0.3-6.8)
Median DOR, months (95% CI)	10.2 (3.0-NE)	13.0 (5.3-NE)

PK and PD Summary

- For both regimens, PK and PD profiles were comparable
- 17.6% of patients (13/74) had low titer antidrug Ab, which did not impact safety, efficacy, or PK
- Both regimens were associated with peripheral induction of PD-1+ T cells and consistent induction of cytokines

Authors' Conclusions

- Both doses of talquetamab had comparable safety, efficacy, and PK/PD profiles in patients with RRMM
- Longer follow-up ORR results (64% to 70%) across triple-class– and penta-drug–refractory patients confirm the efficacy of QW or Q2W schedules
- A phase 2 expansion study of both RP2Ds and phase 1 studies evaluating talquetamab combination therapy are ongoing

Data cutoff: April 6, 2022.

^a Investigator assessment of evaluable patients per 2011 IMWG response criteria; includes unconfirmed responses.

^b Due to rounding, individual response rates do not sum to the ORR.

1. Minnema MC, et al. ASCO 2022. Abstract 8015. 2. Minnema MC, et al. EHA 2022. Abstract S182.

Phase 1 Study of Cevostamab in Patients With RRMM: Study Design and Patient Characteristics

Cevostamab is a FcRH5/CD3 bispecific T-cell engager

Key eligibility criteria

- ECOG PS 0-1
- Prior CAR Ts, bispecific antibodies, and ADCs allowed

Cevostamab administration

- Q3W IV infusions for 17 cycles
- CRS/infusion-related reaction mitigation
 - C1 single step-up dosing[‡]
 - C1-2 corticosteroid premedication; C1-17 acetaminophen, diphenhydramine
- Hospitalization after each C1 infusions (≥72 hours)

Dose Escalation

SS cohorts: step dose (0.05-3.6 mg) on c1d1 and the target dose (0.15-198 mg) on c1d8 IV q3w 17 cycles

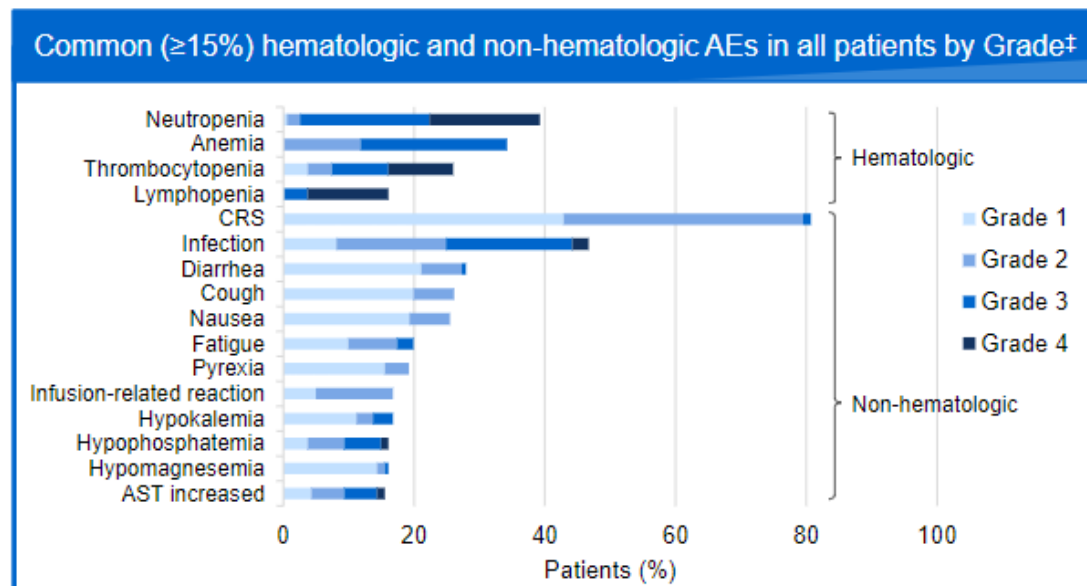
DS cohorts: step doses are given on c1d1 (0.3-1.2 mg) and c1d8 (3.6 mg), and the target dose (60-160 mg) on c1d15 IV q3w 17 cycles

Patient Characteristics

(N=161)

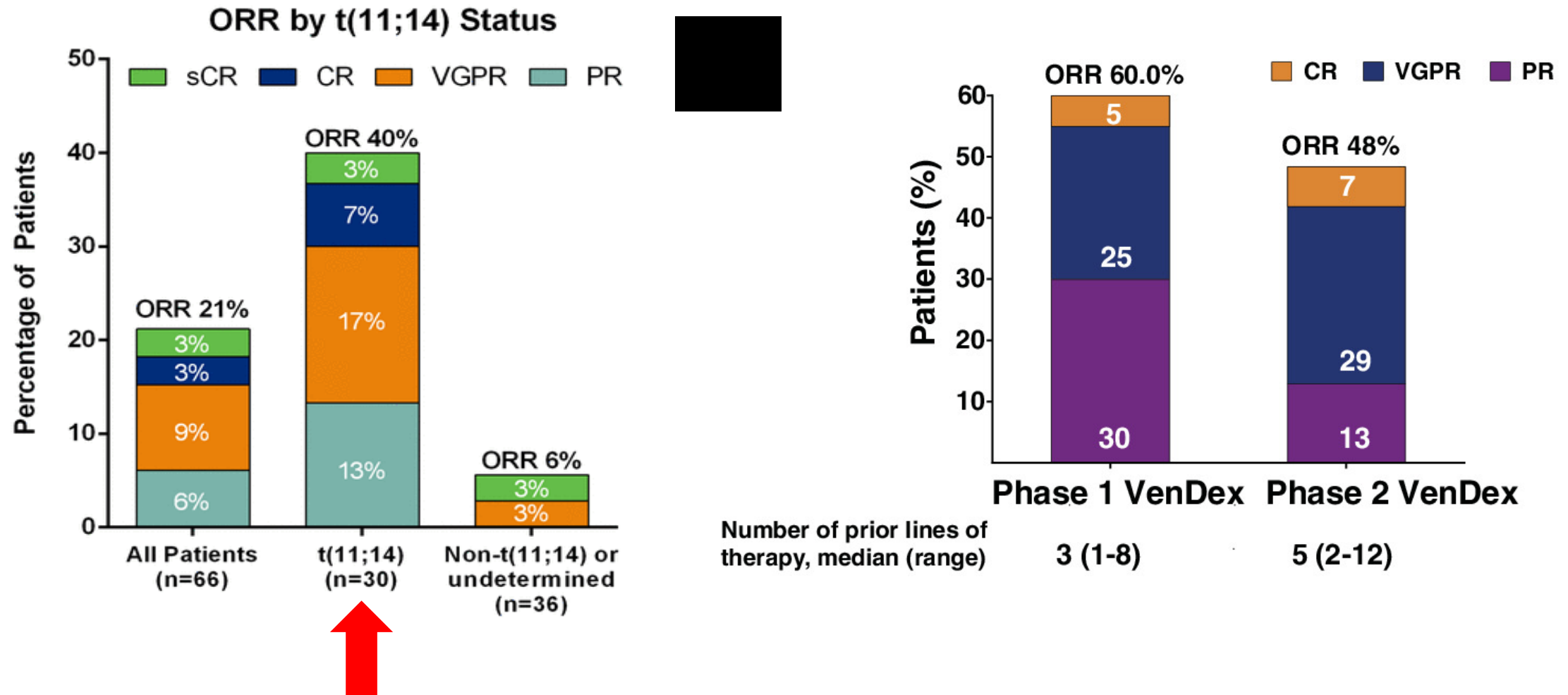
Median age (range), y		64 (33-82)
Extramedullary disease at screening, n (%)		34 (21)
High-risk cytogenetics, n/N (%)		67/95 (71)
	1q21	50/90 (56)
	t(4;14)	13/96 (14)
	t(14;16)	2/90 (2)
	del(17p)	27/112 (24)
Time since first MM therapy, median (range), y		6.1 (0.3-22.8)
No. of prior lines of therapy, median (range)		6 (2-18)
Prior therapy, n (%)	Anti-CD38 Ab	142 (88)
	Anti-BCMA	54 (36)
	CAR T-cell therapy	28 (17)
	ADC	27 (17)
	Bispecific antibody	13 (8)
	Triple-class refractory	136 (85)
	Penta-drug refractory	110 (68)
Refractory to last prior therapy, n (%)		143 (89)

Phase 1 Study of Cevostamab



Efficacy	20-90 mg (n=83)	132-198 mg (n=60)
ORR, %	36.1	56.7
sCR	8.4	6.7
CR	1.2	1.7
VGPR	10.8	25
PR	15.7	23.3
	C1 single step-up	C1 double step-up
Median follow-up, mo (range)	14.3 (2.7-31.8)	6.5 (4.8-21.4)
mDOR, mo	11.5	Not reported

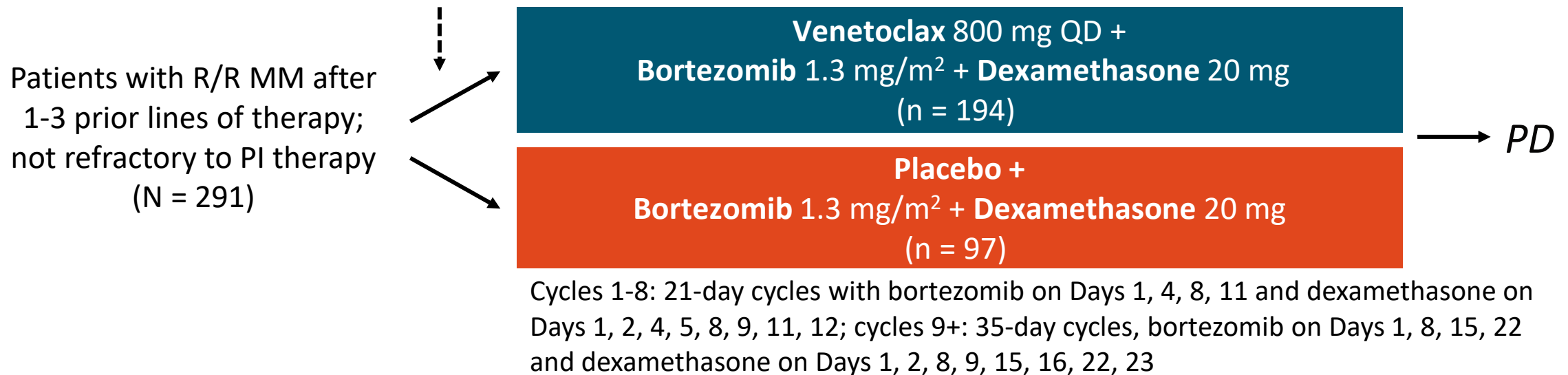
Targeting BCL2 Is Effective in Patients With t(11;14) MM



BELLINI: Venetoclax, Bortezomib, and Dexamethasone vs Vd in RRMM

- Double-blind, randomized 2:1, placebo-controlled phase III trial

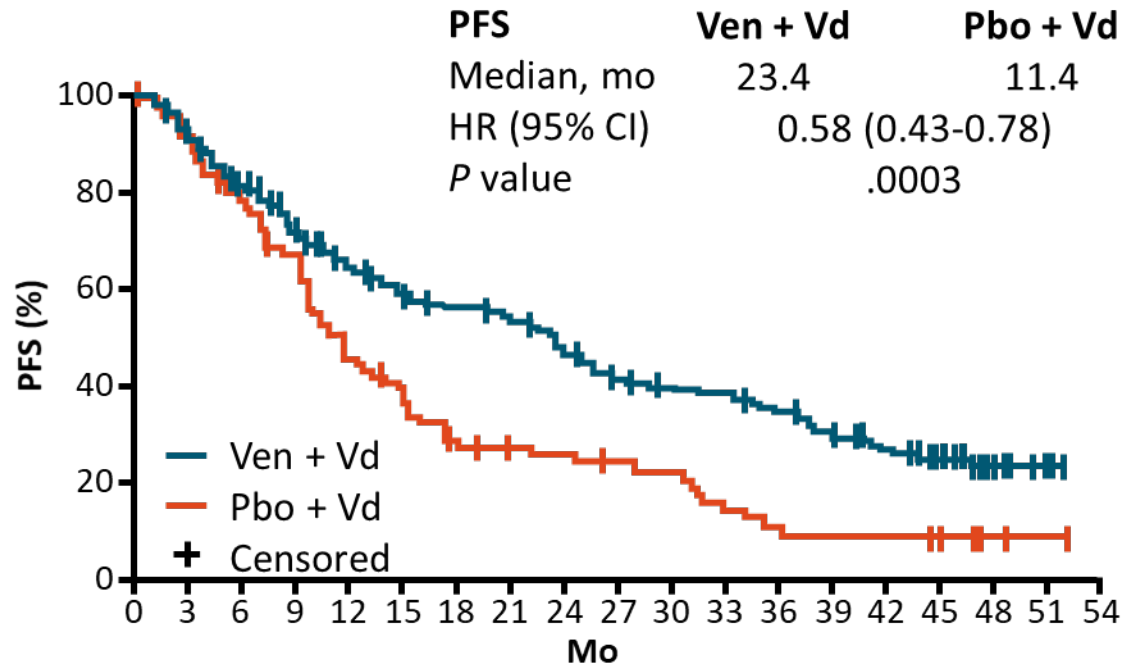
*Stratification by bortezomib sensitive vs naive
and prior lines of therapy (1 vs 2-3)*



- Primary endpoint:** PFS (per IRC)
- Key secondary endpoints:** ORR, $\geq$ VGPR, OS, QoL/PRO parameters (PFS was investigator-assessed in final OS analysis)

BELLINI Final Survival Analysis: PFS, OS in All Patients

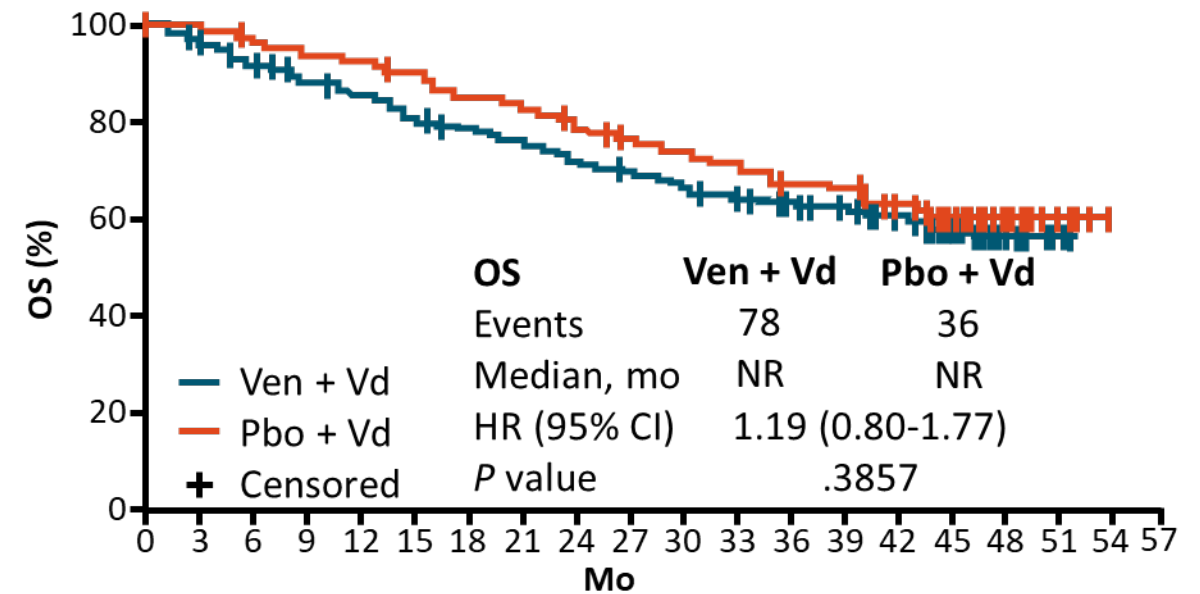
Investigator-Assessed PFS in All Patients



Patients at Risk, n

194	163	140	118	101	89	84	79	68	59	55	53	47	39	32	21	8	2	0
97	83	69	57	39	30	22	20	19	17	15	10	6	7	7	4	2	1	0

OS in All Patients

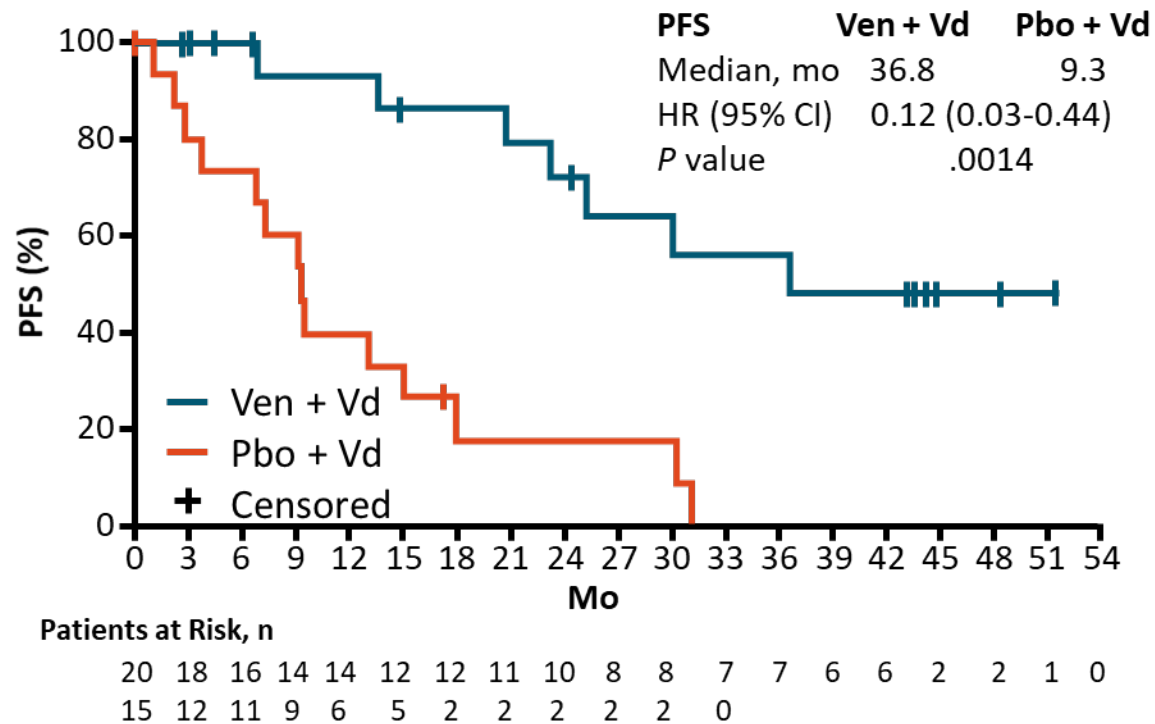


Patients at Risk, n

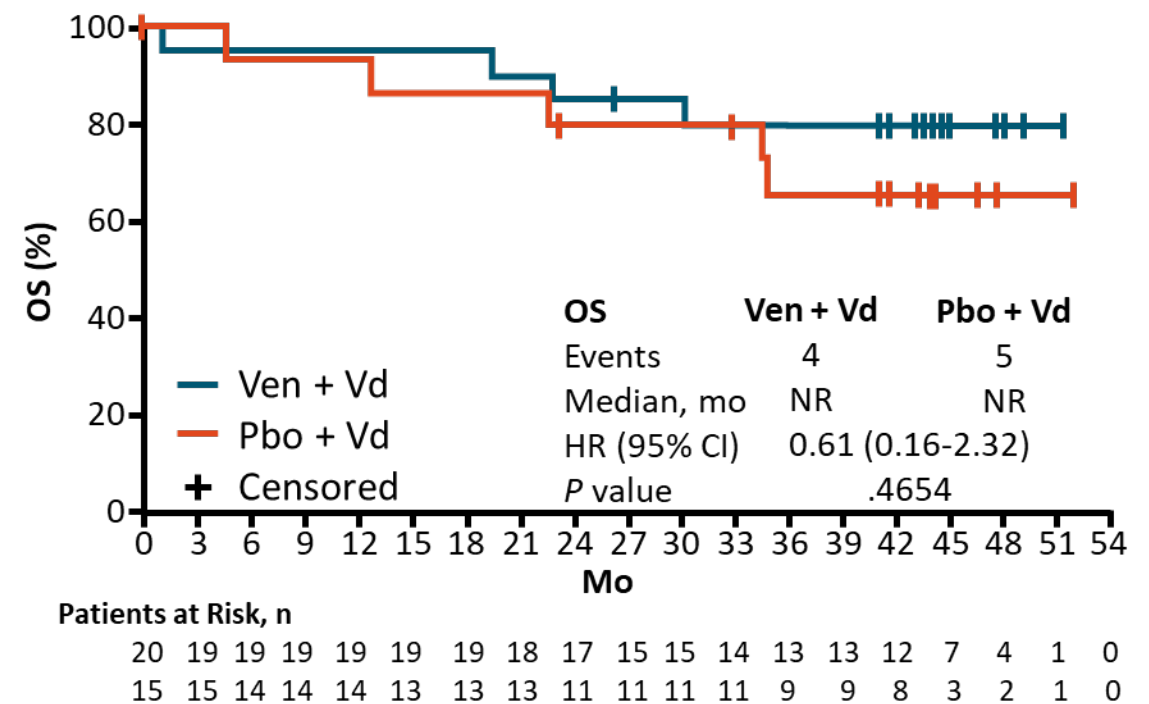
194	186	173	164	158	149	143	139	131	121	118	113	107	104	89	68	30	6	0
97	95	91	88	87	84	79	78	73	67	65	63	58	57	50	37	20	6	1

BELLINI Final Survival Analysis: PFS, OS in t(11;14) Subgroup

Investigator-Assessed PFS in Patients With t(11;14)

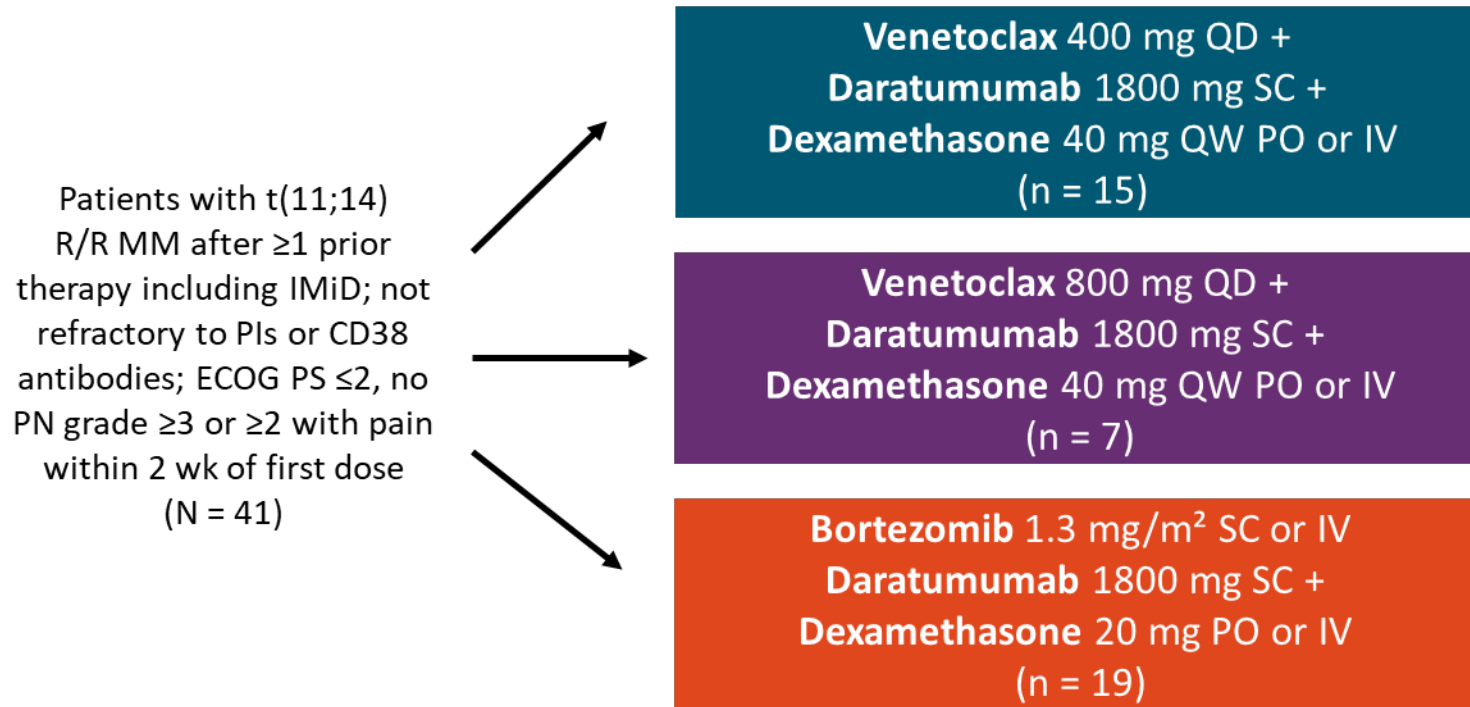


OS in Patients With t(11;14)



Venetoclax, Daratumumab, Dexamethasone vs Bortezomib, Daratumumab, Dexamethasone in t(11;14) RRMM: Part 3 Design

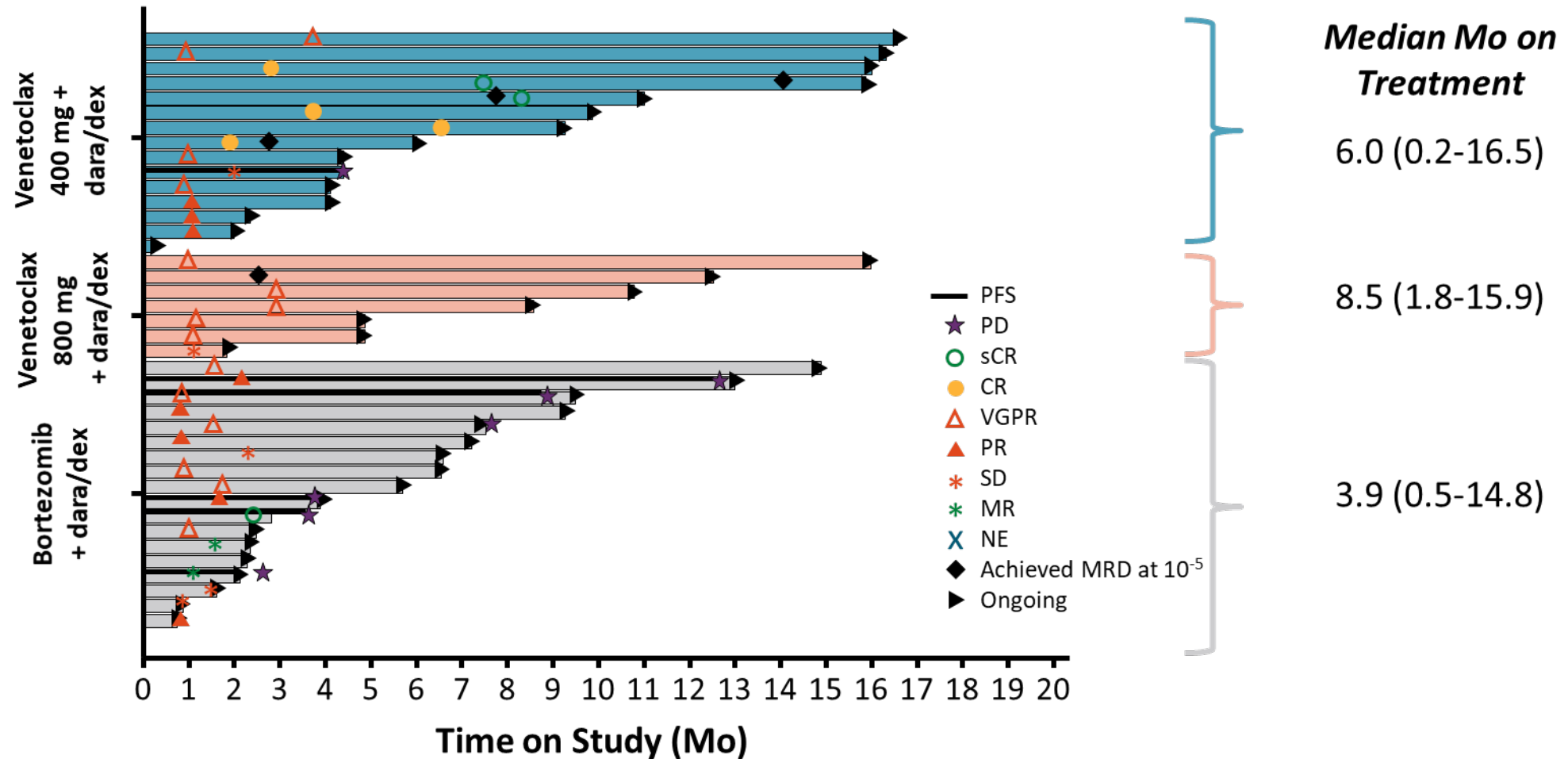
Open-label, randomized phase I/II study (trial not fully accrued)



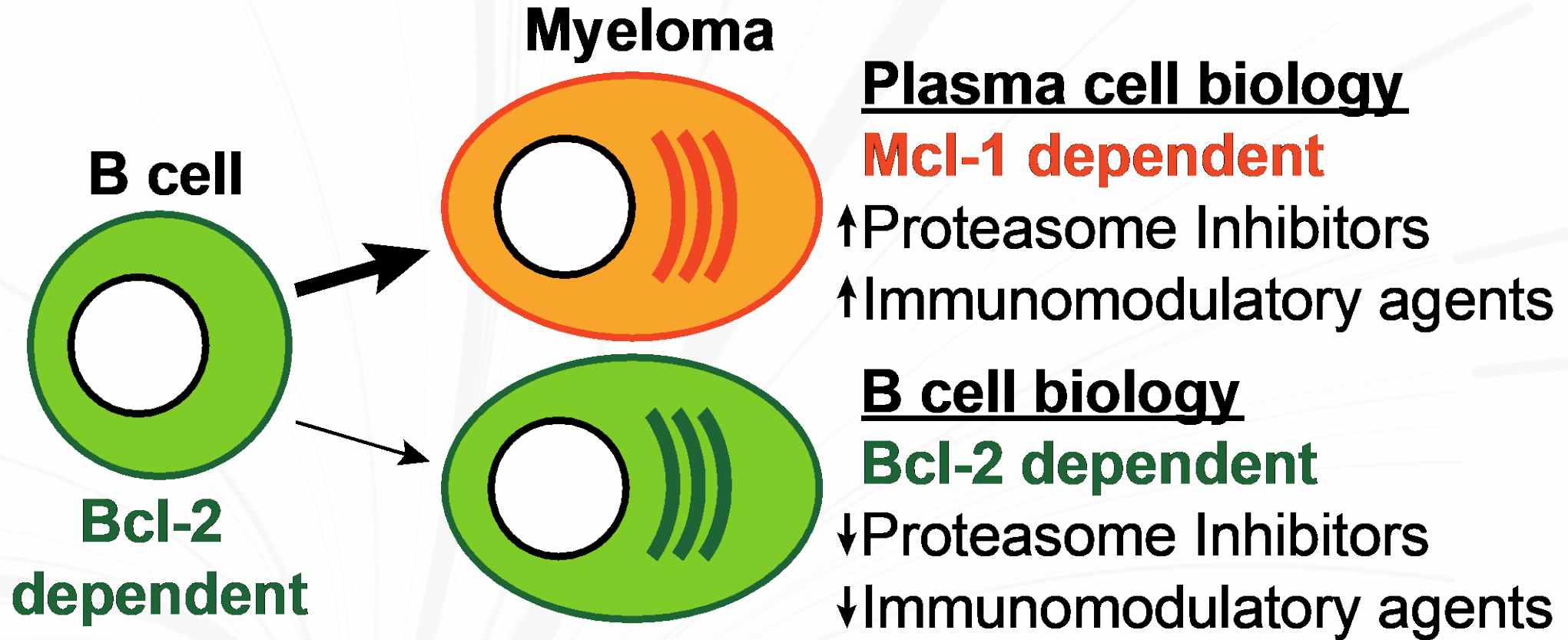
Cycle	Venetoclax	Dara	Dex
1 to 2 (28 days)	Once daily	D1, 8, 15, 22	Weekly
3 to 6 (28 days)	Once daily	D1, 15	Weekly
7+ (28 days)	Once daily	D1	Weekly
Cycle	Bortez	Dara	Dex
1 to 3 (21 days)	D1, 4, 8, 11	D1, 8, 15	D1, 2, 4, 5, 8, 9, 11, 12, 15
4 to 8 (21 days)	D1, 4, 8, 11	D1	D1, 2, 4, 5, 8, 9, 11, 12
9+ (28 days)	--	D1	D1

Primary objective: safety and preliminary efficacy

Venetoclax, Daratumumab, Dexamethasone vs Bortezomib, Daratumumab, Dexamethasone in t(11;14) RRMM: DOR

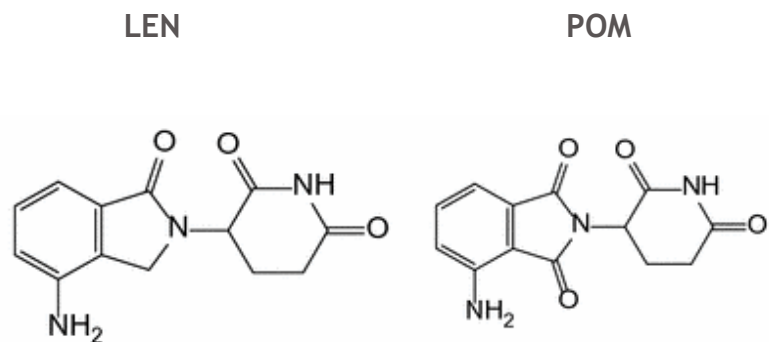


SUMMARY



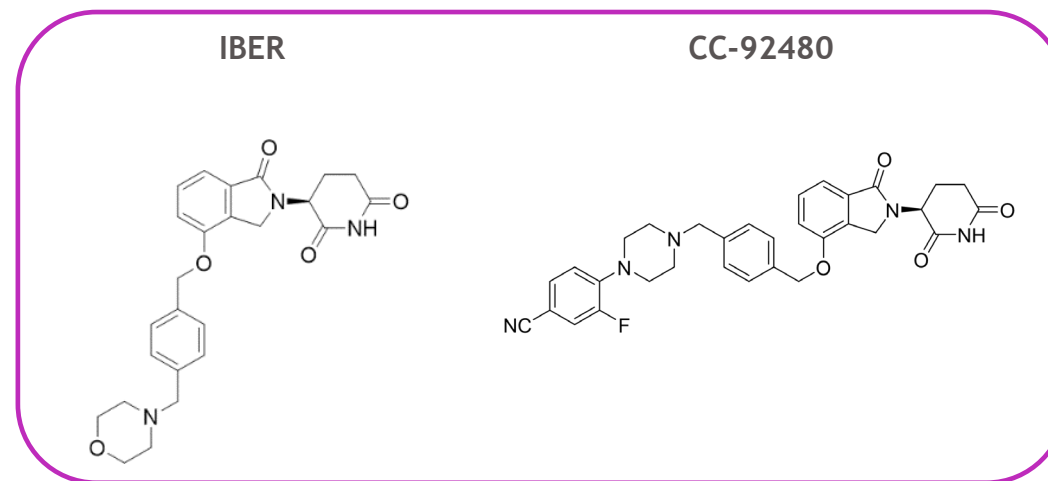
New CELMoD[®] agents in development

- LEN and POM (a subgroup of CELMoD[®] agents) helped to transform therapy and drive survival in MM¹⁻³
- Rational selection of molecules based on **deep scientific understanding of CRBN and MM biology: IBER and CC-92480**⁴⁻⁶



2019 and 2020:

First clinical data for new CELMoD[®] agents (IBER and CC-92480) in MM



IBER (CC-220) and CC-92480 are investigational products, currently not approved by any regulatory agency.

CELMoD[®], cereblon E3 ligase modulator; CRBN, cereblon; IBER, iberdomide; LEN, lenalidomide; MM, multiple myeloma; POM, pomalidomide.

1. Rajkumar SV, et al. *Lancet Oncol* 2010;11:29-37; 2. Facon T, et al. *Blood* 2018;131:301-310; 3. Durie BGM, et al. *Blood Cancer J* 2020;10:53; 4. Ito T, Handa H. *Int J Hematol* 2016;104:293-299; 5. Matyskiela ME, et al. *J Med Chem* 2018;61:535-542; 6. Hansen JD, et al. *J Med Chem* 2020;63:6648-6676.

CC-220-MM-001: dose-expansion phase; Cohorts D and I

Key eligibility criteria

Cohort D

- RRMM
- ≥ 3 prior therapies^a
- PD on or within 60 days of last antimyeloma therapy
- Refractory to an IMiD[®] agent, a PI, a glucocorticoid, and a CD38 mAb

Cohort I

- RRMM
- ≥ 3 prior therapies^b
- Prior treatment with a BCMA targeted therapy
- PD on or within 60 days of last antimyeloma therapy (documented PD if CAR T cell therapy as last therapy)

Cohort D IBER (RP2D) + DEX

IBER (oral): 1.6 mg days 1-21
DEX (oral): 40 mg days 1, 8, 15, 22^a

28-day cycles

Cohort I (post BCMA) IBER (RP2D) + DEX

IBER (oral): 1.6 mg days 1-21
DEX (oral): 40 mg days 1, 8, 15, 22^a

28-day cycles

Endpoints

- **Primary:** efficacy (ORR)
- **Secondary:** safety and additional efficacy parameters (including DOR, PFS, OS)

- **Primary:** preliminary efficacy and safety

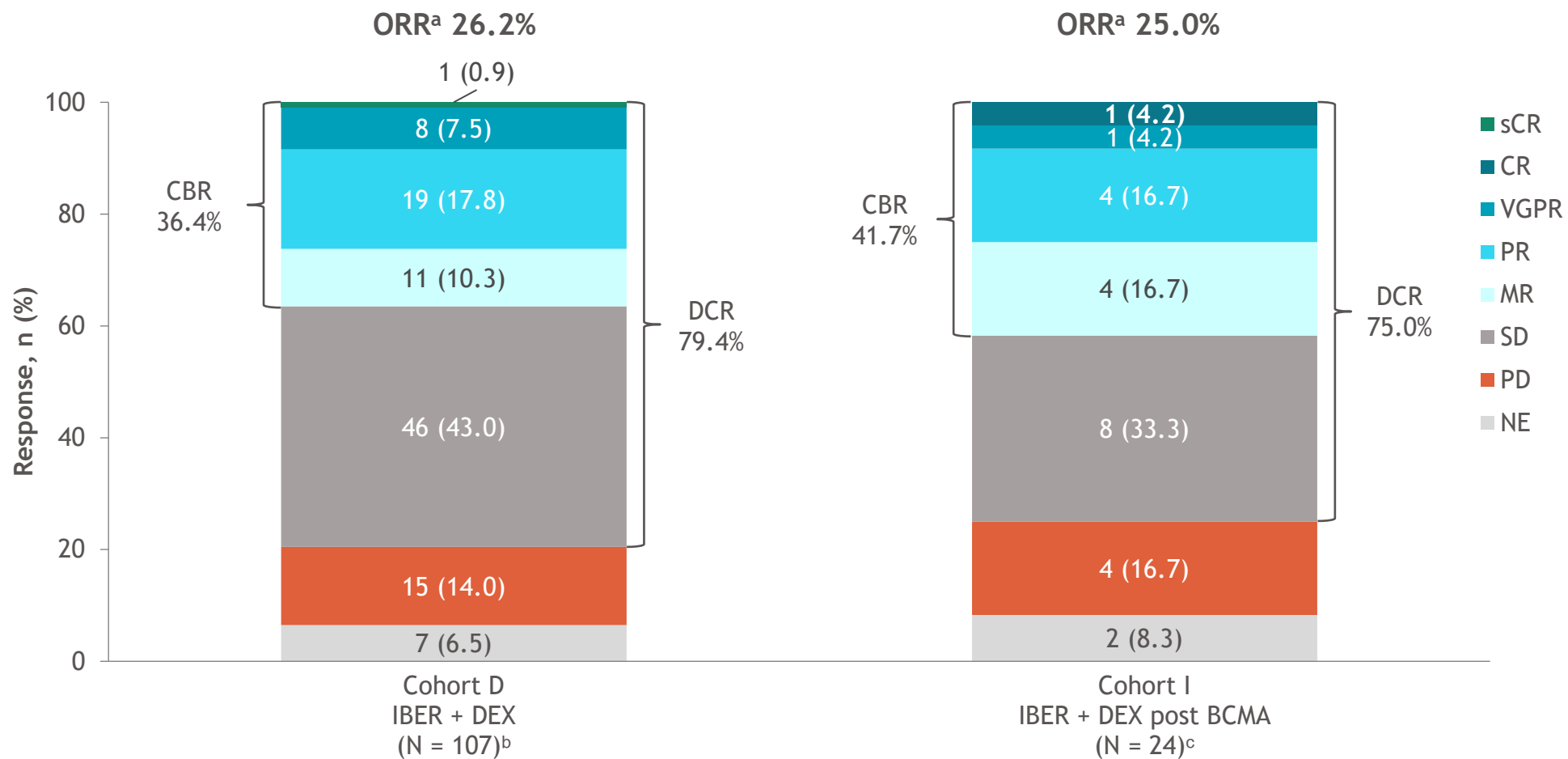
IBER (CC-220) is an investigational product, currently not approved by any regulatory agency.

^a Including LEN, POM, a PI, a glucocorticoid, and an anti-CD38 mAb; ^b Including LEN or POM, a PI, an anti-CD38 mAb, and a BCMA therapy.

CAR, chimeric antigen receptor; DOR, duration of response; OS, overall survival; PFS, progression-free survival.

Lonial S, et al. Oral presentation at ASH 2021; abstract 162.

CC-220-MM-001: response



IBER (CC-220) is an investigational product, currently not approved by any regulatory agency.

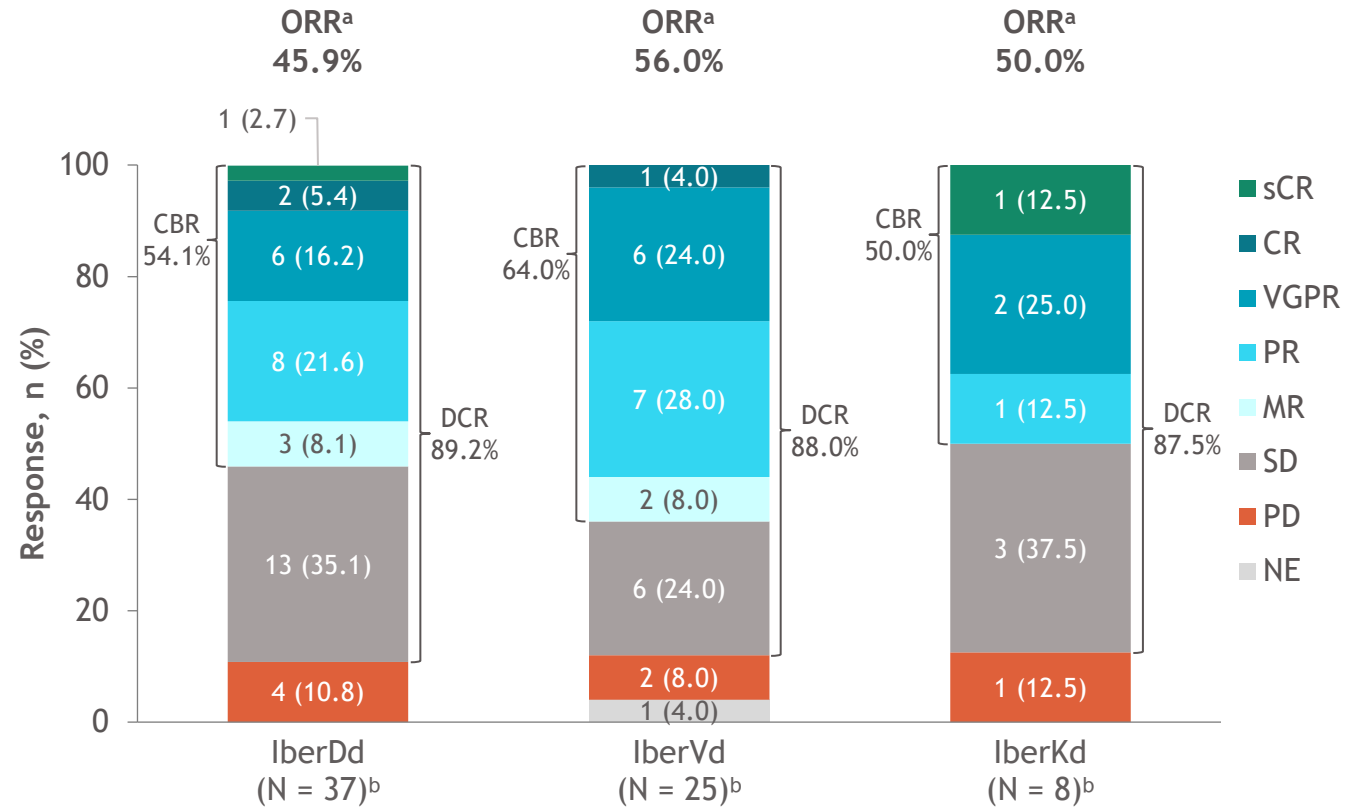
^a PR or better; ^b 2 patients in SD and MR discontinued treatment because of death due to COVID-19; ^c Includes all treated patients who have post-baseline efficacy assessment or have discontinued treatment before any post-baseline efficacy assessment (2 patients were in C1 with no post-baseline efficacy assessments so were excluded from analysis).

C, cycle; CBR, clinical benefit rate; COVID, coronavirus disease; CR, complete response; DCR, disease control rate; NE, not evaluable; sCR, stringent complete response.

Lonial S, et al. Oral presentation at ASH 2021; abstract 162.

CC-220-MM-001: IBER in combination with DEX and DARA, BORT, or CFZ (Cohorts E, F and G) in patients with RRMM

- IBER + DEX in combination with DARA or BORT or CFZ showed a favourable safety profile in patients with heavily pretreated RRMM; TEAEs were mainly hematologic and well manageable
- The RP2D was determined at 1.6 mg in the IberDd cohort, while dose evaluation continues in the IberVd and IberKd cohorts
- Promising efficacy was observed even among patients refractory to IMiD[®] agents, DARA, and PIs

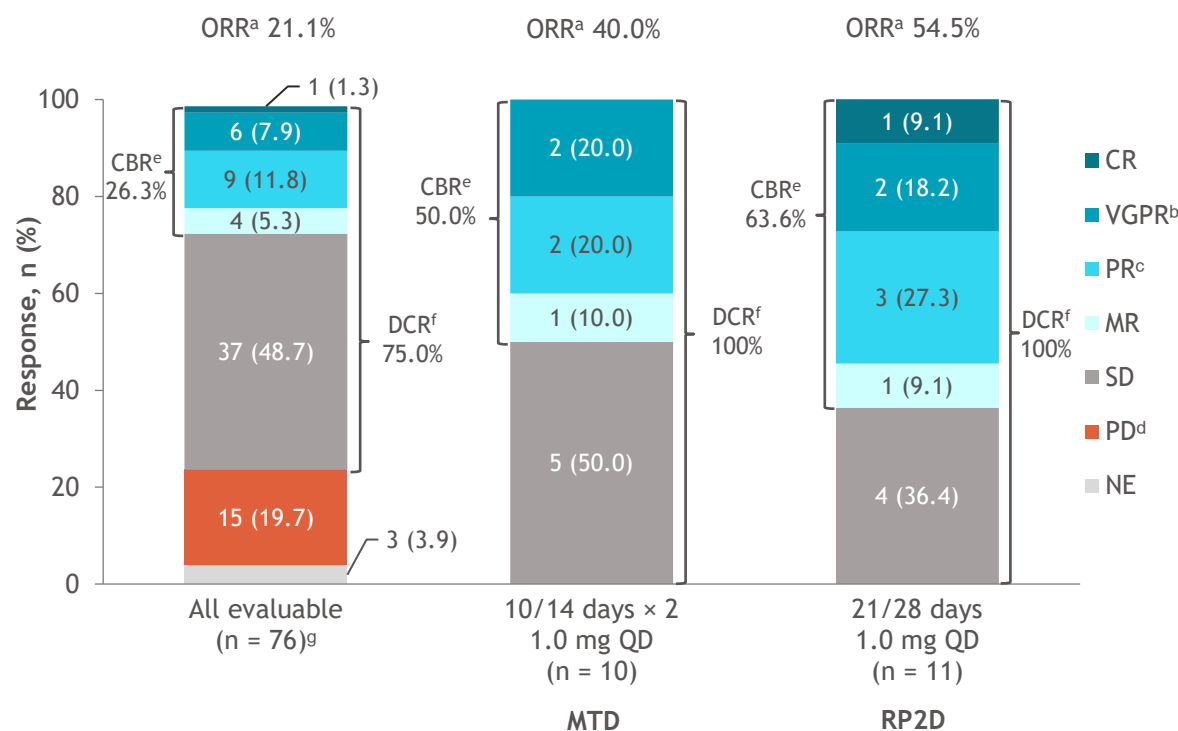


IBER (CC-220) is an investigational product, currently not approved by any regulatory agency.

^a PR or better; ^b Excludes treated patients who did not reach any post-baseline efficacy assessment and were still on treatment at time of data cut-off.

Lonial S, et al. Oral presentation at EHA 2021; abstract S187.

CC-92480-MM-001: efficacy and safety in patients with heavily pretreated RRMM



Common (> 20% all grade) TEAEs and events of interest, n (%)	All doses (N = 76)	
	Grade 3	Grade 4
Neutropenia	23 (30.3)	26 (34.2)
Febrile neutropenia	4 (5.3)	1 (1.3)
Anaemia	24 (31.6)	-
Thrombocytopenia	5 (6.6)	7 (9.2)
Fatigue	7 (9.2)	-
Pyrexia	3 (3.9)	-
Peripheral sensory neuropathy	-	-
Diarrhoea	1 (1.3)	-
Nausea	1 (1.3)	-
Deep vein thrombosis	-	-
Infections	25 (32.9)	2 (2.6)
Pneumonia ^h	11 (14.5)	-

- Prophylactic G-CSF was not permitted during C1
- Neutropenia was managed with dose interruption/reduction and G-CSF
- Dose reduction of CC-92480 occurred in 17 (22.4%) patients
- No patients discontinued due to treatment-related AEs

CC-92480 is an investigational product, currently not approved by any regulatory agency.

^a PR or better; ^b 1 patient in the 21/28-day 1.0-mg QD cohort had an unconfirmed VGPR at time of data cut-off; ^c 2 patients in the 21/28-day 0.8-mg QD cohort had an unconfirmed PR at time of data cut-off; ^d 1 patient in the 21/28-day 0.8-mg QD cohort had an unconfirmed PD at time of data cut-off; ^e CBR defined as MR; ^f DCR defined as SD; ^g 1 patient had a pending response assessment at time of data cut-off; ^h Includes Medical Dictionary for Regulatory Activities Terminology version 22.0 preferred terms pneumonia, pneumocystis jirovecii pneumonia, respiratory syncytial viral pneumonia, and staphylococcal pneumonia. AE, adverse event; G-CSF, granulocyte-colony stimulating factor.

Richardson PG, et al. Oral presentation at ASCO 2020; abstract 8500.

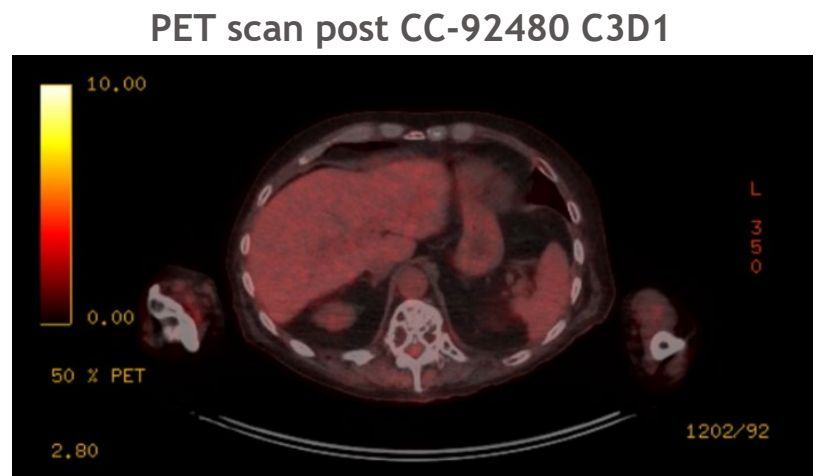
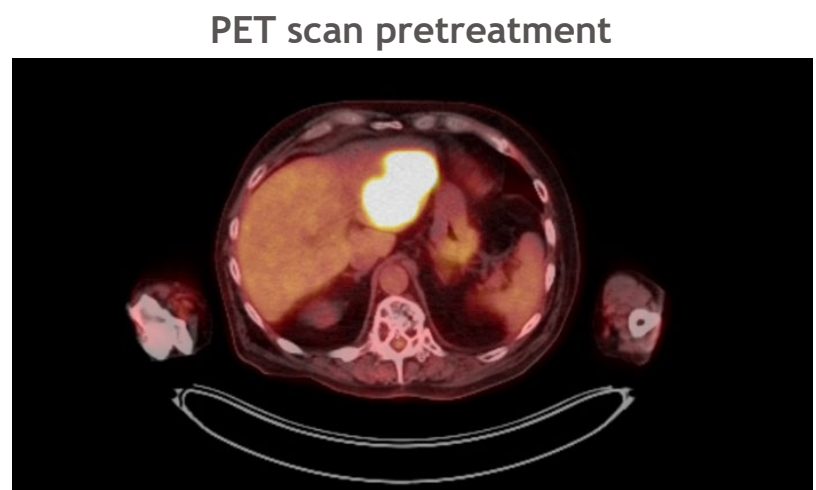
CC-92480-MM-001: responses in patients with extramedullary disease

Only patients on continuous schedules are shown

Dosing schedule ^a	Dose level	C2	C3	C4	C5	C6	C7	C8	C9	C10
10/14 days × 2	0.1 mg QD	SD	PD							
	0.2 mg QD	PD								
	0.3 mg QD	SD	PD							
	0.6 mg QD	SD	PD							
21/28 days	0.8 mg QD	SD								
		SD	PD							
		PR								
		SD								
10/14 days × 2	1.0 mg QD	MR	PR	VGPR						
		SD								
21/28 days	1.0 mg QD	SD	PR	PD						
		SD	PR	VGPR						
		PR	VGPR	CR						
		PR (case study)								

- CR
- VGPR^a
- PR^b
- MR
- SD
- PD^c
- On treatment at time of data cut-off

1.0-mg dose active in EMP



CC-92480 is an investigational product, currently not approved by any regulatory agency.
^a 1 patient in the 21/28-day 1.0-mg QD cohort had an unconfirmed VGPR at time of data cut-off; ^b 1 patient in the 21/28-day 0.8-mg QD cohort had an unconfirmed PR at time of data cut-off; ^c 1 patient in the 21/28-day 0.8-mg QD cohort had an unconfirmed PD at time of data cut-off. EMP, extramedullary plasmacytoma; PET, positron emission tomography.
Richardson PG, et al. Oral presentation at ASCO 2020; abstract 8500.

The Future is very Bright

- New targets and modalities (CART, TCE, ADC) and others in development have the potential to bring together multiple modalities to eliminate the malignant clone
- Trials testing combinations that rely not only on immune but existing targets such as PIs, IMiDs, steroids, and CD38 will be key
- Precision medicine currently a reality and hopefully will be more important as we develop drugs for common mutations

Thanks to:

Jonathan Kaufman

Ajay Nooka

Craig Hofmeister

Madhav Dhodapkar

L.T. Heffner

Vikas Gupta

Nisha Joseph

Leon Bernal

Charise Gleason

Donald Harvey

Colleen Lewis

Amelia Langston

Y. Gu

S-Y Sun

Jing Chen

Mala Shanmugan

Larry Boise

Cathy Sharp

Jennifer Shipp

**And the Clinical
Research Team**

IMS

Patients and Families



sloni01@emory.edu



**Golfers Against Cancer
T.J. Martell Foundation**

**And Many Others who
are part of the B-cell Team**



The image features a central white rectangular area containing the text "Q&A". This central area is framed by a decorative border at the top and bottom. The border consists of fluid, wavy lines in various shades of blue and purple, creating a sense of motion and depth. The colors transition from deep purples on the left to bright blues on the right, with lighter, almost white highlights that suggest a glowing or liquid-like texture.

Q&A

The background of the image is an abstract, fluid pattern of flowing waves in various shades of blue and purple. The colors transition from deep, dark purples and blues on the left to lighter, more vibrant blues and purples on the right. The waves are smooth and undulating, creating a sense of movement and depth. The overall effect is a dynamic and visually appealing abstract design.

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