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Multiple Myeloma Updates from ASH 2024

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Disclosures

- *Research Funding:*
- Janssen, BMS, Juno/Celgene, Sanofi, Regeneron, IGM BIosciences, Nektar, Harpoon, Adaptive Biotechnologies, Caelum, Abbvie, OpnaBio, Karyopharm

- *Advisory/Consulting:*
- Sebia, Janssen, BMS, Sanofi, HopeAI, Adaptive Biotechnologies, Abbvie, Pfizer

Overview – ASH Updates 2024

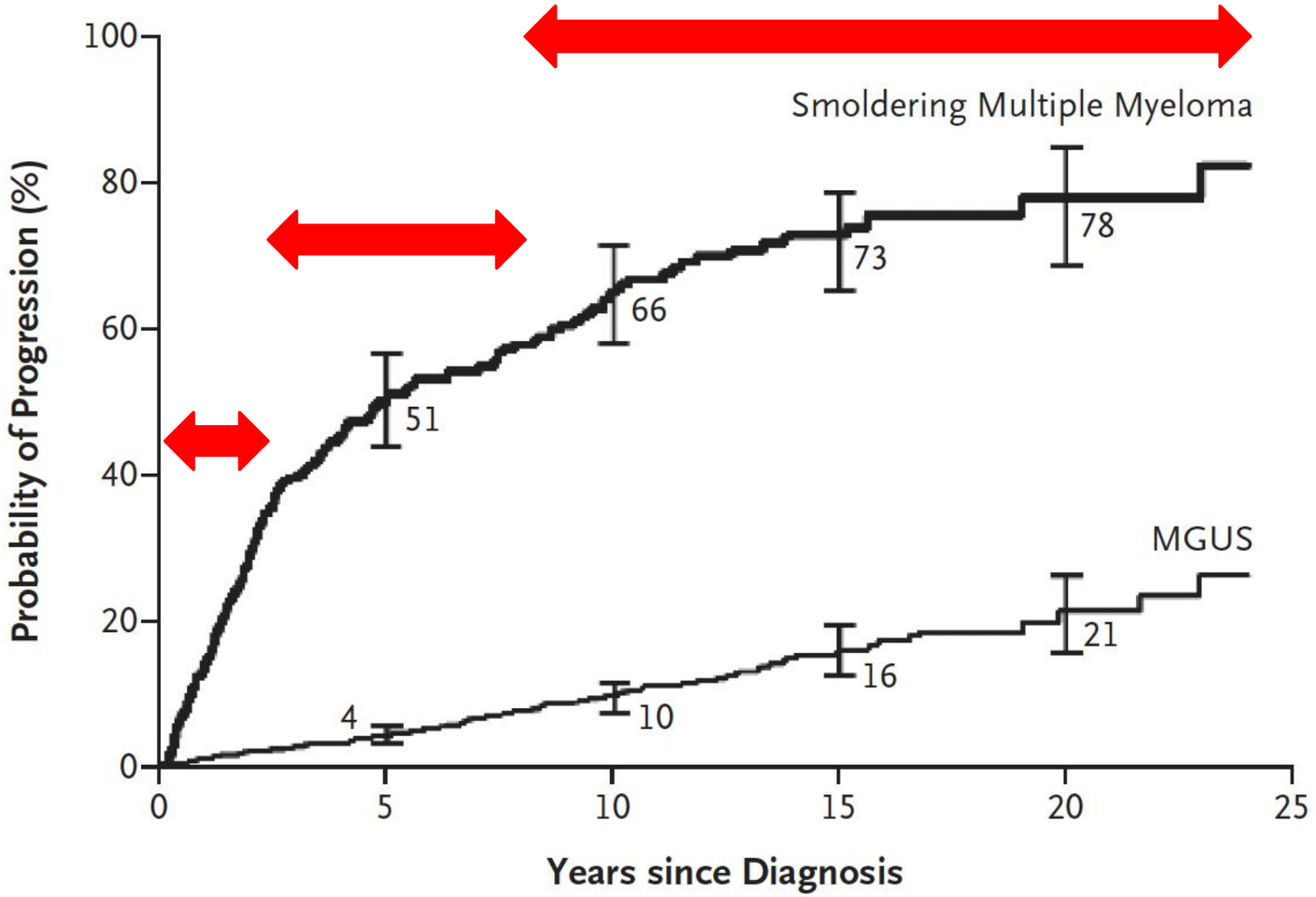
- Smoldering MM
- Newly diagnosed MM – novel BsAb combinations, quad therapies
- MRD relapse
- Relapsed / refractory MM
- AL Amyloidosis

Smoldering multiple myeloma in 2025

High risk SMM: Median time to progression ~2 years

Intermediate risk SMM: Median time to progression 2.5-7 years

Low risk SMM: Much more like MGUS; 2-3% risk of progression/year



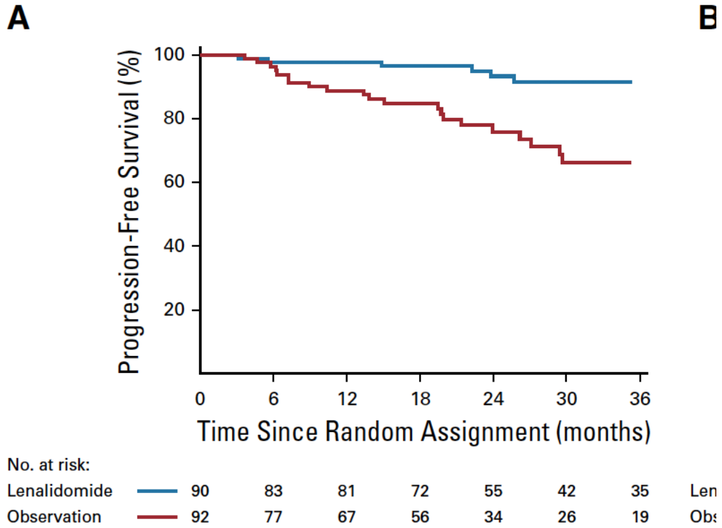
Standard of care for SMM:

- Observation: Q3 month monitoring with annual to biannual imaging
- Escalate to monthly monitoring if change in FLC/M spike kinetics or evolving anemia

Treatment:
New data from AQUILA presented at ASH upends this paradigm for high risk SMM

Kyle RA NEJM 2007

SMM treatment trials to date



B

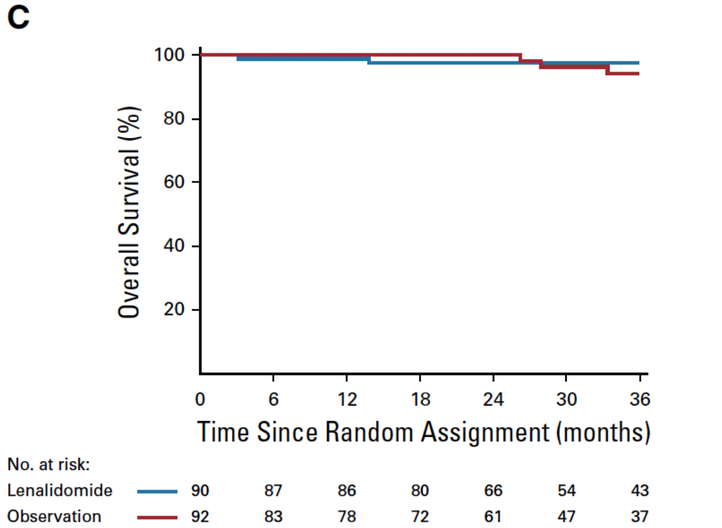
ECOG E3A06:

Randomized trial comparing lenalidomide to placebo for SMM

US only; Intergroup trial

Intermediate or HR SMM, as defined by:

- BMPC > 10% + abnormal FLC ratio

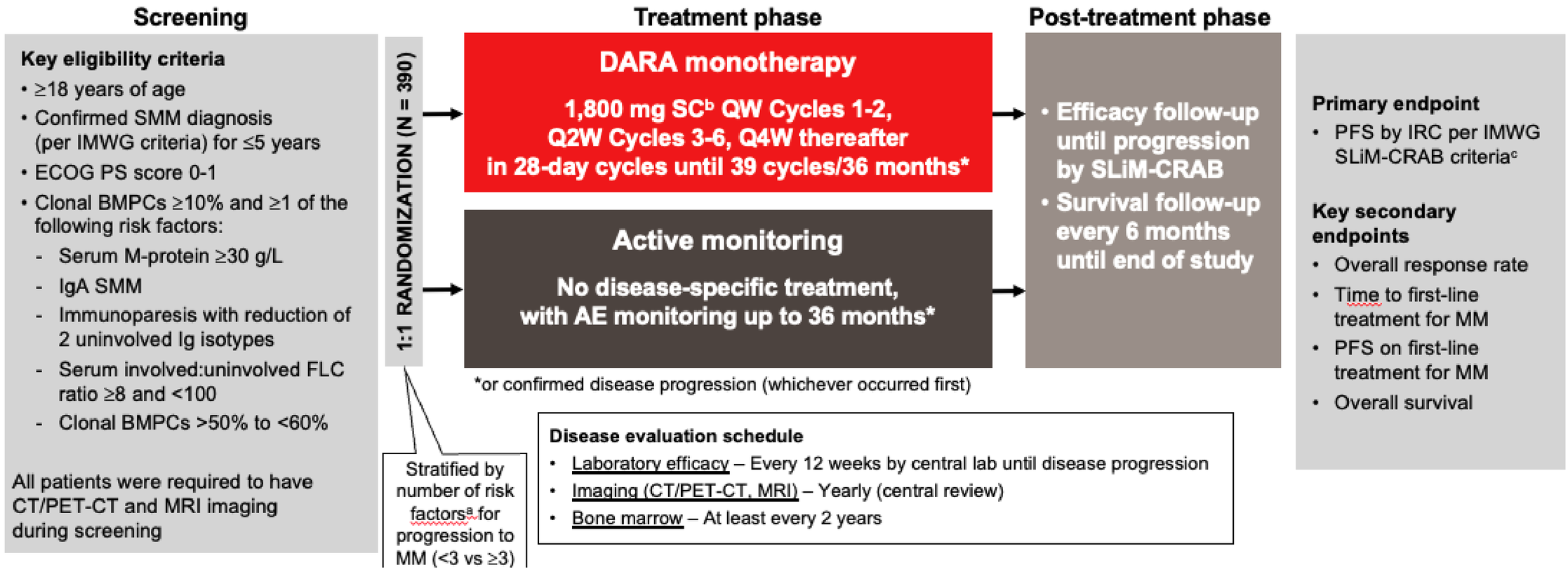


Crossover allowed… OS not evaluable!

In my opinion, the results of this trial did not really change practice in the US. Most oncologists still prefer observation over treatment!

Lonial S et al JCO 2020

AQUILA: Study Design



- High risk criteria – evolving; most now use 20/2/20 criteria
- No crossover allowed (as compared to ECOG E3A06)

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Progression criteria

Progression to active MM was based on the IMWG SLiM-CRAB diagnostic criteria for MM[1]

Clonal BMPCs ≥10% or biopsy-proven bony or extramedullary plasmacytoma AND **≥1 of the below multiple myeloma-defining events:**	
CRAB criteria	**Calcium elevation:** serum calcium >0.25 mmol/L (>1 mg/dL) higher than the upper limit of normal of >2.75 mmol/L (>11 mg/dL)
	Renal insufficiency: creatinine clearance <40 mL/min† or serum creatinine >177 µmol/L (>2 mg/dL)
	Anemia: hemoglobin value >20 g/L below the limit of normal or a hemoglobin value <100 g/L
	Bone disease: ≥1 osteolytic lesions on skeletal radiography, CT, or PET-CT
SLiM criteria	**Clonal BMPCs:** ≥60% BMPCs
	Serum FLC: involved:uninvolved serum FLC ≥100
	Focal lesions: ≥1 focal lesions on MRI studies

- Clinical significance of SLiM criteria – debatable
- What's really most important – morbidity due to progression of myeloma CRAB criteria

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Baseline demographics, disease characteristics

Characteristic	DARA (n = 194)	Active monitoring (n = 196)
Age		
Median (range), years	63.0 (31-86)	64.5 (36-83)
18 to <65 years, n (%)	106 (54.6)	98 (50.0)
65 to <75 years, n (%)	67 (34.5)	74 (37.8)
≥75 years, n (%)	21 (10.8)	24 (12.2)
Sex, n (%)		
Female	99 (51.0)	103 (52.6)
Male	95 (49.0)	93 (47.4)
ECOG PS score, n (%)		
0	165 (85.1)	160 (81.6)
1	29 (14.9)	36 (18.4)
Median time from diagnosis of SMM to randomization (range), years	0.80 (0-4.7)	0.67 (0-5.0)
Median BMPCs (range), %	20.0 (8.0-59.5)	20.0 (10.0-55.0)

Characteristic	DARA (n = 194)	Active monitoring (n = 196)
Type of SMM, n (%)		
IgG	127 (65.5)	138 (70.4)
IgA	55 (28.4)	42 (21.4)
Other	12 (6.2)	16 (8.2)
AQUILA risk factors for progression to MM, n (%)[a]		
<3	154 (79.4)	156 (79.6)
≥3	40 (20.6)	40 (20.4)
Cytogenetic risk profile[b]	n = 167	n = 170
≥1 of del(17p), t(4;14), and/or t(14;16), n (%)	29 (17.4)	22 (12.9)
Mayo 2018 risk criteria, n (%)[c]		
Low	45 (23.2)	34 (17.3)
Intermediate	77 (39.7)	76 (38.8)
High	72 (37.1)	86 (43.9)

- Median age mid 60's
- Median time from diagnosis to randomization: 0.8 and 0.67 years
- 37% in Dara group, and 43% in obs group had high risk by Mayo 2018 criteria (20/2/20)

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Treatment and disposition

	DARA	Active monitoring
Randomized patients (ITT population), n	194	196
Median (range) duration of DARA or monitoring, months	35.0 (0-36.1)	25.9 (0.1-36.0)
Median (range) number of DARA cycles	38 (1-39)	–
Completed 39 cycles of DARA or 36 months of treatment/monitoring, n (%)[a]	127 (65.5)	80 (40.8)
Patients who discontinued treatment/monitoring, n (%)[b]	66 (34.2)	116 (59.2)
Reason for treatment/monitoring discontinuation, n (%)[b]		
Progressive disease	42 (21.8)	82 (41.8)
AE[c]	13 (6.7)	1 (0.5)
Patient refused further treatment/monitoring	5 (2.6)	22 (11.2)
Physician decision	3 (1.6)	1 (0.5)
Death	1 (0.5)	4 (2.0)
Other	2 (1.0)	6 (3.1)

- Majority (65%) of patients completed all 39 cycles of daratumumab
- Most common reason for discontinuation was progressive disease; only 6.7% of patients in dara arm discontinued due to AEs

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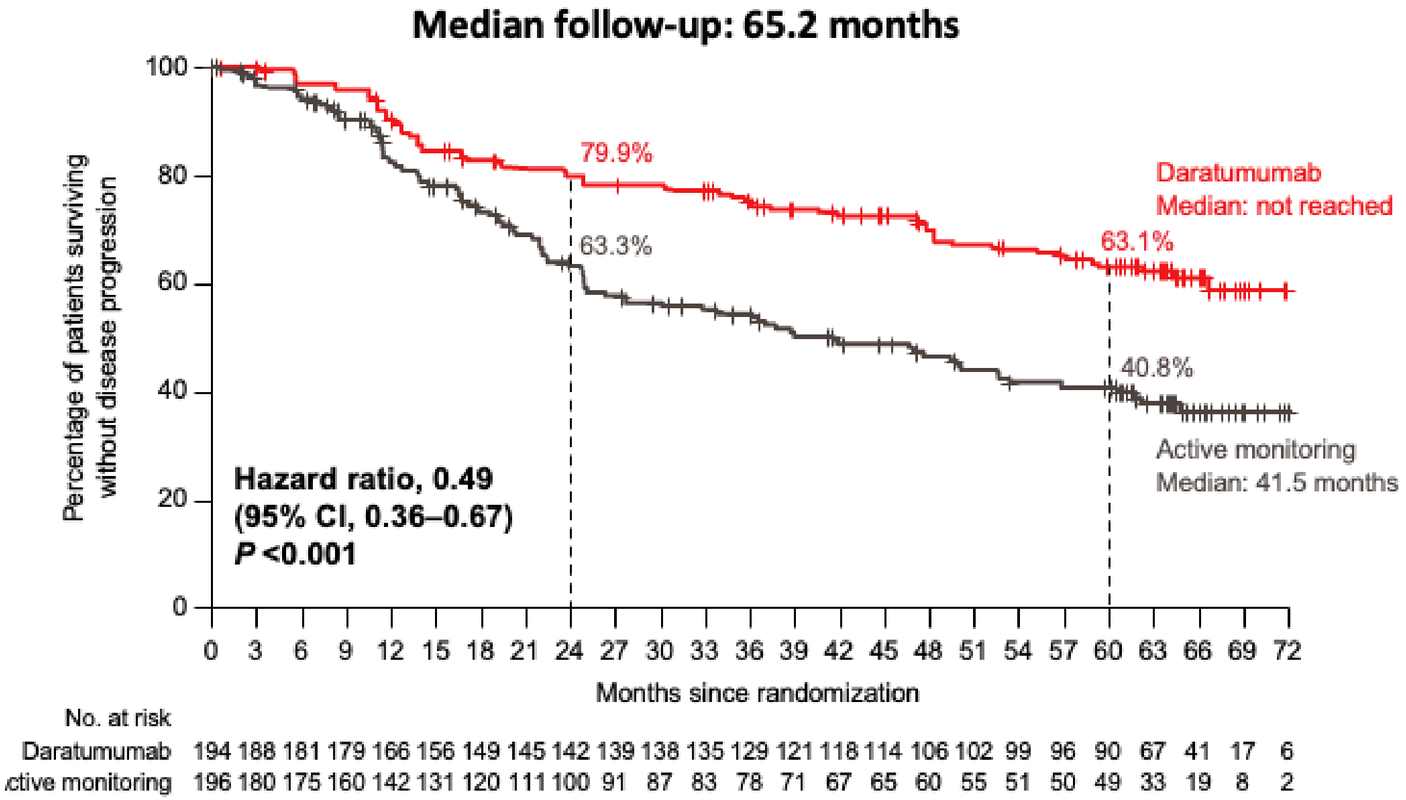
Progression to MM Improved With Daratumumab Monotherapy



	DARA (n = 194)	Active monitoring (n = 196)
PFS event, n (%)	67 (34.5)	99 (50.5)
Death without disease progression	5 (7.5)	5 (5.1)
Disease progression[a,b]	62 (92.5)	94 (94.9)
CRAB criteria[c]	12 (19.4)	34 (36.2)
Calcium elevation	0	2 (2.1)
Renal insufficiency[d]	0	0
Anemia	2 (3.2)	14 (14.9)
Bone disease	10 (16.1)	18 (19.1)
SLiM criteria[c]	50 (80.6)	65 (69.1)
Clonal BMPCs	5 (8.1)	16 (17.0)
Serum FLC	33 (53.2)	33 (35.1)
Focal lesion by MRI	12 (19.4)	16 (17.0)

- Note early drop off in first 12 months – these patients likely had evolving MM
- Real benefit seems to be amongst group of patients with high risk of progression in the first 24 months
- Note high rate of CRAB progression amongst active monitoring

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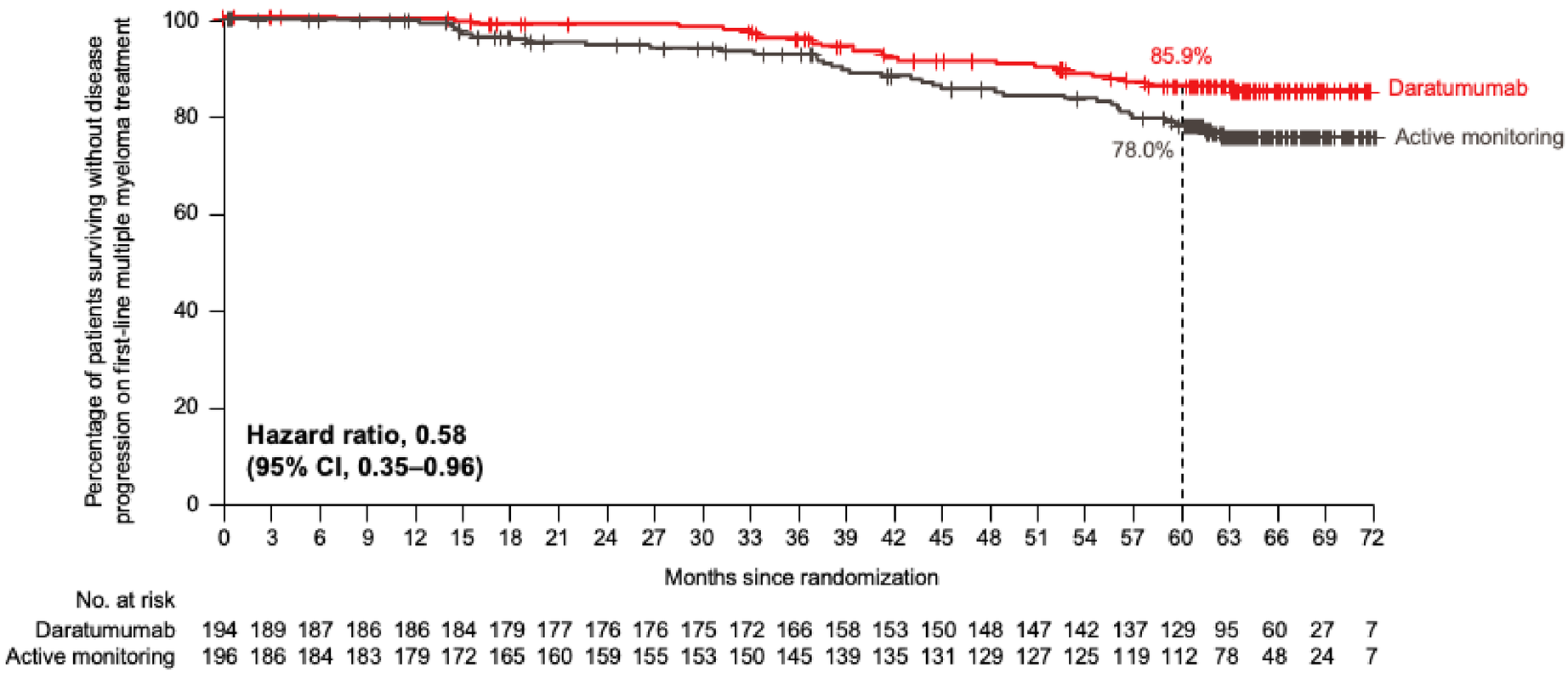
PFS2 was also improved with Daratumumab monotherapy



- RVD was the most common front line treatment for MM (dara in 9.8%, active monitoring 14.8%)
- 25% in Dara group, and 33% in active monitoring group received anti CD38 regimens
- Addresses concerns about impact on subsequent LOT

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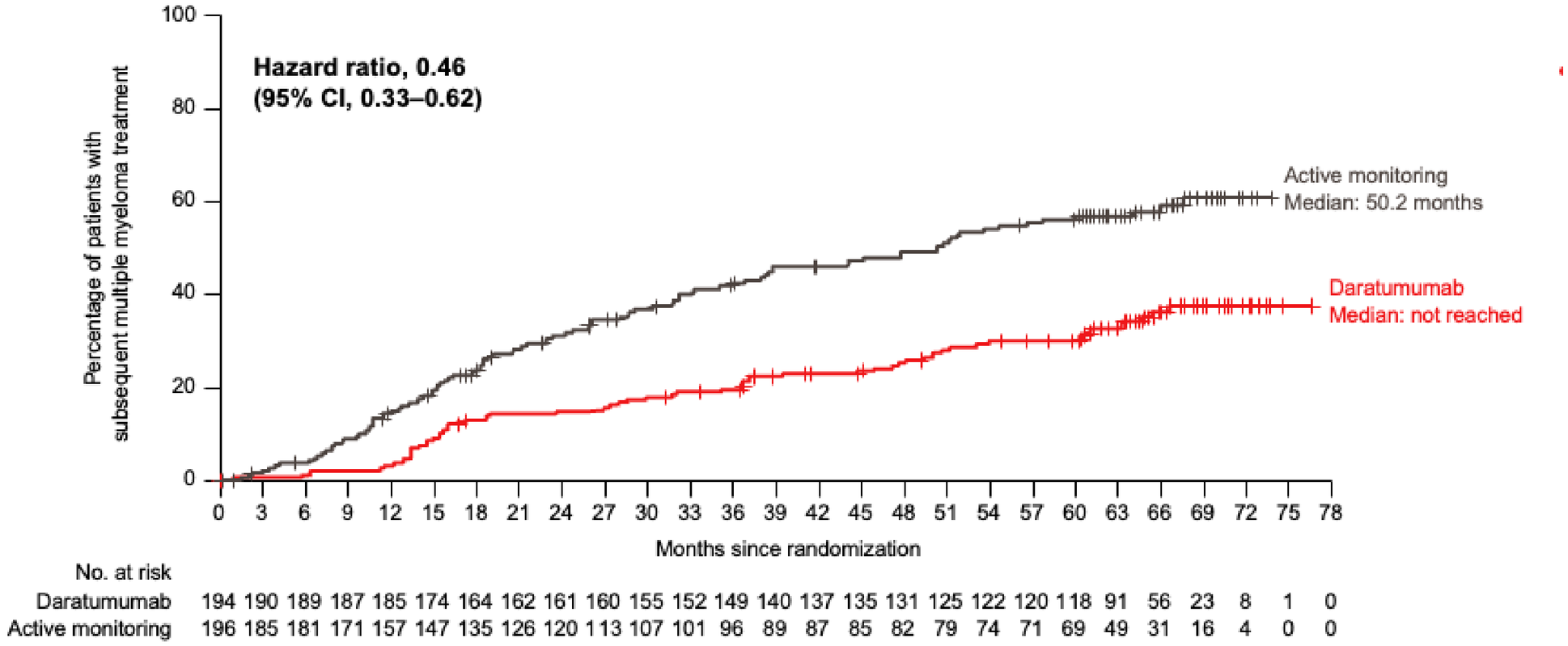
Time to initiation of treatment improved with Daratumumab for smoldering MM



- First line treatment for MM initiated by 33.2% in DARA group and 53.6% in the active monitoring group
- Median time to initiation of treatment in active monitoring: 50.2 months; daratumumab

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Summary

- Data from the AQUILA randomized trial in high risk SMM shows that daratumumab monotherapy improves:
  - PFS
  - OS
  - PFS2
  - Time to next treatment

- Side effect profile manageable

- Awaiting FDA approval

- Is this practice changing? – YES, in my opinion
- I will recommend this (daratumumab monotherapy) for patients who fit the eligibility criteria for AQUILA given OS, PFS2, and PFS benefits

Current treatment of Newly Diagnosed MM in 2025

Transplant Eligible

4 drug combinations
Dara-RVd or Dara KRd
3 drug combinations**:**
RVd, KRd,
VCd (renal failure)

→ Autologous stem cell transplantation Vs Deferred

→ Maintenance
Standard: Lenalidomide
High risk: PI/IMiD, CD38/IMID

Not Transplant Eligible

Dara Rd
Dara-RVd
Isa-RVd/Dara
RVd

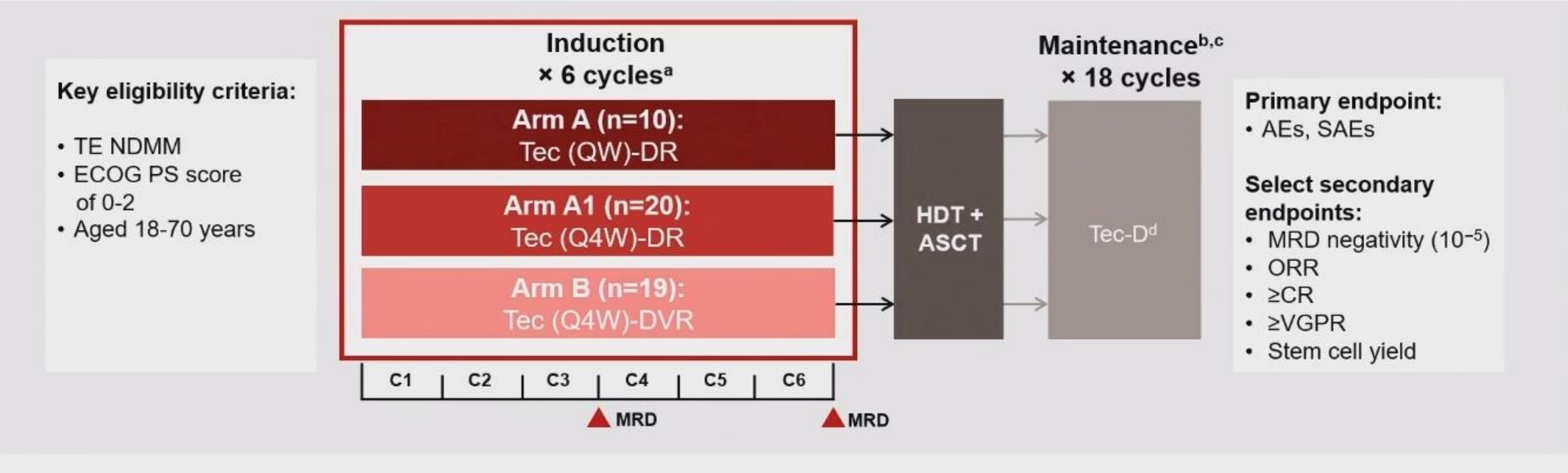
→ Maintenance

Supportive Care →

Newly diagnosed multiple myeloma, ASH 2024 updates

- Addition of BCMA Bispecific antibodies to upfront treatment: MAJESTEC-5 results
- Updated results for transplant ineligible: IMROZ MRD analysis
- Updated results for GMMG HD7: First randomization PFS analysis
- Frailty-guided treatment de-escalation and dexamethasone dose reductions
- Significance of MRD only progression compared to traditional methods of assessing progression

MAJESTEC-5: Role of using BCMA BsAb in Frontline Therapy



- Teclistamab – BCMA x CD3 bispecific antibody; FDA approved in >4 LOT based on MAJESTEC 1 trial
- MAJESTEC-5: Frontline MM trial incorporating teclistamab with 3 arms of 6 cycle induction:
  - Tec weekly + DR
  - Tec Q4 week + DR
  - Tec Q4 week + RVD

- AHCT consolidation for all followed by Tec-D maintenance

Raab et al, ASH 2024

MAJESTEC-5: Nonhematologic AEs

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

- Rates of grade 3 and 4 events were low
- All CRS events were grade 1 and 2, mostly during cycle 1
- No ICANS
- No grade 5 TEAEs

Raab MS et al ASH 2024

MAJESTEC-5: Infections

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

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

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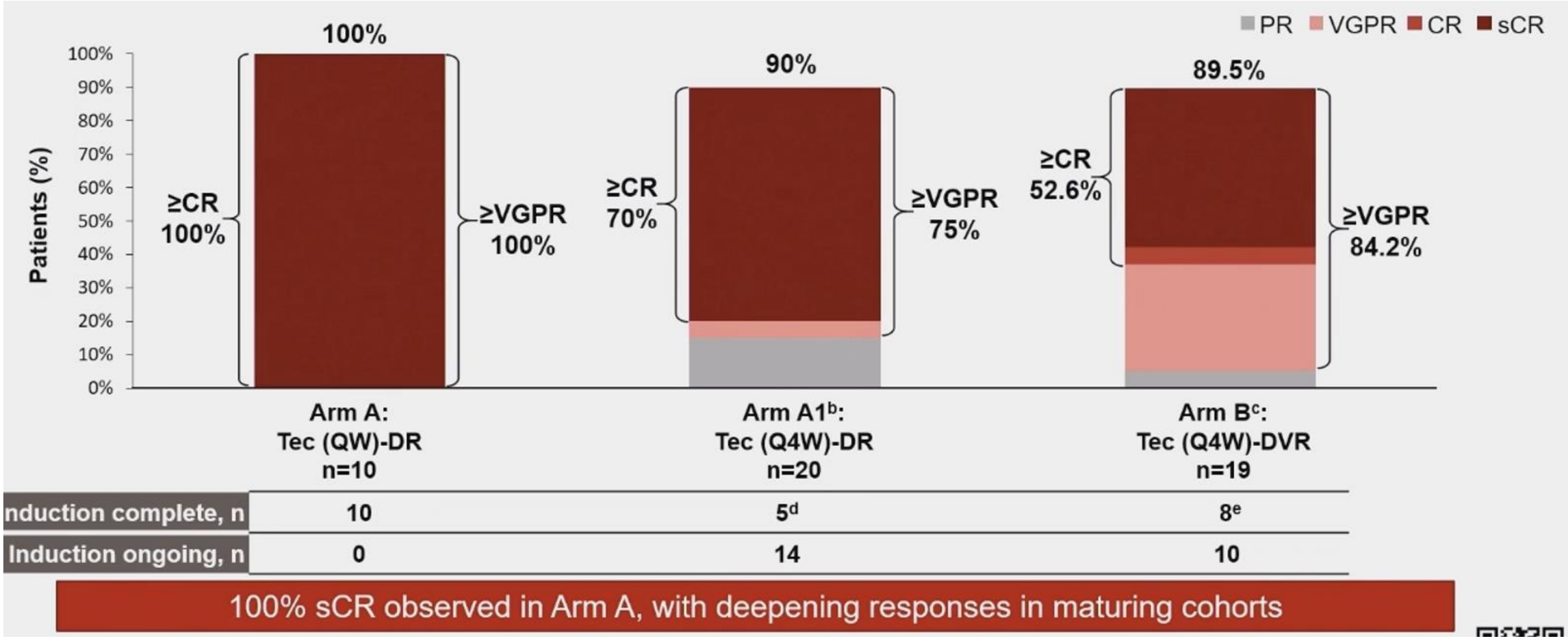
MAJESTEC-5 Response Rates



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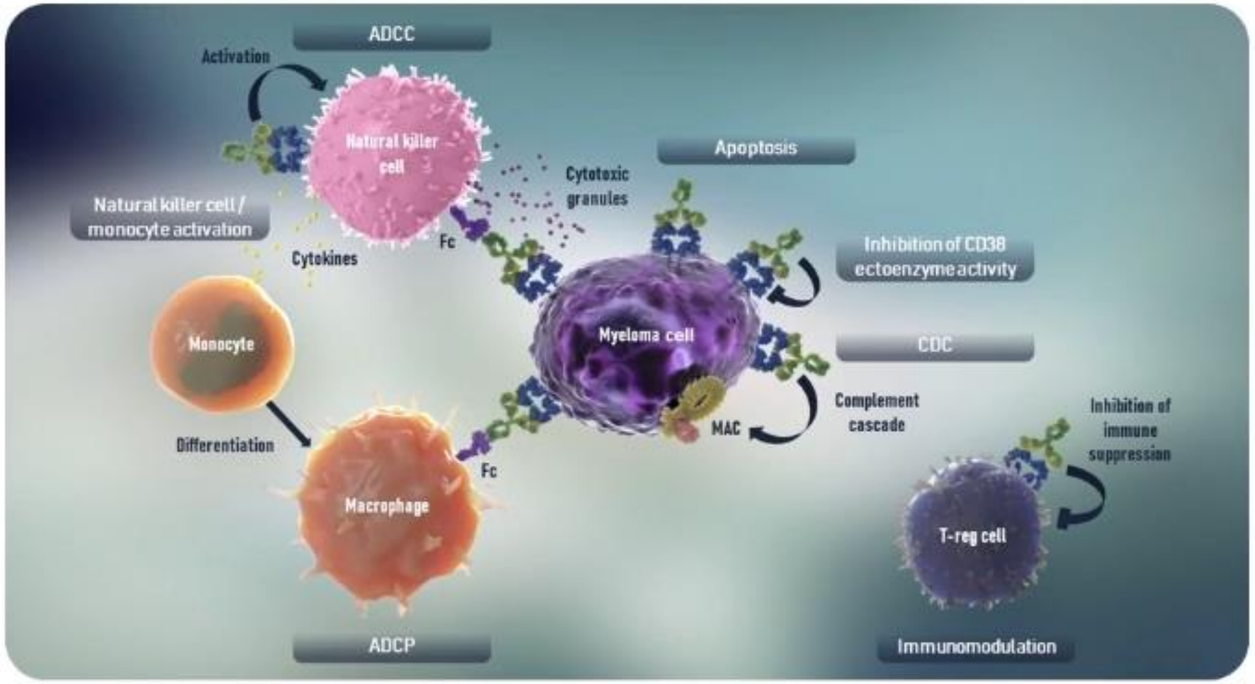
Isatuximab: Background



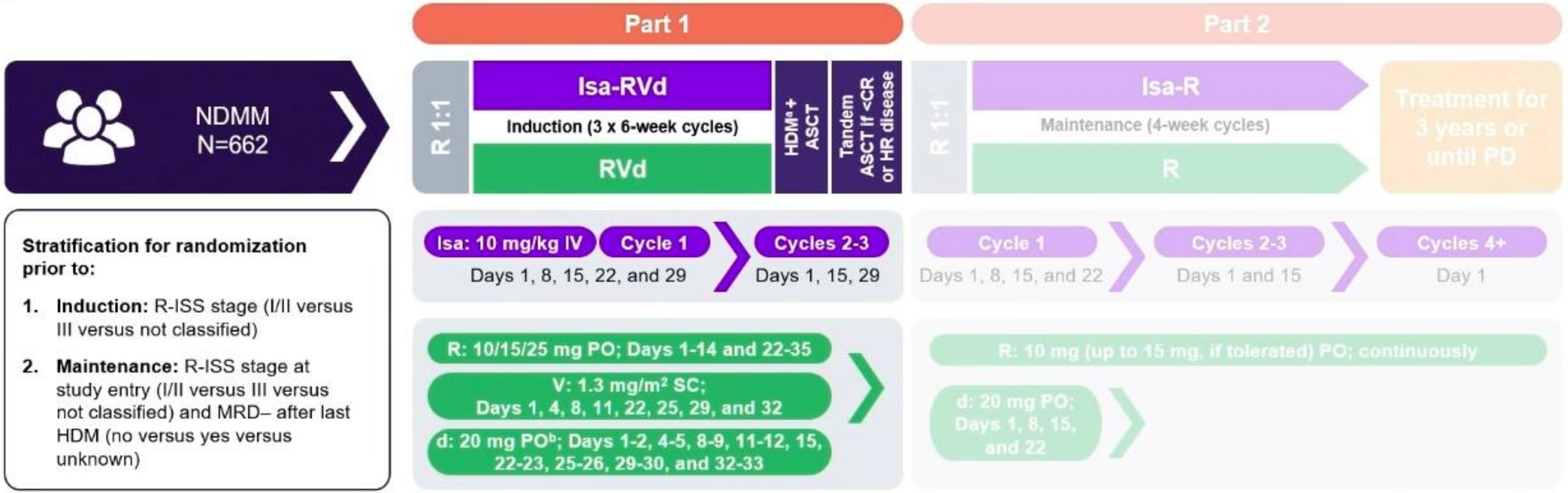
Isatuximab has recently been approved in combination with RVd for adults with Ti NDMM based on the results of the Phase 3 IMROZ trial[1]

Isatuximab is approved in several countries in combination with dexamethasone plus either pomalidomide or carfilzomib in adult patients with relapsed/refractory MM who have received prior therapies[2,3]

Isatuximab targets a specific epitope of CD38, a transmembrane glycoprotein widely and uniformly expressed on myeloma cells[4,5]

Goldschimdt et al, ASH 2024

Study Design – Part 1



Primary end points[c]: Post-induction MRD– (NGF, 10^{-5}); PFS after second randomization

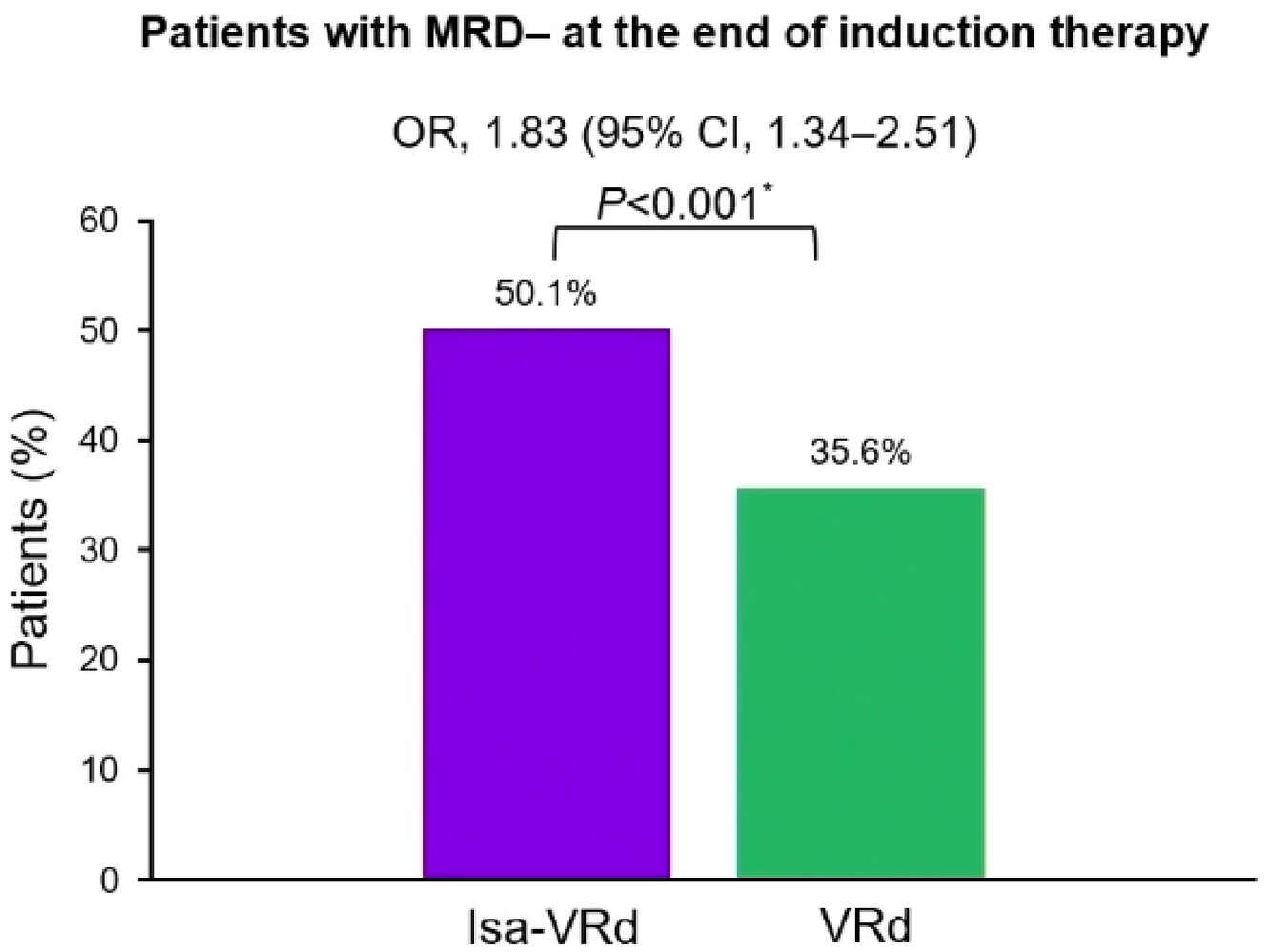
Key secondary end points: PFS (whole study); OS (whole study and from second randomization); post-induction CR; CR and MRD– after HDM and during and after maintenance therapy

Selected secondary end point: PFS after first randomization

Goldschimdt et al, ASH 2024

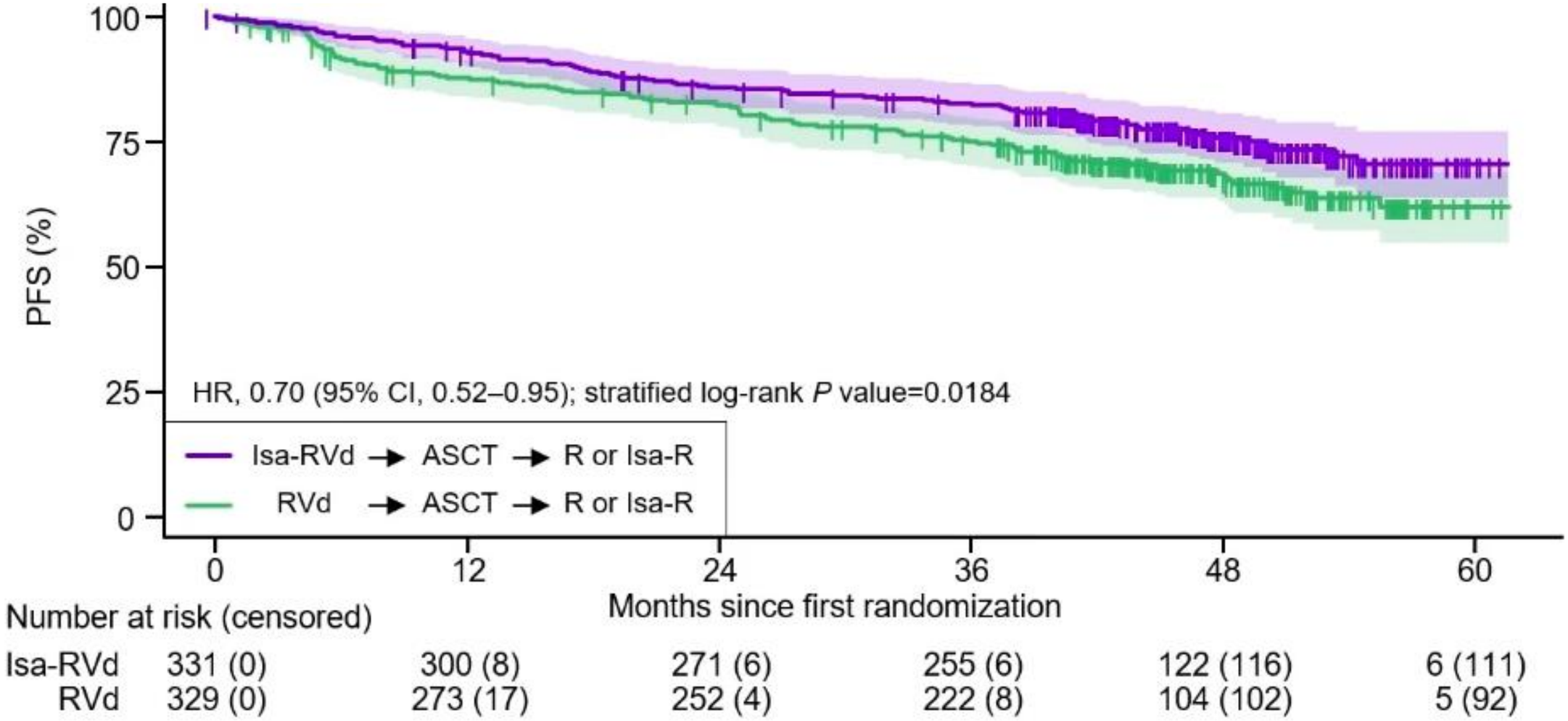
GMMG HD7 – Initial results – MRD at end of induction

- First primary endpoint met – improvement in MRD– status after induction therapy



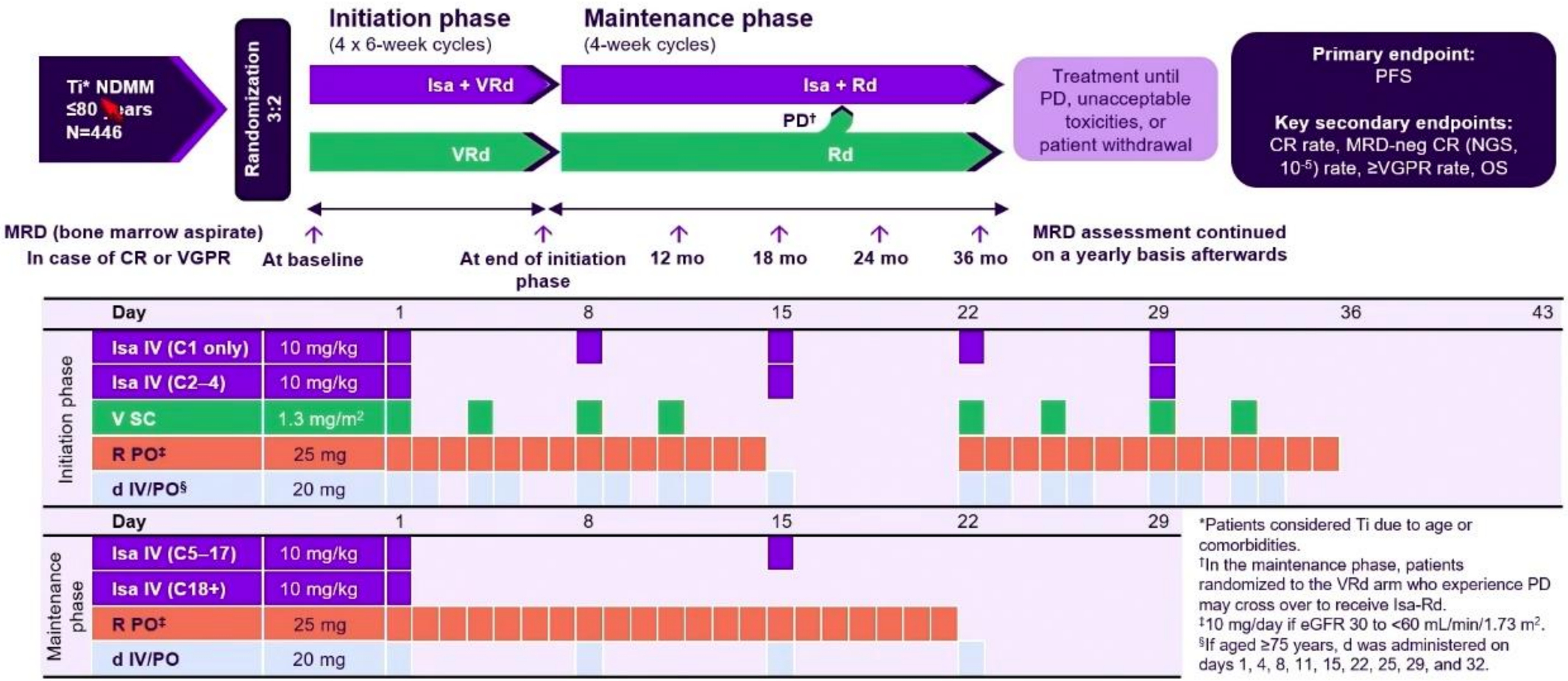
Goldschmidt H et al Lancet Onc 2022

PFS from time of first randomization



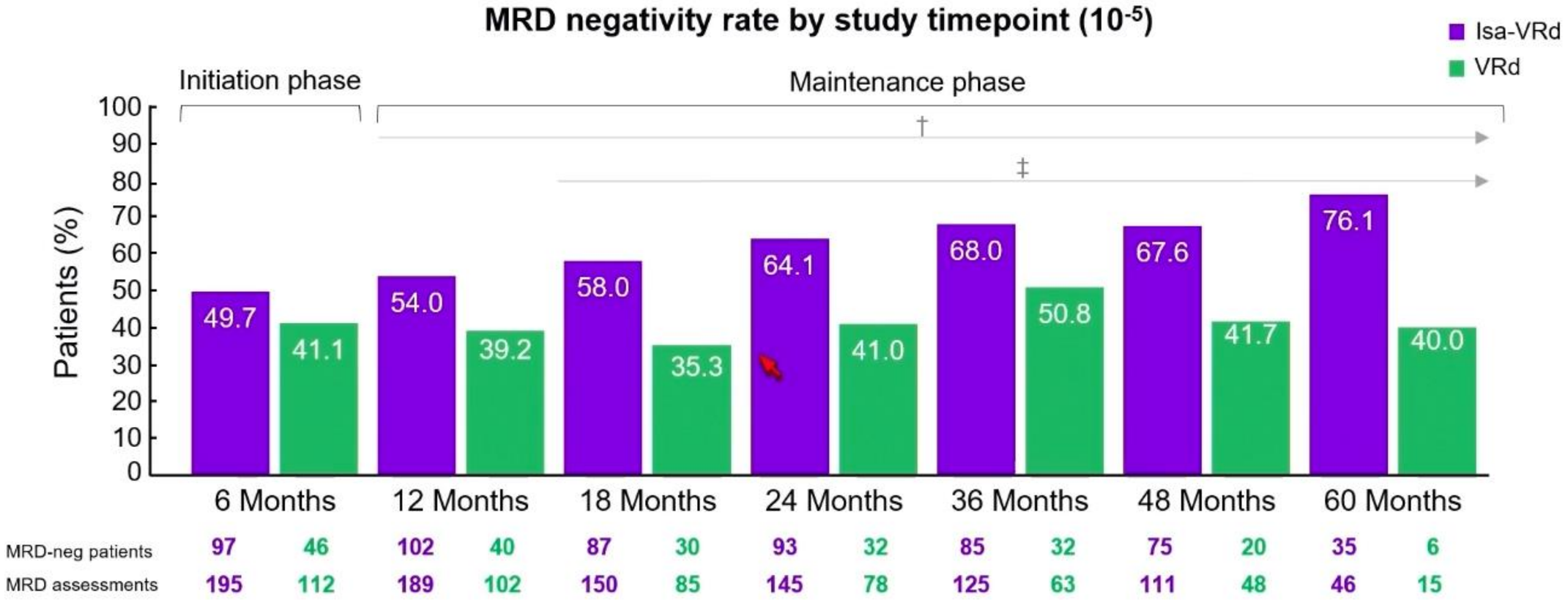
Goldschmidt H et al, ASH 2024

MRD updates from IMROZ



Orlowski RZ et al, ASH 2024

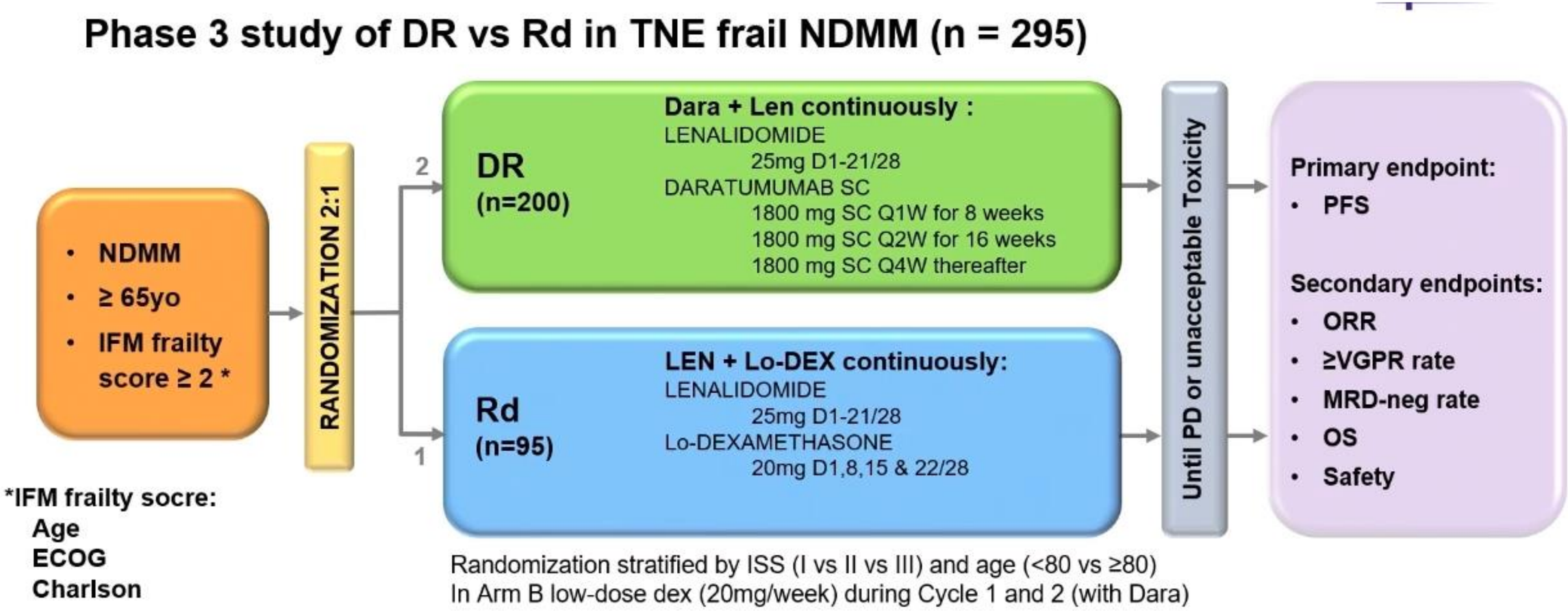
MRD Analyses on IMROZ



- MRD results show deepening of responses over time, much more pronounced in the Isa RVD arm
- At 60 months, 76% of evaluable patients were MRD negative at 10^-5

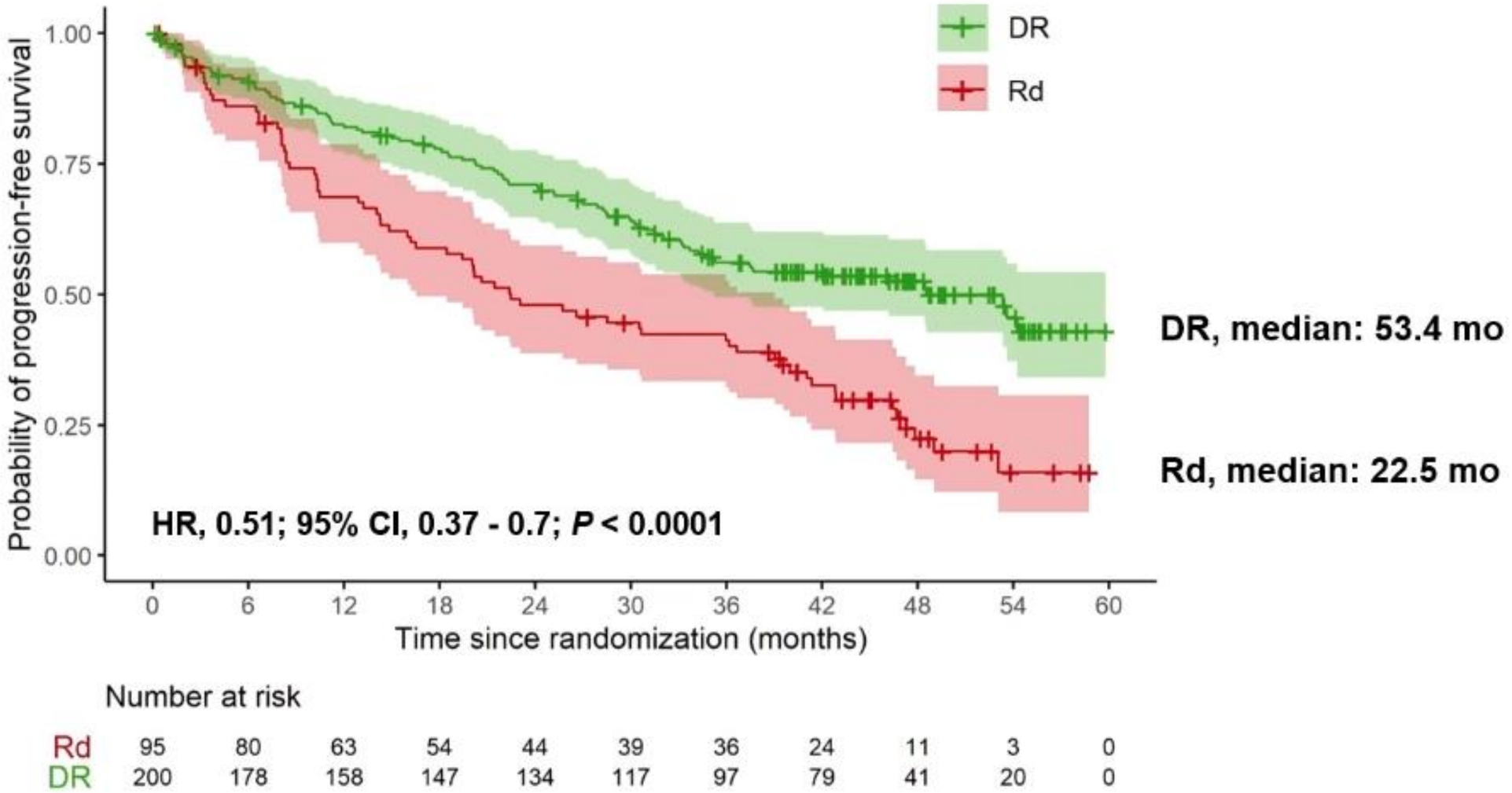
Orlowski RZ et al, ASH 2024

IFM 2017-03 – Newly diagnosed MM, Frail – dexamethasone sparing



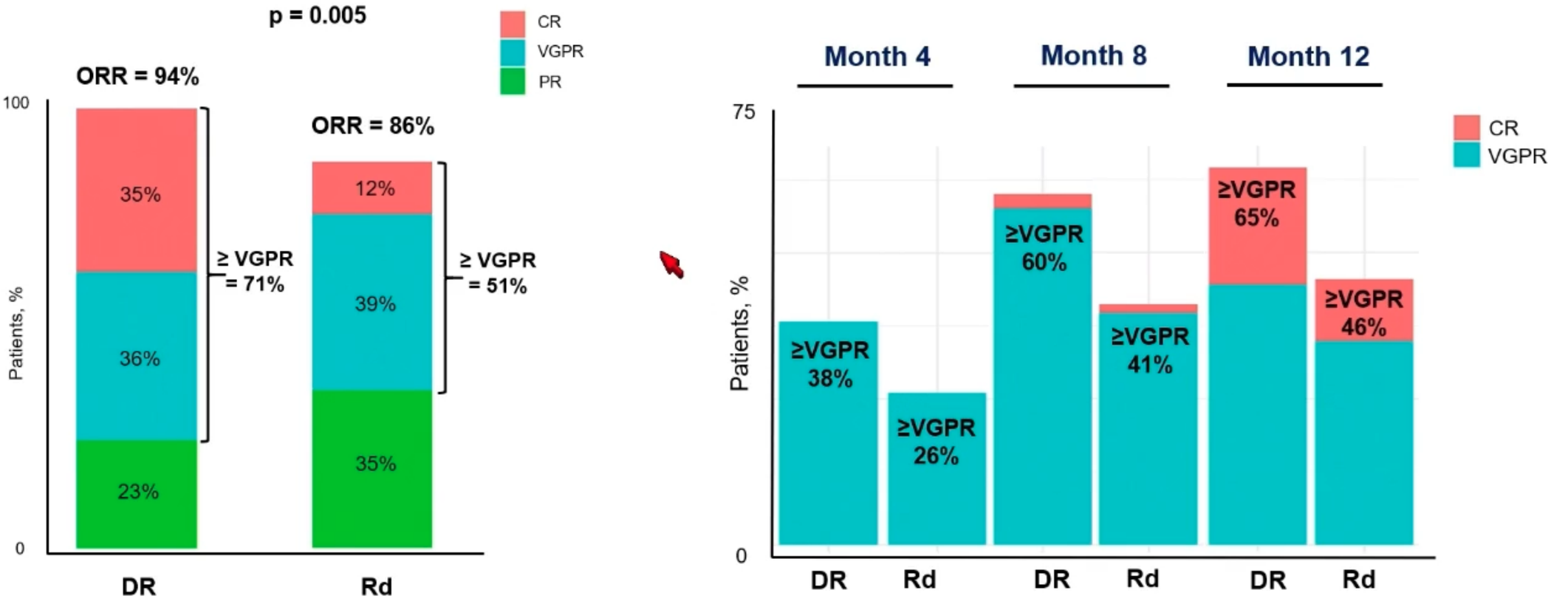
Manier S et al, ASH 2024

IFM 2017-03 PFS results



Manier S et al, ASH 2024

IFM 2017-03 – Response rates



VGPR or better rate was significantly higher with DR

Deeper responses were obtained with DR at all time points, including at early time points

Manier S et al, ASH 2024

UKMRA
UK Myeloma
Research Alliance

IMWG Frailty Score-adjusted therapy delivery reduces the early mortality risk in newly diagnosed TNE multiple myeloma: Results of the UK Myeloma Research Alliance (UK-MRA) Myeloma XIV FiTNEss trial.

Gordon Cook*, Charlotte Pawlyn, Kara-Louise Royle, Ethan Senior, Dax Everritt, Jenny Bird, Stella Bowcock, Bryony Dawkins, Mark Drayson, Sharon Gillson, Catherine Olivier, Matthew Jenner, John Jones, Martin Kaiser, Bhuvan Kishore, David Meads, Neil Rabin, Roger Owen, Ruth de Tute, Christopher Parrish, Alan Chant, David Cairns and Graham Jackson.

FiTNEss UK-MRA Myeloma XIV

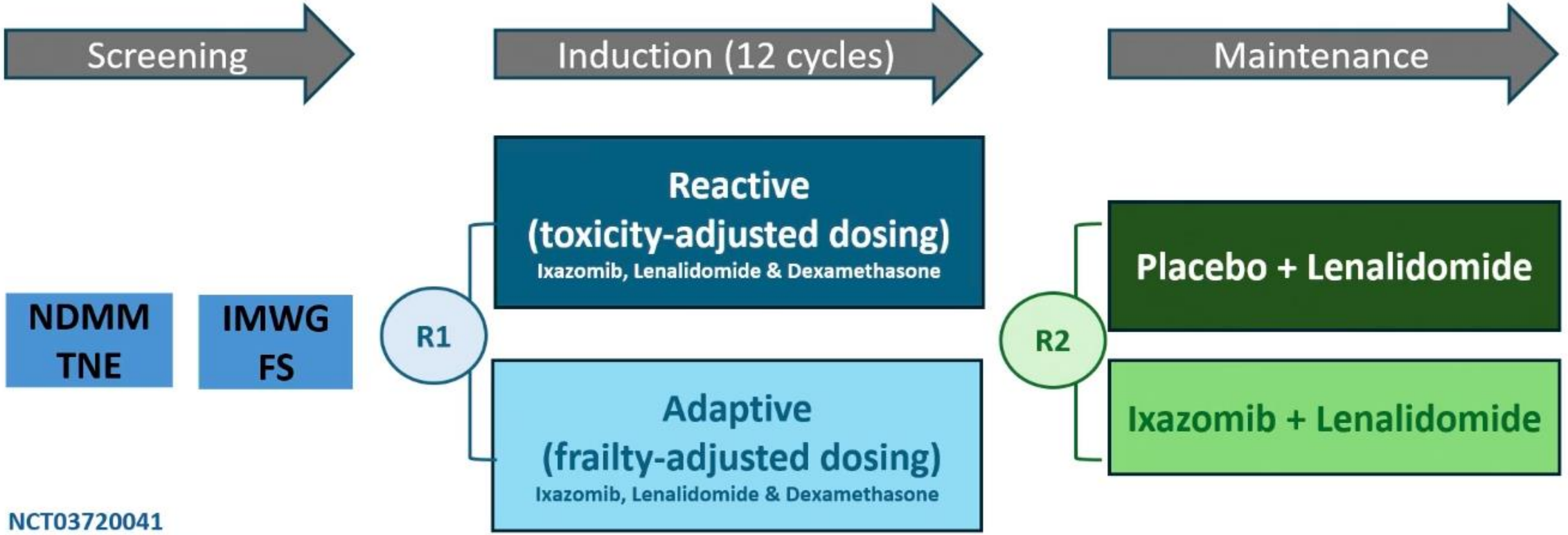
g.cook@leeds.ac.uk

Cook G et al, ASH 2024

UK-MRA Myeloma XIV FiTNEss Trial Design

UKMRA
UK Myeloma
Research Alliance

Chief Investigators: Gordon Cook, Graham Jackson



NCT03720041
REC-19/NE/0215
EudraCT- 2018-003590-10
ISRCTN17973108

FiTNEss UK-MRA Myeloma XIV g.cook@leeds.ac.uk

Cook G et al Ash 2024

Frailty-adjusted therapy - dosing

UKMRA
UK Myeloma Research Alliance

	Reactive	Adaptive		
		FIT	UNFIT	FRAIL
Lenalidomide	25mg D1-21	25mg D1-21	15mg D1-21	10mg D1-21
Ixazomib (weekly)	4mg	4mg	4mg	4mg
Dexamethasone (weekly)	<75: 40mg >75: 20mg	<75: 40mg >75: 20mg	20mg	10mg

FiTNEss UK-MRA Myeloma XIV g.cook@leeds.ac.uk

Cook G et al, ASH 2024

Trial Population: Baseline Characteristics (1)

UKMRA
UK Myeloma Research Alliance

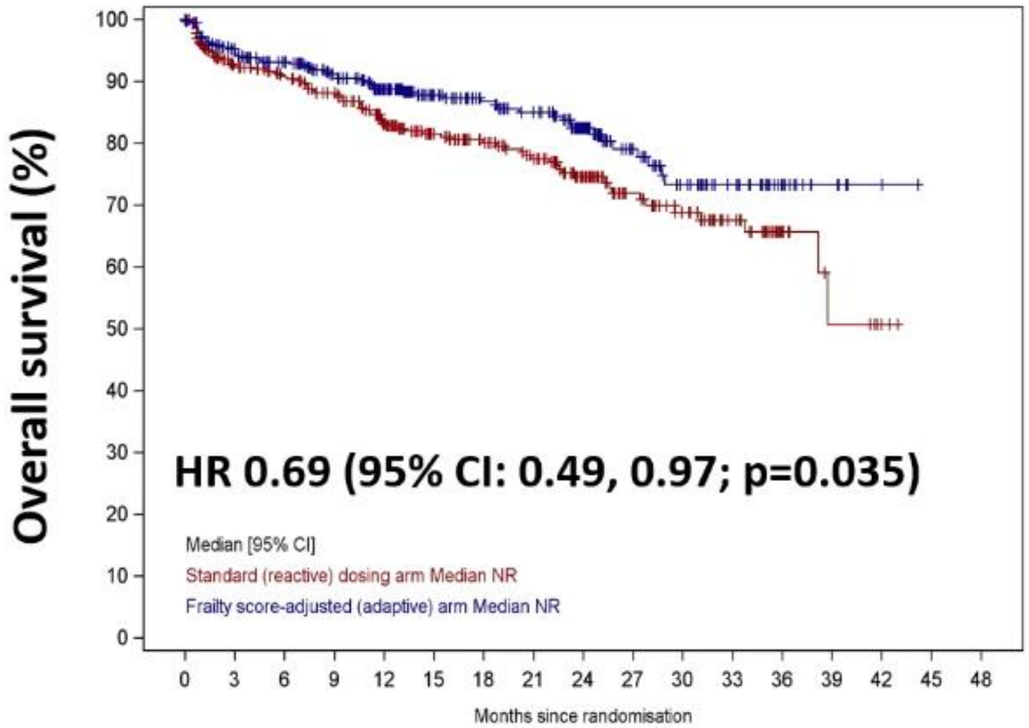
	Reactive (n=365)	Adaptive (n=368)
Median Age (range)	76 (62,90)	77 (62, 93)
<70	3.6%	3.8%
70-79	68.5%	67.7%
≥80	27.9%	28.5%
Male	56.6%	55.6%
Female	43.4%	44.4%
Ethnicity		
White	94%	94.8%
Black	0.8%	1.9%
Asian	3.1%	1.1%
CA		
Standard Risk	43.8%	38.9%
High Risk	8.3%	4.8%
missing	30.2%	35.6%
ECOG PS		
0-1	71.7%	67%
≥ 2	28.3%	33.1%

Cook G et al ASH 2024

Results – Overall survival (OS)

UKMRA
UK Myeloma Research Alliance

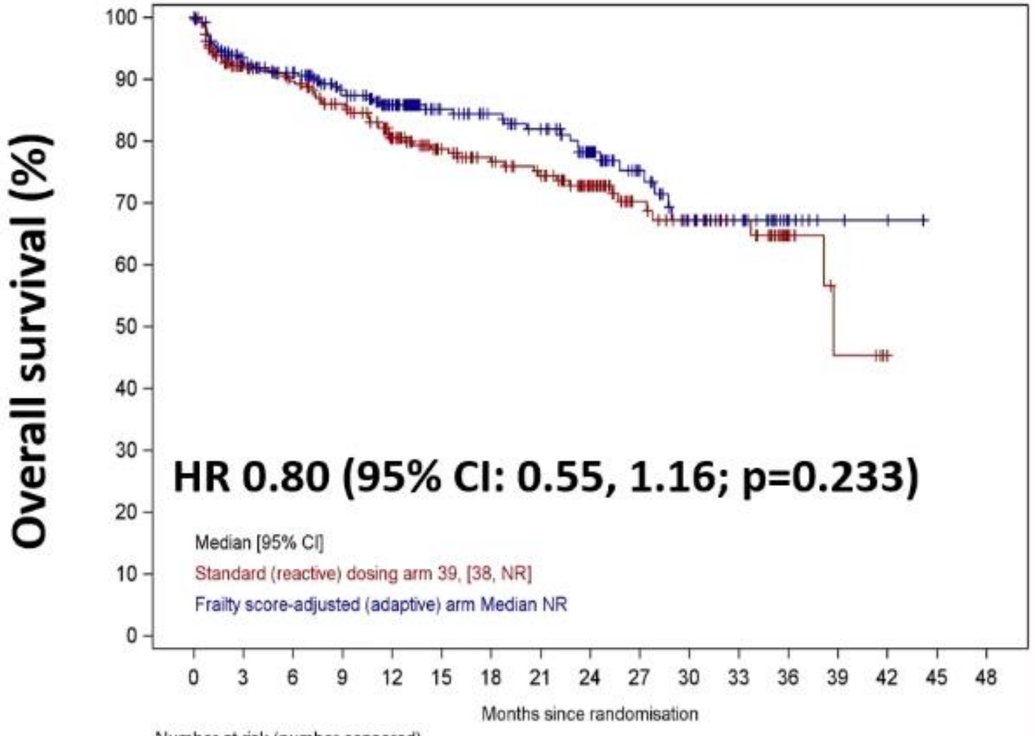
OS ITT Population



Number at risk (number censored)

Standard (reactive) dosing arm	365 (1)	285 (48)	217 (94)	161 (143)	106 (188)	58 (230)	16 (270)	2 (282)	0 (284)
Frailty score-adjusted (adaptive) arm	368 (2)	302 (42)	229 (102)	155 (172)	96 (224)	43 (270)	15 (298)	2 (311)	0 (313)

OS Unfit/Frail Population



Number at risk (number censored)

Standard (reactive) dosing arm	265 (0)	204 (35)	148 (72)	107 (107)	72 (137)	39 (166)	11 (193)	0 (202)	
Frailty score-adjusted (adaptive) arm	270 (2)	213 (34)	156 (80)	104 (130)	66 (161)	29 (192)	9 (212)	2 (219)	0 (221)

FiTNESs UK-MRA Myeloma XIV g.cook@leeds.ac.uk

Median Follow-up: 14.7 mns (7.6,24,4)

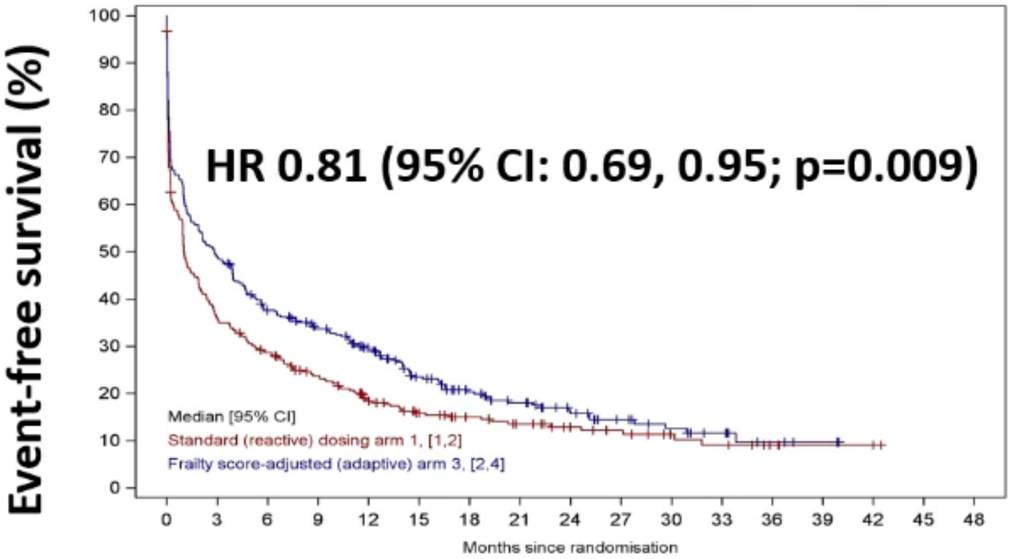
Cook G et al ASH 2024

Results – Event-free survival (EFS)

UKMRA UK Myeloma Research Alliance

EFS defined as: PD, death from any cause, withdrawal from trial treatment, non-haematological (gd≥3) & haematological (gd≥4) toxicities

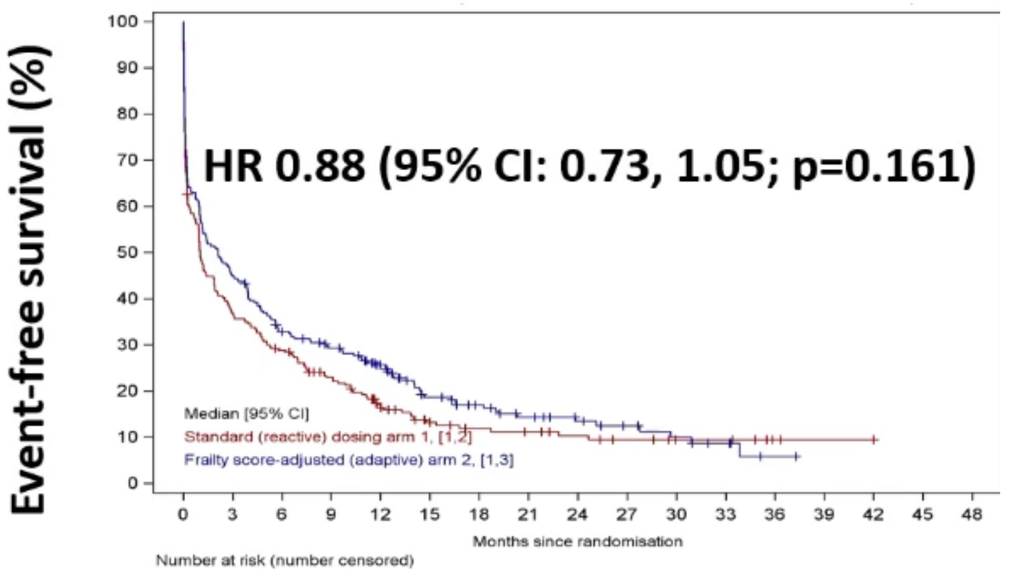
EFS ITT Population



Number at risk (number censored)

Standard (reactive) dosing arm	365 (1)	102 (4)	55 (18)	31 (32)	18 (41)	10 (47)	4 (51)	1 (54)	0 (55)
Frailty score-adjusted (adaptive) arm	368 (0)	134 (5)	91 (21)	47 (39)	26 (51)	13 (60)	4 (67)	0 (71)	

EFS Unfit/Frail Population



Number at risk (number censored)

Standard (reactive) dosing arm	265 (0)	75 (2)	35 (13)	17 (22)	12 (25)	6 (30)	2 (34)	0 (36)
Frailty score-adjusted (adaptive) arm	270 (0)	86 (3)	56 (15)	27 (27)	15 (34)	8 (38)	1 (43)	0 (44)

1-year EFS:

- **Reactive arm 18.8% (95% CI: 14.8%, 23.0%)**
- **Adaptive arm 29.7% (95% CI: 25.0%, 34.5%)**

1-year EFS:

- **Reactive arm 16.9% (95% CI: 12.6%, 21.8%)**
- **Adaptive arm 25.7% (95% CI: 20.6%, 31.1%)**

FiTNEss UK-MRA Myeloma XIV

g.cook@leeds.ac.uk

Median Follow-up: 14.7 mns (7.6,24,4)

Cook G et al ASH 2024

Background

Biomarker-based definition of PD in MM

IMWG Criteria (Kumar et al, 2016)	1990s, 2000s	Current
• ***>25% increase in serum M (absolute of 5 g/l, confirmed by repeat).*** • ***>25% increase in 24 h urinary M (absolute of 200 mg/24 h, confirmed by repeat)***	• *Most patients achieve plateau* • *CR uncommon, almost exclusive to context of ASCT* • *Paradigm of observation after ASCT/Plateau. Conservative thresholds to prevent overtreatment*	• *Most patients achieve CR* • *Paradigm of continuous therapy. PD most often means replacing an ongoing therapy that is no longer adequate.*
• ***>25% increase in Δ FLC, (absolute of 10 mg/dL, confirmation by repeat). Only if no measurable serum and Urine M***	• *FLC not broadly available* • *FLC seen as hierarchically inferior to M component quantification*	• *FLC near-ubiquitously available* • *FLC measurement reliable and precise* • *FLC more rapidly reflect disease course*
• ***>25% increase in PC in a bone marrow, absolute increase by 10%.***	• *High PC burden common at "plateau"* • *Morphology as main tool for PC burden quantification (10% means 0.042 log_{10})*	• *Most patients will achieve <1% PC* • *NGF and NGS can quantify PC burden across a 6 log_{10} range*

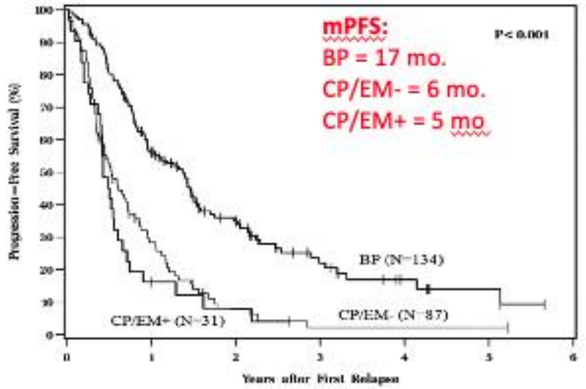
In addition to biomarkers PD is also defined by the "appearance of a new lesion(s), ≥50% increase from nadir in SPD of >1 lesion, or ≥50% increase in the longest diameter of a previous lesion >1 cm in short axis; ≥50% increase in circulating plasma cells (minimum of 200 cells per µL) if this is the only measure of disease."

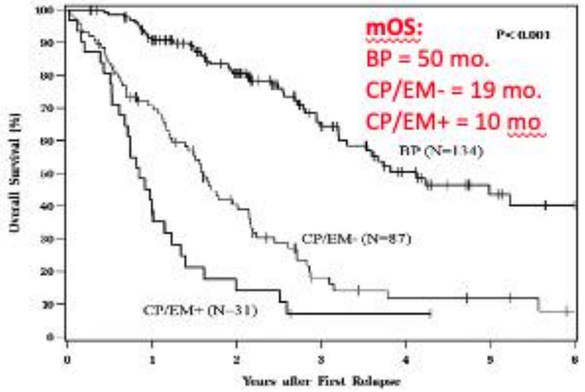
Blade et al. Br J Haematol 102:1115-1123, 1998
Durie et al. Leukemia 20:1467–1473, 2006
Kumar et al. Lancet Oncol 17: e328–46, 2016

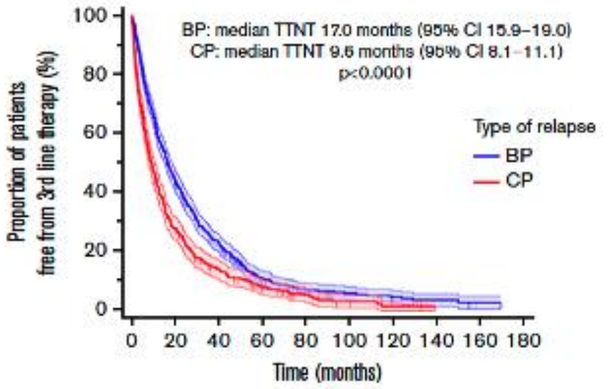
Costa LJ et al ASH 2024

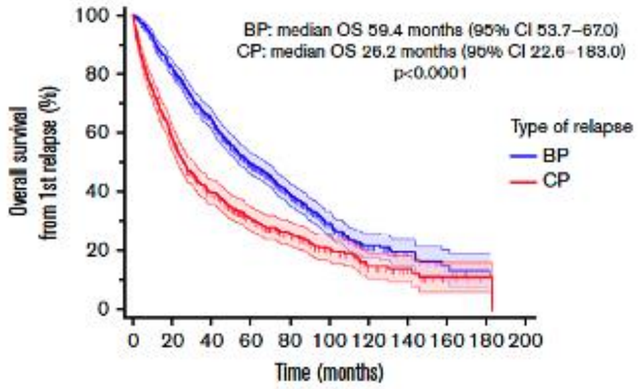
Background

Pattern of PD - Impact on Outcome







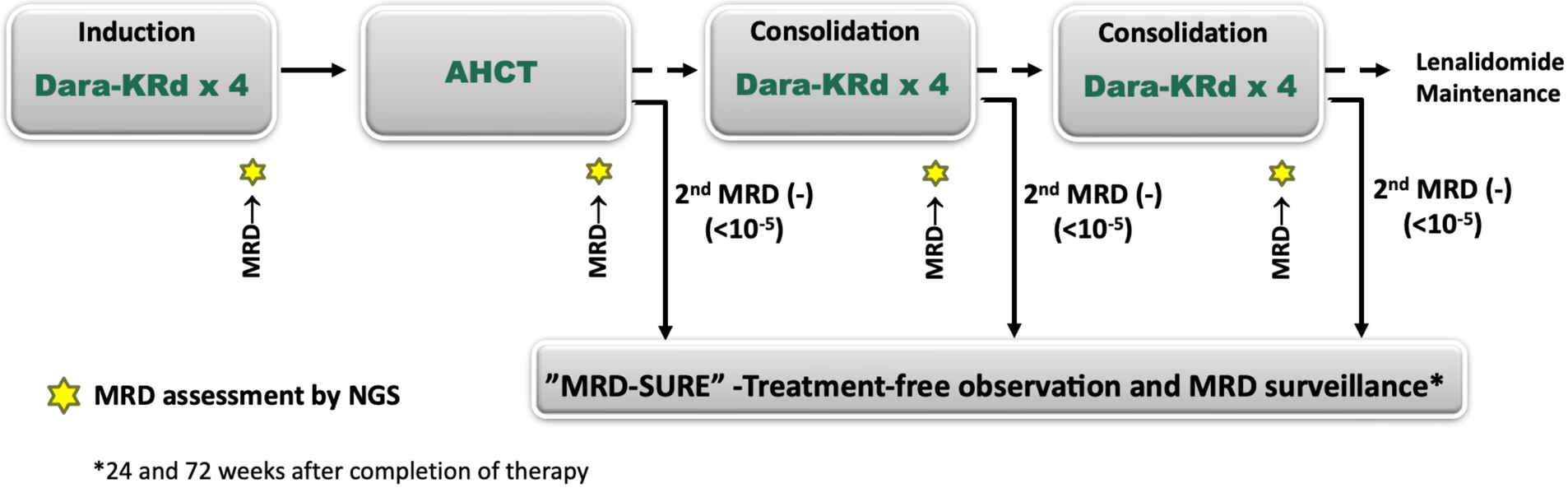


- For 40-50% patients, current biomarker-based criteria fail to anticipate clinical progression
- Clinical progression more likely to have high-risk features: High LDH, HRCA, ISS3
- In 70-80% clinical progression is skeletal event

Chakraborty et al. Am J Hematol 94:439, 2019
Goldman-Mazur et al. Blood Advances 7:909-917, 2023

Methods

- Patients with NDMM, enrichment for high-risk disease
- MASTER trial (N=113)



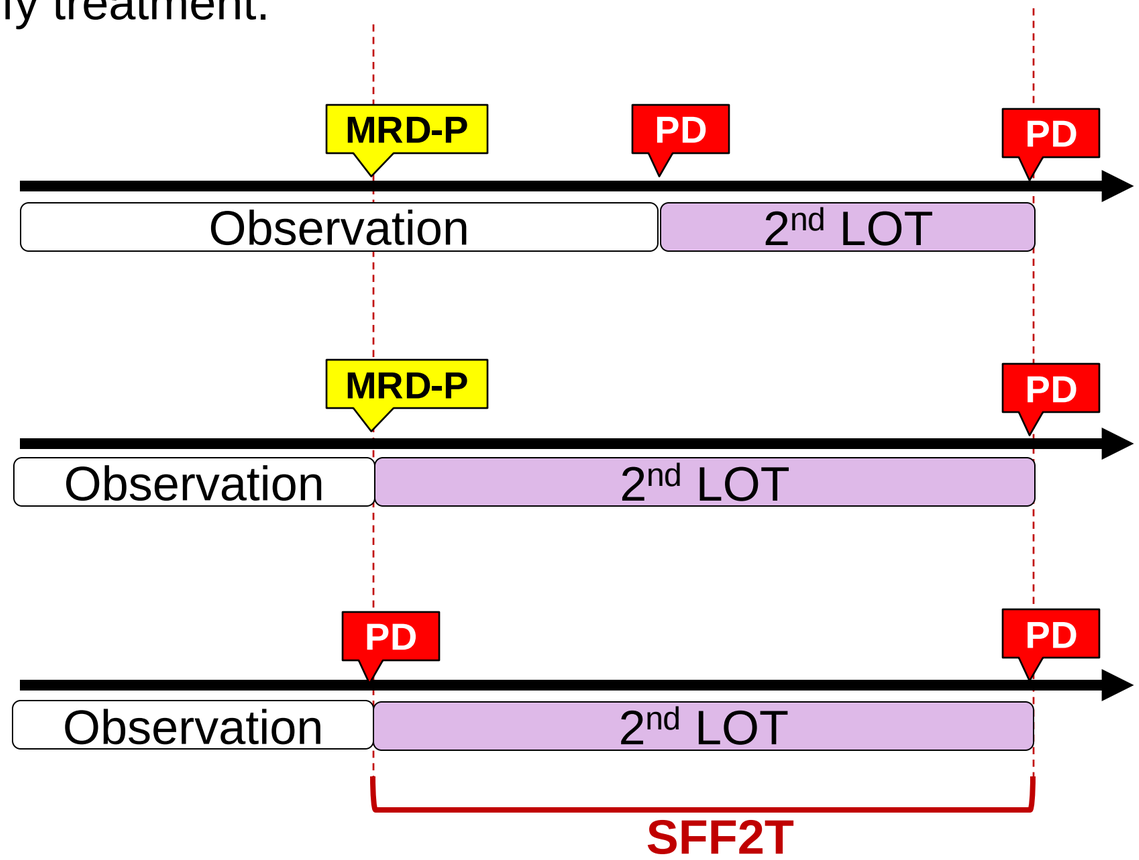
*24 and 72 weeks after completion of therapy

- Consecutive, similarly treated and monitored patients from institutional database (N=103)
  - —Dara-VRd instead of Dara-KRd

Costa LJ et al. Lancet Haematol10:e890, 2023
Ravi G et al. Blood 140(suppl 1):8048, 2022

Methods

- MRD by clonoSEQ® assessed not less often than every 12 months, regardless of IMWG response category.
- MRD-P arbitrarily defined as at least 1 x $\log_{10}$ increment of MRD burden from nadir.
- Treating physician informed of MRD result and could modify treatment.
- Described and compared outcomes for
  - —MRD-P
  - —IMWG-defined PD not preceded by MRD-P
- Survival free of failure of 2nd line therapy (SFF2T)
  - —From progression event (MRD-P or PD)
  - —Regardless of when 2nd LOT was started
- Overall survival (OS)
  - —From progression event (MRD-P or PD)
  - —Regardless of when 2nd LOT was started



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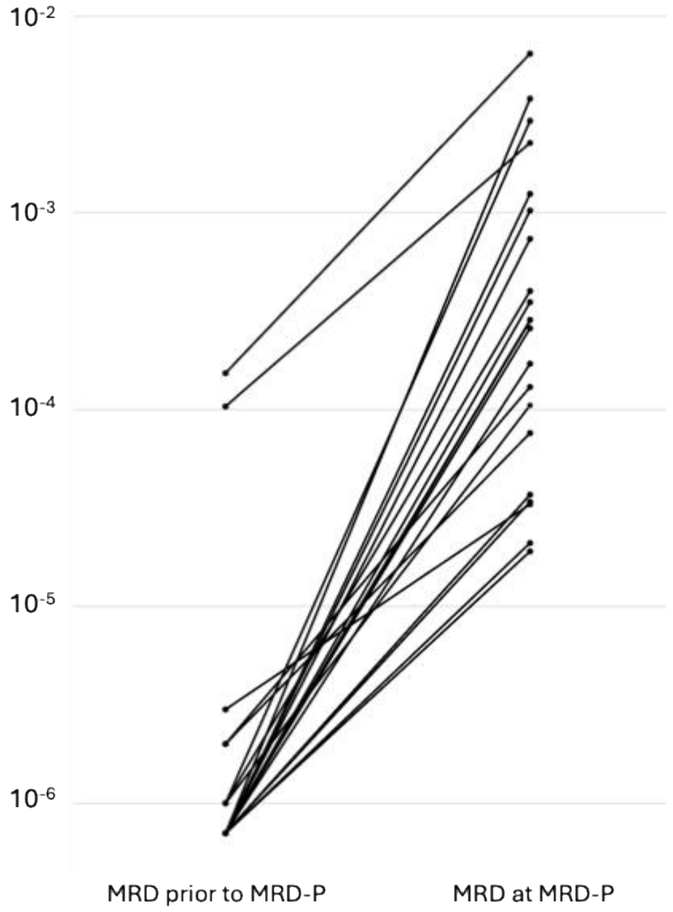
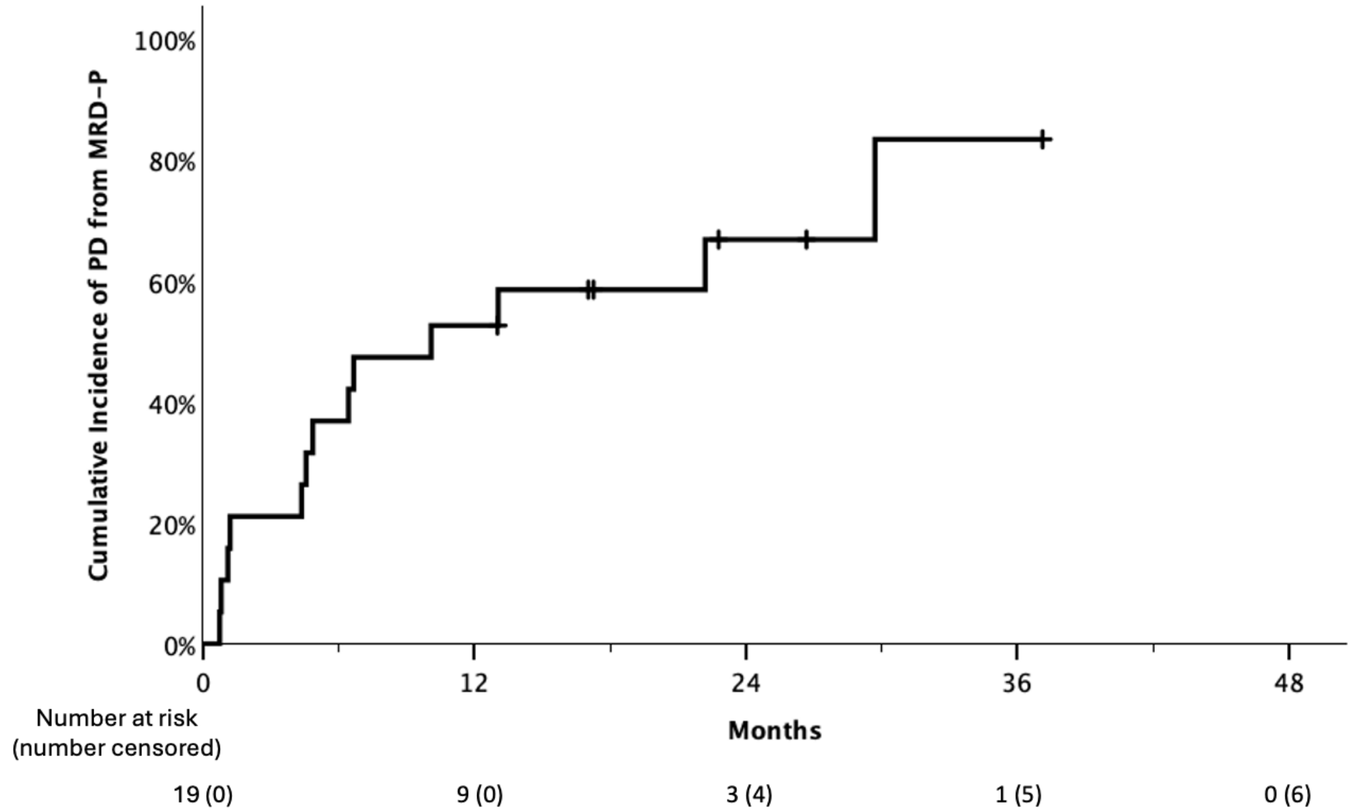
Results

MRD-P events

- 17 (89%) most recent MRD $<10^{-5}$
- 10 (53%) most recent MRD $< 10^{-6}$

Median T from MRD-P to PD was 10.1 mo.



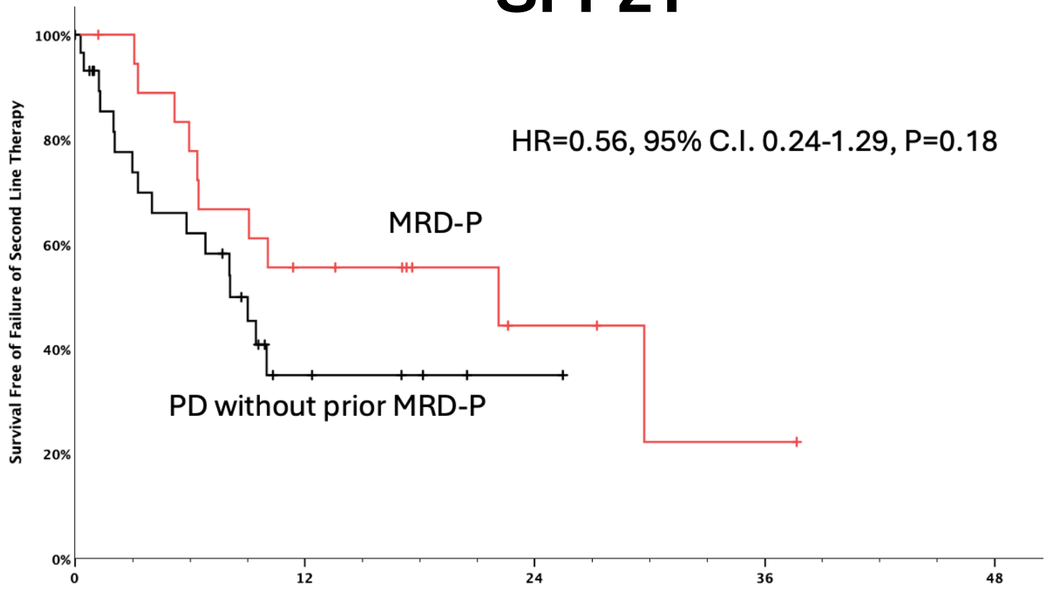


Costa LJ et al ASH 2024

Results

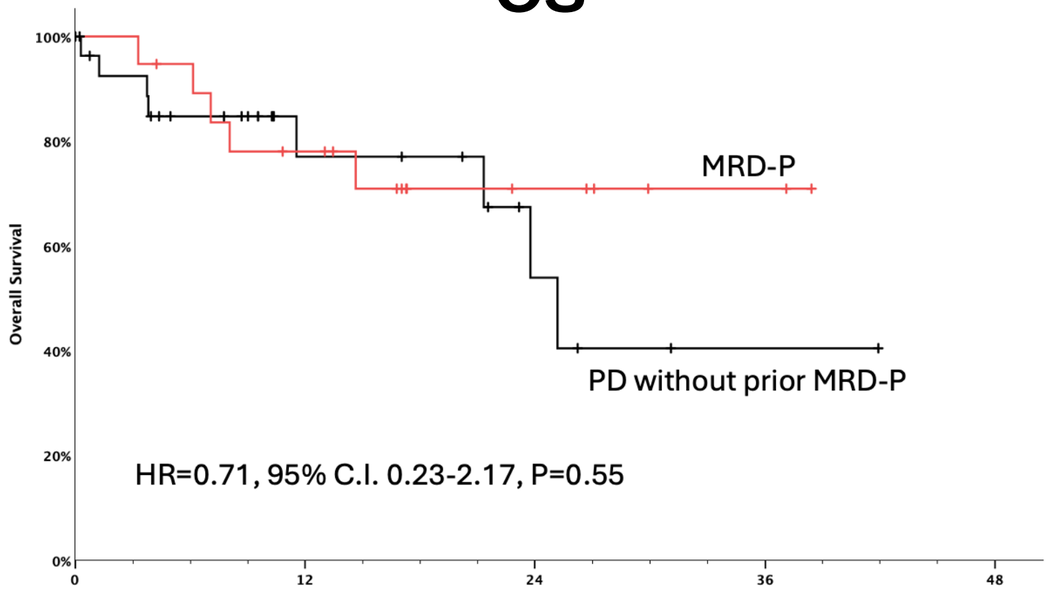
SFF2T and OS

SFF2T



Number at risk (number censored)					
MRD-P	19 (0)	9 (2)	3 (7)	1 (8)	0 (9)
IMWG PD	30 (0)	5 (9)	2 (11)	0 (14)	0 (14)

OS



Number at risk (number censored)					
MRD-P	19 (0)	13 (2)	5 (9)	2 (12)	0 (14)
IMWG PD	30 (0)	10 (15)	4 (19)	1 (21)	0 (22)

1-year SFF2T
MRD-P = 56%
PD not preceded by MRD-P= 35%

2-year OS
MRD-P = 78%
PD not preceded by MRD-P= 54%

Costa LJ et al ASH 2024

Summary – ASH 2024 Newly Diagnosed Multiple Myeloma

- Benefit of CD38, IMID, PI and dexamethasone induction regimens in transplanted and non-transplanted patients
- MRD negative response continue to deepen with time (IMROZ)
- Significance of MRD progression is clear (MASTER analysis)
- Frailty adjusted dosing has significant impact on outcomes (UK MRA Fitness Trial)

Management of Relapsed Multiple Myeloma in 1+ line of therapy in 2025

Most patients:

Dara RVD → autologous HCT → Lenalidomide (+/- Dara) maintenance

OR

Dara/Isa RD / RVD → lenalidomide maintenance

Progression of Disease

1-3 Lines of therapy

- CD38 + IMID: Carfilzomib, pomalidomide, dexamethasone
- CD38 + PI:Carfilzomib + either Daratumumab/Isatuximab and dexamethasone
- BCMA CAR T cells: Cilta-cel (1 LOT) or ide-cel (2 LOT)
- Selinexor regimens
- Clinical trial

4+ Lines of therapy

- BCMA CAR T cells:Cilta-cel, or Ide-cel
- BCMA Bispecific: Teclistamab, elrantabamab
- GPRC5D Bispecific: Talquetamab
- Clinical trial

Post-BCMA relapse

- Clinical trials
- GPRC5D bispecific: Talquetamab (if not already given)
- Selinexor based regimens

CAR T cell therapy

- Two approved BCMA CAR T products
  - Ide cel (Abecma), approved 2021
  - Cilta-cel (Carvykti), approved 2022

- Both are now approved for > 1 LOT (Cilta-cel) and >2 LOT (Ide-cel)

- Efficacy – seems to favor cilta-cel over id—cel

- Safety – potentially favoring ide-cel over cilta-cel

Flow Diagram: Multicenter Retrospective Study Population

Intention to Treat (ITT) Cohort (N=641)
- April 8, 2021-December 31,2022
- **Ide-cel (N=386) or Cilta-cel (N=255)**

55 Patients not infused
- **Ide-cel (N=36)**
  - 26 due to disease progression or death
  - 10 due to manufacturing failures
- **Cilta-cel (N=19)**
  - 13 due to disease progression or death
  - 3 due to manufacturing failures
  - 1 due to transition of care at another facility
  - 2 due to developing another cancer

Out of specification product:
- 23/350 (7%) patients treated with ide-cel
- 43/236 (18%) patients for cilta-cel

Infused Cohort (N=586)
Ide-cel (N=350) or Cilta-cel (N=236)

Same Time Period Cohort (N=397)
Ide-cel: N=161 or Cilta-cel: N=236

Propensity Score Matching Cohort (N=380)

Same Site Cohort (N=427)
Ide-cel: N=314 or Cilta-cel: N=113

Complete Case (N=371)
Ide-cel: N=266 or Cilta-cel: N=105

Hansen et al. ASH 2024 [Abstract #936]

Baseline Characteristics

Characteristic		Ide-cel (N=350)	Cilta-cel (N=236)	P
Age (years)		65 (36, 90)	64 (30, 84)	0.2
Male sex		203 (58)	134 (57)	0.8
Race/ethnicity				0.4
	Non-Hispanic Black	55 (16)	26 (11)	
	Hispanic	32 (9)	19 (8)	
	Non-Hispanic White	245 (70)	177 (76)	
	Other	18 (5)	12 (5)	
Extramedullary disease		84 (24)	60 (26)	0.7
Bone marrow plasma cell %		5 (0, 100)	10 (0, 95)	0.14
High-risk cytogenetics		109 (33)	81 (38)	0.2
Prior BCMA therapy		64 (18)	33 (14)	0.2
Penta-class refractory		124 (35)	70 (30)	0.15
ECOG PS				0.03
	0	68 (20)	62 (30)	
	1	218 (66)	121 (59)	
	2	39 (12)	15 (7)	
	3	6 (2)	7 (3)	
	4	1 (0.3)	1 (0.5)	
Lymphodepleting chemotherapy				<0.001
	Fludarabine/cyclophosphamide	319 (91)	191 (81)	
	Others	31 (9)	44 (19)	
Ferritin (ng/mL)		345 (8, 27260)	208 (7, 5316)	<0.001
Low Cell Dose		5 (1)	9 (4)	0.04
Bridging therapy and response				0.003
	No, Bridging	88 (28)	51 (24)	
	Yes, ≥ PR	32 (10)	44 (21)	
	Yes, SD/PD	199 (62)	117 (55)	
	Yes, Unknown response	31	23	

Hansen et al. ASH 2024 [Abstract #936]

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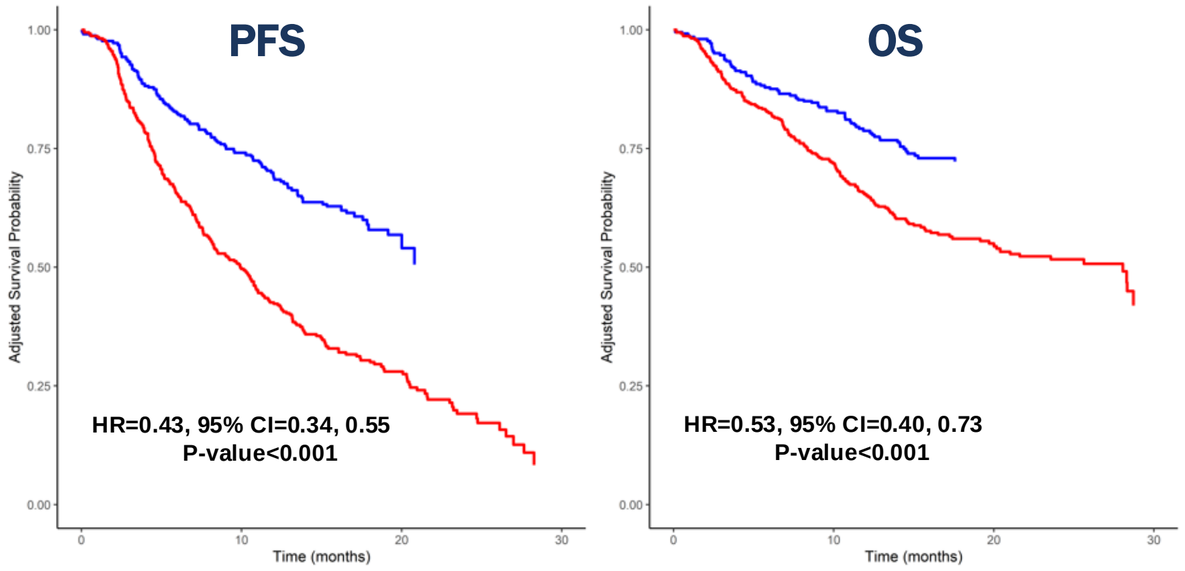
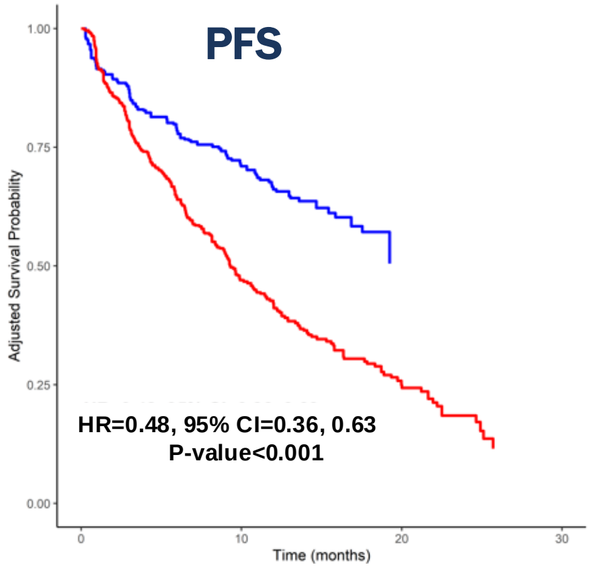
Hansen et al. ASH 2024 [Abstract #936]

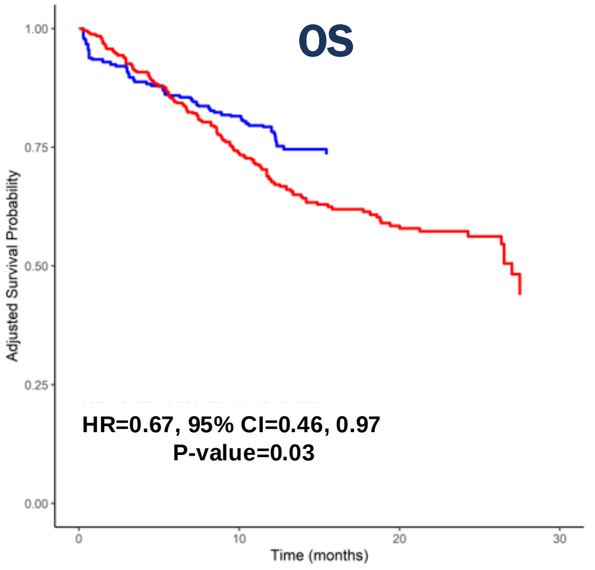
PFS and OS by Therapy Type

Intention to Treat Cohort (ITT)



Infused Cohort

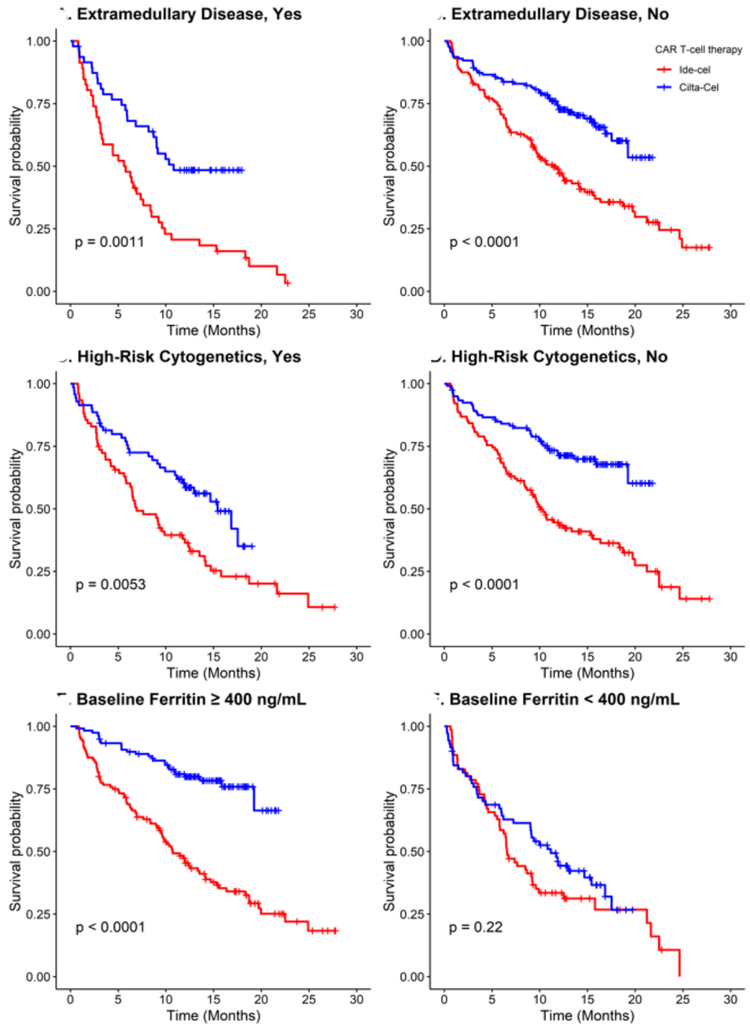




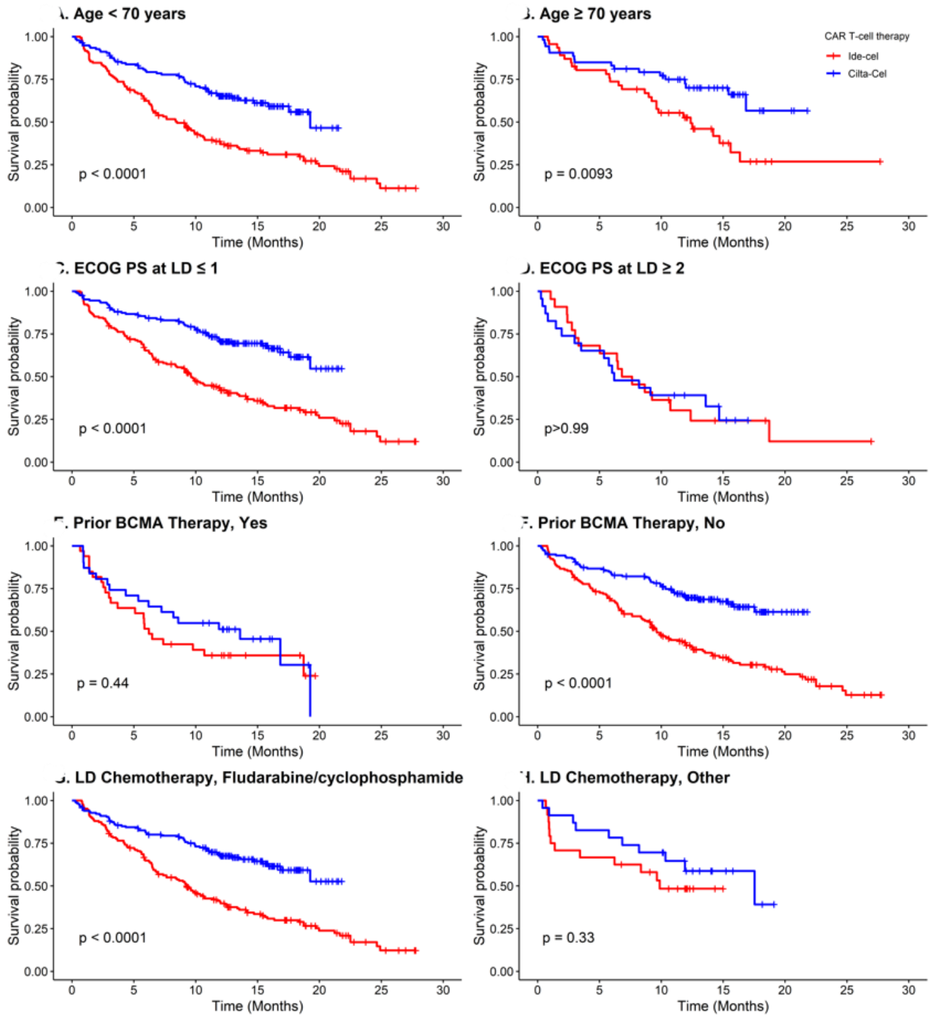
Hansen et al. ASH 2024 [Abstract #936]

Cilta-cel: Superior PFS Across Patient Subgroups (PSM)

PFS by Disease Characteristics



PFS by Patient and Treatment Characteristics



Hansen et al. ASH 2024 [Abstract #936]

Can we improve on BCMA CAR T therapy?

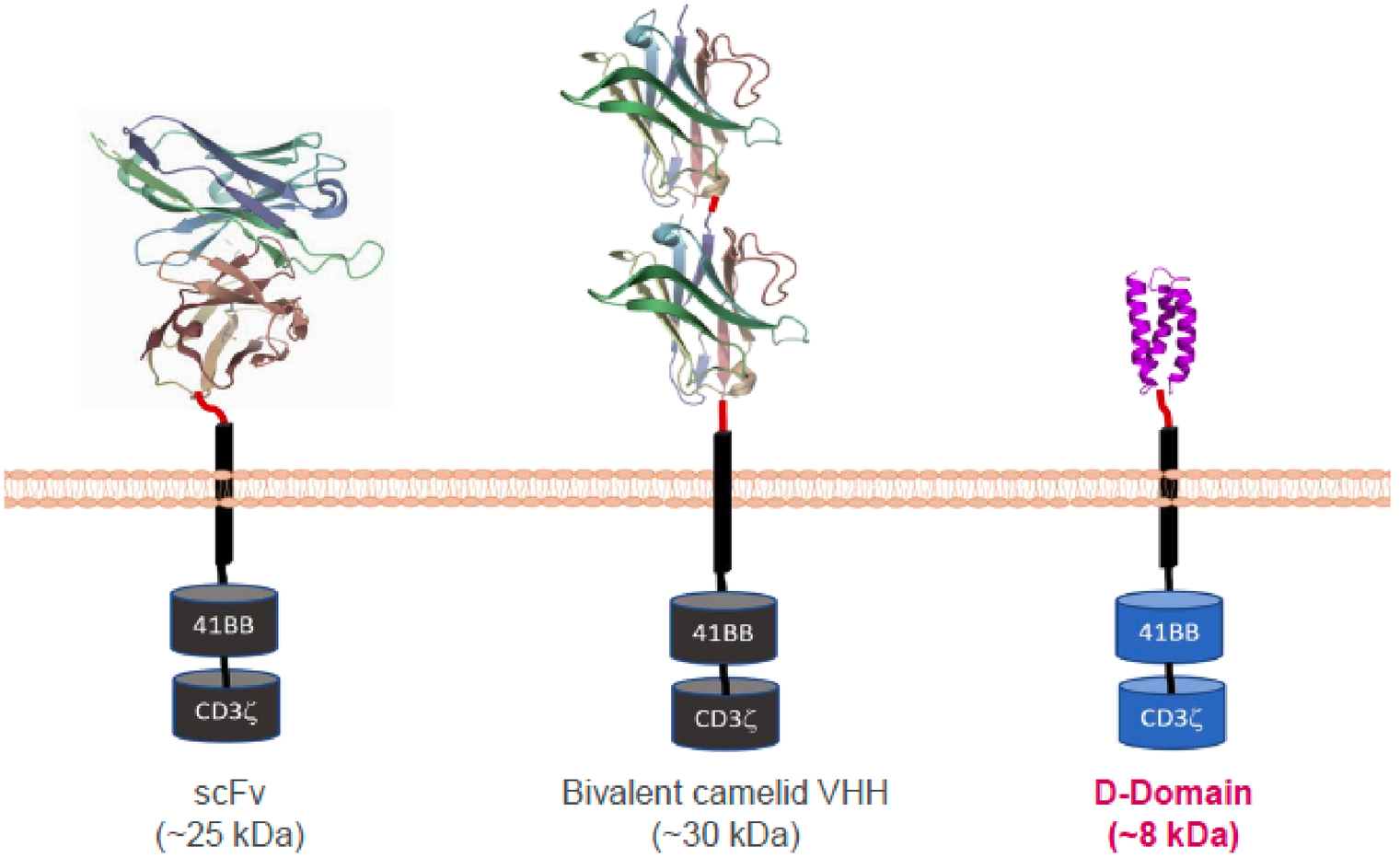
- Use of Gamma secretase inhibitors to increase BCMA density (Cowan et al Lancet Onc 2023)

- Alternative binding constructs:
  - ddBCMA (anito-cel)
  - Camelid binding domains (Cilta-cel)

- Additional of CELMOD to potentiate T cells (Upcoming ALLIANCE trial with iberdomide post ide-cel)

Anitocabtagene autoleucel (anito-cel/CART-ddBCMA)

Autologous BCMA-directed CAR T-cell therapy using a novel, D-Domain binder[1,2]



scFv
(~25 kDa)

Bivalent camelid VHH
(~30 kDa)

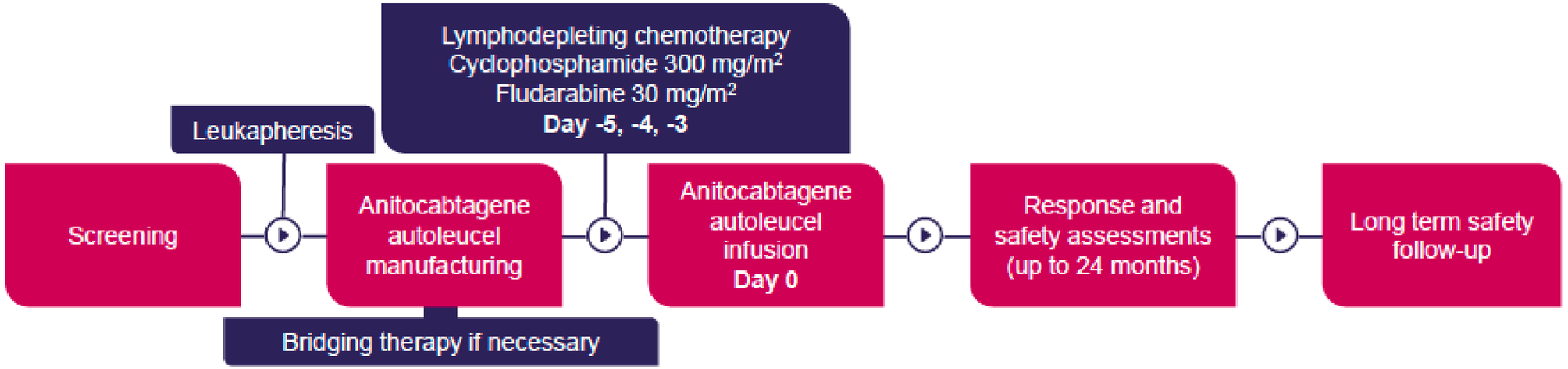
D-Domain
(~8 kDa)

D-Domain Attributes:
Non-Antibody Derived Synthetic Protein[1,2]

Size	**Small D-Domain construct facilitates high transduction efficiency and CAR positivity[2-4] resulting in a low total cell dose**
Structure & Stability	**D-Domain CARs are stable and lack tonic signaling[4,6] due to the rapid folding, lack of disulfide bonds, and hydrophobic core[5,6] of the D-Domain**
Binding	**The D-Domain binder has a fast off-rate[4] and high CAR surface expression[4]. This combination may allow optimal tumor cell killing without prolonged inflammation**

[1]Rotte, et al. Immuno-Oncology Insights 2022; 3(1), 13–24; [2]Frigault, et al. Blood Adv. 2023; 7(5):768-777; [3]Cante-Barrett, et al. BMC Res. Notes 2016; 9:13; [4]Buonato, et al. Mol. Cancer Ther. 2022; 21(7):1171-1183; [5]Zhu, et al. Proc. Nat. Acad. Sci. 2003; 100(26): 15486-15491; [6]Qin, et al. Mol. Ther. 2019; 27(7): 1262-1274.

iMMagine-1: Phase 2 Study Design



Key Eligibility Criteria

- Prior IMiD, PI, and CD38-targeted therapy
- Received ≥3 prior lines of therapy
- Refractory to the last line of therapy
- ECOG PS of 0 or 1
- Evidence of measurable disease

Primary Endpoint:

- ORR, per 2016 IMWG criteria

Key Secondary Endpoints:

- sCR/CR rate, per 2016 IMWG criteria
- ORR in patients limited to 3 prior LoT, per 2016 IMWG criteria

Target Dose of 115 x 10^6 CAR+ T cells

Primary and key secondary endpoints to be assessed per Independent Review Committee (IRC); Investigator assessment of response per IMWG also permitted per protocol.
CR, complete response; ECOG PS, Eastern Cooperative Oncology Group Performance Status; IMiD, immunomodulatory drug; IMWG, International Myeloma Working Group; LoT, line of therapy; ORR, overall response rate; PI, proteosome inhibitor; sCR, stringent complete response.

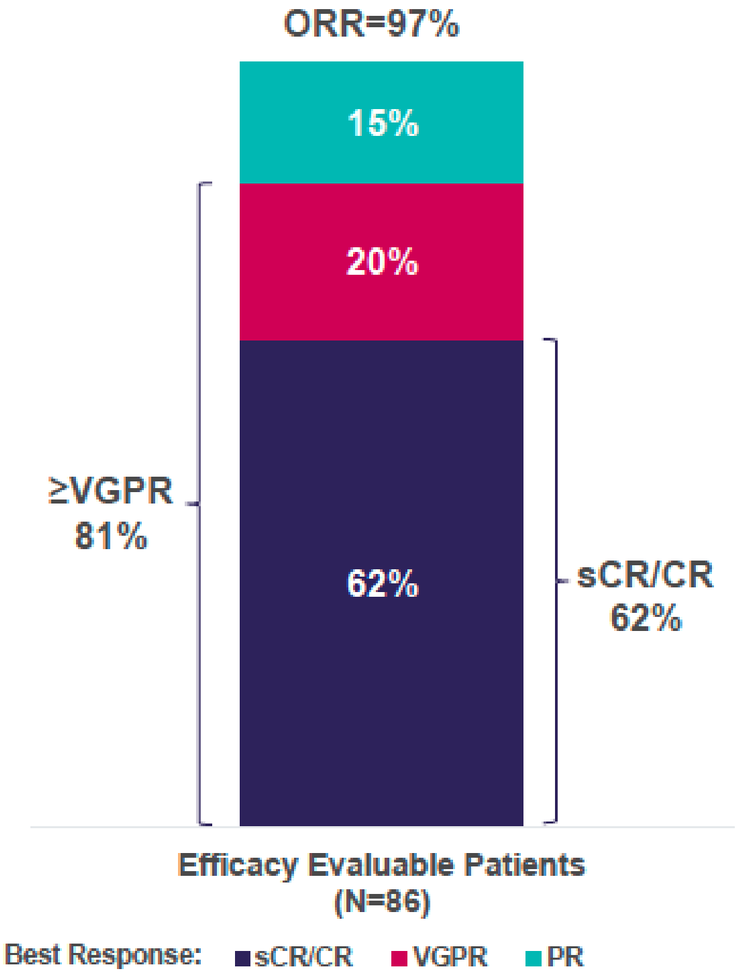
iMMagine-1: Patient and Disease Characteristics

Characteristics	Safety Evaluable (n=98)	Efficacy Evaluable (n=86)
Age (yrs), median (min - max)	65 (38 – 78)	65 (38 – 78)
Age ≥ 65	51 (52%)	47 (55%)
Age ≥ 70	30 (31%)	28 (33%)
Age ≥ 75	10 (10%)	10 (12%)
Gender (male / female)	55 (56%) / 43 (44%)	48 (56%) / 38 (44%)
Race		
White	79 (81%)	70 (81%)
Black / African American	9 (9%)	8 (9%)
Asian / Other	10 (10%)	8 (9%)
ECOG PS 0 / 1	45 (46%) / 53 (54%)	39 (45%) / 47 (55%)
Extramedullary disease[a]	16 (16%)	13 (15%)
High Risk Cytogenetics[b]	39 (40%)	33 (38%)
Refractory to last line of therapy	98 (100%)	86 (100%)
Triple refractory	85 (87%)	74 (86%)
Penta refractory	41 (42%)	37 (43%)
Prior Lines of Therapy, median (min - max)	4 (3 – 8)	4 (3 – 8)
3 Prior LoT	45 (46%)	37 (43%)
Time since diagnosis (yrs), median (min-max)	7.2 (1 – 23)	7.5 (1 – 23)
Prior ASCT	73 (75%)	64 (74%)
Bridging therapy	65 (66%)	61 (71%)
Outpatient administration	8 (8%)	5 (6%)

a) Presence of a non-bone based plasmacytoma; b) Defined as the presence of Del 17p, t(14;16), or t(4;14).
ASCT, autologous stem cell transplant; ECOG PS, Eastern Cooperative Oncology Group Performance Status; LoT, line of therapy

iMMagine-1: Overall Response Rate and MRD Negativity

Efficacy Evaluable Patients (N=86)



- At a median follow-up of 9.5 months, ORR was 97% and sCR/CR rate was 62%
- 93.1% (n=54/58) of evaluable patients were MRD negative at minimum of 10^{-5} sensitivity

	Evaluable Patients	Months (min - max)
Median time to first response	83	1.0 (0.9 - 7.3)
Median time to MRD negativity of $\leq 10^{-5}$	54	1.0 (0.9 - 6.4)

Responses are investigator assessed per IMWG criteria, ORR defined as partial response or better; MRD evaluable patients had an identifiable malignant clone in the baseline bone marrow sample and had a post-treatment bone marrow sample sufficient to assess MRD negativity
CR, complete response; MRD, minimal residual disease; ORR, overall response rate; PR, partial response; sCR, stringent complete response; VGPR, very good partial response

iMMagine-1: PFS and OS Rates Estimated by Kaplan-Meier

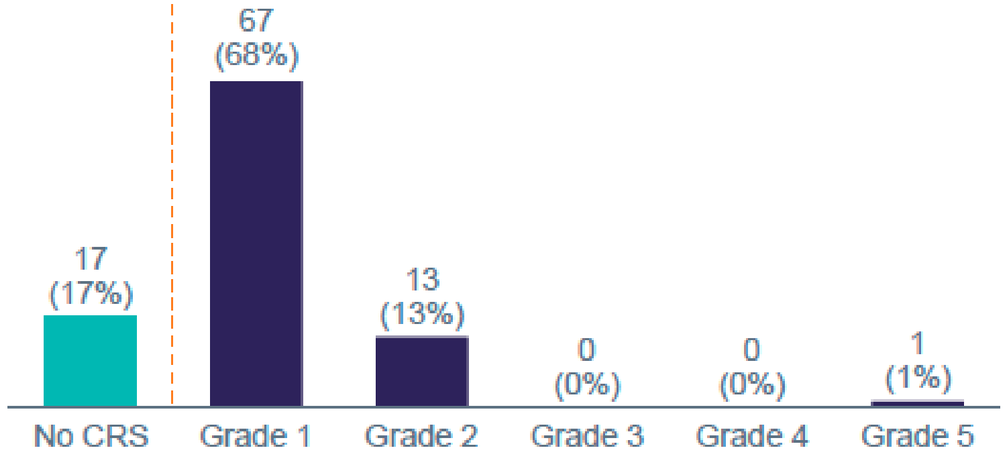
Efficacy Evaluable Patients (N=86)

	PFS Rate (%) (95% CI)	OS Rate (%) (95% CI)
6-Month	93.3% (84.4%, 97.2%)	96.5% (89.6%, 98.9%)
12-Month	78.5% (63.5%, 87.9%)	96.5% (89.6%, 98.9%)

Median follow-up of 9.5 months (range 2 to 23 months)
PFS, progression-free survival; OS, overall survival

iMMagine-1: Cytokine Release Syndrome

Maximum CRS Grade (N=98)



- 83% (81/98) of patients had CRS of any Grade; the median onset was 4 days
- 86% (84/98) of patients had CRS Grade 1 or less, including 17% (17/98) with no CRS
- % of patients with either no CRS or CRS that resolved by:
  - ≤7 days of anito-cel infusion: 63% (62/98)
  - ≤10 days of anito-cel infusion: 92% (90/98)
  - ≤14 days of anito-cel infusion: 98% (96/98)

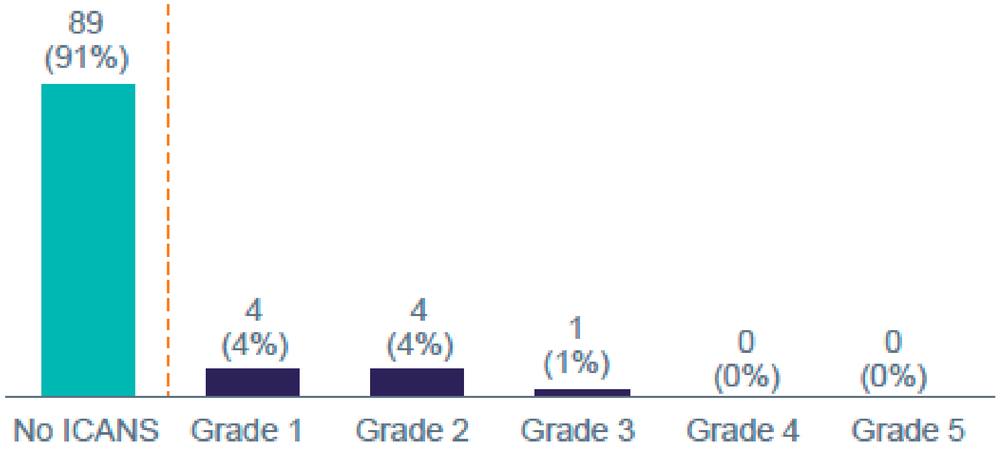
Cytokine Release Syndrome (CRS) Per ASTCT criteria	Safety Evaluable Patients N=98
Median onset (min-max)	4 days (1-17 days)
Median duration (min-max)	3 days (1-9 days)
Supportive Measures	
Tocilizumab	72% (71/98)
Dexamethasone	65% (64/98)
Anakinra	8% (8/98)
Siltuximab	4% (4/98)
Vasopressor used	1% (1/98)
Intubation/mechanical ventilation	1% (1/98)

- CRS management per protocol was in line with standard medical practice with no prophylactic administration of tocilizumab or dexamethasone
  - For CRS onset in the first 48 hours, tocilizumab and dexamethasone were protocol recommended
  - For CRS onset after the first 48 hours, if tocilizumab was administered at investigator discretion, dexamethasone was also recommended
- Grade 5 CRS occurred in a 76-year-old patient who had rapidly progressive disease between screening and baseline and did not receive bridging therapy

ASTCT, American Society for Transplantation and Cellular Therapy

iMMagine-1: Immune-effector Cell-associated Neurotoxicity Syndrome (ICANS)

Maximum ICANS Grade (N=98)



- 9% (9/98) of patients had ICANS of any grade; all cases resolved
- No delayed or non-ICANS neurotoxicities were observed, including no incidence of Parkinsonism, no cranial nerve palsies, and no Guillain-Barré syndrome (n=98)
- Similarly, no delayed or non-ICANS neurotoxicities have been observed in the Phase 1 study[1] (n=38, median follow-up of 38.1 months with minimum follow-up of 25 months)

ICANS Per ASTCT criteria	Safety Evaluable Patients N=98
Median onset (min-max[a])	7 days (2 - 10[a] days)
Median duration (min-max[b])	4 days (1 - 10[b] days)
Supportive Measures	
Tocilizumab	3% (3/98)
Dexamethasone	6% (6/98)
Anakinra	1% (1/98)
Siltuximab	1% (1/98)

[a] With the exception of n=1 Grade 1 ICANS (confusion) on day 34 post infusion that rapidly resolved
[b] With the exception of n=1 max Grade 2 ICANS with 29-day duration to resolution

1. Bishop, et al. Blood 2024; ASH Annual Meeting, Poster #4825.
ASTCT, American Society for Transplantation and Cellular Therapy

Common strategies for the patient awaiting leukapheresis (“holding” therapy)

- PACE or HyperCVAD based regimens
- Cytoxan based regimens, or high-dose Cy
- Selinexor based regimens
- If t(11;14) - Venetoclax regimens
- Talquetamab – GPRC5DxCD3 bispecific
- **What to avoid?**
  - **Bendamustine**
  - **BCMA Targeted therapies**

Bridging after leukapheresis

- Reduction in disease burden = goal; ICANS and delayed MNT associated with high disease burden with Carvykti
- A few that we have used recently at FHCC:
  - Talquetamab
  - PACE or HyperCVAD with aggressive disease relapse
  - High dose Cytoxan
  - Continuation of last line of therapy if stable disease or better

Maintaining disease control while awaiting CAR-T manufacturing is challenging

Clinical trials: 10-15%

Do not receive CAR-T due to progression/death while awaiting manufacturing

Real World: 25%

Do not receive CAR-T due to progression/death while awaiting manufacturing

Manufacturing time for CAR-T: **6-8 weeks**

<u>75% of patients need bridging therapy</u>

Increased disease burden prior to lymphodepletion is associated with

- decreased CAR-T efficacy,
- increased immune-mediated toxicity

There is an urgent need for an effective bridging strategy in these patients

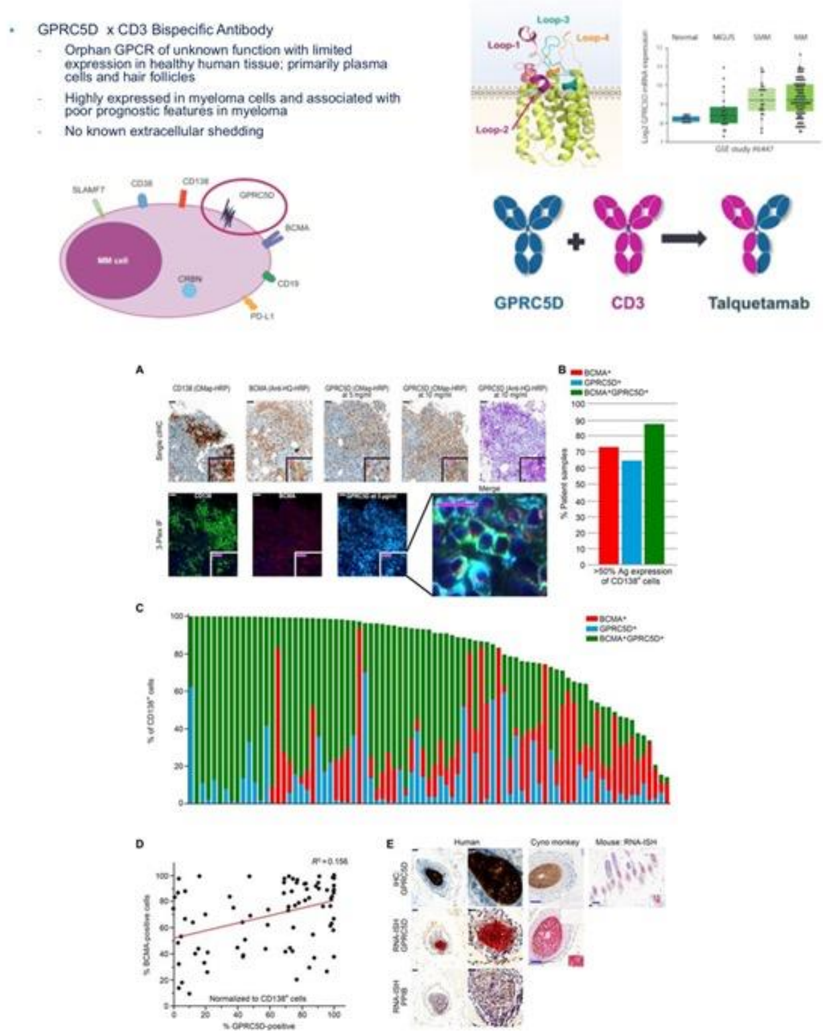
Berdeja et al. Lancet 2021. San Miguel J, Dhakal B; et al. NEJM 2023
Hadidi et al. Bone Marrow Transplant (2023)

Talquetamab as a bridge to BCMA CAR

- Talquetamab (Talq), a GPRC5D bispecific antibody, is approved in patients with 4 LOT based on a pivotal study showing ORR 70% and median DOR 10 months (Monumental -1).

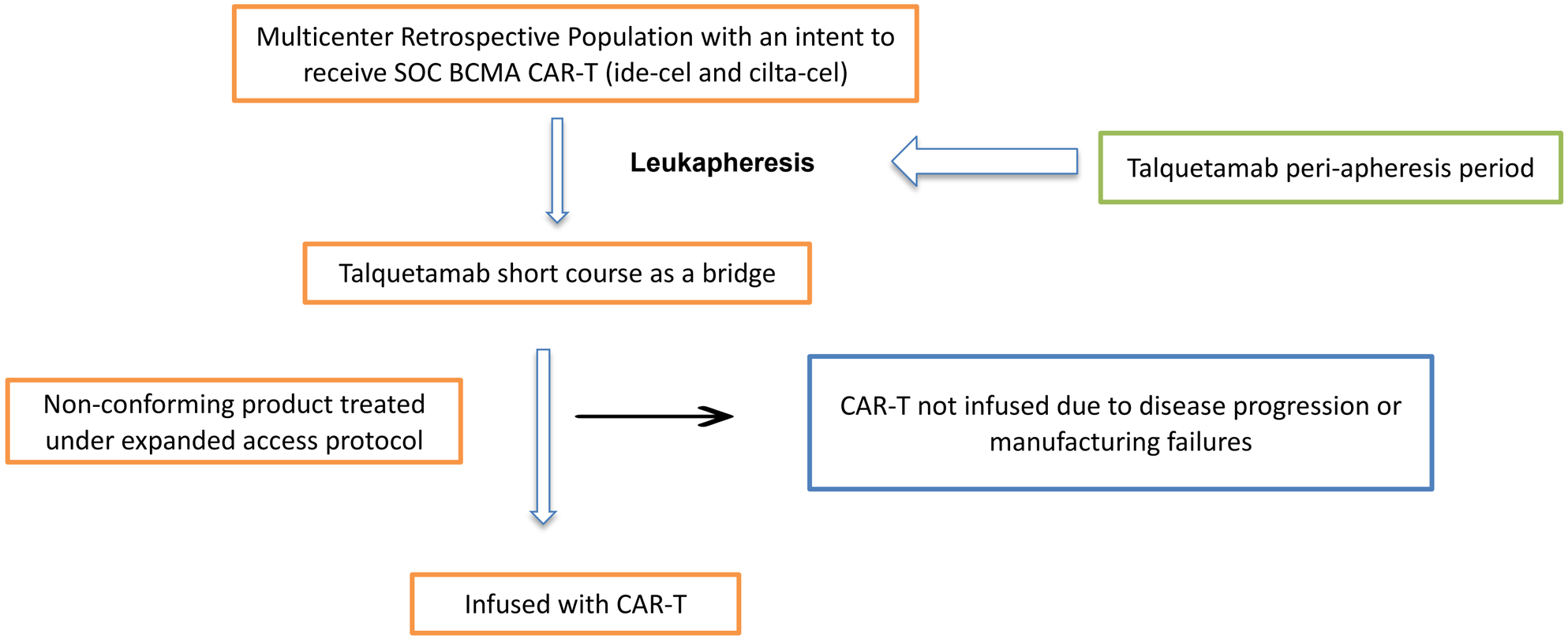
- Talq is associated with dysgeusia (60%) and weight loss (30%) and skin changes (70%) complicating its long-term use.

- Talq can achieve significant disease debulking with no impact on BCMA antigen target (non-overlapping antigen).



Smith E et.al Sci Translational Medicine 2019; Chari et. al NEJM 2022

Study Design and Methods



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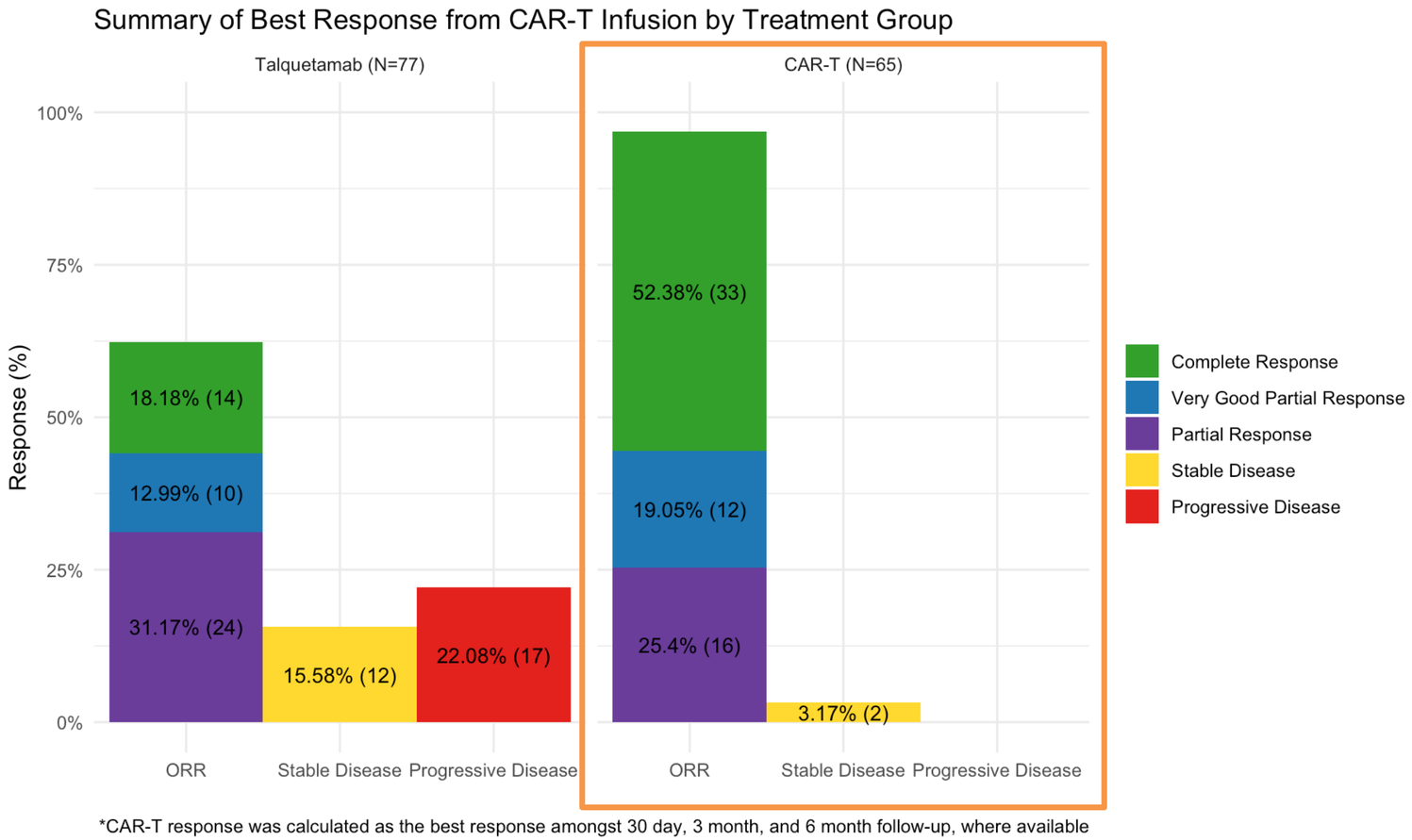
Best overall response to Talq and to CAR-T



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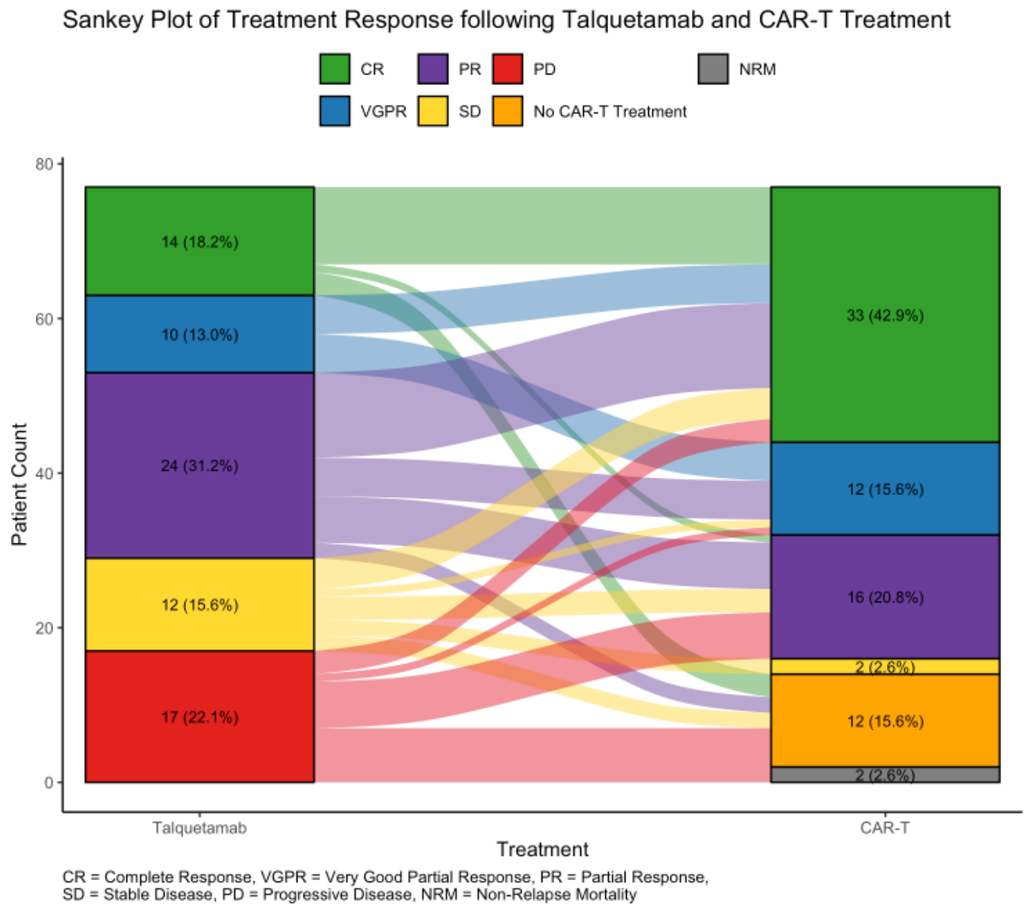
Flow of patient response from Talq to CAR-T



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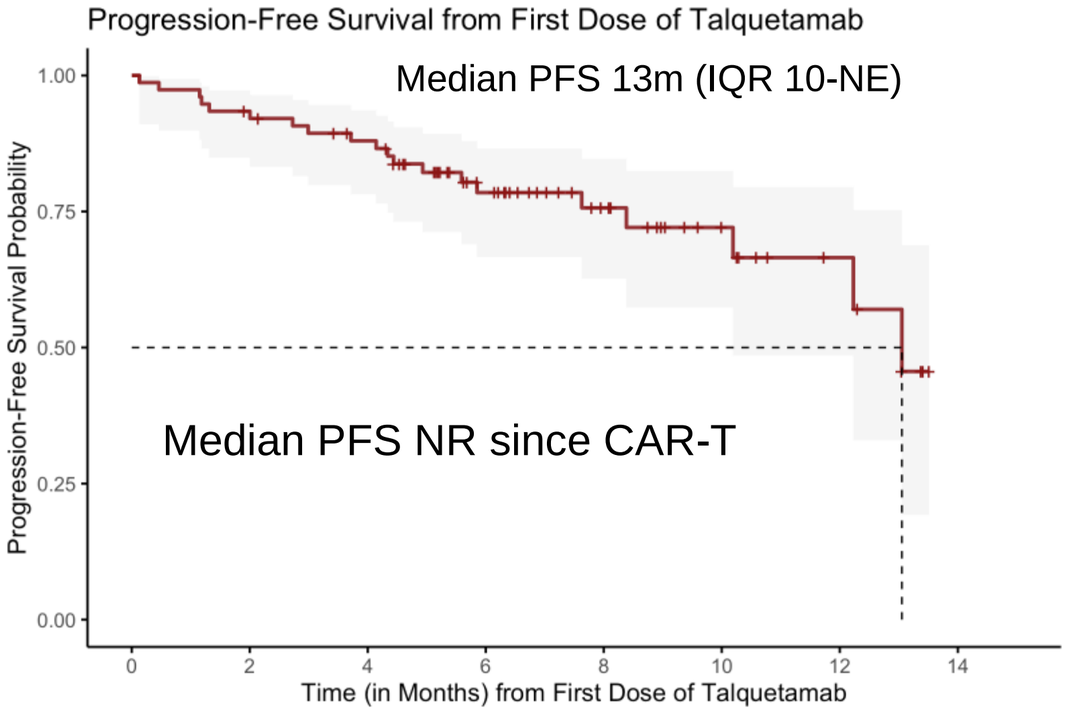
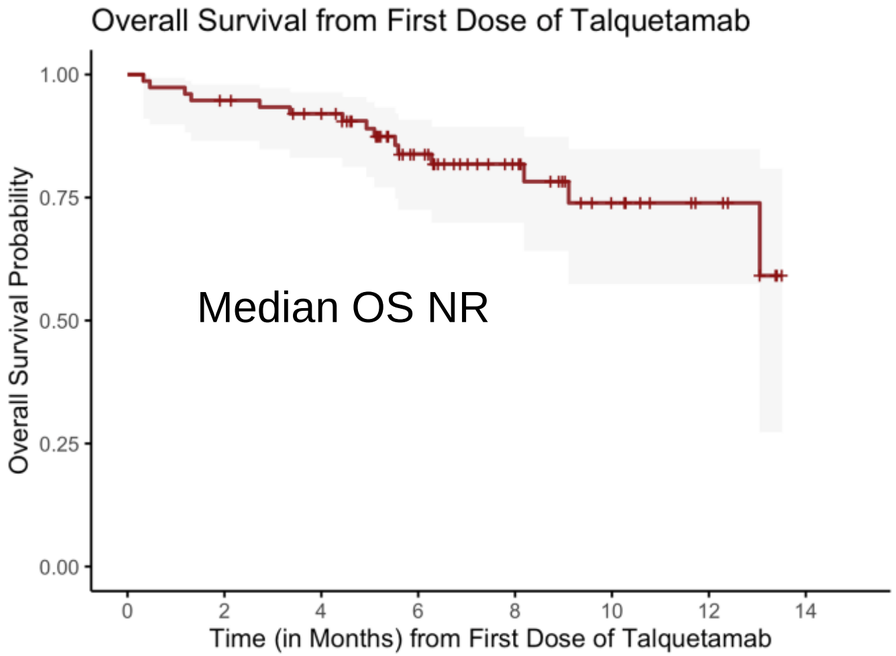
Talq bridging: PFS and OS





Median follow up time: from Talquetamab first dose 227 days (IQR 164-312)

Median follow up from CAR-T infusion 149 days (IQR 109-209)

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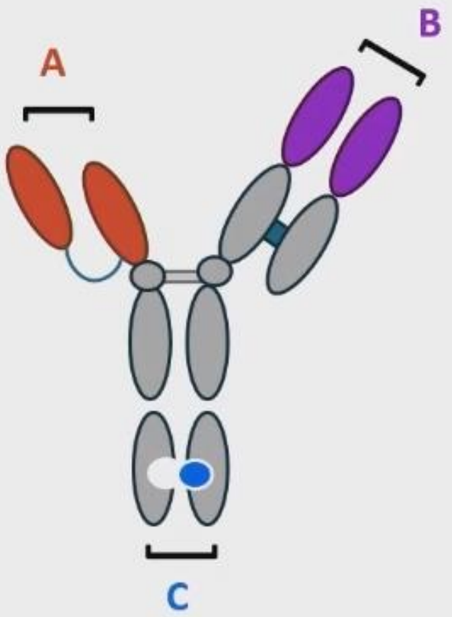
Etentamig (ABBV-383), a BCMA x CD3 bispecific antibody with a unique design

- Etentamig targets BCMA and CD3 on the surface of MM cells and T cells, respectively, resulting in T-cell activation and selective destruction of BCMA-positive MM cells
- Etentamig monotherapy showed promising results in heavily pretreated patients with RRMM in a phase 1 first-in-human dose-escalation study (NCT03933735)[1,2]
  - ORR of 65% (median follow-up of 12 months)
- Daratumumab may have the potential to eliminate immunosuppressor cells and reduce T-cell exhaustion[3]

Etentamig Design and Mechanism of Action



A: Bivalent BCMA binding

Designed for high avidity to target cell-surface BCMA

B: Low-affinity CD3 binding

Binding domain designed to reduce cytokine release, with potential for minimal T-cell exhaustion

C: Silenced-Fc tail, Q4W dosing

Allowing for extended half-life and simplified, convenient dosing (Q4W)

Here, we evaluate the safety and efficacy of combining etentamig with daratumumab and dexamethasone in patients with RRMM

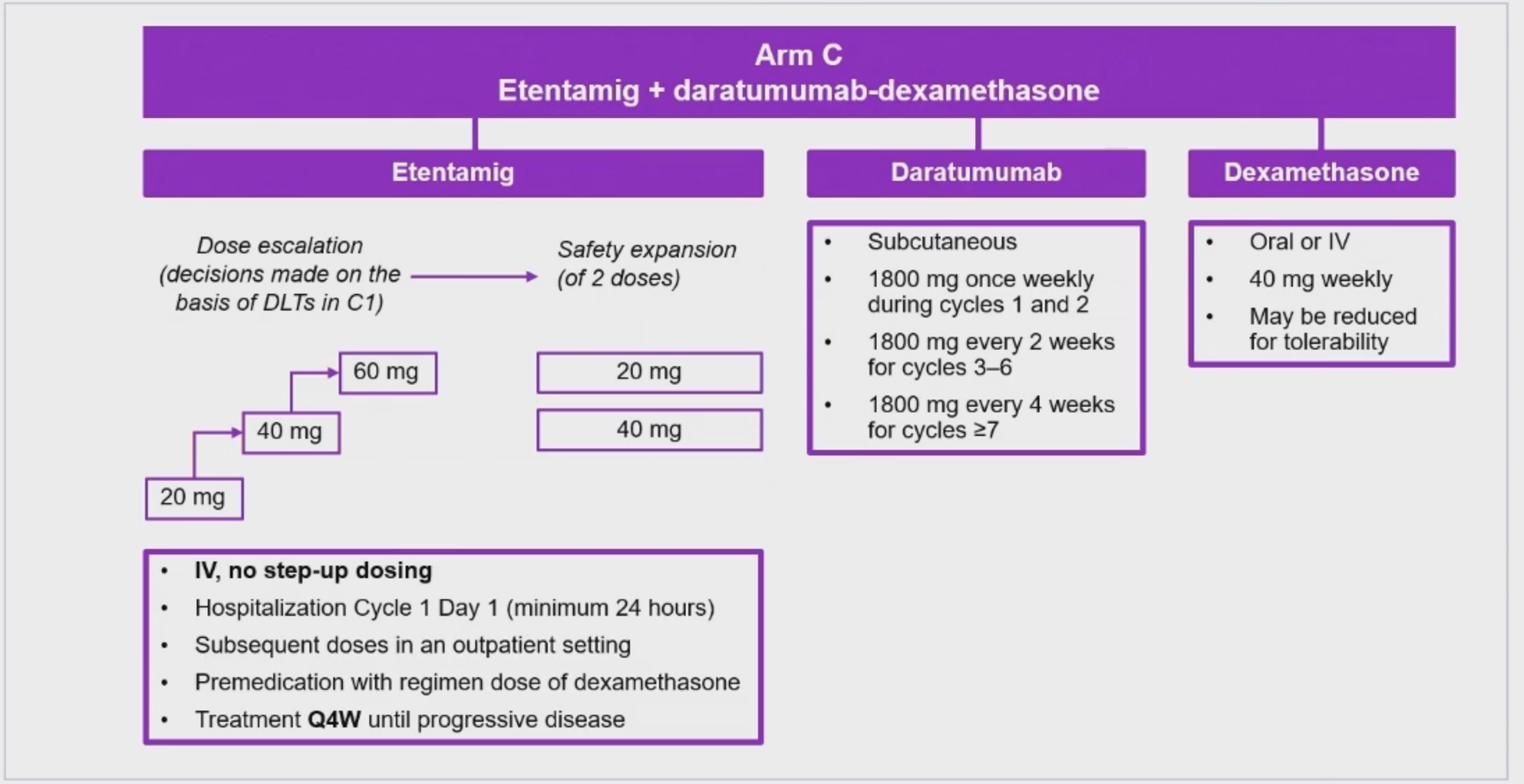
BCMA, B-cell maturation antigen; CRS, cytokine release syndrome; MM, multiple myeloma; ORR, overall response rate; Q4W, every 4 weeks; RRMM, relapsed/refractory multiple myeloma; VGPR, very good partial response.

1. Rodriguez Valdes C, et al. *J Clin Oncol*. 2024;42:7531. 2. Weisel K, et al. *HemaSphere*. 2024;8. Abstract 211. doi:10.1002/hem3.104. 3. Krejcik J, et al. *Blood*. 2016;128:384-394.

Rodriguez C et al ASH 2024

Arm C Kilimanjaro: etentamig + daratumumab-dexamethasone

Dosing Schema



C, cycle; DLT, dose-limiting toxicity; IV, intravenous; Q4W, every 4 weeks.

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Kilimanjaro Arm C: Safety Data

TEAEs, n (%)	20 mg n=37[b]		40 mg n=35[b]		60 mg n=14		Total N=86	
	Any grade	Grade 3–4	Any grade	Grade 3–4	Any grade	Grade 3–4	Any grade	Grade 3–4
Any TEAE	36 (97)	27 (73)	35 (100)	30 (86)	14 (100)	11 (79)	85 (99)	68 (79)
Hematologic[a]								
Neutropenia	13 (35)	11 (30)	20 (57)	19 (54)	8 (57)	8 (57)	41 (48)	38 (44)
Anemia	10 (27)	7 (19)	12 (34)	7 (20)	5 (36)	4 (29)	27 (31)	18 (21)
Thrombocytopenia	10 (27)	4 (11)	11 (31)	7 (20)	6 (43)	5 (36)	27 (31)	16 (19)
Nonhematologic[a]								
CRS	9 (24)	1 (3)	12 (34)	1 (3)	4 (29)	1 (7)	25 (29)	3 (4)
ICANS	1 (3)	0	1 (3)	0	1 (7)	1 (7)	3 (4)	1 (1)
Fatigue	9 (24)	1 (3)	10 (29)	0	3 (21)	0	22 (26)	1 (1)
Insomnia	10 (27)	1 (3)	7 (20)	0	2 (14)	1 (7)	19 (22)	2 (2)
Increased AST	2 (5)	1 (3)	6 (17)	2 (6)	4 (29)	0	12 (14)	3 (4)
Diarrhea	4 (11)	0	9 (26)	0	2 (14)	1 (7)	19 (22)	1 (1)
Cough	3 (8)	0	8 (23)	0	2 (14)	0	13 (15)	0
Upper respiratory infection	10 (27)	0	7 (20)	0	2 (14)	0	19 (22)	0
Infections	21 (57)	8 (22)	27 (77)	12 (34)	10 (71)	2 (14)	58 (67)	22 (26)

No new safety signals emerged with etentamig combination therapy when compared to prior monotherapy study, including grade 3/4 infection rates

[a]Cutoff: any grade TEAEs in ≥12.5% of patients. [b]Data combined for dose-escalation and safety expansion cohorts.
AST, aspartate aminotransferase; CRS, cytokine release syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome; TEAE, treatment-emergent adverse event.

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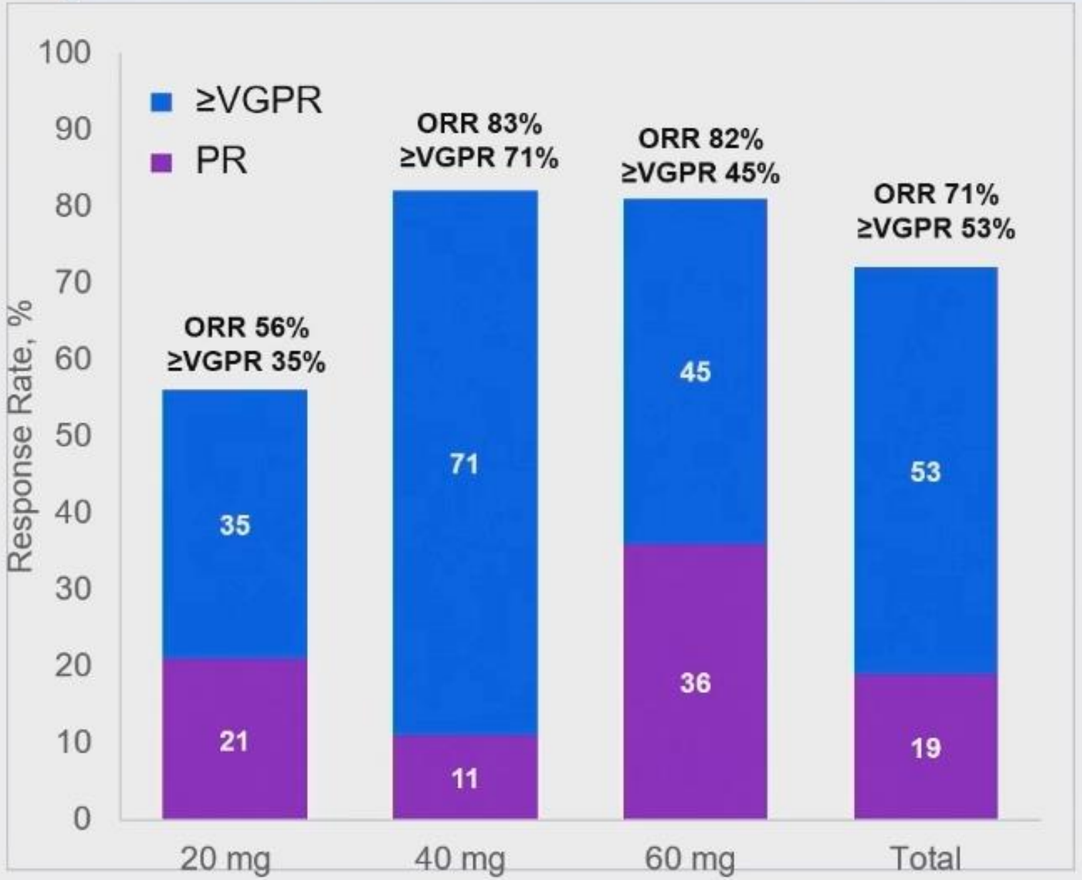
Kilimanjaro Arm C: Efficacy Data



	Etentamig + Daratumumab-Dexamethasone			
	20 mg n=34[a]	40 mg n=35[a]	60 mg n=11	Total N=80
Median follow-up, months[b] (range)	4 (0–17)	8 (1–13)	8 (1–10)	7 (0–17)
Median time to first response, months (range)	1.1 (1–6)	1.0 (1–4)	1.0 (0–1)	1.0 (0–6)
Depth of response				
sCR/CR	5 (15)	14 (40)	3 (27)	22 (28)
MRD neg ($<10^{-5}$) among evaluable sCR/CR	1/2 (50)	12/12 (100)	3/3 (100)	16/17 (94)

Responses expected to deepen with continued follow-up

Preliminary efficacy suggests etentamig + daratumumab-dexamethasone achieves deep responses

[a]Data combined for dose-escalation and safety expansion cohorts. [b]Based on N=86 total patients in the Full Analysis Set. Median follow-up is 16 months (1–17) and 4 months (0–5) for 20-mg dose-escalation and -expansion cohorts, respectively, and 13 months (9–13) and 7 months (1–9) for 40-mg dose-escalation and safety expansion cohorts, respectively.
ORR, overall response rate; PR, partial response; VGPR, very good partial response, MRD negativity determined by NGS (ClonoSEQ)

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Summary

- Exciting data supporting early treatment with daratumumab for high risk SMM – AQUILA trial

- Continued data supporting quad induction in transplanted and non-transplanted patients
  - MRD dynamics – deepening of responses (IMROZ) and progression (MASTER)
  - Frailty adjusted treatment (UK trial)

- Relapsed MM
  - For the first time, maybe a less toxic, efficacious BCMA CAR T(Immagine1)- - phase 3 will start soon
  - Updates on BCMA BsAb – Etentamig
  - Talquetamab bridging – US Myeloma Immunotherapy Consortium

Fred Hutch
Cancer Center

Thank you

Questions?
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