

IN PURSUIT OF *YOUR CURE.*<sup>®</sup>

# Early Disease, Immunological Prevention, and Curative Strategies

## The Future of Multiple Myeloma

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*Sao Paulo, Brazil  
May 15,  
2026*



**MYELOMA  
INSTITUTE**



@SylvesterCancer



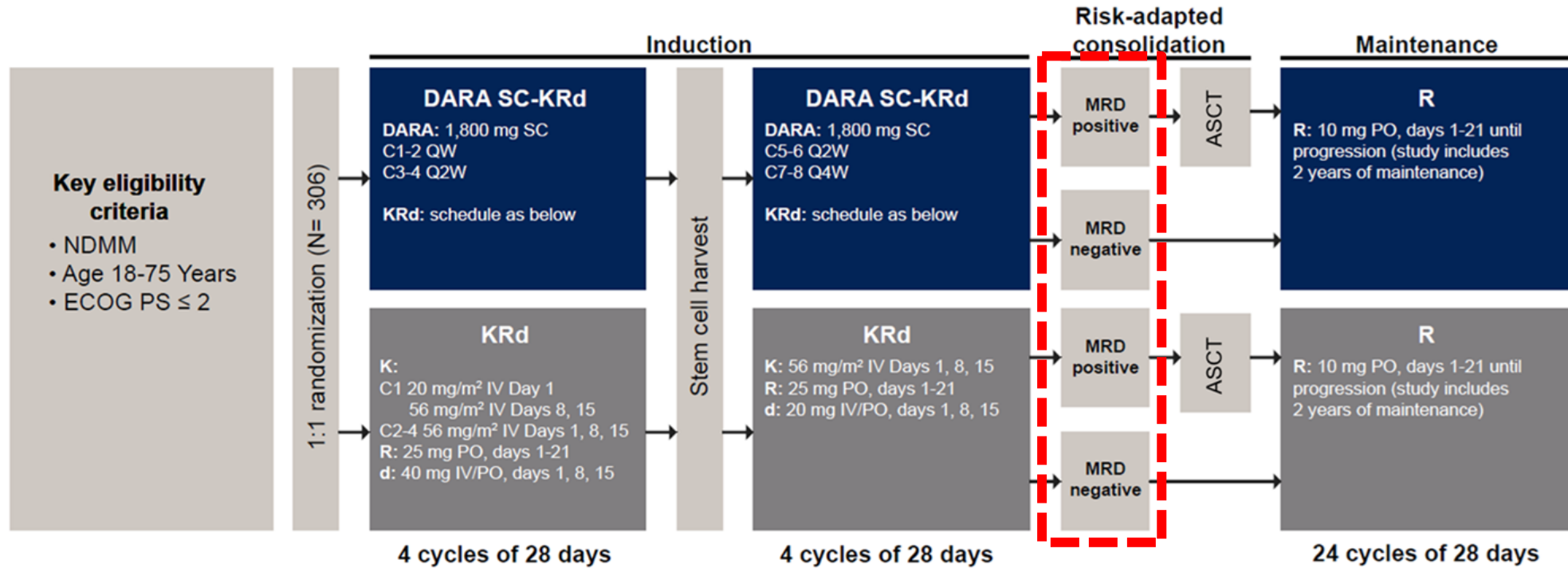
# Disclosures

- Grant support: NCI, NIH, FDA, LLS, Rising Tide Foundation, MMRF, IMF, Riney Family Foundation, Perelman Family Foundation, Myeloma Solutions Fund, Tow Foundation, Amgen, Celgene, J&J, Pfizer, Abbvie
- Honoraria/ad boards: AbbVie, Adaptive, Amgen, Binding Site, BMS, Celgene, GSK, J&J, Juno, Pfizer, Sanofi
- Chairman for “Medscape Myeloma”: 2014-ongoing
- Chairman for “Myeloma Rounds in the US” (CME): 2023-ongoing
- Independent Data Monitoring Committee (IDMC): Takeda, Merck, J&J, Novartis, Arcellx/Kite

# Outline

- Bispecific monoclonal antibodies in newly diagnosed myeloma (NDMM)
- Immuno-consolidation
- Novel MRD tracking
- Better imaging to identify (all) disease
- Treating (even) earlier

# ADVANCE 1.0: Phase 2 Study for NDMM



**Primary endpoint:** Overall MRD negativity rate  $\geq$ VGPR

**Key secondary endpoints:** PFS, EFS,  $\geq$ CR, OS, Safety, MRD negativity rate in peripheral blood

Transplant-eligible patients with MRD  $\geq 10^{-5}$  by NGS after combination therapy were recommended to proceed with high-dose melphalan chemotherapy followed by autologous stem cell transplant (ASCT)

MRD negativity rate was defined as the proportion of patients who achieved both MRD negativity and  $\geq$ VGPR in the ITT population. Patients who were not evaluable for MRD testing were considered MRD positive.

# ADVANCE 2.0: Phase 2 Study for NDMM (NCT06997081)

## Key eligibility criteria

NDMM  
Age  $\geq 18$   
ECOG PS  $\leq 2$

Total N=150

## Dosing schedule

### Cycle 1

Elranatamab, SUD D1,3  
Elranatamab 76mg sc, D8,15,22  
Dexamethasone 20 mg PO,  
D1,2,8,15,22

### Cycle 2-6

Elranatamab 76mg sc, D1,15  
**Dexamethasone 8 mg** PO, D1,15  
Lenalidomide 25 mg, D1-21  
+/- Carfilzomib 56 mg/m<sup>2</sup> D1,8,15

### Cycle 7-24

Elranatamab 76mg sc, D1  
Lenalidomide\*, D1-21  
  
\*25 mg C7-12, then 10mg

ADVANCE 2.0 is open for transplant eligible (TE), transplant deferred (TD), and transplant ineligible (TI) patients

## Primary endpoint

Overall MRD negativity rate  $\geq$ VGPR at 12 months

## Key secondary endpoints

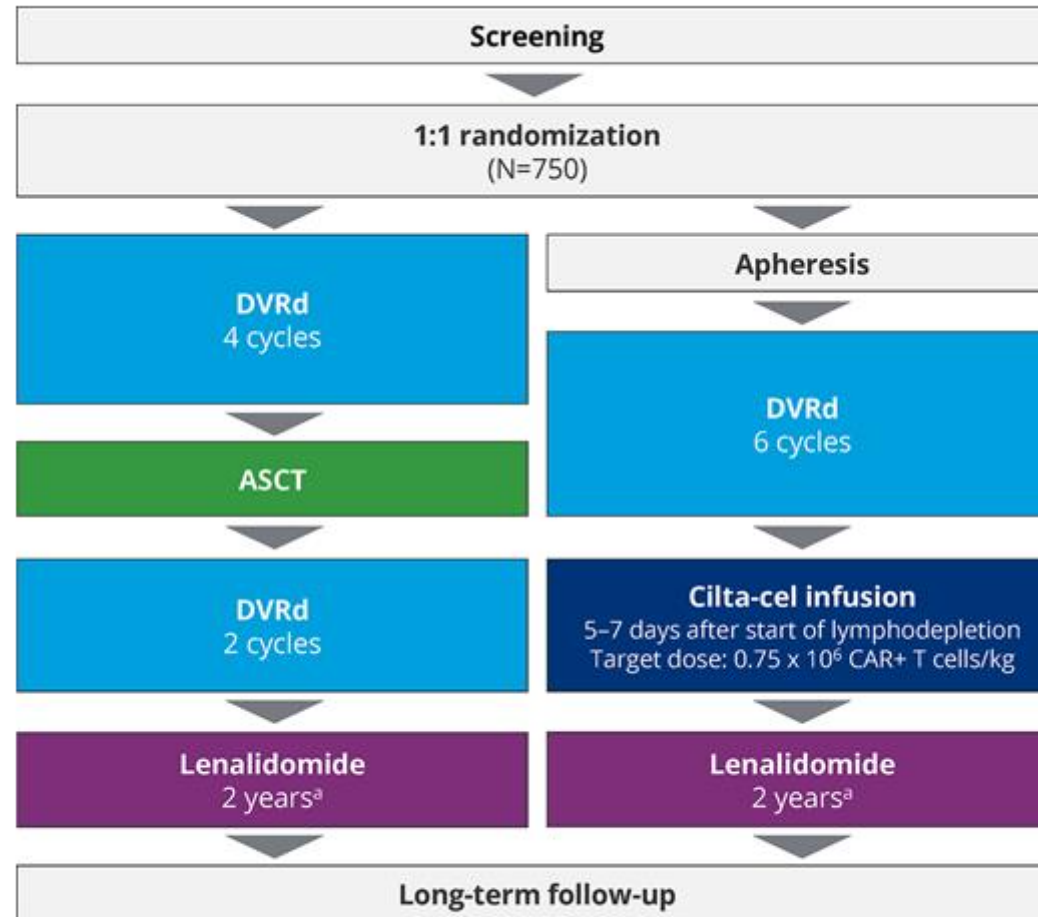
PFS, OS, clinical response per IMWG, safety, MRD negativity rate in blood, correlative studies

# Outline

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- **Immuno-consolidation**
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# D-VRd Followed by Cilta-Cel or HDM (Emagine/CARTITUDE-6)

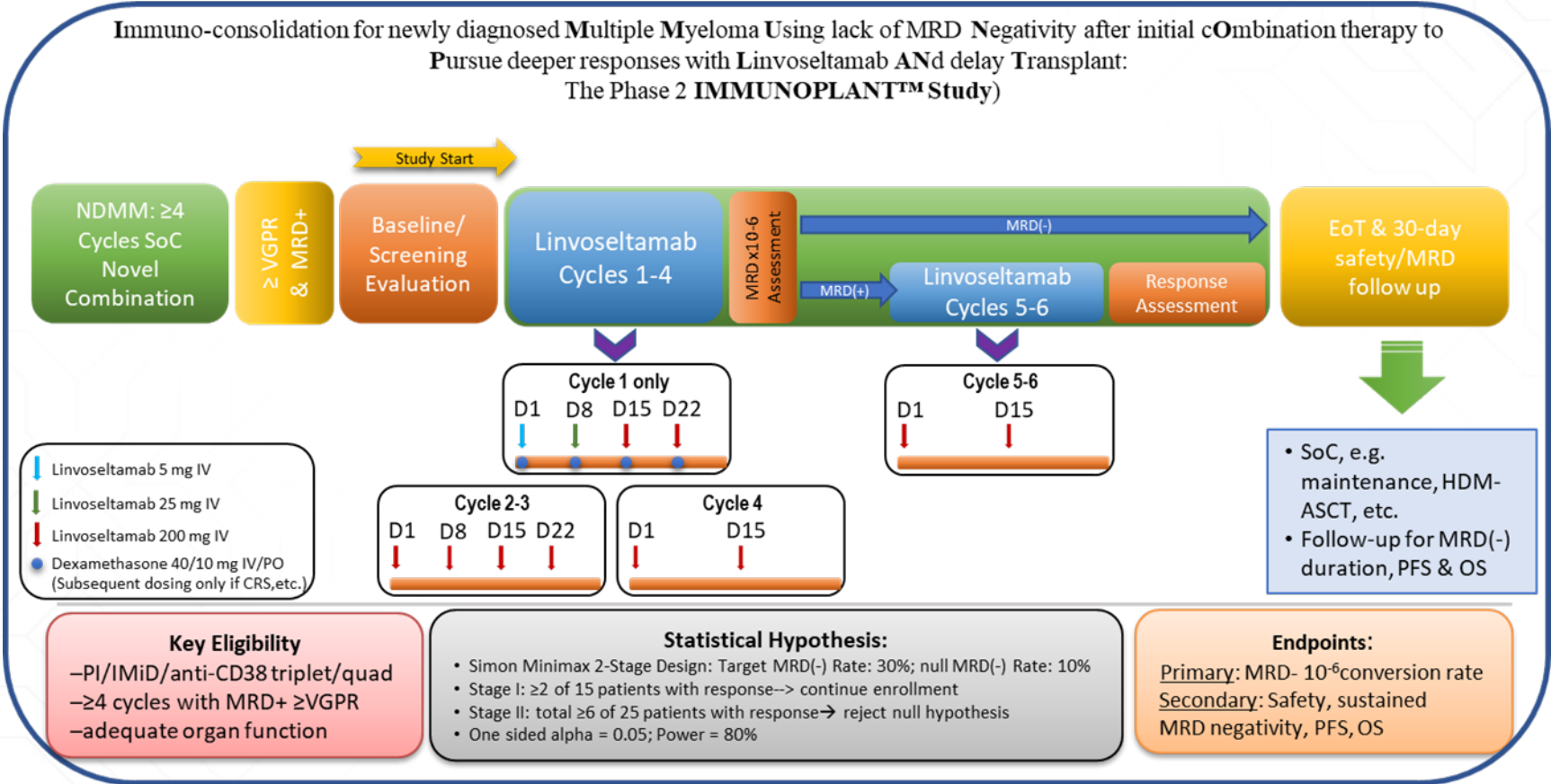
Eligible patients are aged  $\geq 18$  years with NDMM per IMWG diagnostic criteria, have measurable disease at screening, and have high-dose therapy and ASCT as part of their intended initial treatment plan



<sup>a</sup>Patients benefiting from therapy have the option to continue lenalidomide therapy until progressive disease per investigator's discretion after benefit-risk assessment and review by the medical monitor.

# ImmunoPLANT: Phase 2 Study (NCT06376526)

## Immuno-Consolidation



# ImmunoPLANT: Phase 2 Study, Immuno-Consolidation

Patient Demographics	N=25
Median age, years (range)	62 (40-77)
≥65, n (%)	8 (32)
Female, n (%)	8 (32)
ECOG PS, n (%)	
0	19 (76)
1	6 (24)
Ethnicity/Race, n (%)	
Black	4 (16)
Hispanic	11 (44)

Disease Characteristics	N = 25
MM Isotype, n (%)	
IgG	13 (52)
IgA	5 (20)
IgD	1 (4)
Light Chain only	6 (24)
FISH/Cytogenetics, n (%)	
High-Risk	7 (28)
Standard	14 (56)
Unknown	4 (16)
Median # of Initial Induction Cycles (range)	8 (6-13)
Initial NDMM Regimens, n (%)	
D-VRd	8 (32)
KRd	8 (32)
D-KRd	7 (28)
DRd	1 (4)
Isa-VRd	1 (4)
MRD+ ClonoSEQ at Study Start, n (%)	25 (100)
sCR	4 (16)
VGPR	21 (84)

# ImmunoPLANT: Phase 2 Study, Immuno-Consolidation

Data Cut-off date: November 1, 2025

Linvo Start  
ClonoSEQ  
BM MRD+  
N=25

Linvo C1-4

Start C5-6,  
n=2

Post C6 BMBx, N=1  
NGS <math>10^{-6}</math> MRDneg: 1/1  
Flow <math>10^{-5}</math> MRDneg: 1/1

Linvo C5-6

SoC Maintenance Len-based

6-Month Post Linvo BMBx, N=10  
BM MRD negativity, n (%)  
NGS <math>\leq 10^{-6}</math> MRDneg: 10 (100; 95%CI: 69.2-100%)  
Flow <math>\leq 10^{-5}</math> MRDneg: 10 (100; 95%CI: 69.15-100%)

Received >math>\geq 1</math>C  
N=25  
MM Biochemical  
Response, n (%)  
sCR: 22 (88.0)  
VGPR: 3 (12.0)

Post C4 BMBx, N=19  
BM MRD negativity, n (%)  
NGS <math>10^{-6}</math> MRDneg: 17 (89.5)  
(95% CI: 66.9-98.7%)  
Flow <math>10^{-5}</math> MRDneg: 19 (100)  
(95%CI: 82.4-100%)  
MM Biochemical Response, n (%)  
sCR: 17 (89.5)  
VGPR: 2 (10.5)

12-Month Post Linvo BMBx  
Pending

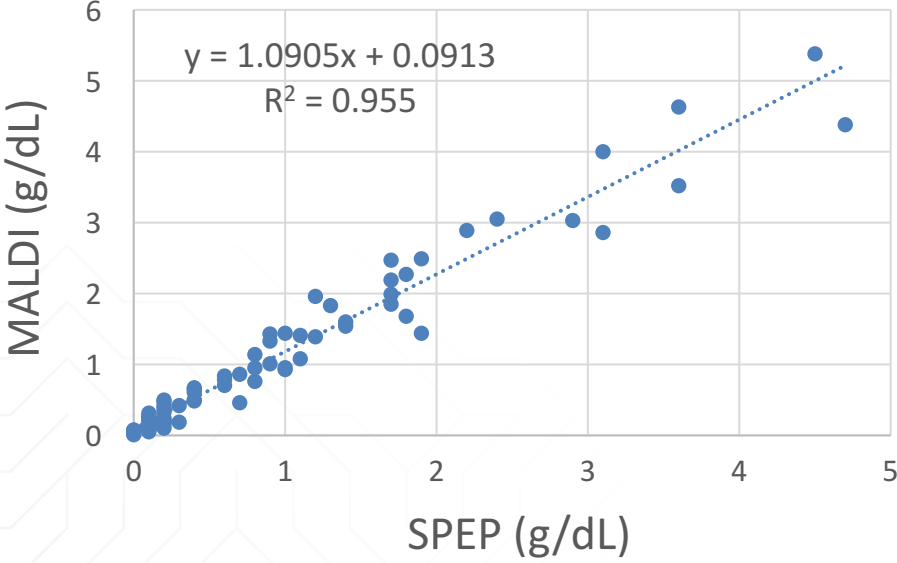
24-Month Post Linvo BMBx  
Pending

Overall Post Livoseltamab Response  
BM MRD negativity, n/N (%)  
NGS <math>10^{-6}</math> MRDneg: 18/18 (100; 95%CI: 81.5-100%)  
Flow <math>10^{-5}</math> MRDneg: 19/19 (100; 95%CI: 82.4-100%)

# Outline

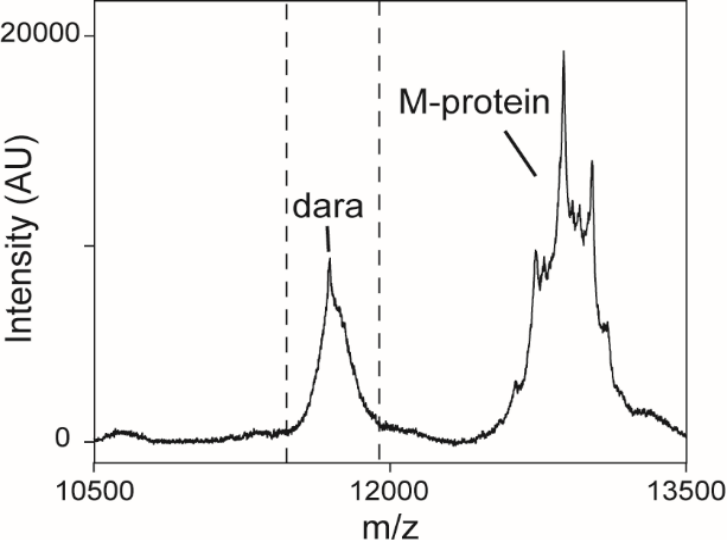
- Bispecific monoclonal antibodies in newly diagnosed myeloma (NDMM)
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# MALDI-TOF Mass Spectrometry of Peripheral Blood



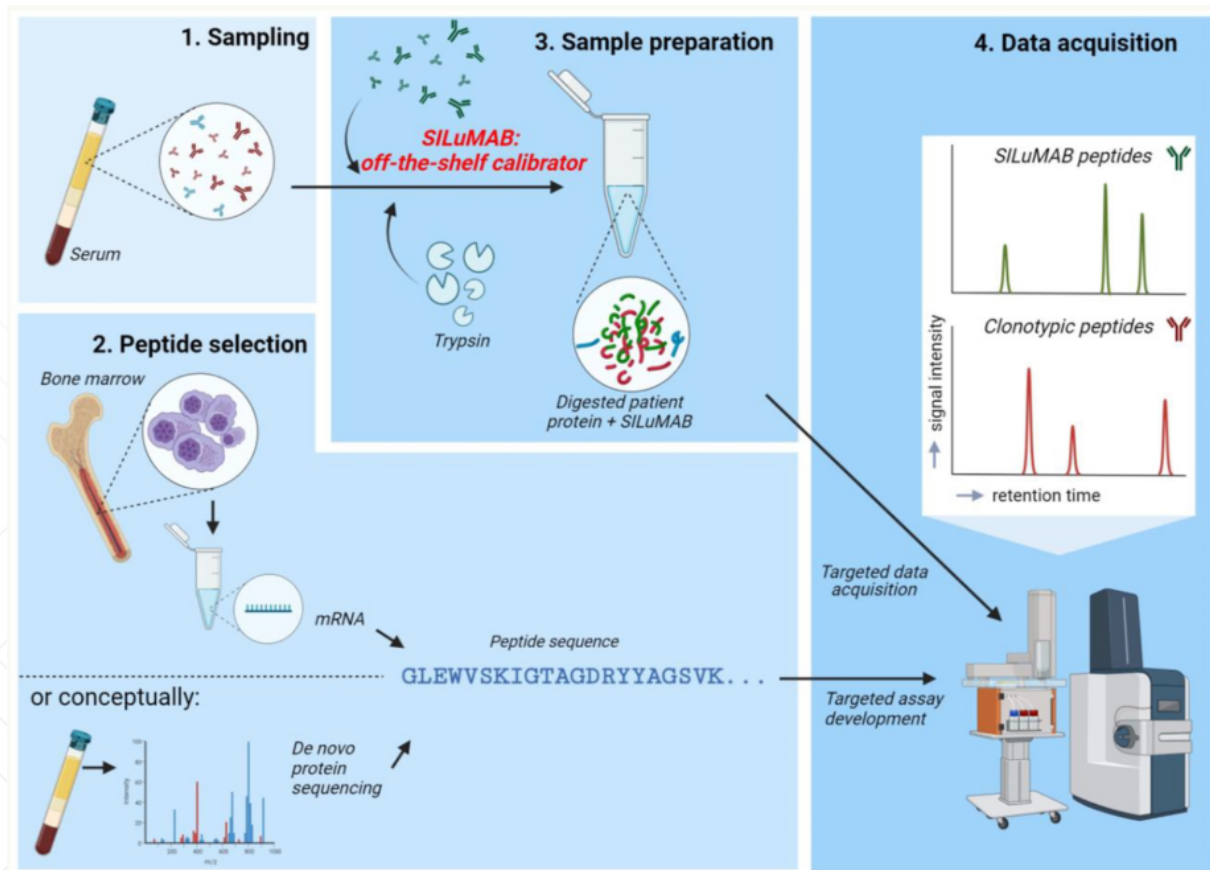
Isotype	m/z	g/dL
IgGk	11,713.2	0.0961
IgGk	11,691.1	0.0531

QData



Eveillard M et al and Thoren K. *Br J Haematol.* 2020;189:904

# Clonotypic Peptide Mass Spectrometry for MRD Testing



**1. Sampling:** patient serum sample is required

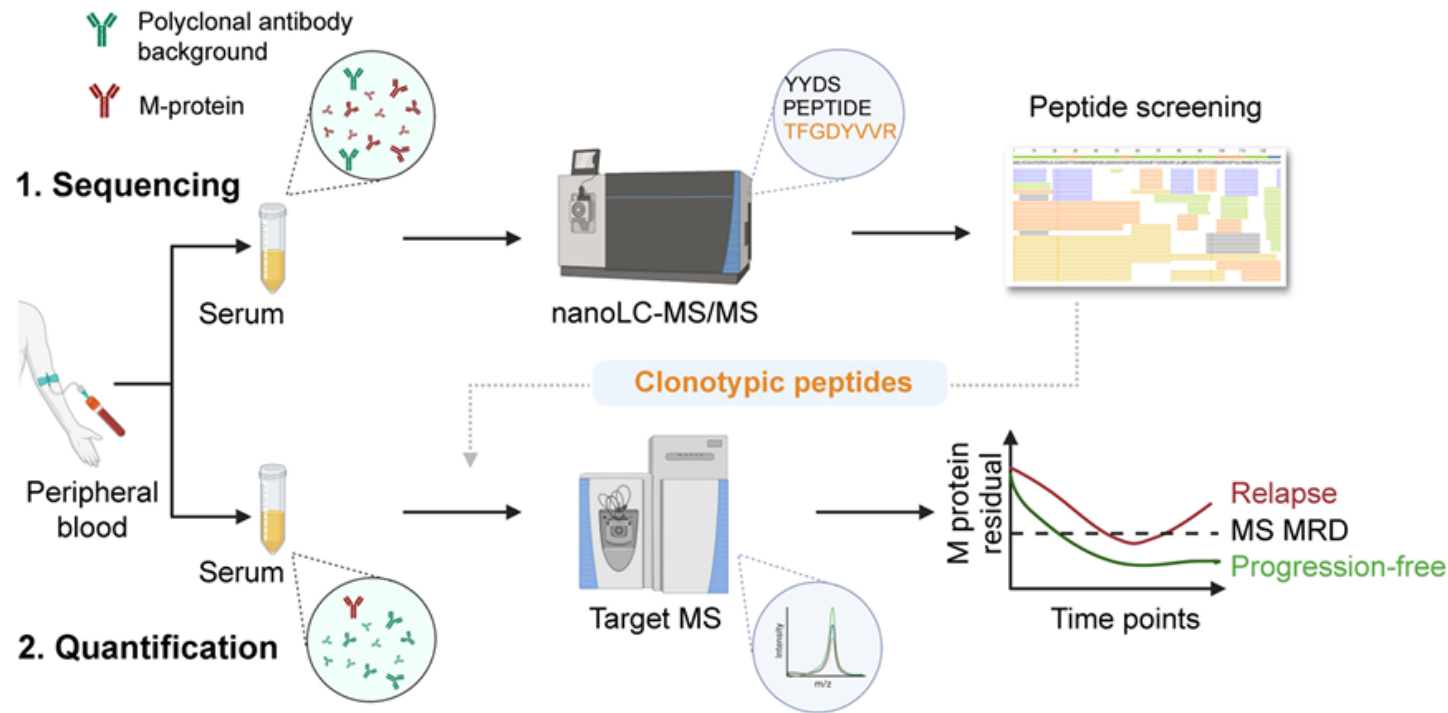
**2. Peptide selection:** clonotypic peptides can either be determined from mRNA (from bone marrow), or *de novo* peripheral blood serum sample

**3. Sample preparation:** stable-isotope labelled human IgG-Kappa (off-the-shelf calibrator) is spiked in the serum and the sample is digested

**4. Data acquisition:** samples are analyzed by liquid-chromatography tandem mass spectrometry

Ultra sensitive, no interference with polyclonal background or MoAb's, can monitor multiple sequences

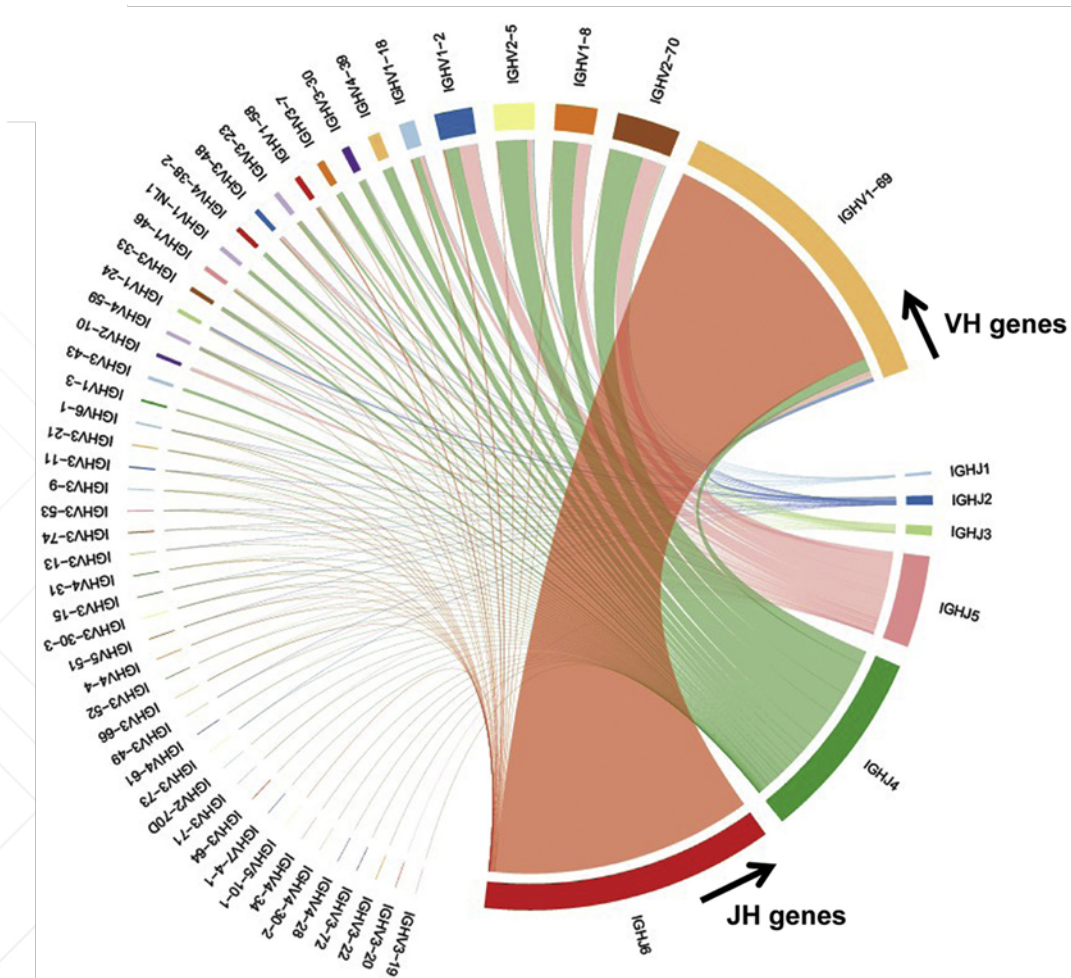
# Clonotypic Peptide Mass Spectrometry for MRD Testing (*cont.*)



**Step 1:** the M-protein is *de novo* sequenced from diagnostic serum of patients, then specific clonotypic peptides were selected for quantification   
**Step 2:** unique patient-specific tryptic peptides from heavy and light chains are measured throughout all time points

Ultra sensitive, no interference with polyclonal background or MoAb's, can monitor multiple sequences

# Cell-Free DNA Whole Genome Sequencing of Peripheral Plasma



cfWGS demonstrated 82% concordance with Clonotypic Peptide Mass Spec (n=11), 67% with PET (n=6), 50% with MFC (n=12), and 25% with clonoSEQ (n=8).

The lower concordance rates with MFC and clonoSEQ were primarily due to cfWGS detecting additional positive cases missed by these methods but identified as positive by Clonotypic Peptide Mass Spec. For example, cfWGS identified four clonoSEQ-negative cases as positive, with one case leading to relapse within a year.

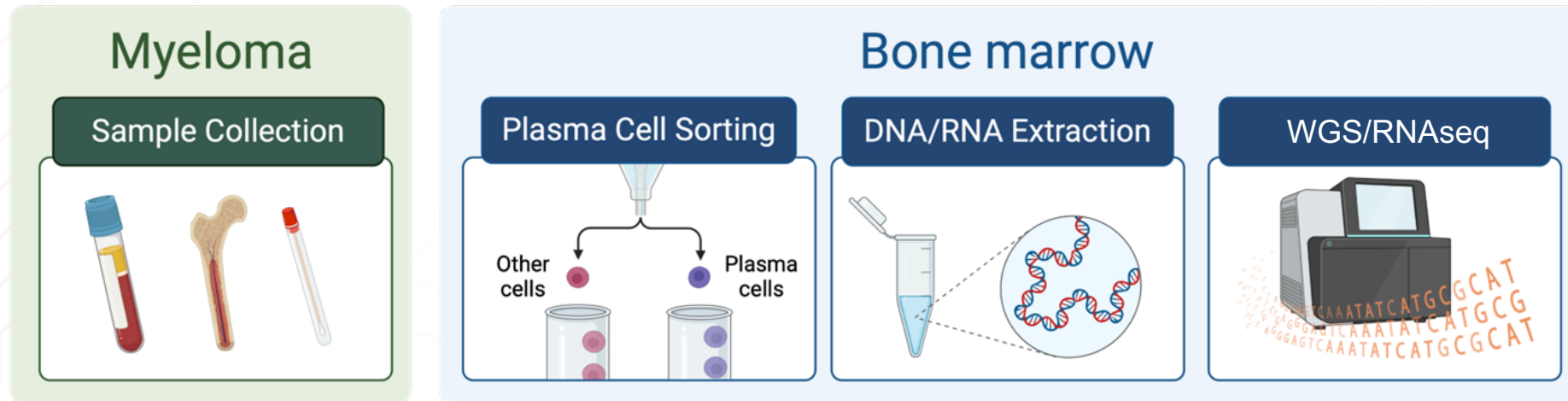
Conversely, two clonoSEQ-positive cases were below the LOD for cfWGS.

There is need for further method optimization.

# Urgent Need: FISH/Cytogenetics → Molecular Profiling

Myeloma field needs molecular profiling for standard-of-care bone marrow samples:

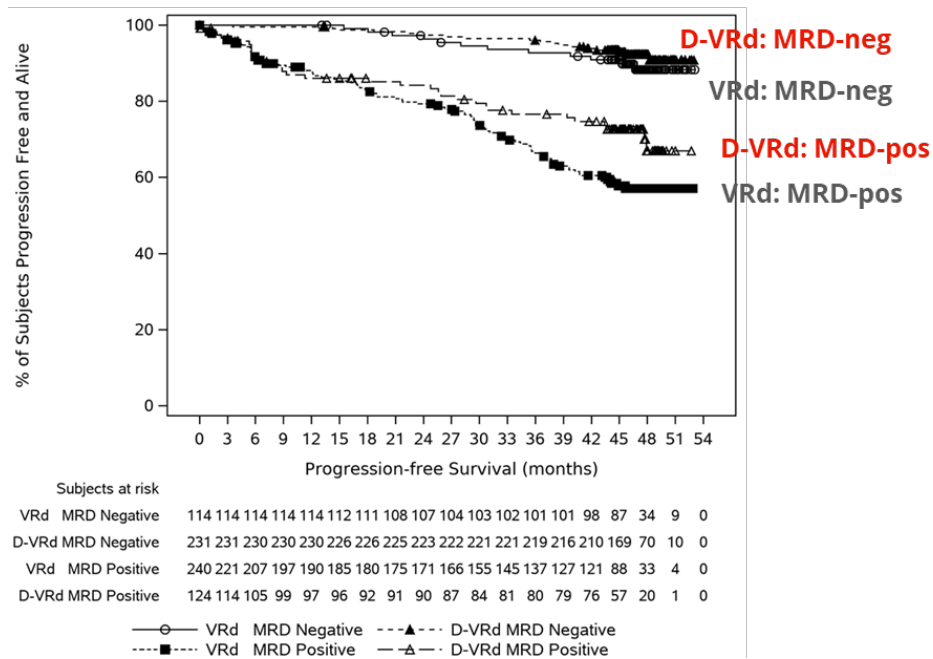
- **Mutational status in real-time** (e.g., biallelic losses, *TP53* mutations, for targeted therapies)
- Access to genomic **data for discovery science**



# Future Directions: We Need Precision Medicine!

## Some patients achieve MRD negativity with less therapy

PFS According to MRD Status (10<sup>-6</sup>)



D-VRd: 65.1% MRD neg

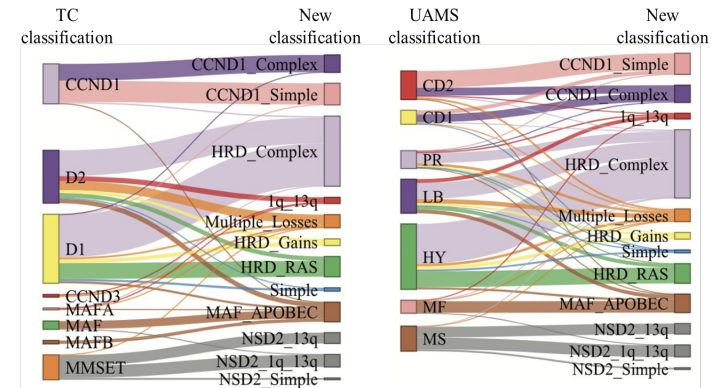
VRd: 32.3% MRD neg

Abstract #7502; Rodríguez-Otero *et al*

Original Reports | Hematologic Malignancy

### Genomic Classification and Individualized Prognosis in Multiple Myeloma

Francesco Maura, MD<sup>1</sup>; Arjun Raj Rajanna, MSc<sup>1</sup>; Bachisio Ziccheddu, MSc<sup>1</sup>; Alexandra M. Poos, PhD<sup>2,3</sup>; Andriy Derkach, PhD<sup>4</sup>; Kylee MacLachlan, MD, PhD<sup>5</sup>; Michael Durante, MD, PhD<sup>6</sup>; Benjamin Diamond, MD<sup>1</sup>; Marios Papadimitriou, MD<sup>1</sup>; Faith Davies, MD<sup>6</sup>; Eileen M. Boyle, MD<sup>6</sup>; Brian Walker, PhD<sup>7</sup>; Malin Hultcrantz, MD, PhD<sup>8</sup>; Ariosto Silva, PhD<sup>9</sup>; Oliver Hampton, PhD<sup>9</sup>; Jamie K. Teer, PhD<sup>10</sup>; Erin M. Siegel, PhD<sup>11</sup>; Niccolò Bolli, MD, PhD<sup>12,13</sup>; Graham H. Jackson, MD, PhD<sup>14</sup>; Martin Kaiser, MD<sup>15</sup>; Charlotte Pawlyn, MD, PhD<sup>16</sup>; Gordon Cook, MD, PhD<sup>17</sup>; Dickran Kazandjian, MD<sup>18</sup>; Caleb Stein, PhD<sup>17</sup>; Marta Chesi, PhD<sup>17</sup>; Leif Bergsagel, MD, PhD<sup>17</sup>; Elias K. Mai, MD<sup>2</sup>; Hartmut Goldschmidt, MD<sup>2</sup>; Katja C. Weisel, MD<sup>18</sup>; Roland Fenk, MD, PhD<sup>19</sup>; Marc S. Raab, MD<sup>2,3</sup>; Fritz Van Rhee, MD, PhD<sup>20</sup>; Saad Usmani, MD<sup>3</sup>; Kenneth H. Shain, MD, PhD<sup>9</sup>; Niels Weinhold, PhD<sup>2,3</sup>; Gareth Morgan, MD, PhD<sup>9</sup>; and Ola Landgren, MD, PhD<sup>15</sup>



New genomic classification allows us to better decipher clinical and biological heterogeneity

Maura F, *et al*. J Clin Oncol. 2024

# Outline

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# Novel Imaging for Multiple Myeloma: CD38 Targeted ImmunoPET



76 y/o male  
with multiple  
myeloma

Slowly rising  
blood markers

# Novel Imaging for Multiple Myeloma: CD38 Targeted ImmunoPET

- CD38-targeted immunoPET successfully identifies and localizes active myeloma disease, **even in some patients where the myeloma cells are not FDG-avid**
- In ~30% of the participants, **immunoPET identified more sites of disease than standard-of-care FDG PET/CT, including 7 patients where disease was only detected on immunoPET**
- In two cases that were negative by standard-of-care FDG PET/CT, we found **more than 100 sites of detectable disease using immunoPET**
- **Overall, targeted immunoPET-based imaging has higher sensitivity compared to metabolic-based standard-of-care FDG PET/CT**

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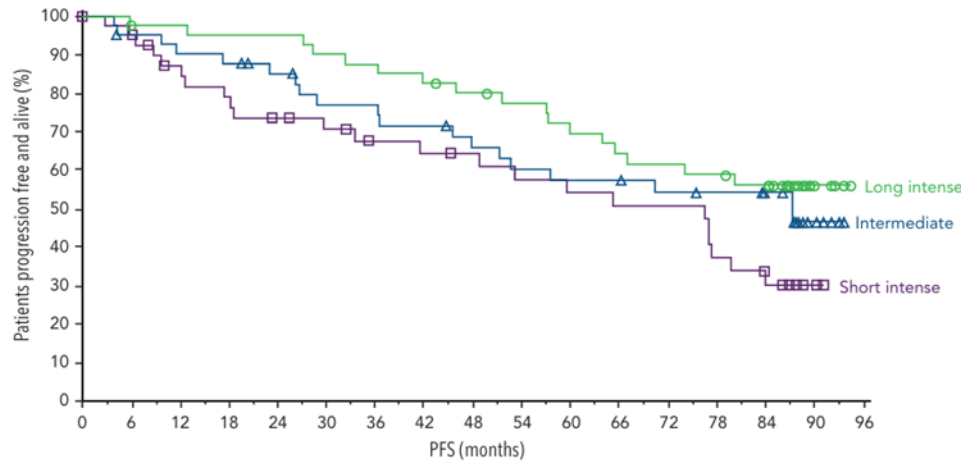
# Myeloma Precursor Disease and Approaches for Intervention

## High points

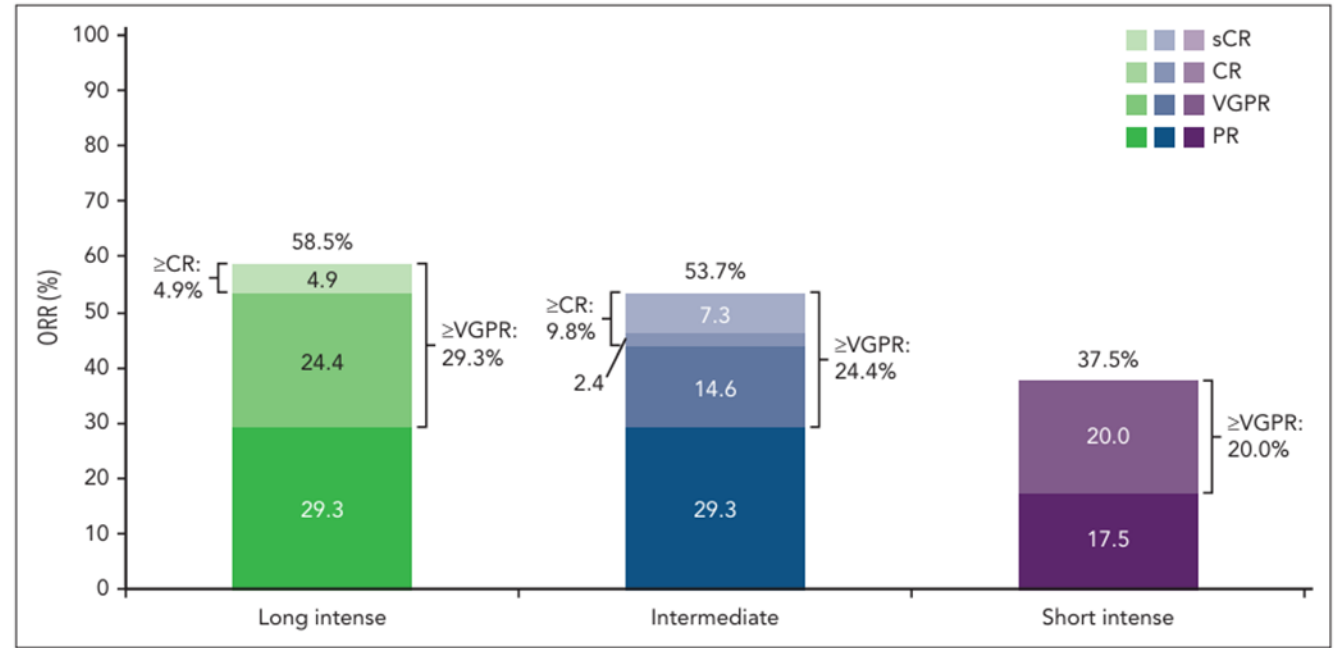
- Less is more, focus on avoiding toxicities
- Simplicity
- The disease may not be (easily) curable (?), but it is controllable



# Daratumumab Monotherapy: CENTAURUS Phase 2 Trial



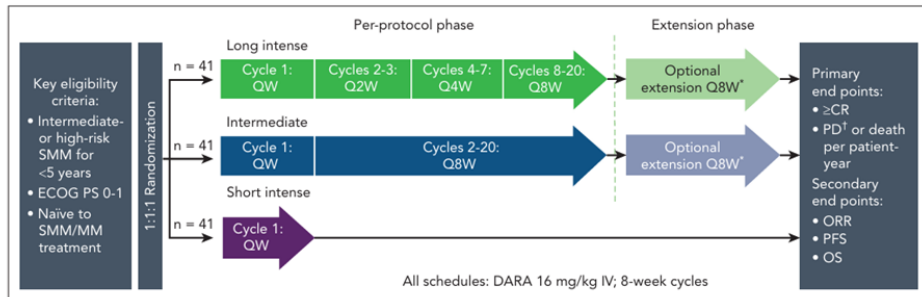
Continued clinical activity of daratumumab monotherapy in intermediate- or high-risk SMM after ~7 years of follow-up with no new safety concerns



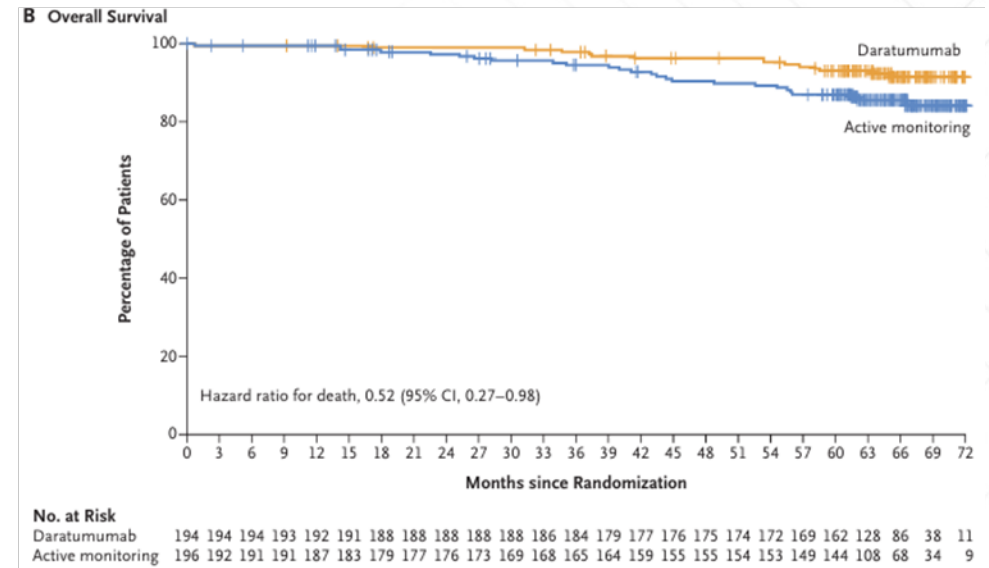
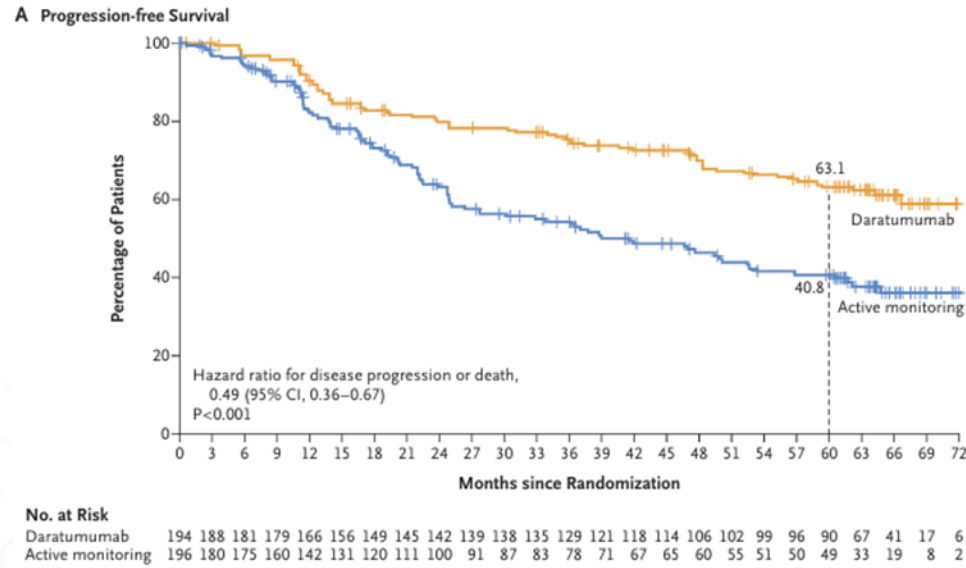
**Figure 2. Best investigator-assessed ORR.** Response was assessed according to IMWG guidelines<sup>19,20</sup> inclusive of extension phase in the response-evaluable population (patients who had measurable disease at baseline, received ≥1 dose of study treatment, and had ≥1 postbaseline disease assessment). ≥CR, CR or better; PR, partial response; sCR, stringent CR; VGPR, very good partial response; ≥VGPR, VGPR or better.

Patients at risk:

Long intense	41	41	39	39	39	38	38	38	38	38	37	36	35	34	34	33	31	31	29	29	27	26	25	23	23	22	20	20	15	5	2	0	0
Intermediate	41	41	38	38	36	36	35	33	32	29	28	28	26	26	26	24	23	21	21	20	20	20	19	18	18	17	17	16	14	5	2	0	0
Short intense	41	39	37	34	31	30	28	27	26	25	24	22	21	21	20	19	18	18	17	17	16	16	15	15	15	11	10	6	2	0	0	0	



# Daratumumab Monotherapy: AQUILA Phase 3 Trial



Total of 390 enrolled patients: 194 daratumumab and 196 active-monitoring. Median follow-up of 65.2 months. **Risk of disease progression or death was 51% lower with daratumumab than with active monitoring (hazard ratio, 0.49; 95% confidence interval [CI], 0.36 to 0.67; P<0.001). Progression-free survival at 5 years was 63.1% with daratumumab and 40.8% with active monitoring. Overall survival at 5 years was 93.0% with daratumumab and 86.9% with active monitoring**

**Among patients with high-risk smoldering multiple myeloma, subcutaneous daratumumab monotherapy associated with a significantly lower risk of progression to active multiple myeloma or death and with higher overall survival than active monitoring. No unexpected safety concerns identified**

# Myeloma Precursor Disease and Approaches for Intervention

## High points

- Less is more, focus on avoiding toxicities
- Simplicity
- The disease may not be (easily) curable (?), but it is controllable



## High points

- High risk smoldering myeloma = “early multiple myeloma”
- Use effective combination therapy
- Effective combination therapy for this indication may have a shot on goal for a cure (?)

# First KRd-Based High-Risk SMM Study: BETHESDA Phase 2 Trial



September 16, 2021

## Carfilzomib, Lenalidomide, and Dexamethasone Followed by Lenalidomide Maintenance for Prevention of Symptomatic Multiple Myeloma in Patients With High-risk Smoldering Myeloma

### A Phase 2 Nonrandomized Controlled Trial

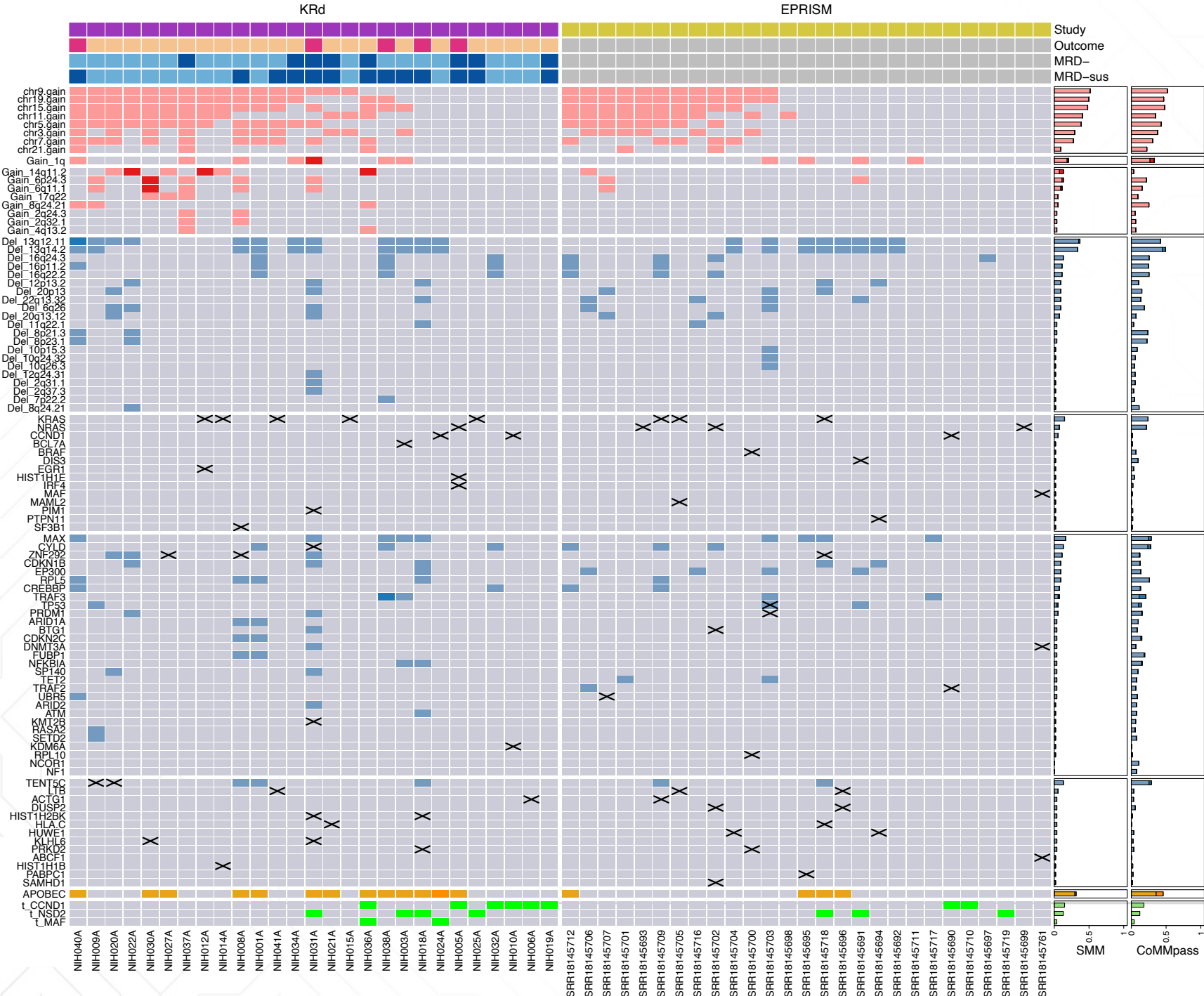
Dickran Kazandjian, MD<sup>1,2</sup>; Elizabeth Hill, MD<sup>1</sup>; Alexander Dew, DO<sup>1,3</sup>; Candis Morrison, PhD<sup>1</sup>; Joseph Roswarski, MD<sup>1,3</sup>; Neha Korde, MD<sup>1,4</sup>; Michael Emanuel, RN<sup>1</sup>; Ani Petrosyan, BS<sup>1</sup>; Manisha Bhutani, MD<sup>1,5</sup>; Katherine R. Calvo, MD, PhD<sup>6</sup>; Alina Dulau-Florea, MD<sup>6</sup>; Mary Kwok, MD<sup>1,7</sup>; Min-Jung Lee, PhD<sup>8</sup>; Sunmin Lee, PhD<sup>8</sup>; Liza Lindenberg, MD<sup>9</sup>; Sham Mailankody, MD<sup>1,4</sup>; Elisabet Manasanch, MD<sup>1,10</sup>; Irina Maric, MD<sup>6</sup>; Esther Mena, MD<sup>9</sup>; Nisha Patel, DO<sup>6</sup>; Nishant Tajeja, MD<sup>1,11</sup>; Jane B. Trepel, PhD<sup>8</sup>; Baris Turkbey, MD<sup>9</sup>; Hao-Wei Wang, MD, PhD<sup>12</sup>; Weixin Wang, PhD<sup>6</sup>; Constance Yuan, MD, PhD<sup>12</sup>; Yong Zhang, PhD<sup>1</sup>; Raul Braylan, MD<sup>6</sup>; Peter Choyke, MD<sup>9</sup>; Maryalice Stetter-Stevenson, MD, PhD<sup>12</sup>; Seth M. Steinberg, PhD<sup>13</sup>; William D. Figg Sr, PharmD<sup>14</sup>; Mark Roschewski, MD<sup>1</sup>; Ola Landgren, MD, PhD<sup>1,2</sup>

[» Author Affiliations](#) | [Article Information](#)

*JAMA Oncol.* 2021;7(11):1678-1685. doi:10.1001/jamaoncol.2021.3971

**Patient population:** High-risk SMM (N=54)  
**Treatment:** “KRd” x 8 → 2 yrs LEN maintenance  
**MRD:** 70% of pts achieved sustained MRD negativity  
**Progression to myeloma:** 9% at 8 years





**Outcome**  
 Progression  
 No progression  
 MRD-  
 MRD+  
 NA

**Alterations**  
 gain  
 amp  
 monoallelic  
 biallelic  
 snv  
 apobec  
 hyperapobec  
 translocation

# Treated high-risk SMM is less complex than NDMM

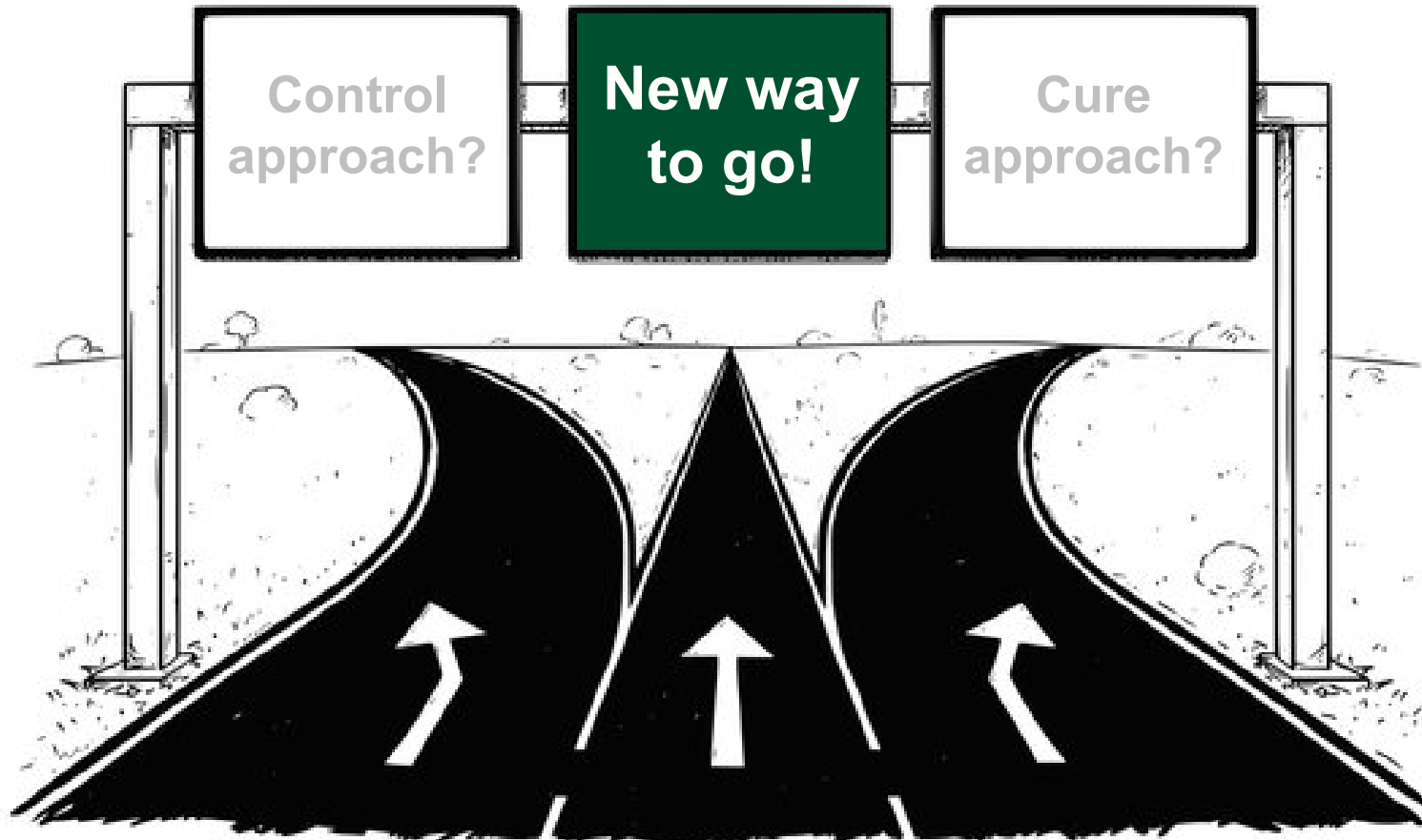
Combination of Driver Gene Mutations and CNV at Driver Loci (n = 139)

HR-SMM vs. NDMM has less

- Gain/Amp 1q
- MYC amplification
- RAS pathway mutations
- Inactivation of tumor suppressor genes
- APOBEC

Kazandjian et al. Clin Cancer Research 2024

# Myeloma Precursor Disease and Approaches for Intervention



# Immuno-PRISM: a Randomized Phase 2 Trial (NCT05469893)

**Dana-Farber.** Randomized, phase 2, study evaluating teclistamab vs lenalidomide and dexamethasone in HR-SMM (2:1 randomization; 2 years lenalidomide/dex). Target: 30 vs 15 pts total

- Eligibility criteria included HR-SMM per Mayo 2018 “20-2-20” model, total IMWG risk score of 9 or greater, and other previously established high-risk criteria
- At the time of data cut off, 19 patients have been enrolled to study with median follow up of 6 months. The median age is 59 years old (range 35-73) with 9 females (47%) and 10 males (53%). Sixty-four percent of patients that had evaluable FISH results had high-risk abnormalities as follows: 1q gain (7 pts), t(4;14) 1 patient
- In the teclistamab-treated cohort (12 patients), the **ORR is 100% with 42% achieving a CR, 25% VGPR, 33% PR**. Four patients with high-risk FISH receiving teclistamab have achieved a CR within 5 cycles. In control arm of lenalidomide and dexamethasone (3 patients), the ORR is 66% without any complete responses to date. Of the 8 evaluable patients treated with teclistamab, the MRD negative rate at  $10^{-6}$  is 100%, including 2 patients with VGPR-MRD negative disease. Average time to MRD negativity observed among evaluable patients was 4.25 cycles

# Developing Synergistic Immunotherapy Combinations

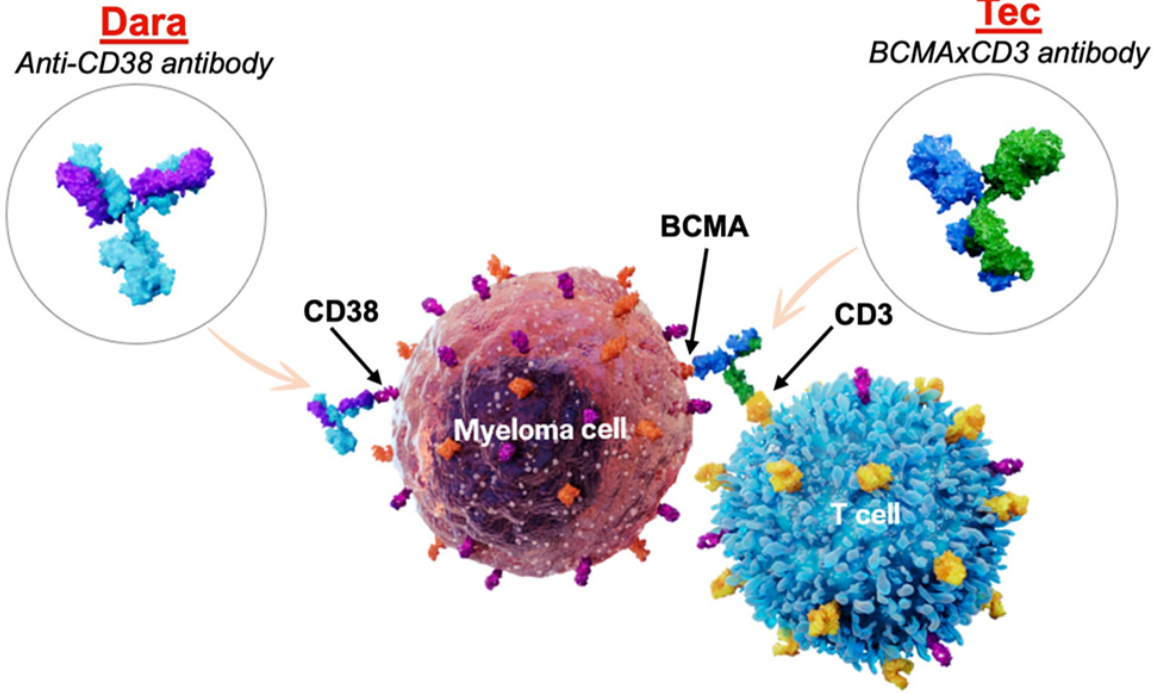
**Dara PRIMES**  
the microenvironment by clearing immunosuppressive CD38+ T<sub>regs</sub> and B<sub>regs</sub>, in addition to Dara's direct on-tumor effects<sup>2</sup>

+

**Tec + Dara ACTIVATE**  
CD8+ T cells for sustained immune enhancement

+

**Tec REDIRECTS**  
activated CD8+ T cells to effectively kill myeloma cells



Daratumumab primes and enables optimized Teclistamab-(Tec)-Daratumumab-(Dara) immune mediated killing of myeloma cells

Adapted from Mateos MV et al, ASH 2025

# MajesTEC-3: Phase 3, Study Design

## Key inclusion criteria

- RRMM
- 1-3 prior LOTs including a PI and lenalidomide
  - Patients with only 1 prior LOT must have been lenalidomide refractory per IMWG criteria
- ECOG PS score of 0-2

## Key exclusion criteria

- Prior BCMA-directed therapy
- Refractory to anti-CD38 mAbs<sup>a</sup>

**1:1  
randomization  
N=587**

22 Oct 2021 to  
29 Sept 2023<sup>b</sup>

**Tec-Dara**  
N=291  
SC dosing following Dara schedule

**DPd/DVd**  
N=296 (91% DPd)  
by investigator's choice<sup>c</sup>

## Primary endpoint

- PFS per IRC

## Key secondary endpoints

- $\geq$ CR<sup>d</sup> and ORR<sup>d</sup>
- MRD negativity ( $10^{-5}$ )
- OS
- MySIm-Q Total Symptom score

## Other secondary endpoints

- Safety
- PK and immunogenicity

● Tec 1.5 mg/kg

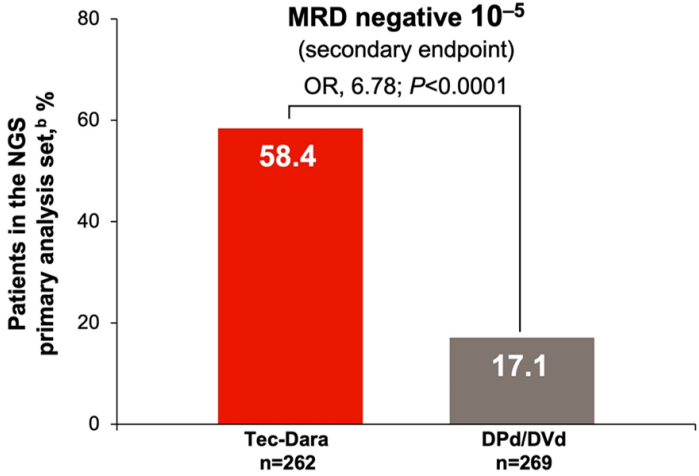
● Tec 3 mg/kg

○ Dara 1800 mg

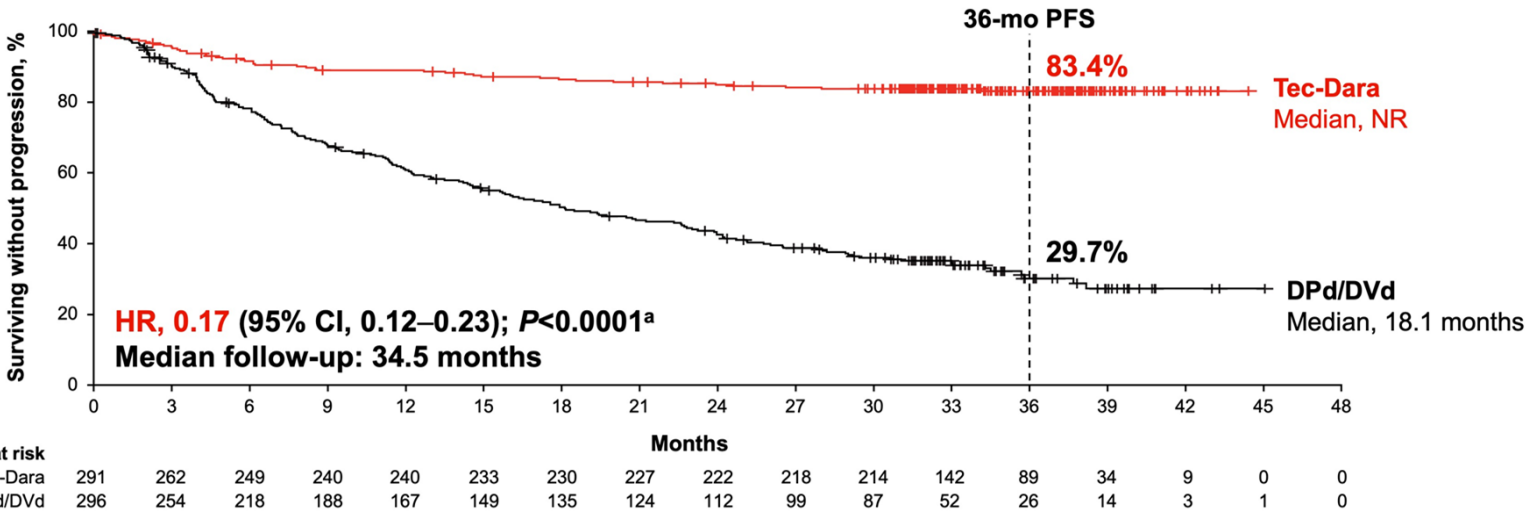
	Cycle 1 QW						Cycle 2 QW				Cycle 3-6 Q2W				Cycle 7+ Q4W			
	D1	D2	D4	D8	D15	D22	D1	D8	D15	D22	D1	D8	D15	D22	D1	D8	D15	D22
Tec		○ SUD <sup>f</sup> ○		●	●	●	●	●	●	●	●		●		●			
Dara	○			○	○	○	○	○	○	○	○		○		○			
Dex (pre-med) <sup>e</sup>	●	●	●	●														

**SC dosing aligned with Dara schedule, with monthly dosing after 6 cycles;  
steroid sparing after Cycle 1 Day 8**

# MajesTEC-3: Phase 3, MRD Negativity and PFS



	MRD-negative $\geq CR$ ( $10^{-5}$ )	MRD-negative $\geq CR$ ( $10^{-6}$ )
<b>Tec-Dara, %</b>		
Primary NGS <sup>b</sup>	57.6	53.8
<b>Evaluable<sup>c</sup></b>	<b>89.3</b>	<b>87.5</b>
<b>DPd/DVd, %</b>		
Primary NGS <sup>b</sup>	17.1	10.4
Evaluable <sup>c</sup>	63.0	41.8



Adapted from Mateos MV et al, ASH 2025



# The REVIVE Study: a Single-Arm Phase 2 Trial (NCT06100237)

**University of Miami.** Single-arm, phase 2, study evaluating teclistamab plus daratumumab in HR-SMM. Target: 50 pts total

- Eligibility criteria included HR-SMM per Mayo 2018 “20-2-20” model, total IMWG risk score of 9 or greater, and other previously established high-risk criteria
- Dosing schedule: **once a week (cycle 1), thereafter once a month until completion of cycle 24. MRD testing annually up to 5 years after stopping therapy**
- Primary objective: **To determine the rate of deep responses (MRD negative  $10^{-5}$  sensitivity NGS by end of cycle 12**
- Select secondary objectives:
  - To determine the overall safety profile of the combination treatment
  - To determine rate of deep responses at  $10^{-6}$  sensitivity by end of treatment
  - To determine fraction of patients with long-term deep remissions (sustained MRD negativity; cure)
  - To identify tumor cell genomics and host immune microenvironmental changes as predictors of response

# The REVIVE Study: a Single-Arm Phase 2 Trial (NCT06100237)

University of Miami. Single-arm, phase 2, study evaluating teclistamab plus daratumumab in HR-SMM. Target: 50 pts total

- Of the first 13 enrolled patients, 11 have achieved stringent complete response (sCR) and had an MRD assessment, **MRD testing by clonoSEQ NGS confirms that all 11 evaluated patients attained  $10^{-6}$  MRD-negativity.** Median time to MRD negativity was 7 (range 6-13) months
- Among the remaining 2 patients, 1 had obtained sCR and was pending MRD assessment at the time of data cutoff (completed 3 cycles of treatment); 1 patient had a positive immunofixation IgG band (completed 4 cycles of treatment)
- **None of the patients have had CRS or ICANS**
- **There have been no serious AEs**
- **Currently, we have ~10 open slots available**

**Open study:  
enrolling  
patients at Univ  
of Miami!**

Lead PI: Dr Ola Landgren

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# Myeloma Program at Sylvester Comprehensive Cancer Center, University of Miami

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## Funding Support



**Paula and Rodger Riney  
Multiple Myeloma  
Research Program Fund**



**Cannon Guzy  
Family Fund**



***And many, many more!***

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