

**The Clinical Implications of Key  
Recent Data Sets in Oncology: A Daylong  
Multitumor Educational Symposium in  
Partnership with Florida Cancer Specialists**

*A CME/MOC- and NCPD-Accredited Event*

**Saturday, October 22, 2022  
7:30 AM – 5:30 PM ET**

# Agenda

**Module 1 — Lung Cancer:** *Drs Langer and Lovly*

**Module 2 — Chronic Lymphocytic Leukemia and Lymphomas:**  
*Drs LaCasce and Smith*

**Module 3 — Prostate and Bladder Cancers:** *Drs Morgans and Yu*

**Module 4 — Renal Cell Carcinoma:** *Prof Powles*

**Module 5 — Multiple Myeloma:** *Dr Usmani*

**Module 6 — Hepatobiliary Cancers:** *Dr Abou-Alfa*

# Agenda

**Module 7 — Breast Cancer:** *Drs Goetz and Krop*

**Module 8 — Endometrial Cancer:** *Dr Westin*

**Module 9 — Ovarian Cancer and PARP Inhibitors:** *Dr O'Malley*

**Module 10 — Gastrointestinal Cancers:** *Drs Messersmith and Strickler*

**Module 11 — Melanoma:** *Prof Long*

# Multiple Myeloma Faculty



**Saad Zafar Usmani, MD, MBA**

Chief of Myeloma Service

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# Multiple Myeloma Agenda

**MODULE 1: BCMA-Directed Therapies in MM**

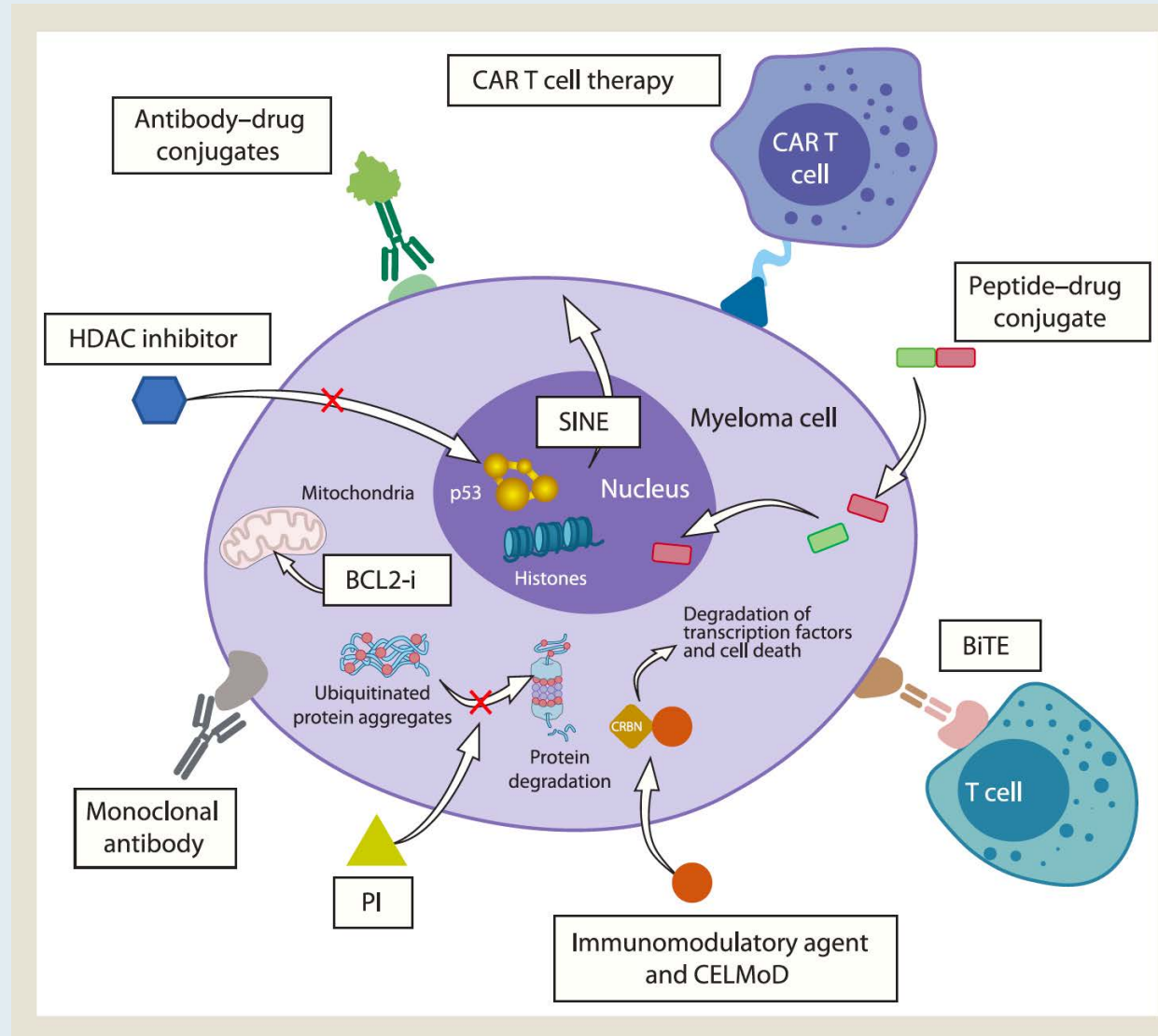
**MODULE 2: Up-Front Treatment of Newly Diagnosed MM**

# Multiple Myeloma Agenda

**MODULE 1: BCMA-Directed Therapies in MM**

**MODULE 2: Up-Front Treatment of Newly Diagnosed MM**

# Mechanisms of Action of Drug Classes for the Treatment of Refractory Multiple Myeloma



# Discussion Questions

- What are the current targets of treatment for MM?





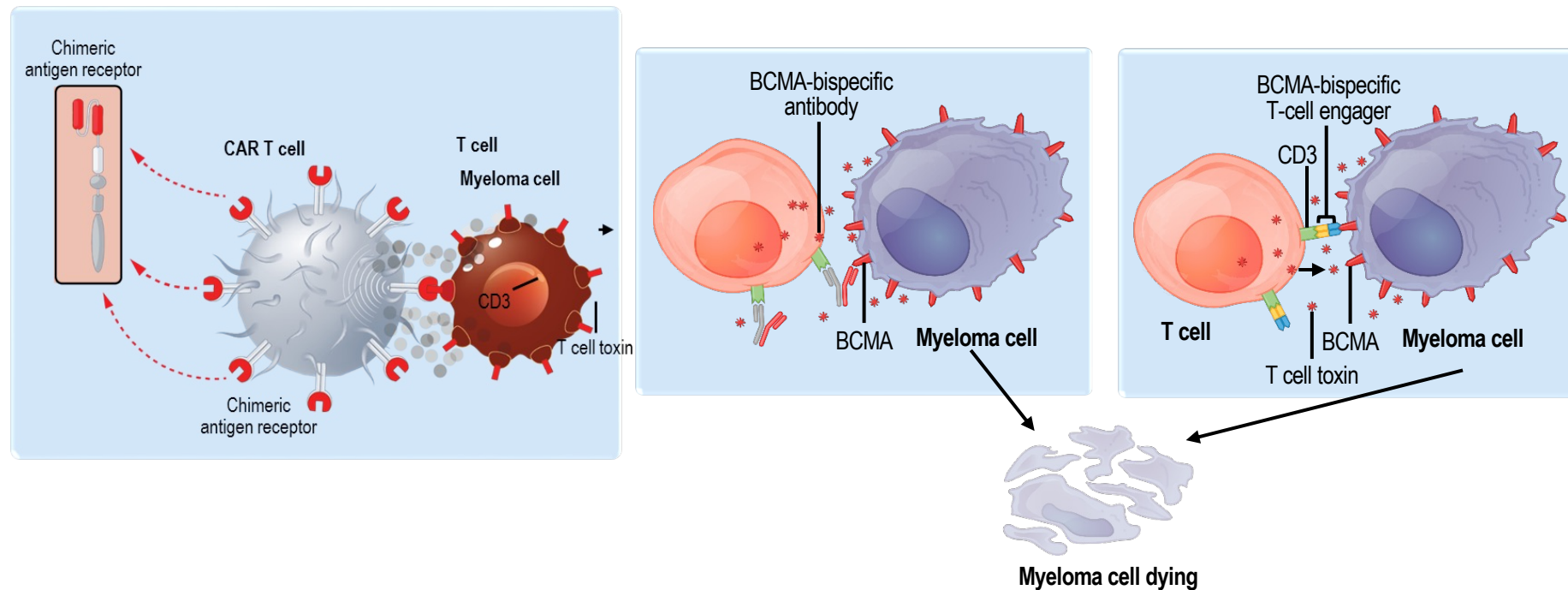
Memorial Sloan Kettering  
Cancer Center

# Bispecific Antibodies and CAR T-Cell Therapies in MM.

Saad Z. Usmani, MD MBA FACP  
Chief of Myeloma Service



# The Promise of T-cell redirection



CAR, chimeric antigen receptor; MM, multiple myeloma  
CAR T-cell therapy is not yet FDA-approved for patients with MM.

Adapted from Cho S-F et al. *Front Immunol.* 2018;9:1821.



## BCMA Bispecific Antibodies (ASH 2021 Updates)

	Teclistamab <sup>1</sup>	Elranatamab <sup>2</sup>	TNB-383B <sup>3</sup>	REGN5458 <sup>4</sup>
<b>Schedule</b>	Weekly SC	Weekly SC or Q2W SC	IV q3W	Weekly IV
<b>Patients</b>	165	55	118	73
<b>Median prior lines</b>	5	6	5	5
<b>Triple Class and Penta Refractory</b>	78% and 30%	91% and NA	61% and NA	89% and 38%
<b>Prior BCMA</b>	No	22%	No	No
<b>CRS, All (Gr 3/4)</b>	72% (0.6%)	87% (0%)	54% (3%)	38% (0%)
<b>ICANS, All (Gr 3/4)</b>	3% (0%)	NA	2% (NA)	4% (0%)
<b>ORR at higher doses</b>	62%	69% 70% in prior BCMA	60%	75%
<b>CR at higher doses</b>	29%	Not reported	20%	16%

1. Moreau et al. Abstract #896; 2. Sebag et al. Abstract #895; 3. Kumar et al. Abstract #900; 4. Zonder et al. Abstract #160 (ASH 2021)

# Teclistamab-Daratumumab Combination

Teclistamab + Daratumumab	
<b>Schedule</b>	Weekly & Q2W SC
<b>Patients</b>	37
<b>Median prior lines</b>	5
<b>Prior BCMA</b>	19%
<b>CD38 refractory</b>	60%
<b>Triple Class and Penta Refractory</b>	54% and 19%
<b>CRS, All (Gr 3/4)</b>	65% (0%)
<b>ICANS, All (Gr 3/4)</b>	3% (0%)
<b>ORR at higher doses</b>	82%
<b>CR at higher doses</b>	27%

Rodriguez-Otero et al. ASH 2021 Annual Meeting.

# MajesTEC Trials

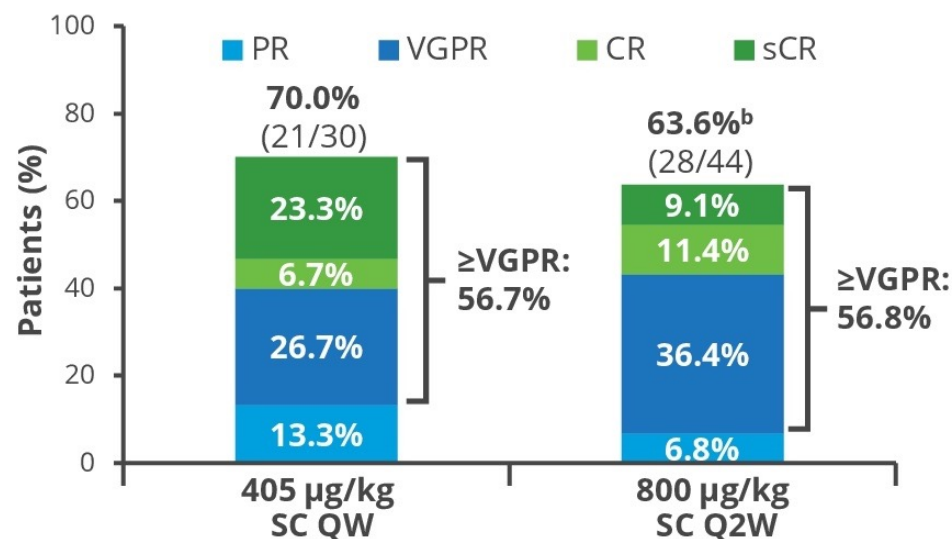
- Majest-TEC-2: A Multi-arm Phase 1b Study of Teclistamab With Other Anticancer Therapies in Participants With Multiple Myeloma
- Majest-TEC-3: Phase III Study of Teclistamab in Combination With Daratumumab Subcutaneously (SC) (Tec-Dara) Versus Daratumumab SC, Pomalidomide, and Dexamethasone (DPd) or Daratumumab SC, Bortezomib, and Dexamethasone (DVd) in Participants With Relapsed or Refractory Multiple Myeloma
- MajesTEC-4: Phase III Study of Teclistamab in Combination With Lenalidomide Versus Lenalidomide Alone in Participants With Newly Diagnosed Multiple Myeloma as Maintenance Therapy Following Autologous Stem Cell Transplantation
- MajesTEC-7: Phase III Study to Compare Teclistamab in Combination With Daratumumab and Lenalidomide (Tec-DR) in Participants With Newly Diagnosed Multiple Myeloma



# Talquetamab: A GPRC<sub>5D</sub> × CD<sub>3</sub> bispecific antibody

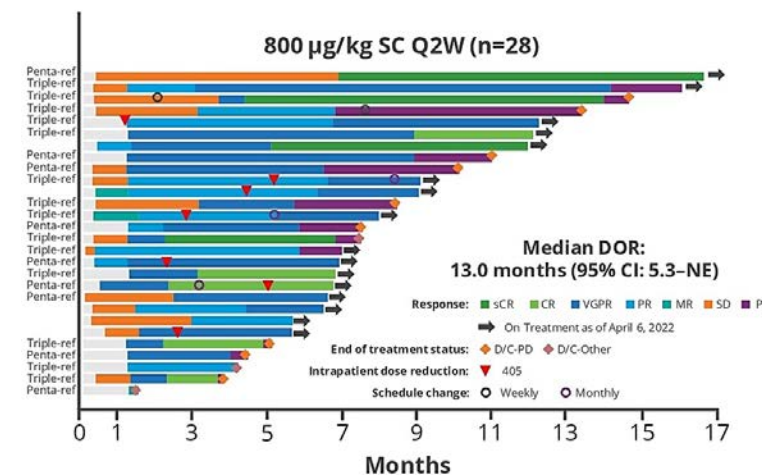
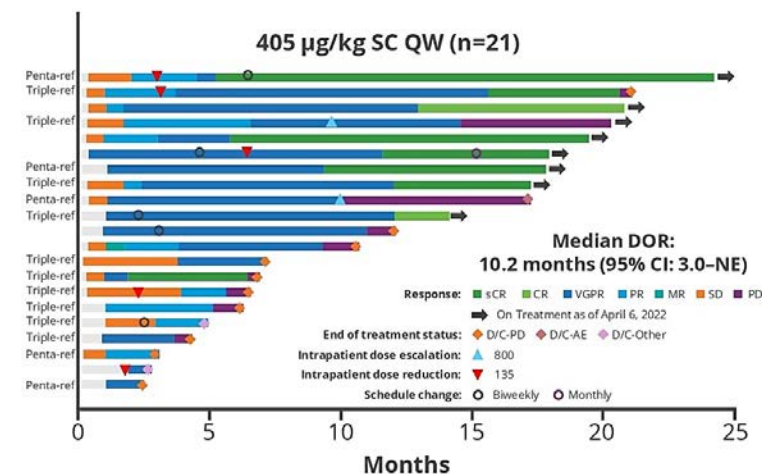
- Median age, years: 405  $\mu$ g/Kg 61.5 (46-80); 800  $\mu$ g/Kg 64 (47-84)
- Median PL: 6; 5
- High-risk cytogenetics: 3 (11.1%); 9 (22.5%)
- Triple-class refractory: 23 (76.7%); 34 (77.3%)
- CRS: all grade 23 (76.7%), grade 3 1 (3.3%); 35 (79.5%), grade 3 0

## Overall response rate<sup>a</sup>



<sup>a</sup>Investigator assessment of evaluable patients per 2011 IMWG response criteria; includes unconfirmed responses. <sup>b</sup>Due to rounding, individual response rates do not sum to the ORR. CR, complete response; IMWG, International Myeloma Working Group; PR, partial response; sCR, stringent complete response; VGPR, very good partial response

## Duration of response



D/C, discontinued; DOR, duration of response; NE, not estimable; MR, minimal response; PD, progressive disease; Penta-ref, penta-drug refractory; SD, stable disease; Triple-ref, triple-class refractory



# TRIMM-2: Talquetamab and daratumumab

Tal	Dara SC	Patients enrolled to date (n)
800 µg/kg SC Q2W	1800 mg SC Cycles 1–2: QW Cycles 3–6: Q2W Cycles 7+: monthly	44
400 µg/kg SC QW		14

Analysis cutoff date: 06 April 2022

<sup>a</sup>Including a PI and an IMiD. <sup>b</sup>1–3 step-up doses given within 1 week before a full dose.

<sup>c</sup>Glucocorticoid, antihistamine, and antipyretic.

- Median age, years: 400 µg/Kg 68 (50-77); 800 µg/Kg 62 (44-81)
- Median PL: 6; 5
- High-risk cytogenetics: 1 (10.0%); 5 (19.2%)
- Triple-class refractory: 8 (57.1%); 28 (63.6%)
- Anti-CD38 mAb refractory: 11 (78.6%); 33 (75.0%)

- Median follow-up 5.1 months
- CRS all grades: 10 (71.4%); 34 (77.3%); Grade 3/4 0; 0
- ICANS: 2 patients, both grade 1 and resolved within 1 day
- Dysgeusia, all grades: 10 (71.4%), grade 3/4 NA; 26 (59.1%), grade 3/4 NA. Dry mouth, all grades: 10 (71.4%), grade 3/4 0; 18 (40.9%), grade 3/4 0
- 31 patients (53.4%) had infections (grade ≥3: 17.2%)
- Skin- and/or nail-related AEs: 81.0 % (47/58) patients

CR, complete response; CRS, cytokine release syndrome; dara, daratumumab; ICANS, immune effector cell-associated neurotoxicity syndrome; mAb, monoclonal antibody; ORR, overall response rate; PL, prior lines of treatment; PR, partial response; QW/Q2W, weekly/every 2 weeks; SC, subcutaneous; sCR, stringent CR; SD, stable disease; Tal, talquetamab; VGPR, very good partial response

Parameter	Evaluable patients <sup>a</sup>	
	Tal 400 µg/kg QW + dara (n=14)	Tal 800 µg/kg Q2W + dara (n=37)
Follow-up, median (range)	6.7 months (1.9–19.6)	4.2 months (0.2–12.3)
ORR <sup>b</sup> , n (%)	10 (71.4)	31 (83.8)
CR/sCR	4 (28.6)	11 (29.7)
VGPR	4 (28.6)	13 (35.1)
PR	2 (14.3)	7 (18.9)
SD	4 (28.6)	4 (10.8)
PD	0	2 (5.4)
Time to first confirmed response, median (range)	1.0 month (0.9–2.4)	1.0 month (0.9–6.5)

<sup>a</sup>Response-evaluable patients had received ≥1 study treatment and had ≥1 postbaseline response evaluation by the investigator. <sup>b</sup>PR or better in response-evaluable patients; includes unconfirmed responses.



## BCMA CARTs: Summary

	CARTITUDE-1 <sup>1</sup> Cilta-cel Phase 1/2	CRB-401 <sup>2</sup> Ide-cel Phase 1	KarMMa <sup>3</sup> Ide-cel Phase 2	LUMMICAR-2 <sup>4</sup> Zivo-Cel Phase 1b	PRIME <sup>5</sup> P-BCMA-101 Phase 1/2	GC012F <sup>6</sup> Dual CAR-T BCMA+CD19
Patients	97	62	128	20	55	19
Median prior regimens	6	6	6	5	8	5
Triple refractory, %	87.6%	69.4%	84.0%	85%	60%	95%
CAR-T dose	0.71×10 <sup>6</sup> (range 0.5–0.95×10 <sup>6</sup> )	50, 150, 450 and 800 x 10 <sup>6</sup>	150, 300, 450 x10 <sup>6</sup>	1.5-1.8/2.5-3.0 x10 <sup>8</sup>	0.75-15 x10 <sup>6</sup>	1.0-3.0 x10 <sup>5</sup>
ORR	97.9%	75.8%	50%/69%/82.0%	94.0%	67% <sup>b</sup>	94.7%
CR/sCR	80.4%	38.7%	25%/29%/39%	28%	NR	84.2%
PFS	66% @ 18m	8.8m	12m @450mil			
CRS, all grades	94.8%	75.8%	50%/76%/96%	77%/83% <sup>a</sup>	17%	95%
CRS, grade 3/4	4%	6.5%	0/7%/6%	0%	0%	11%
Neurotoxicity, all grades	20.6%	35.5%	0/17%/20%	15%/17% <sup>a</sup>	3.8%	0%
Neurotoxicity, grade 3/4	10.3%	1.6%	0/1%/6%	8%/0 <sup>a</sup>	3.8%	0%

<sup>a</sup>1.5-1.8/2.5-3.0 x10<sup>8</sup> dose, <sup>b</sup>0.75x10<sup>6</sup> dose

BCMA, B-cell maturation antigen; CAR-T, chimeric antigen receptor T-cell therapy; CRS, cytokine release syndrome; NR, not reported

1. Usmani et al., ASCO 2021: Abstract 8005; 2. Lin et al., ASH 2020: Abstract 131;

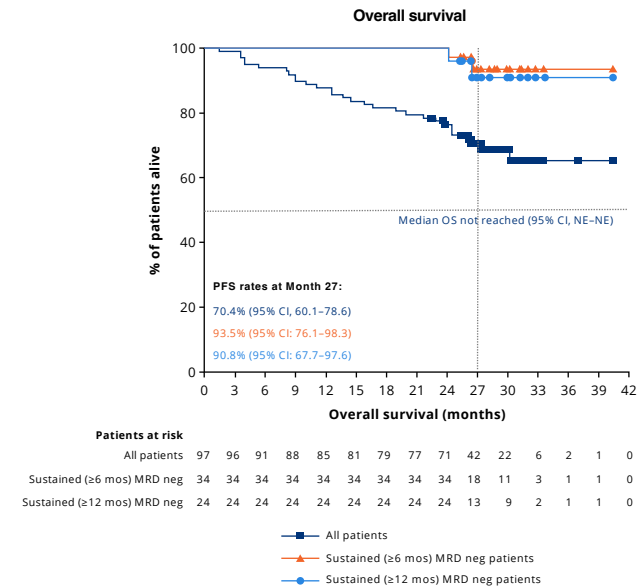
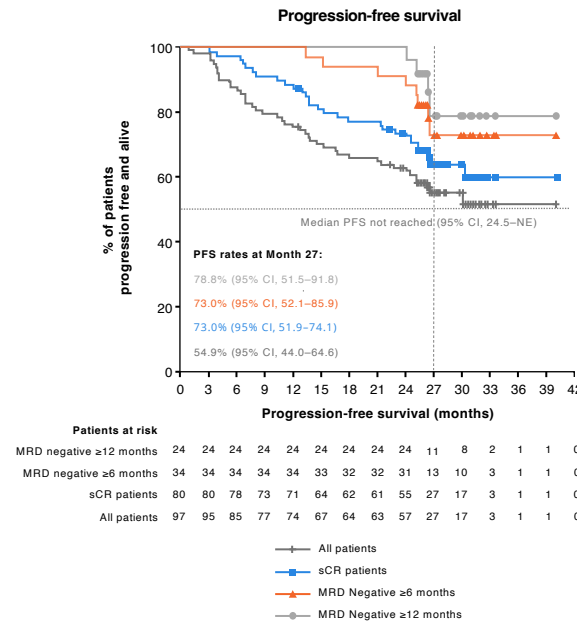
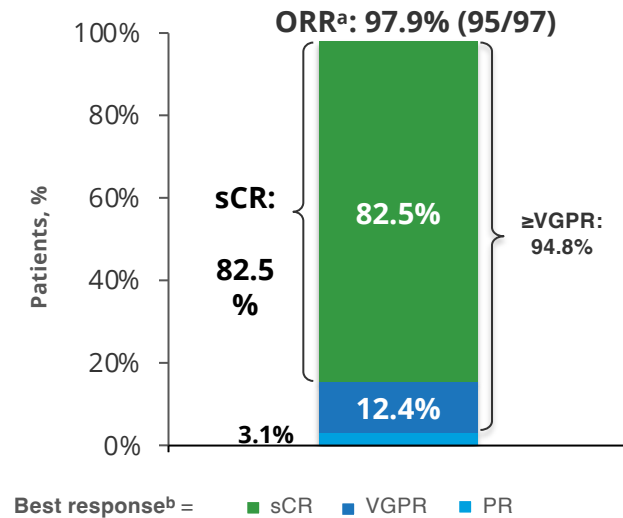
3. Anderson et al., ASCO 2021: Abstract 130; 4. Kumar et al., ASH 2020: Abstract 133;

5. Costello et al., ASH 2020: Abstract 134; 6. Jiang et al., ASCO 2021: Abstract 8014





# CARTITUDE-1: Efficacy



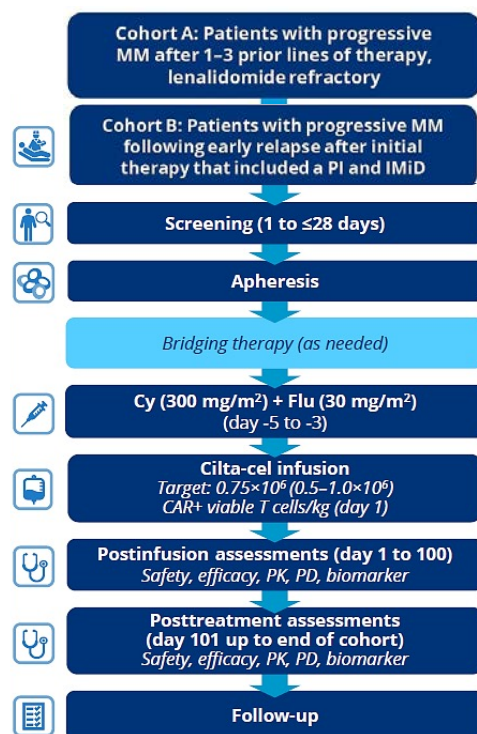
- Median PFS and OS were not reached
- Patients who achieved sCR had improved PFS compared with the overall population
- Of 61 patients evaluable for MRD, 91.8% were MRD-negative at ( $10^{-5}$ )
- Patients with sustained MRD negativity ( $10^{-5}$ ) for ≥6 and ≥12 months had improved PFS and OS compared with the overall population

<sup>a</sup>ORR assessed by independent review committee. <sup>b</sup>No patient had CR or stable disease. CAR, chimeric antigen receptor; DOR, duration of response; ISS, International Staging System; MRD, minimal residual disease;

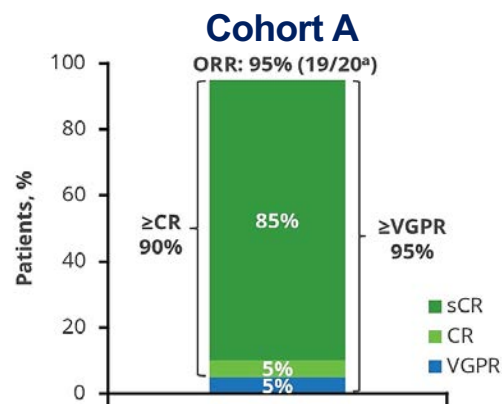
NE, not estimable; ORR, overall response rate; OS, overall survival; PR, partial response; PFS, progression-free survival; sCR, stringent CR; VGPR, very good partial response



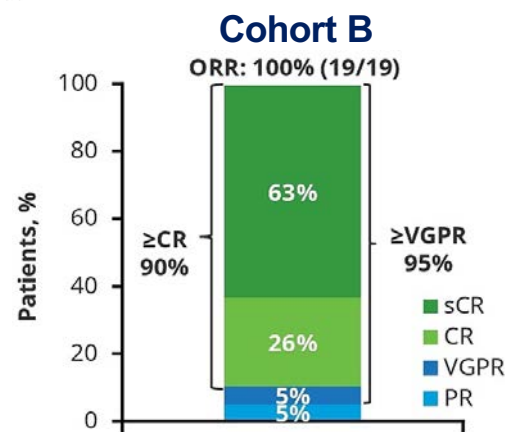
# Using CAR T-cell therapy at earlier lines of therapy: CARTITUDE-2



CR, complete response; CRS, cytokine release syndrome; Cy, cytarabine; Flu, fludarabine; ORR, overall response rate; PD, pharmacodynamics; PK, pharmacokinetics; PR, partial response; sCR, stringent CR; VGPR, very good partial response



<sup>a</sup>One patient demonstrated a minimal response.  
sCR, stringent CR



AEs ≥20%, n (%)	N=20	
	Any Grade	Grade 3/4
<b>Hematologic</b>		
Neutropenia	19 (95)	19 (95)
Thrombocytopenia	16 (80)	7 (35)
Anemia	15 (75)	9 (45)
Lymphopenia	14 (70)	14 (70)
Leukopenia	11 (55)	11 (55)
<b>CAR-T-related AEs</b>		
CRS	19 (95)	2 (10)
Neurotoxicity	6 (30)	1 (5)
ICANS	3 (15)	0
Other	3 (15) <sup>a</sup>	1 (5)

<sup>a</sup>One patient had peripheral sensorimotor neuropathy, one had anosmia and dysgeusia, and one had facial paralysis.

AEs ≥20%, n (%)	N=19	
	Any Grade	Grade 3/4
<b>Hematologic</b>		
Neutropenia	18 (95)	17 (90)
Anemia	11 (58)	9 (47)
Thrombocytopenia	11 (58)	5 (26)
Lymphopenia	6 (32)	6 (32)
Leukopenia	5 (26)	5 (26)
<b>CAR-T-related AEs</b>		
CRS	16 (84)	1 (5)
Neurotoxicity	5 (26)	1 (5)
ICANS	1 (5)	0
Other	4 (21)	1 (5)
Parkinsonism	1 (5)	1 (5)

# Ongoing CAR T Trials

## **KarMMa-2**

Phase 2 study NCT03601078  
Ide-cel in early relapse + high-risk or late relapsed MM

## **KarMMa-3**

Phase 3 study NCT03651128  
Ide-cel vs standard regimens in RRMM after 2 – 4 prior lines

## **KarMMa-4**

Phase 1 study NCT04196491  
Ide-cel in high-risk NDMM

## **KarMMa-7**

Phase 1/2 study NCT04855136  
Ide-cel in combination with various agents in RRMM

## **CARTITUDE-4**

Phase 3 study NCT04181827  
Cilta-cel vs DPd or PVd in RRMM after 1 – 3 prior lines

## **CARTITUDE-5**

Phase 3 study NCT04923893  
VRd + Cilta-cel vs VRd + Rd maintenance in transplant-ineligible NDMM

## **CARTITUDE-6**

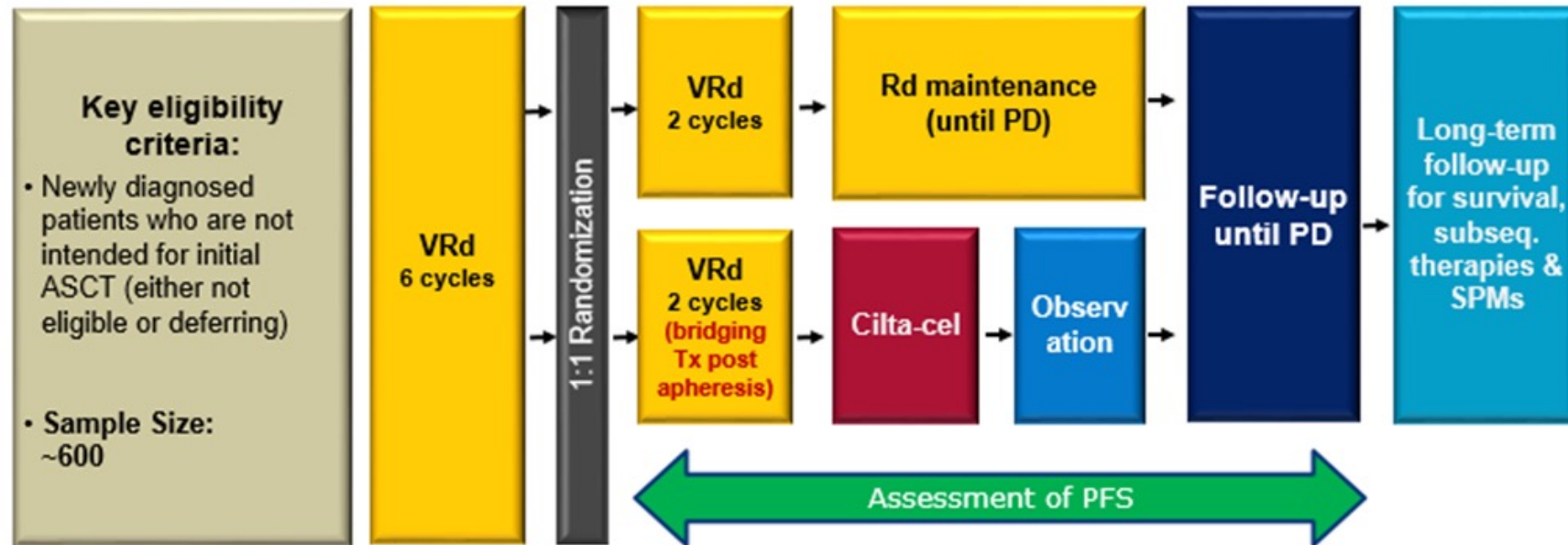
Phase 3 study NCT04923893  
DVRd + Cilta-cel vs DVRd + AutoSCT in transplant-eligible NDMM

## **Phase 1 development**

Many agents in early development with various constructs.



# CARTITUDE-5: Randomized, phase 3 in NDMM, not intended for transplant



# Discussion Questions

- Regulatory and reimbursement issues aside, what do you believe is the ideal time to integrate bispecifics into the MM treatment algorithm?
- What are the key tolerability issues with bispecifics, and which patients have adequate fitness to be treated?
- In the (near) future, do believe bispecifics will be given in the community setting?
- What is the optimal sequence of bispecifics and CAR T-cell therapy now and in the future?
- At the present time, how do you compare the efficacy and tolerability of the two approved CAR T-cell platforms? Does your approach change in patients with prior CNS disease (eg, Parkinson's)?

# Topline Results from KarMMa-3: Idecabtagene Vicleucel Significantly Improves PFS for Relapsed and Refractory Multiple Myeloma

Press Release: August 10, 2022

Positive topline results were announced from KarMMa-3, a Phase III, global, randomized, multicenter, open-label study evaluating idecabtagene vicleucel compared to standard combination regimens for adults with multiple myeloma that is relapsed and refractory after 2 to 4 prior lines of therapy and refractory to the last regimen.

“KarMMa-3 is the first randomized clinical trial to evaluate a CAR T cell therapy in multiple myeloma. Results of a pre-specified interim analysis conducted through an independent review committee showed that KarMMa-3 met its primary endpoint of demonstrating a statistically significant improvement in progression-free survival. Treatment with idecabtagene vicleucel also showed an improvement in the key secondary endpoint of overall response rate compared to standard regimens. Follow-up for overall survival, a key secondary endpoint, remains ongoing.

Safety results in the trial were consistent with the well-established and predictable safety profile of idecabtagene vicleucel previously demonstrated in the pivotal KarMMa trial. No new safety signals were reported in this study.”

<https://news.bms.com/news/corporate-financial/2022/Bristol-Myers-Squibb-and-2seventy-bio-Announce-Topline-Results-from-KarMMa-3-Trial-Showing-Abecma-idecabtagene-vicleucel-Significantly-Improves-Progression-Free-Survival-Versus-Standard-Regimens-in-Relapsed-and-Refractory-Multiple-Myeloma/default.aspx>

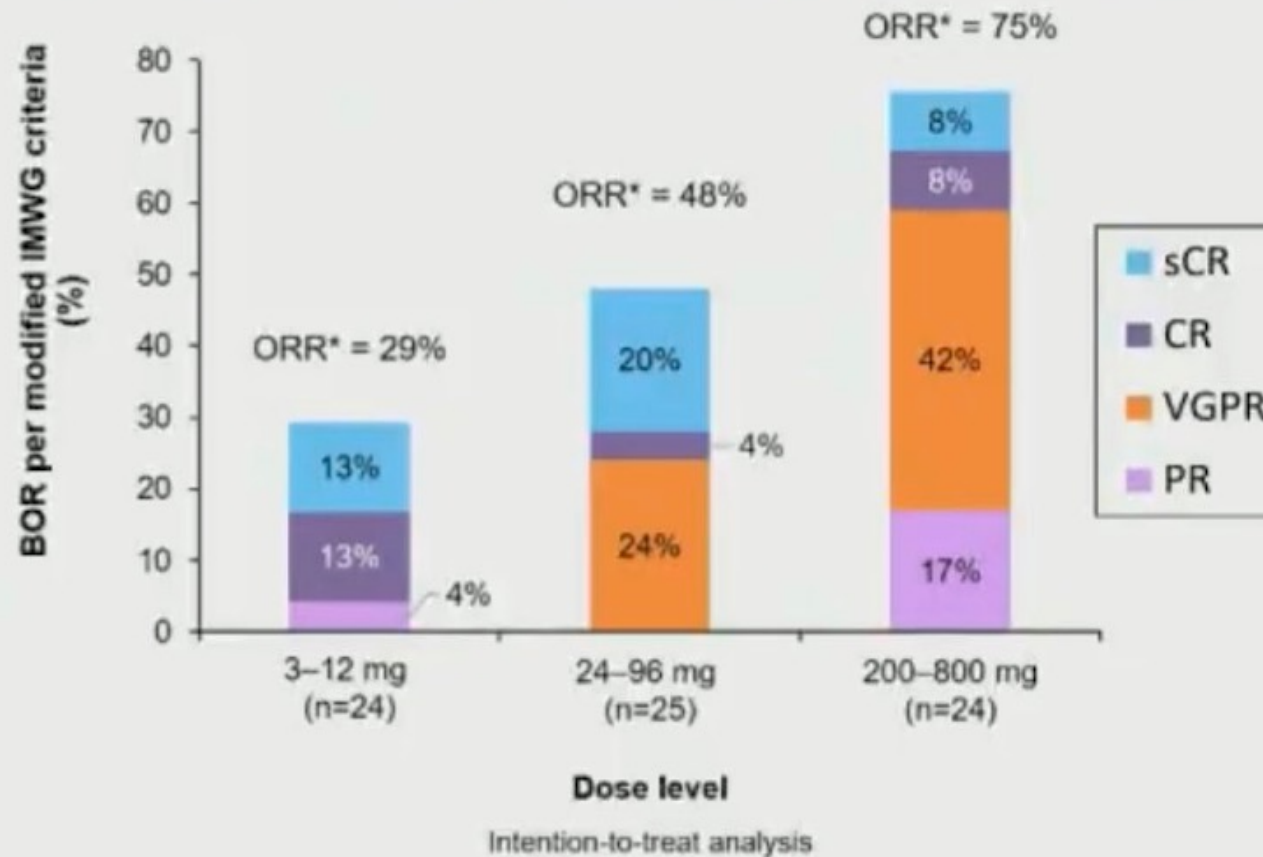
# **LINKER-MM1 — Early, Deep, and Durable Responses, and Low Rates of Cytokine Release Syndrome with REGN5458, a BCMA x CD3 Bispecific Antibody, in a Phase 1/2 Study in Patients with Relapsed/Refractory Multiple Myeloma**

Zonder JA et al.

International Myeloma Society Meeting 2022;Abstract OAB-056.



# LINKER-MM1: Phase I Efficacy with REGN5458

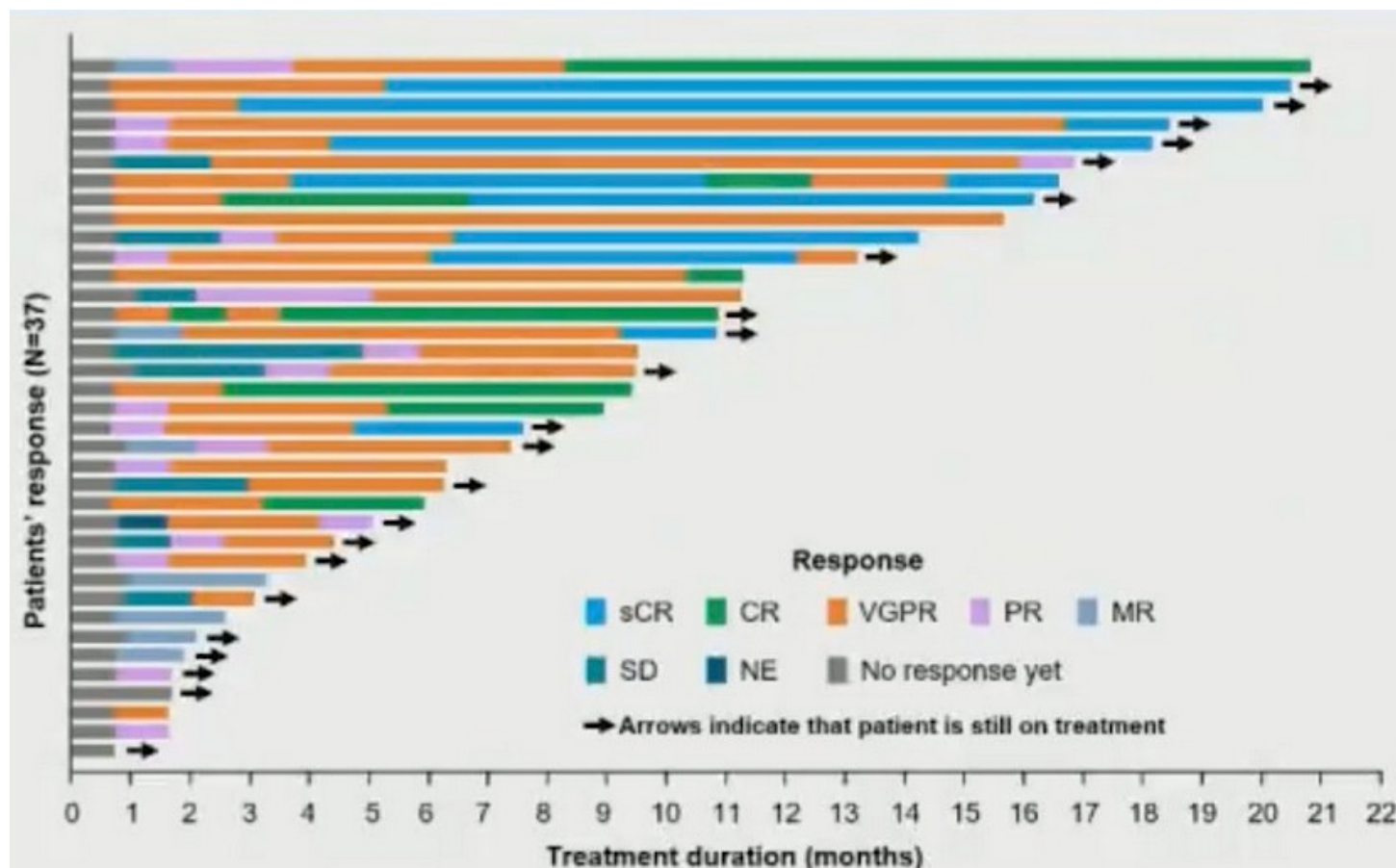


- Responses have been observed across all dose levels, with a trend for higher response rates at higher doses
  - 51% ORR among all enrolled patients\*
- 75% ORR and 58%  $\geq$ VGPR with REGN5458 200–800 mg
- Among all responders, 86% achieved  $\geq$ VGPR, 43%  $\geq$ CR
- Among CR/sCR with available MRD data:
  - 4/10 MRD negative at  $10^{-5}$

ORR = overall response rate



# LINKER-MM1: Duration of Response with REGN5458



- Responses occurred early, were durable, and deepened with time
  - Median time to response is <1 month
  - 70% of responses occurred within the first 2 months
- Estimated\*<sup>†</sup> median DOR was not reached
  - Probability<sup>†</sup> of responders being in response at 8 months was 90.2% (95% CI: 72.6, 96.7)
- The longest responses are ongoing for 19+ months at the latest data cut-off

# LINKER-MM1: Safety with REGN5458

	Total (N=73)		
	Any grade	Grade 3	Grade 4
<b>All treatment-emergent adverse events (TEAEs) n (%)</b>			
Any	73 (100)	31 (42)	24 (33)
<b>Hematologic TEAEs, in <math>\geq 20\%</math> of patients (any grade) n (%)</b>			
Anemia	23 (32)	17 (23)	0
Lymphopenia	17 (23)	7 (10)	7 (10)
Neutropenia	17 (23)	5 (7)	11 (15)
Thrombocytopenia	15 (21)	6 (8)	4 (5)
<b>Non-hematologic TEAEs, in <math>\geq 20\%</math> of patients (any grade) n (%)</b>			
Fatigue	33 (45)	2 (3)	0
CRS	28 (38)	0	0
Pyrexia	26 (36)	3 (4)	0
Nausea	24 (33)	0	0
Dyspnea	19 (26)	0	0
Diarrhea	18 (25)	2 (3)	0
Back pain	18 (25)	4 (5)	0
Vomiting	18 (25)	0	0
Pneumonia	17 (23)	8 (11)	0
Chills	16 (22)	1 (1)	0
Cough	16 (22)	0	0
Headache	15 (21)	2 (3)	0

## Dose-limiting toxicity (DLT)

- DLTs were reported in 2 patients
  - DL4 (24 mg) and DL6 (96 mg)
- Maximum-tolerated dose not reached

## Potential ICANS events

- No Grade 3 ICANS events reported
- Grade 2 events occurred in 3 patients (4%)

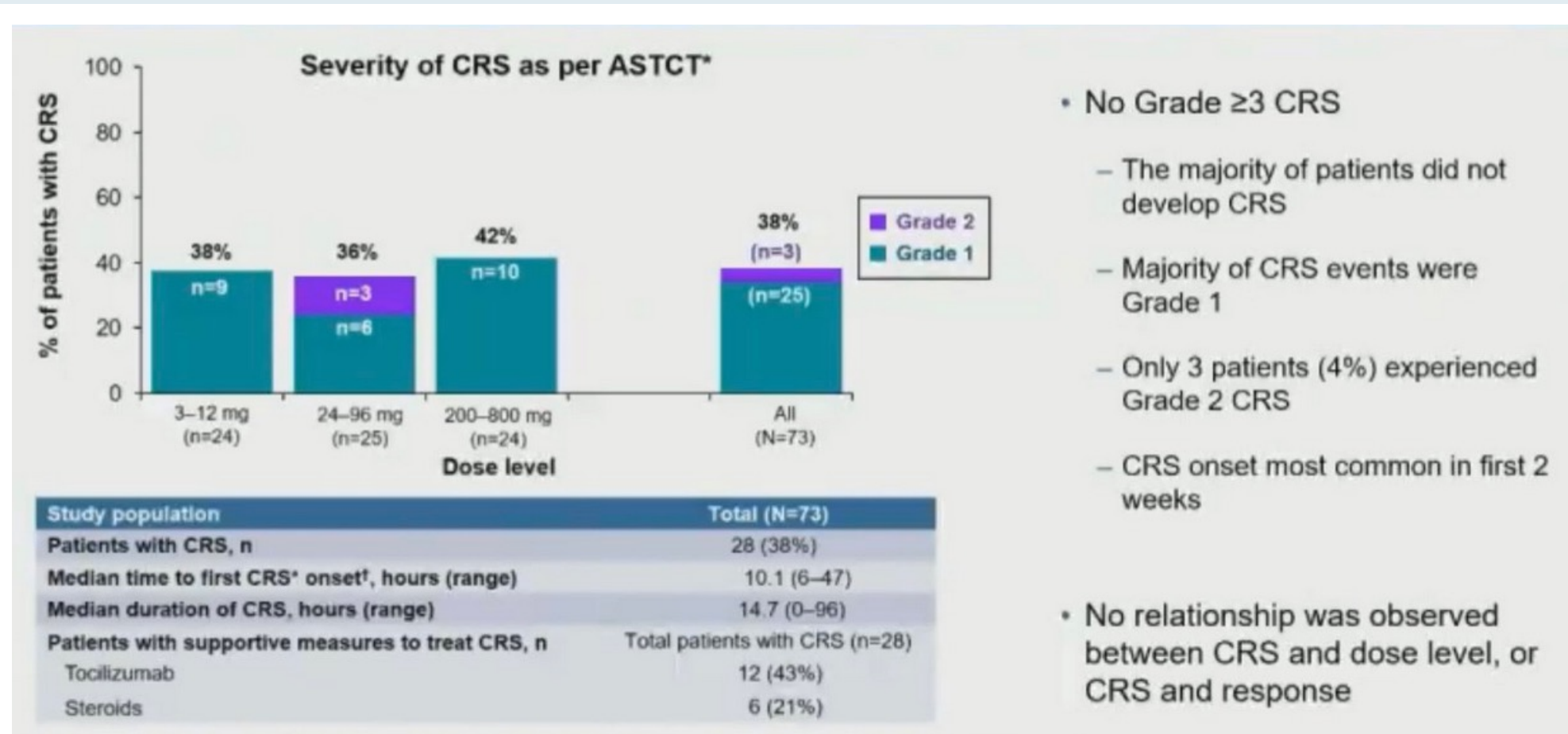
## Deaths

- 5 (7%) Grade 5 AEs were reported [sepsis (n=3); COVID (n=1); pneumonia (n=1)]
- All Grade 5 events were not related to study treatment

## Pharmacokinetics

- REGN5458 serum concentration increased with dose, approximately dose proportionally

# LINKER-MM1: Cytokine Release Syndrome with REGN5458



ASTCT = American Society for Transplantation and Cellular Therapy



# **Synergistic Effects of Low-dose Belantamab Mafodotin in Combination with a Gamma-Secretase Inhibitor (Nirogacestat) in Patients with Relapsed/Refractory Multiple Myeloma (RRMM): DREAMM-5 Study**

Poster No. 443

Speaker: Sagar Lonial, MD, FACP

## **Acknowledgments**

This study was funded by GlaxoSmithKline (GSK Study 208887). Drug linker technology licensed from Seagen, Inc.; monoclonal antibody produced using POTELLIGENT Technology licensed from BioWa; nirogacestat (gamma-secretase inhibitor) is manufactured and provided by SpringWorks Therapeutics as part of a collaborative agreement with GSK. On behalf of all authors, and with their permission, an audio recording was prepared by Sagar Lonial who did not receive any payment for this recording. Writing assistance was provided by Elisabeth Walsby, PhD and Sharon Bryant, DPT of Fishawack Indicia, part of Fishawack Health and funded by GSK.

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# Multiple Myeloma Agenda

**MODULE 1: BCMA-Directed Therapies in MM**

**MODULE 2: Up-Front Treatment of Newly Diagnosed MM**

# Discussion Questions

- Regulatory and reimbursement issues aside, in which situations do you favor the use of daratumumab as part of up-front treatment?
- For patients treated in the community setting, what, if any, is the role of MRD assays, and which assay?



## RVd ± ASCT and Lenalidomide Maintenance to Progression for NDMM

### The Phase 3 DETERMINATION Trial

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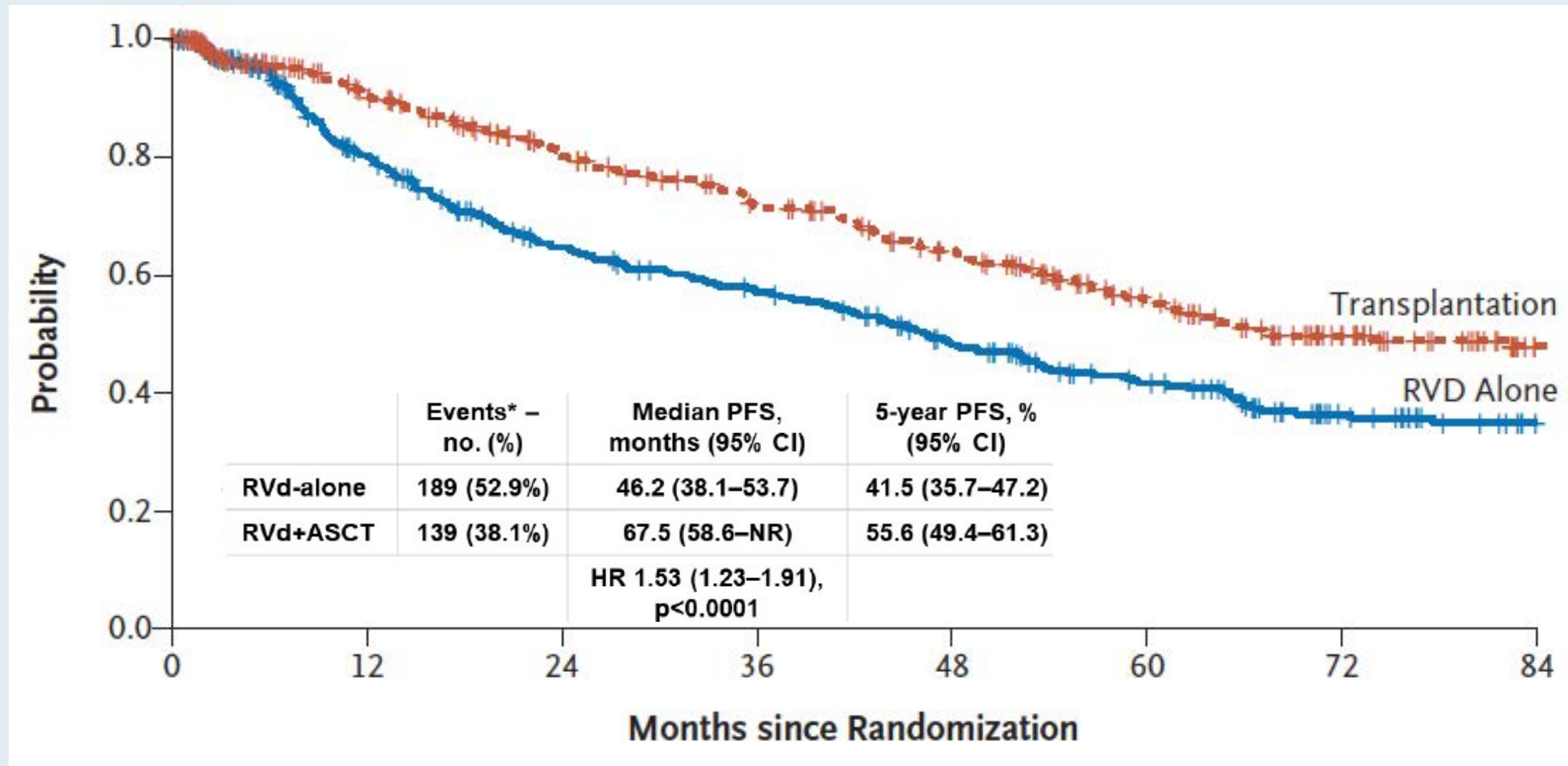
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#### ORIGINAL ARTICLE

## Triplet Therapy, Transplantation, and Maintenance until Progression in Myeloma

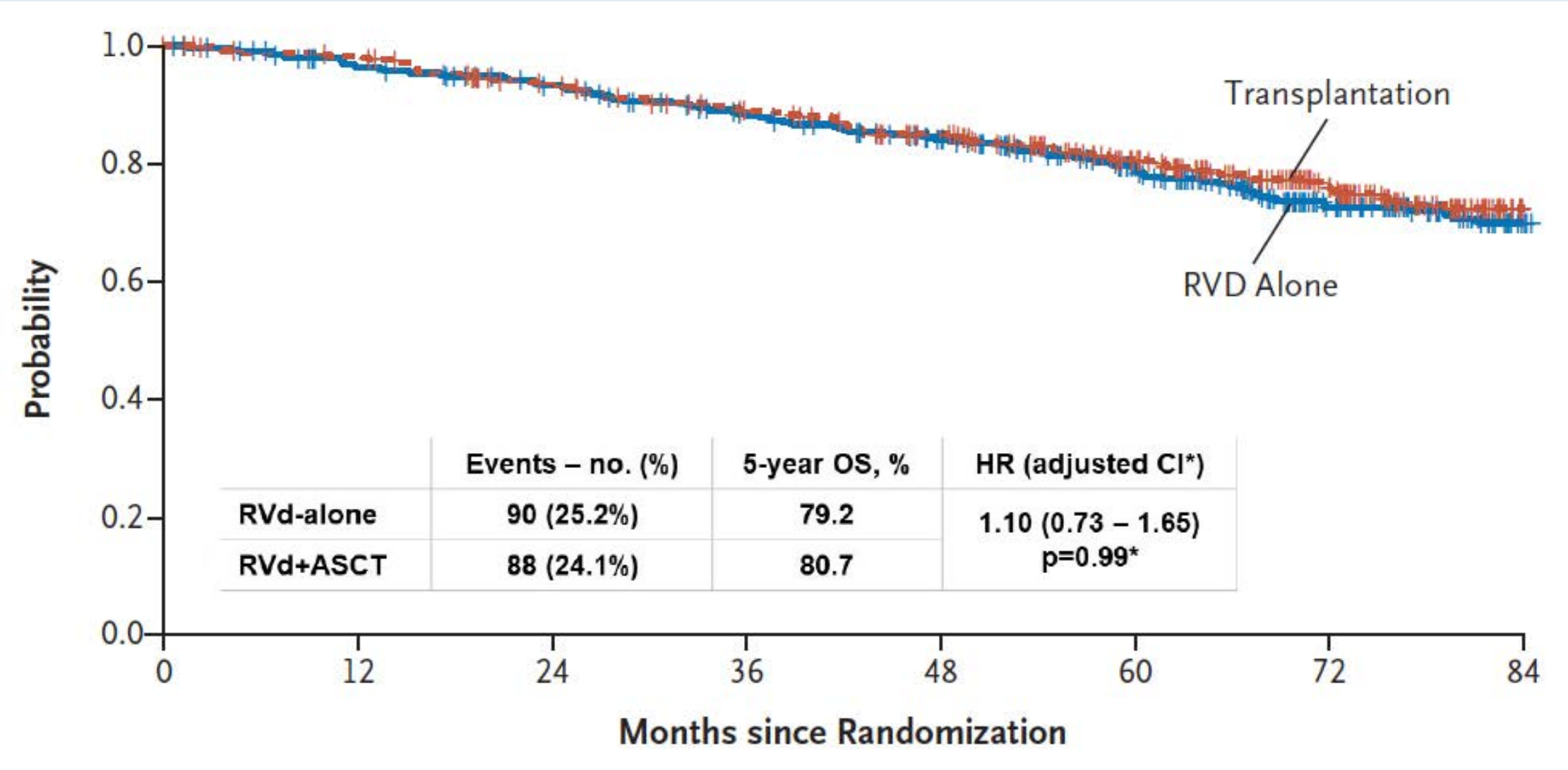
P.G. Richardson, S.J. Jacobus, E.A. Weller, H. Hassoun, S. Lonial, N.S. Raje, E. Medvedova, P.L. McCarthy, E.N. Libby, P.M. Voorhees, R.Z. Orlowski, L.D. Anderson, Jr., J.A. Zonder, C.P. Milner, C. Gasparetto, M.E. Agha, A.M. Khan, D.D. Hurd, K. Gowin, R.T. Kamble, S. Jagannath, N. Nathwani, M. Alsina, R.F. Cornell, H. Hashmi, E.L. Campagnaro, A.C. Andreescu, T. Gentile, M. Liedtke, K.N. Godby, A.D. Cohen, T.H. Openshaw, M.C. Pasquini, S.A. Giralt, J.L. Kaufman, A.J. Yee, E. Scott, P. Torka, A. Foley, M. Fulciniti, K. Hebert, M.K. Samur, K. Masone, M.E. Maglio, A.A. Zeytoonjian, O. Nadeem, R.L. Schlossman, J.P. Laubach, C. Paba-Prada, I.M. Ghobrial, A. Perrot, P. Moreau, H. Avet-Loiseau, M. Attal, K.C. Anderson, and N.C. Munshi, for the DETERMINATION Investigators\*

# DETERMINATION: Progression-Free Survival (Primary Endpoint)





# DETERMINATION: Overall Survival (Key Secondary Endpoint)



***Thank you for joining us!***

***CME/MOC and NCPD credit information will be  
emailed to each participant within 5 business days.***