

13th Annual Oncology Grand Rounds

*A Complimentary NCPD Live Webinar Series
Held During the 46th Annual ONS Congress*

Multiple Myeloma

Tuesday, April 27, 2021

8:30 AM – 10:00 AM ET

Medical Oncologists

Shaji K Kumar, MD

Sagar Lonial, MD

Paul G Richardson, MD

Oncology Nurse Practitioners

Charise Gleason, MSN, NP-C, AOCNP

Patricia Mangan, RN, MSN, CRNP, APN, BC

Tiffany A Richards, PhD, ANP-BC, AOCNP

Moderator

Neil Love, MD

Medical Oncologists



Shaji K Kumar, MD
Mark and Judy Mullins Professor of
Hematological Malignancies
Consultant, Division of Hematology
Professor of Medicine
Mayo Clinic
Rochester, Minnesota



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



Paul G Richardson, MD
Clinical Program Leader and Director of
Clinical Research
Jerome Lipper Multiple Myeloma Center
Dana-Farber Cancer Institute
RJ Corman Professor of Medicine
Harvard Medical School
Boston, Massachusetts

Oncology Nurse Practitioners



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Advanced Practice Provider Chief
Winship Cancer Institute of Emory University
Adjunct Faculty, Nell Hodgson Woodruff
School of Nursing
Atlanta, Georgia



Patricia Mangan, RN, MSN, CRNP, APN, BC
Nurse Lead, Hematologic Malignancies and
Stem Cell Transplant Programs
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Department of Lymphoma/Myeloma
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MD Anderson Cancer Center
Houston, Texas

Commercial Support

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Dr Love — Disclosures

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Planners, scientific staff and independent reviewers for Research To Practice have no relevant conflicts of interest to disclose.

Dr Kumar — Disclosures

Consulting/Advisory Board	Antengene, BeiGene Ltd, Oncopeptides
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Research Funding for Clinical Trials to the Institution	AbbVie Inc, Amgen Inc, AstraZeneca Pharmaceuticals LP, Bristol-Myers Squibb Company, CARsgen Therapeutics, Genentech, a member of the Roche Group, Janssen Biotech Inc, Kite, A Gilead Company, Merck, Novartis, Takeda Oncology, TeneoBio

Dr Lonial — Disclosures

Consulting Agreements	Amgen Inc, Bristol-Myers Squibb Company, Celgene Corporation, GlaxoSmithKline, Janssen Biotech Inc, Novartis, Takeda Oncology
Contracted Research	Celgene Corporation, Janssen Biotech Inc, Takeda Oncology

Dr Richardson — Disclosures

Advisory Committee	Bristol-Myers Squibb Company, Celgene Corporation, GlaxoSmithKline, Janssen Biotech Inc, Karyopharm Therapeutics, Oncoceptives, Sanofi Genzyme, Secura Bio, Takeda Oncology
Contracted Research	Bristol-Myers Squibb Company, Celgene Corporation, Oncoceptives, Takeda Oncology

Ms Gleason — Disclosures

No relevant conflicts of interest to disclose.

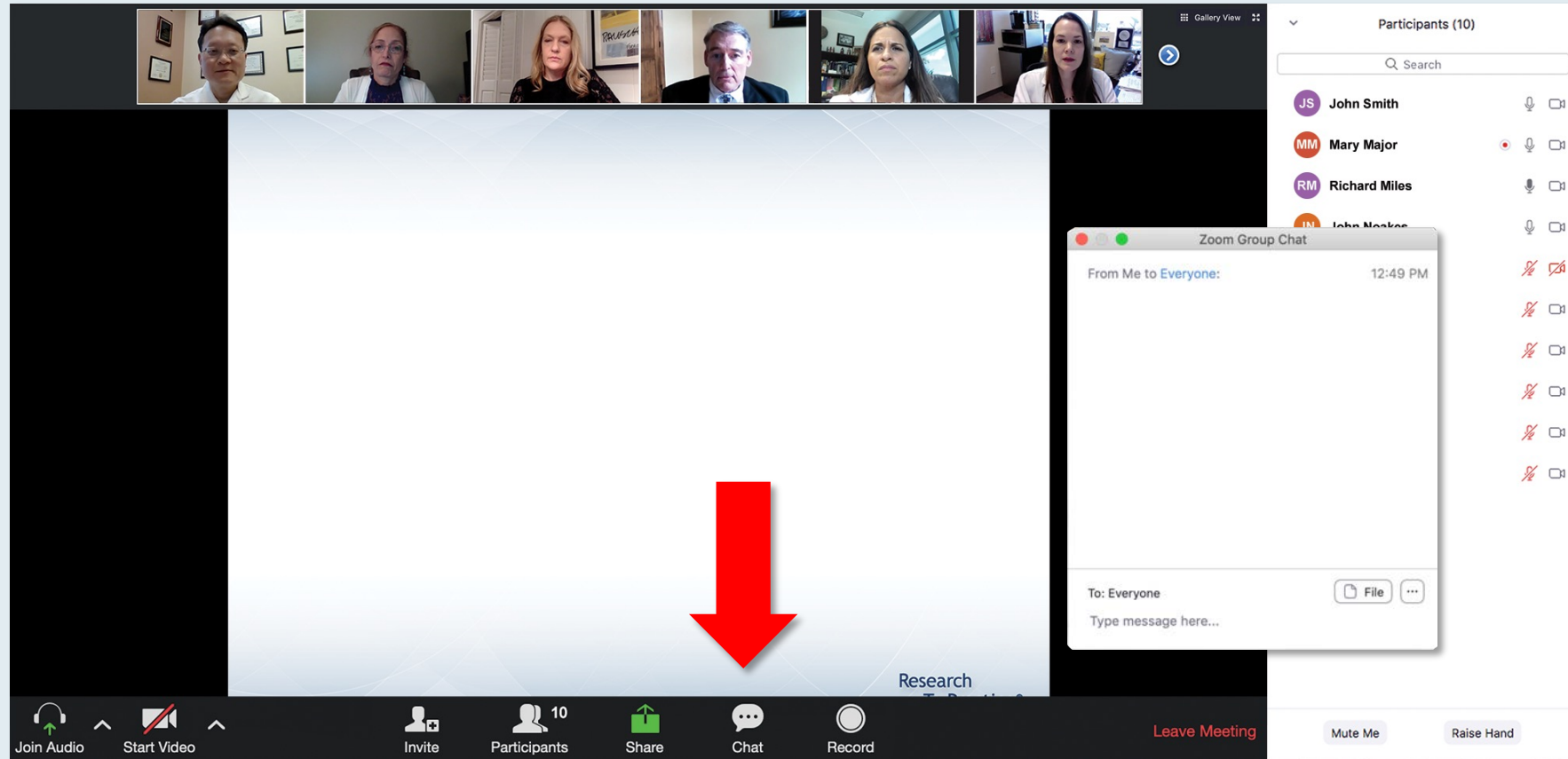
Ms Mangan — Disclosures

Consulting Agreements	GlaxoSmithKline, Merck
Speakers Bureau	Amgen Inc, Bristol-Myers Squibb Company, GlaxoSmithKline, Janssen Biotech Inc, Karyopharm Therapeutics, Oncopeptides, Sanofi Genzyme, Takeda Oncology

Dr Richards — Disclosures

Consulting Agreements	Celgene Corporation, GlaxoSmithKline, Sanofi Genzyme, Takeda Oncology
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We Encourage Clinicians in Practice to Submit Questions



Feel free to submit questions now before the program begins and throughout the program.

Familiarizing Yourself with the Zoom Interface

How to answer poll questions

The screenshot shows a Zoom meeting interface. At the top, there are seven video thumbnails of participants. Below them is a slide with a poll question: "What is your usual treatment recommendation for a patient with MM who has been followed by ASCT and experiences an asymptomatic relapse?" The slide lists ten treatment options. A "Quick Poll" window is overlaid on the first option, "1. Carfilzomib +/- dexamethasone", showing a list of radio button options for each treatment combination. The Zoom control bar at the bottom includes icons for Join Audio, Start Video, Invite, Participants (10), Share, Chat, Record, and Leave Meeting. On the right side, the "Participants (10)" list is visible, showing names and icons for audio and video status.

Participants (10)

Search

- JS John Smith
- MM Mary Major
- RM Richard Miles
- JN John Noakes
- AS Alice Suarez
- JP Jane Perez
- RS Robert Stiles
- JF Juan Fernandez
- AK Ashok Kumar
- JS Jeremy Smith

What is your usual treatment recommendation for a patient with MM who has been followed by ASCT and experiences an asymptomatic relapse?

Quick Poll

- Carfilzomib +/- dexamethasone
- Pomalidomide +/- dexamethasone
- Carfilzomib + pomalidomide +/- dexamethasone
- Elotuzumab + lenalidomide +/- dexamethasone
- Elotuzumab + pomalidomide +/- dexamethasone
- Daratumumab + lenalidomide +/- dexamethasone
- Daratumumab + pomalidomide +/- dexamethasone
- Daratumumab + bortezomib +/- dexamethasone
- Ixazomib + Rd
- Other

Submit

Co-provided by USF Health Research To Practice®

Join Audio Start Video Invite Participants 10 Share Chat Record Leave Meeting Mute Me Raise Hand

When a poll question pops up, click your answer choice from the available options.

Familiarizing Yourself with the Zoom Interface

Expand chat submission box

The screenshot shows a Zoom meeting interface. At the top, there are video thumbnails for participants: RTP Coordinat..., Kirsten Miller, RTP Mike Rivera, and Lisa Suarez. A 'Recording...' indicator is visible on the left. The main content is a slide titled 'Meet The Professor Program Steering Committee' with six members listed:

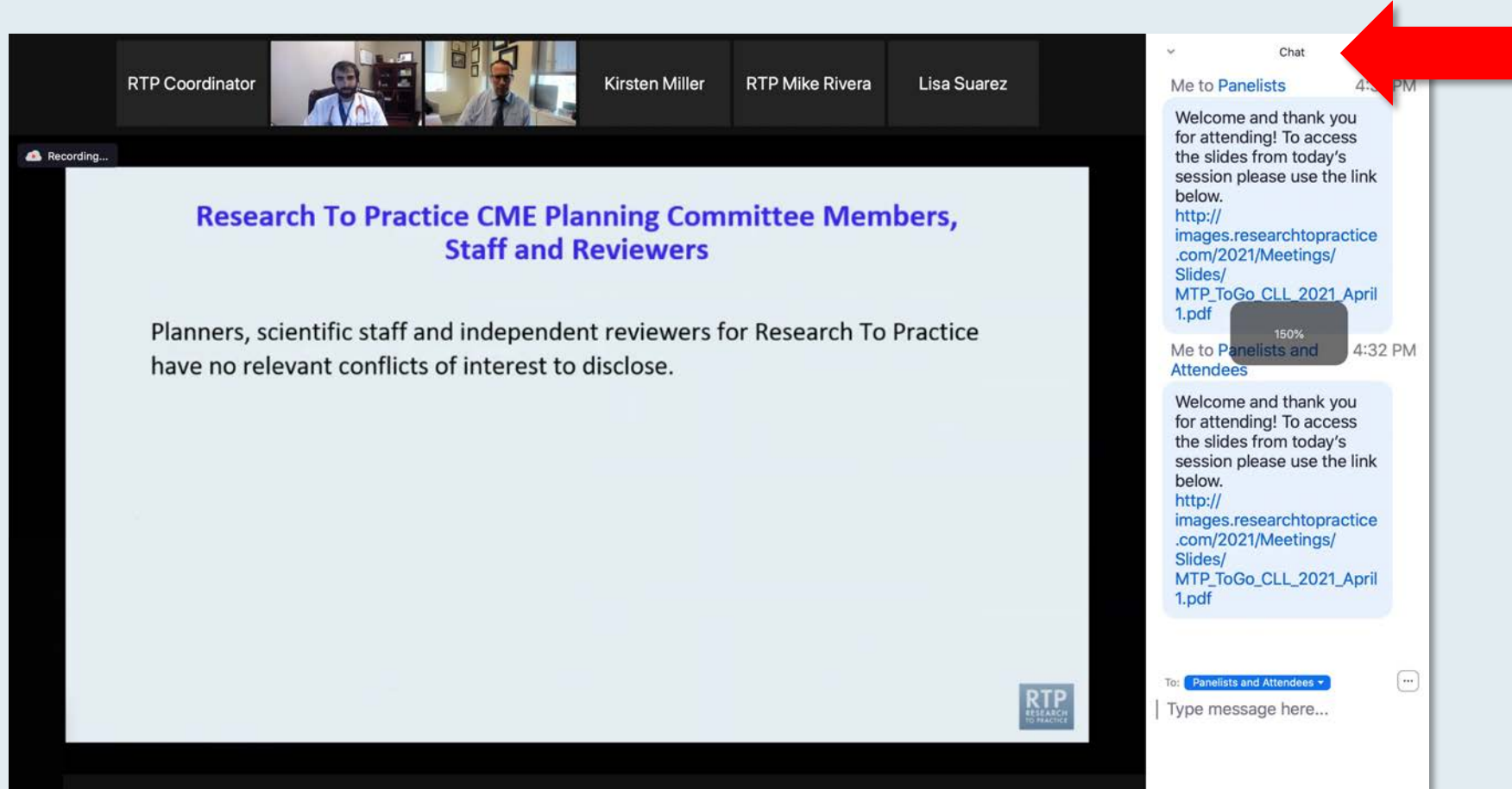
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- Ian W Flinn, MD, PhD**
Director of Lymphoma Research Program
Sarah Cannon Research Institute
Tennessee Oncology
Nashville, Tennessee
- Steven Coutre, MD**
Professor of Medicine (Hematology)
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Stanford, California
- Prof John G Gribben, MD, DSc, FMedSci**
Chair of Medical Oncology
Barts Cancer Institute
Queen Mary University of London
Charterhouse Square
London, United Kingdom
- Matthew S Davids, MD, MMSc**
Associate Professor of Medicine
Harvard Medical School
Director of Clinical Research
Division of Lymphoma
Dana-Farber Cancer Institute
Boston, Massachusetts
- Brian T Hill, MD, PhD**
Director, Lymphoid Malignancy Program
Cleveland Clinic Taussig Cancer Institute
Cleveland, Ohio

The chat window on the right is expanded. It shows two messages from 'Me to Panelists' and 'Me to Panelists and Attendees', both containing a welcome message and a link to a PDF slide: http://images.researchtopractice.com/2021/Meetings/Slides/MTP_ToGo_CLL_2021_April1.pdf. A red arrow points to the white line above the 'Type message here...' input field, indicating how to expand the chat box.

Drag the white line above the submission box up to create more space for your message.

Familiarizing Yourself with the Zoom Interface

Increase chat font size



The screenshot displays a Zoom meeting interface. At the top, there are video thumbnails for participants: RTP Coordinator, Kirsten Miller, RTP Mike Rivera, and Lisa Suarez. Below the thumbnails is a slide titled "Research To Practice CME Planning Committee Members, Staff and Reviewers". The slide content reads: "Planners, scientific staff and independent reviewers for Research To Practice have no relevant conflicts of interest to disclose." A "Recording..." indicator is visible in the top left of the slide area. On the right side, the Zoom chat window is open, showing a message from "Me to Panelists" at 4:32 PM. The message text is: "Welcome and thank you for attending! To access the slides from today's session please use the link below. http://images.researchtopractice.com/2021/Meetings/Slides/MTP_ToGo_CLL_2021_April_1.pdf". A red arrow points to the chat window, and a small grey box with "150%" is overlaid on the chat message, indicating the font size has been increased. The chat input field at the bottom shows "To: Panelists and Attendees" and "Type message here..."

**Press Command (for Mac) or Control (for PC) and the + symbol.
You may do this as many times as you need for readability.**

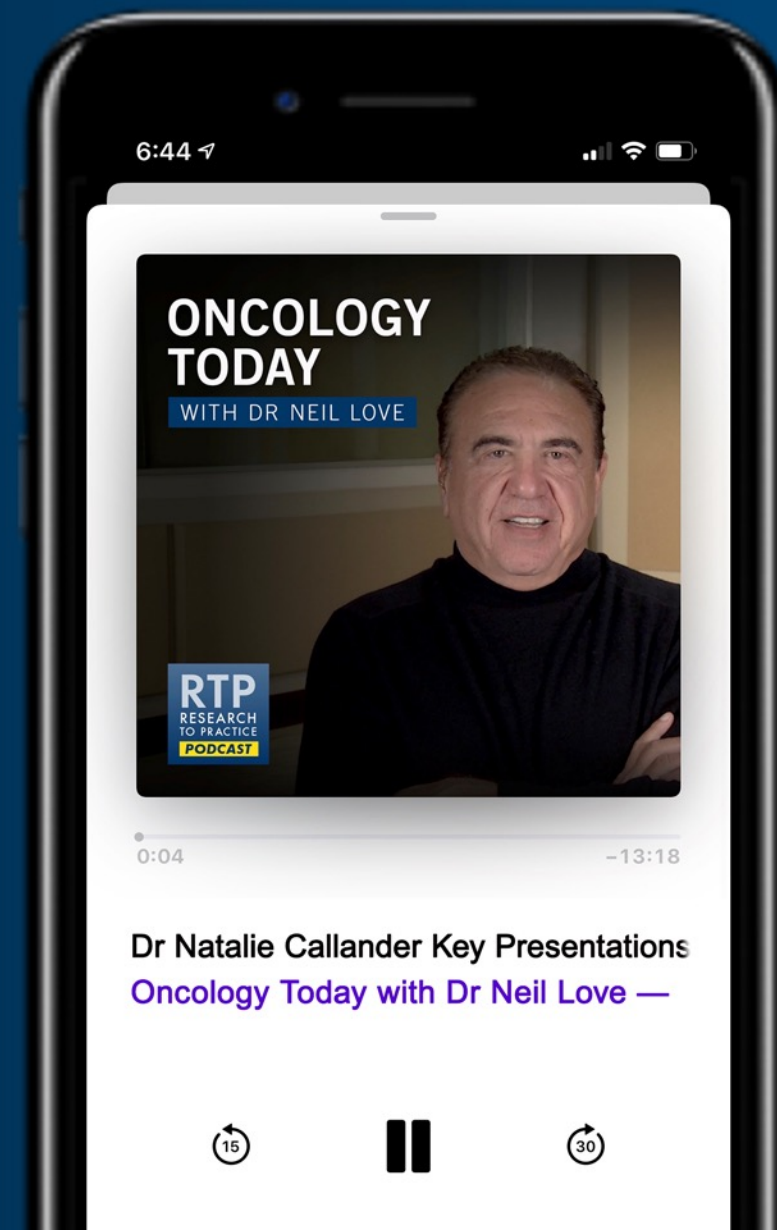
ONCOLOGY TODAY

WITH DR NEIL LOVE

Key Presentations on Multiple Myeloma, Waldenström Macroglobulinemia and Amyloidosis from the 2020 ASH Annual Meeting



DR NATALIE CALLANDER
UNIVERSITY OF WISCONSIN CARBONE
CANCER CENTER



13th Annual Oncology Grand Rounds

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Breast Cancer

Tuesday, April 20, 2021

8:30 AM – 10:00 AM ET

Non-Small Cell Lung Cancer

Tuesday, April 20, 2021

5:00 PM – 6:30 PM ET

Acute Myeloid Leukemia

Wednesday, April 21, 2021

12:00 PM – 1:00 PM ET

Colorectal and Gastroesophageal Cancers

Wednesday, April 21, 2021

4:45 PM – 5:45 PM ET

Prostate Cancer

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Chimeric Antigen Receptor T-Cell Therapy

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5:00 PM – 6:30 PM ET

Ask the Expert: Clinical Investigators Provide Perspectives on the Management of Renal Cell Carcinoma

In Partnership with Project Echo[®] and Florida Cancer Specialists

**Tuesday, May 4, 2021
5:00 PM – 6:00 PM ET**

Faculty

Chung-Han Lee, MD, PhD

Moderator

Neil Love, MD

Current Concepts and Recent Advances in Oncology

*A Daylong Clinical Summit Hosted in
Partnership with Medical Oncology
Association of Southern California (MOASC)*

**Saturday, May 15, 2021
10:30 AM – 6:30 PM ET**

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10:30 AM — Breast Cancer

Ruth O'Regan, Tiffany A Traina

11:30 AM — Multiple Myeloma

Kenneth Anderson, Noopur Raje

12:50 PM — Chronic Lymphocytic Leukemia and Lymphomas

Craig Moskowitz, Jeff Sharman

1:50 PM — Genitourinary Cancers

Joaquim Bellmunt, Sumanta Kumar Pal

Saturday, May 15, 2021

3:15 PM — Gastrointestinal Cancers

Wells A Messersmith, Eileen M O'Reilly

4:15 PM — Acute Myeloid Leukemia and Myelodysplastic Syndromes

Harry Paul Erba, Rami Komrokji

5:35 PM — Lung Cancer

D Ross Camidge, Benjamin Levy

Up for Debate: Oncology Investigators Provide Their Take on Current Controversies in Patient Care

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10:15 AM — Lung Cancer

John V Heymach, Stephen V Liu

11:30 AM — Genitourinary Cancers

Maha Hussain, Elizabeth R Plimack

12:45 PM — Chronic Lymphocytic Leukemia and Lymphomas

Jonathan W Friedberg, Laurie H Sehn

2:00 PM — Multiple Myeloma

Irene M Ghobrial, Sagar Lonial

3:15 PM — Breast Cancer

Virginia Kaklamani, Nancy U Lin

Thank you for joining us!

***NCPD credit information will be emailed
to each participant shortly.***

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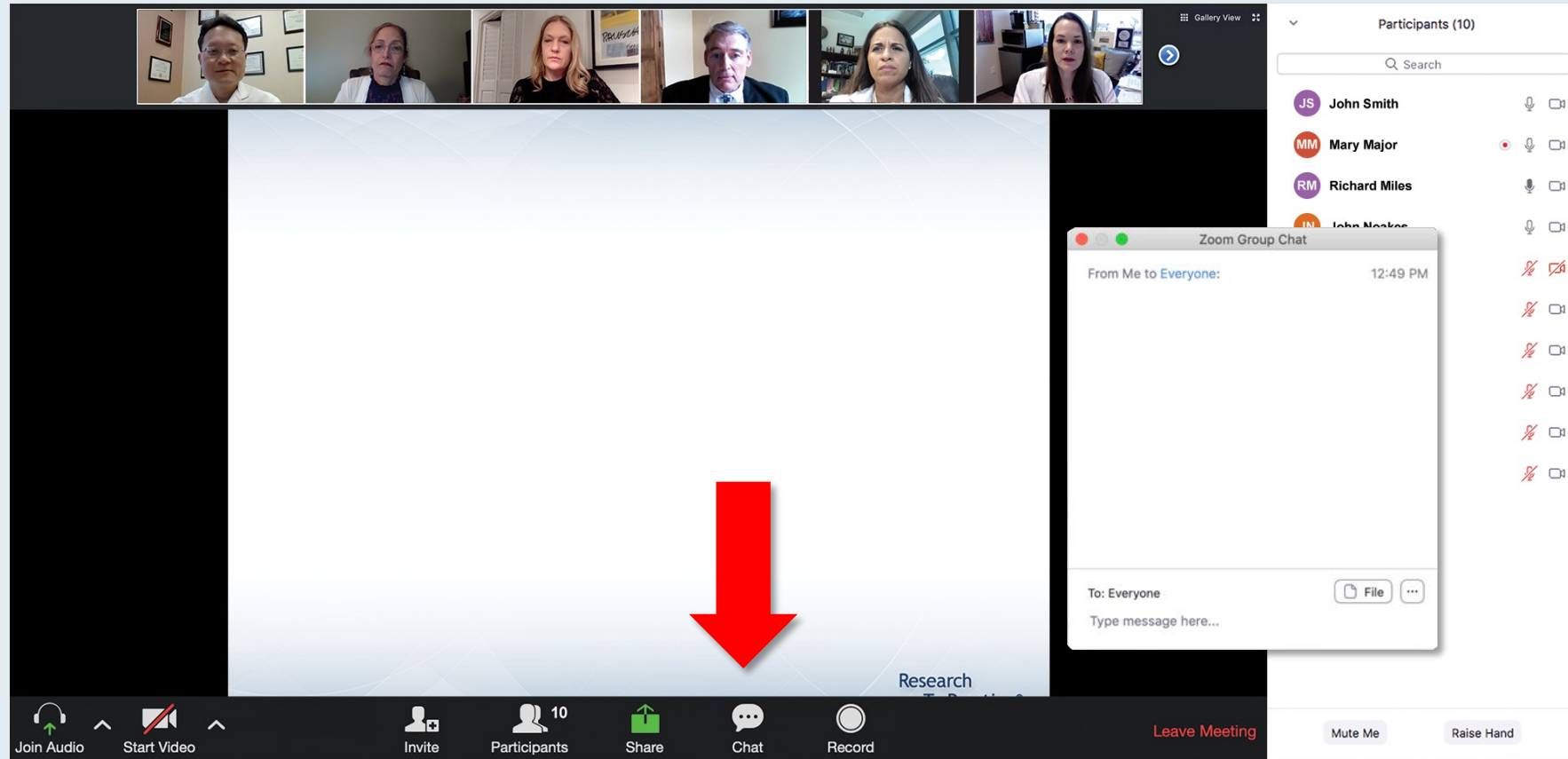


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Senior Physician
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Sarah Cannon Center for Blood Cancer
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Nurse Practitioner
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Nurse Practitioner, Hematology
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Oncology Grand Rounds Nursing Webinar Series

Monday	Tuesday	Wednesday	Thursday	Friday
19	20 Breast Ca 8:30 AM <hr/> Lung Ca 5:00 PM	21 AML 12:00 PM <hr/> CRC and GE Ca 4:45 PM	22 Prostate Ca 8:30 AM <hr/> Lymphomas 5:00 PM	23
26	27 Multiple Myeloma 8:30 AM <hr/> Gynecologic Ca 5:00 PM	28 Bladder Ca 12:00 PM	29 CLL 8:30 AM <hr/> CAR-T 5:00 PM	30





13th Annual Oncology Grand Rounds

Oncology Nurse Practitioners

Case Presentations

- Key patient-education issues
- Biopsychosocial considerations:
 - Family/loved ones
 - The bond that heals

Clinical Investigators

Oncology Strategy

- New agents and regimens
- Predictive biomarkers
- Ongoing research and implications

13th Annual Oncology Grand Rounds

*A Complimentary NCPD Live Webinar Series
Held During the 46th Annual ONS Congress*

Multiple Myeloma

Tuesday, April 27, 2021

8:30 AM – 10:00 AM ET

Medical Oncologists

Shaji K Kumar, MD

Sagar Lonial, MD

Paul G Richardson, MD

Oncology Nurse Practitioners

Charise Gleason, MSN, NP-C, AOCNP

Patricia Mangan, RN, MSN, CRNP, APN, BC

Tiffany A Richards, PhD, ANP-BC, AOCNP

Moderator

Neil Love, MD



Agenda

Module 1: Newly Diagnosed Multiple Myeloma

- Case 1 (Dr Richards): A 73-year-old woman who receives daratumumab, lenalidomide and dexamethasone
- Case 2 (Ms Gleason): A 78-year-old woman who receives kyphoplasty for newly diagnosed multiple myeloma
- Case 3 (Ms Mangan): A 66-year-old woman with newly diagnosed multiple myeloma and lytic lesions

Module 2: Multiagent-Refractory Multiple Myeloma

- Case 4 (Ms Gleason): A 78-year-old woman with t(11;14) multiple regimen-relapsed multiple myeloma
- Case 5 (Ms Mangan): A 77-year-old man with t(11;14) multiple regimen-relapsed multiple myeloma

Module 3: CAR T-Cell Therapy

- Case 6 (Dr Richards): A 56-year-old woman with multiple regimen-relapsed multiple myeloma
- Case 7 (Ms Gleason): A 62-year-old man with multiple regimen-relapsed multiple myeloma

Ms Mangan: Perspective on the evolution of the multiple myeloma treatment landscape



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Case Presentation – A 73-year-old woman who receives daratumumab, lenalidomide and dexamethasone (Part 1)



Dr Richards

- 2020: Retired nurse diagnosed with IgG kappa standard-risk multiple myeloma
 - Daily steroids x 1 month by outside provider → tapered off
- Patient not interested in undergoing transplant
- Daratumumab/lenalidomide/dexamethasone
 - Syncopal episode → treatment hold
 - Great response after 1 dose of daratumumab, 4 doses of lenalidomide
- Observation x 2-3 months → increase in light chains → daratumumab

Case Presentation – A 73-year-old woman who receives daratumumab, lenalidomide and dexamethasone (Part 2)



Dr Richards

- 2020: Retired nurse diagnosed with IgG kappa standard-risk multiple myeloma
 - Daily steroids x 1 month by outside provider → tapered off
- Patient not interested in undergoing transplant
- Daratumumab/lenalidomide/dexamethasone
 - Syncopal episode → treatment hold
 - Great response after 1 dose of daratumumab, 4 doses of lenalidomide
- Observation x 2-3 months → increase in light chains → daratumumab
- ***Workup and education for patients beginning daratumumab***

Ms Mangan: Patient education on subcutaneous daratumumab



Case Presentation – A 78-year-old woman who receives kyphoplasty for newly diagnosed multiple myeloma



Ms Gleason

- Retired teacher who relocated to live with her daughter was diagnosed with IgG kappa standard-risk multiple myeloma soon after moving
- Daratumumab/lenalidomide/dexamethasone → maintenance lenalidomide
- Underwent kyphoplasty for a vertebral fracture
- Pain management; use of complementary strategies to ameliorate pain

The antitumor component of autologous stem cell transplantation (ASCT) is...

1. Re-transplanted marrow cells
2. Chemotherapy
3. The patient's T cells
4. I don't know

The antitumor component of chimeric antigen receptor (CAR) T-cell therapy is...

1. Re-transplanted marrow cells
2. Chemotherapy
3. The patient's T cells
4. I don't know

In general, which patients with multiple myeloma (MM) who are transplant eligible receive post-ASCT maintenance therapy such as lenalidomide?

1. Most or all
2. Most or all except for those who are in complete remission
3. Most or all except for those who are minimal residual disease negative
4. Mainly patients with high-risk MM (eg, 17p deletion)
5. I don't know

Patients with del(17p) MM often receive post-ASCT transplant maintenance with...

1. An IMiD alone (eg, lenalidomide)
2. An IMiD and a proteasome inhibitor (eg, lenalidomide/bortezomib)
3. I don't know

Case Presentation – A 66-year-old woman with newly diagnosed multiple myeloma and lytic lesions (Part 1)



Ms Mangan

- Former NICU nurse who presented to emergency room with worsening back pain after lifting lawn furniture
- Diagnosed with IgG kappa multiple myeloma, anemia and an L2 compression fracture with soft tissue component and other lytic lesions throughout skeleton
- Induction therapy: RVd with XRT and zoledronic acid → maintenance lenalidomide
- Peripheral neuropathy associated with bortezomib

Case Presentation – A 66-year-old woman with newly diagnosed multiple myeloma and lytic lesions (Part 2)



Ms Mangan

- Former NICU nurse who presented to emergency room with worsening back pain after lifting lawn furniture
- Diagnosed with IgG kappa multiple myeloma, anemia and an L2 compression fracture with soft tissue component and other lytic lesions throughout skeleton
- Induction therapy: RVd with XRT and zoledronic acid → maintenance lenalidomide
- Peripheral neuropathy associated with bortezomib
- ***Dermatologic side effects associated with lenalidomide***

Case Presentation – A 66-year-old woman with newly diagnosed multiple myeloma and lytic lesions (Part 3)



Ms Mangan

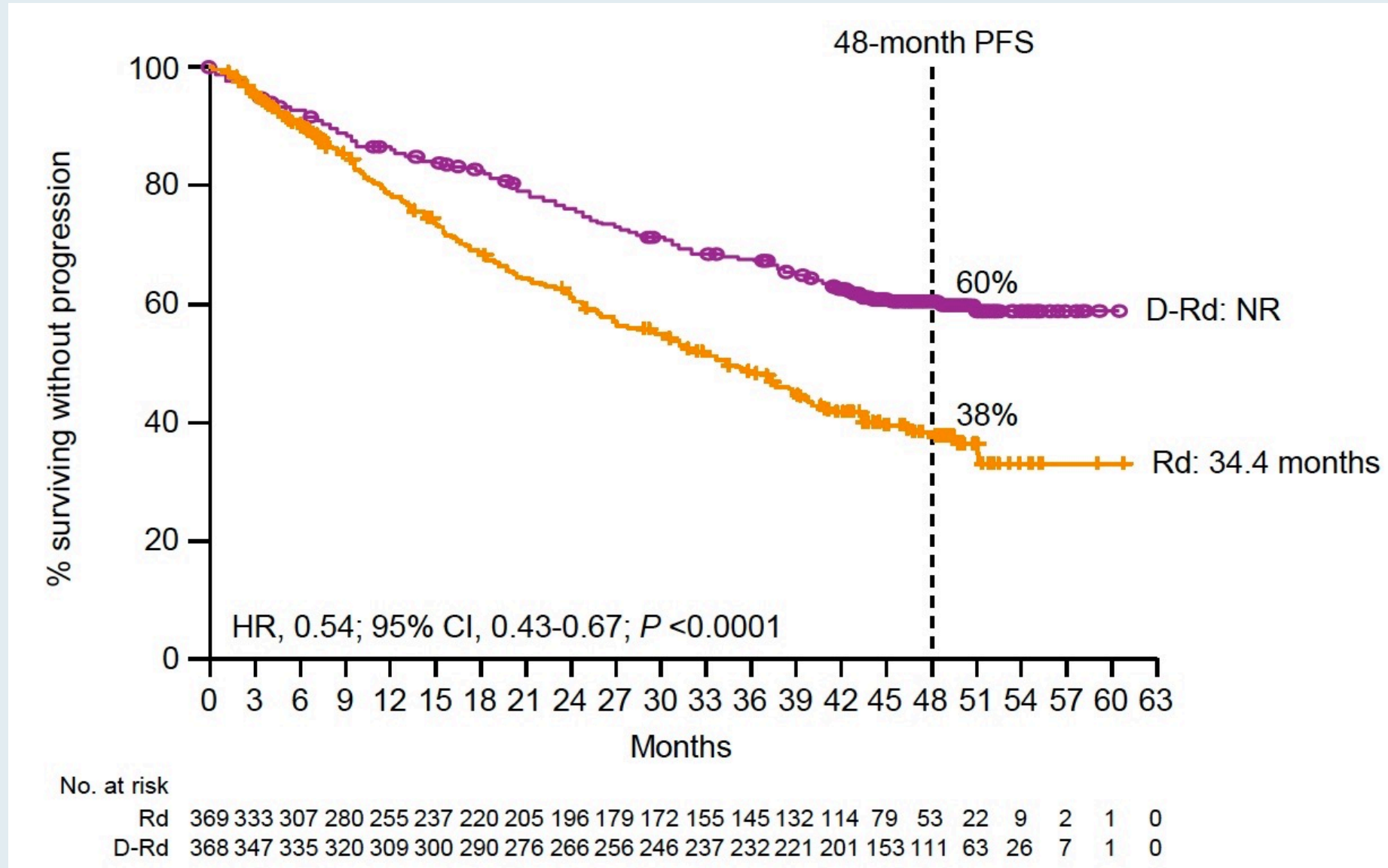
- Former NICU nurse who presented to emergency room with worsening back pain after lifting lawn furniture
- Diagnosed with IgG kappa multiple myeloma, anemia and an L2 compression fracture with soft tissue component and other lytic lesions throughout skeleton
- Induction therapy: RVD with XRT and zoledronic acid → maintenance lenalidomide
- Peripheral neuropathy associated with bortezomib
- Dermatologic side effects associated with lenalidomide
- ***In remission with good quality of life on maintenance lenalidomide***

Updated Analysis of Daratumumab plus Lenalidomide and Dexamethasone (D-Rd) versus Lenalidomide and Dexamethasone (Rd) in Patients with Transplant-Ineligible Newly Diagnosed Multiple Myeloma (NDMM): The Phase 3 MAIA Study

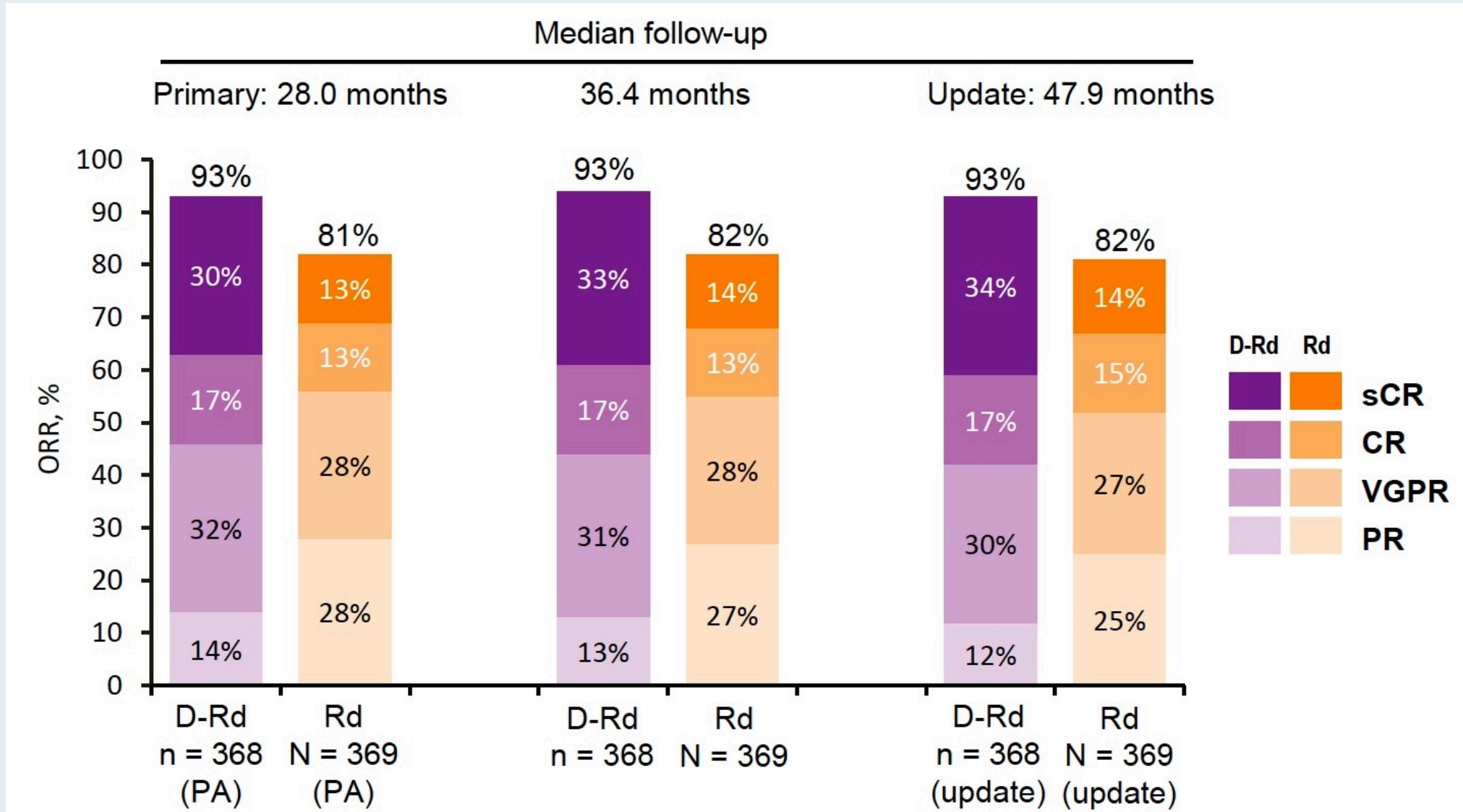
Kumar SK et al.

ASH 2020;Abstract 2276.

MAIA: Updated PFS (Median Follow-Up 48 Months)



MAIA: Updated Response



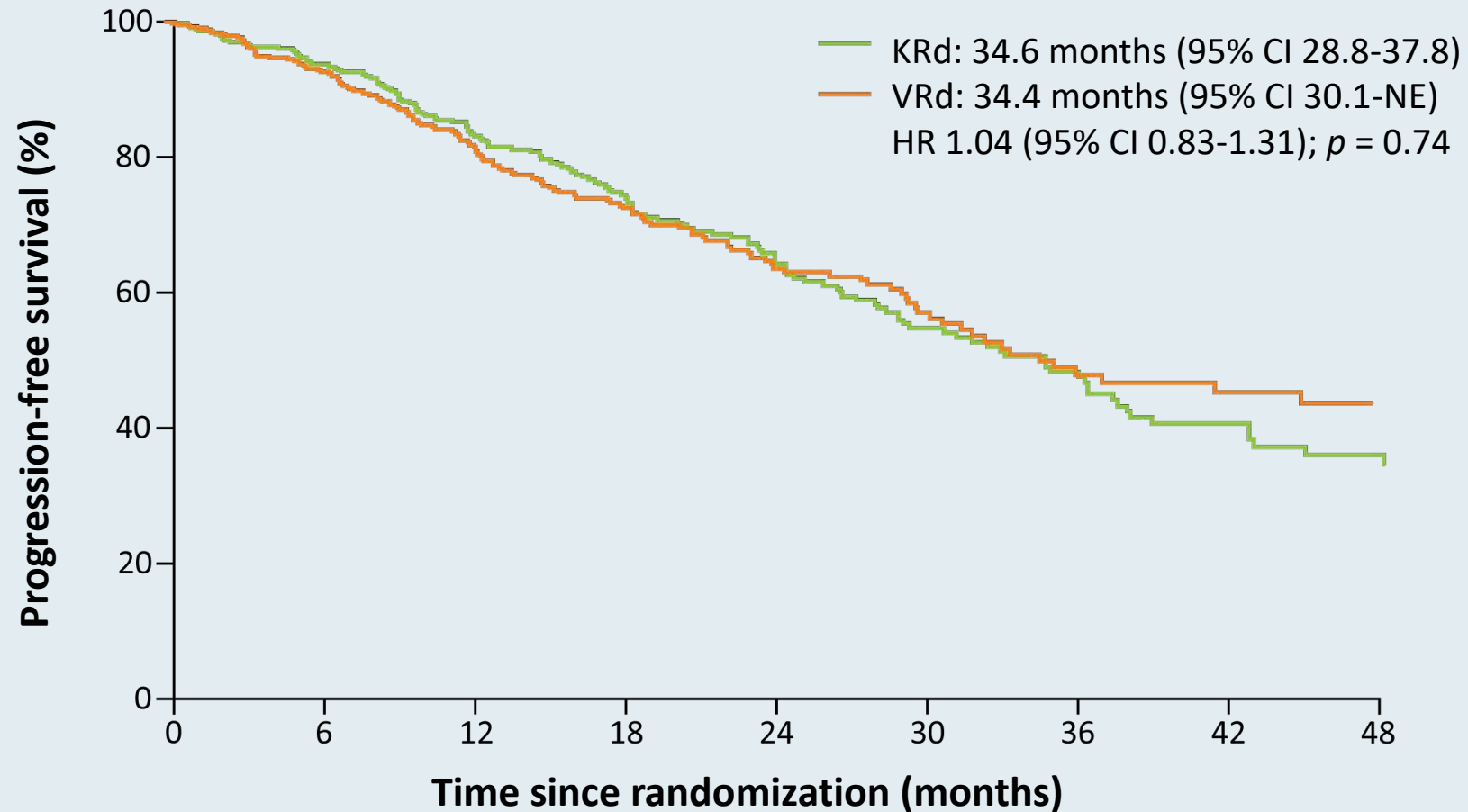


Carfilzomib or bortezomib in combination with lenalidomide and dexamethasone for patients with newly diagnosed multiple myeloma without intention for immediate autologous stem-cell transplantation (ENDURANCE): a multicentre, open-label, phase 3, randomised, controlled trial

Shaji K Kumar, Susanna J Jacobus, Adam D Cohen, Matthias Weiss, Natalie Callander, Avina K Singh, Terri L Parker, Alexander Menter, Xuezhong Yang, Benjamin Parsons, Pankaj Kumar, Prashant Kapoor, Aaron Rosenberg, Jeffrey A Zonder, Edward Faber Jr, Sagar Lonial, Kenneth C Anderson, Paul G Richardson, Robert Z Orlowski, Lynne I Wagner, S Vincent Rajkumar

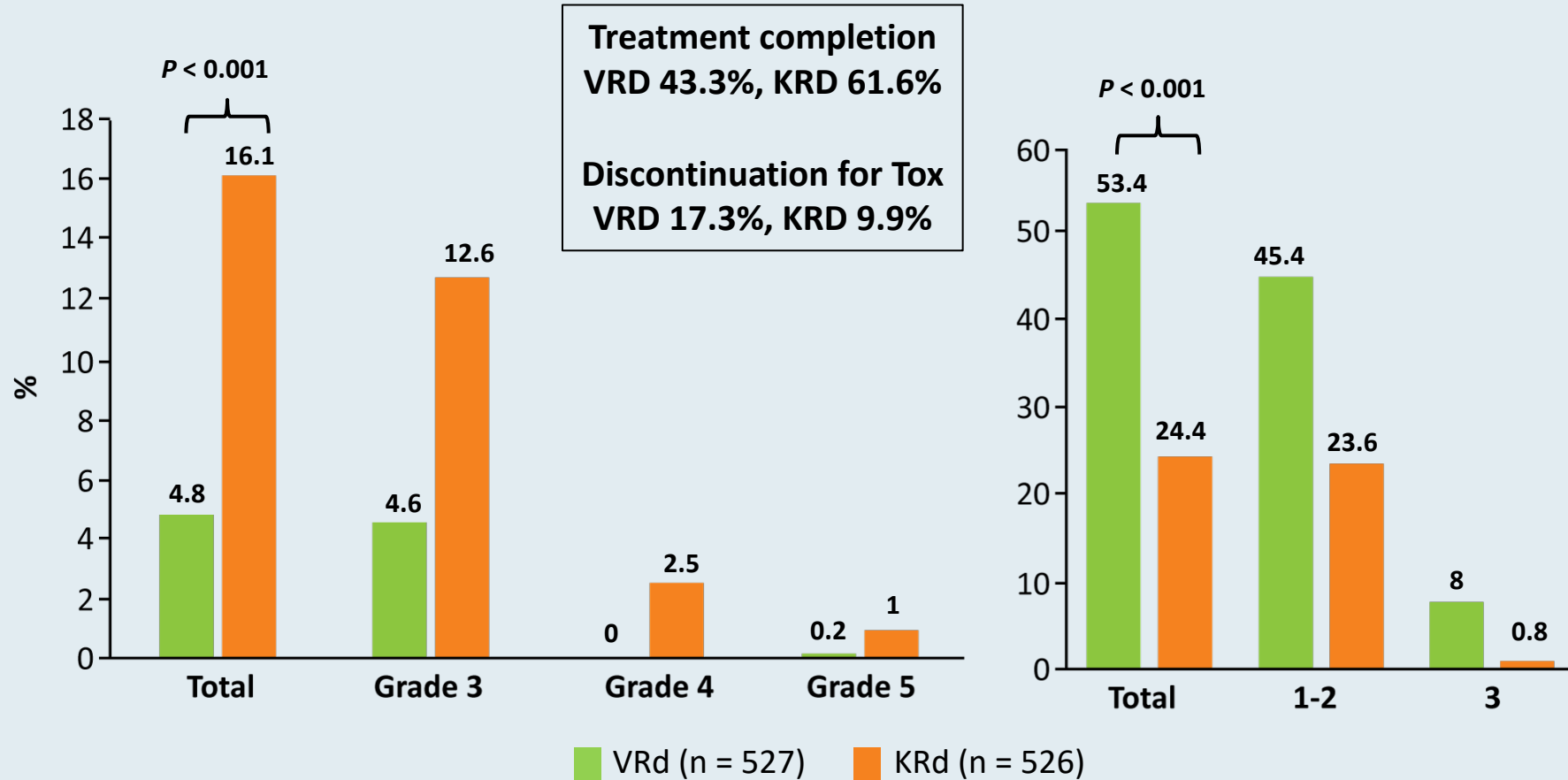
Lancet Oncol 2020;21(10):1317-30

ENDURANCE (E1A11): Primary PFS Endpoint (Second Interim Analysis)



- Median OS has not been reached in either group at median follow-up of 24 months; patients will continue on long-term follow-up for overall survival

ENDURANCE (E1A11): Treatment-Emergent Adverse Events of Interest



Cardiac, pulmonary and renal

Peripheral neuropathy*

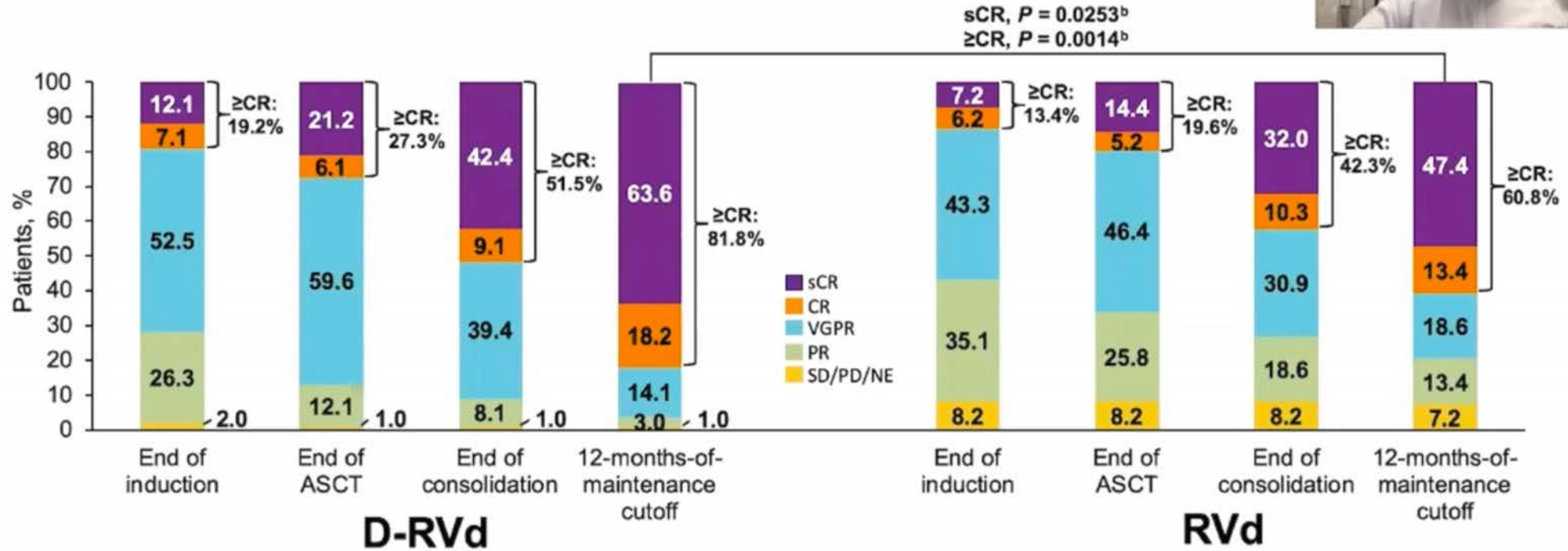
* Grades 1-2 not required reporting

Daratumumab (DARA) plus Lenalidomide, Bortezomib, and Dexamethasone (RVd) in Patients with Transplant-Eligible Newly Diagnosed Multiple Myeloma (NDMM): Updated Analysis of Griffin After 12 Months of Maintenance Therapy

Kaufman JL et al.

ASH 2020;Abstract 549.

Responses Deepened over Time^a

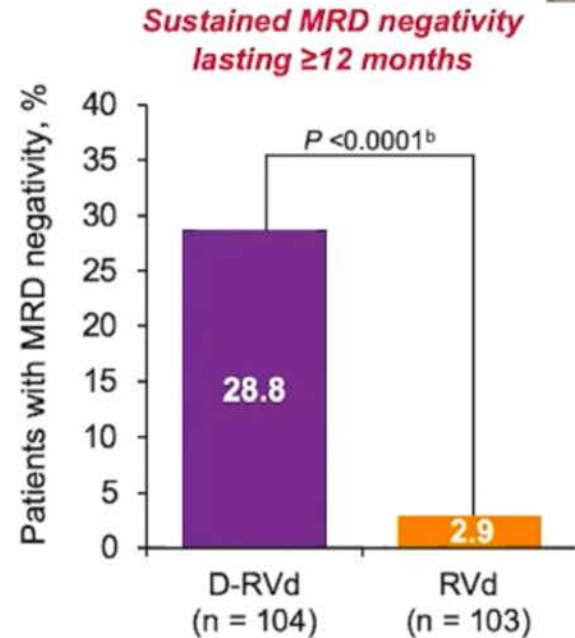
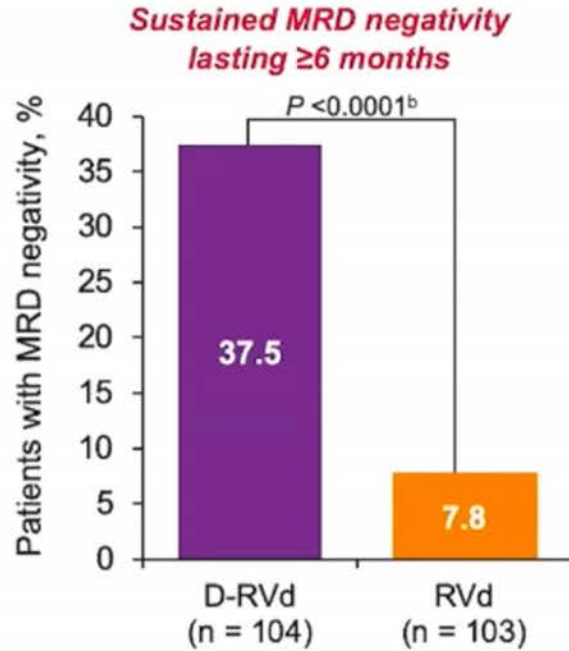


- Results for end of induction, ASCT, and consolidation are based on a median follow up of 13.5 months at the primary analysis
- Median follow up at 12-months-of-maintenance therapy cutoff was 27.4 months

Response rates and depths were greater for D-RVd at all time points

PR, partial response. SD/PD/NE, stable disease/progressive disease/not evaluable. ^aData are shown for the response-evaluable population. ^bP values (2-sided) were calculated using the Cochran–Mantel–Haenszel chi-square test.

Durable MRD (10^{-5}) Negativity^a Lasting ≥ 6 and ≥ 12 Months



- Among patients who achieved MRD negative (10^{-5}) status, sustained MRD negativity lasting ≥ 12 months was noted in 30/65 (46.2%) and 3/28 (10.7%) patients

D-RVd improved rates of sustained MRD negativity versus RVd

^aThe threshold of MRD negativity was defined as 1 tumor cell per 10^5 white cells. MRD status is based on the assessment of bone marrow aspirates by NGS in accordance with International Myeloma Working Group criteria. Median follow-up was 27.4 months, and MRD-negativity rates are among the ITT population. ^bP values were calculated using the Fisher's exact test.

Most Common Infections with First Onset during Maintenance Therapy (Cycles 7+)^a



Patients, n (%)	D-RVd (D-R maintenance, n = 89)		RVd (R maintenance, n = 71)	
	Any grade	Grade 3/4	Any grade	Grade 3/4
Most common (>5%) infections				
Upper respiratory tract infection	47 (53)	4 (4)	29 (41)	2 (3)
Pneumonia	12 (13)	5 (6)	11 (15)	9 (13)
Sinusitis	9 (10)	0	7 (10)	0
Influenza	9 (10)	0	5 (7)	0
Nasopharyngitis	9 (10)	0	1 (1)	0
Urinary tract infection	8 (9)	0	1 (1)	0
Bronchitis	7 (8)	1 (1)	5 (7)	1 (1)
Cellulitis	7 (8)	1 (1)	2 (3)	1 (1)

Similar rates of any grade and grade 3/4 infections occurred for D-RVd vs RVd

^aAny grade TEAEs that occurred in >5% of patients in either group are listed. The safety analysis population included all randomized patients who received ≥1 dose of the study treatment; analysis was according to treatment received.

FDA Approval of Subcutaneous Daratumumab (Daratumumab and Hyaluronidase-fihj) for Newly Diagnosed or Relapsed/Refractory MM

Press Release – May 1, 2020

“On May 1, 2020, the Food and Drug Administration approved daratumumab and hyaluronidase-fihj for adult patients with newly diagnosed or relapsed/refractory multiple myeloma. This new product allows for subcutaneous dosing of daratumumab.”

Daratumumab and hyaluronidase-fihj is approved for certain indications that intravenous daratumumab had previously received.

Efficacy of daratumumab and hyaluronidase-fihj (monotherapy) was evaluated in COLUMBA (NCT03277105), an open-label noninferiority trial randomly assigning 263 patients to daratumumab and hyaluronidase-fihj and 259 to intravenous daratumumab.

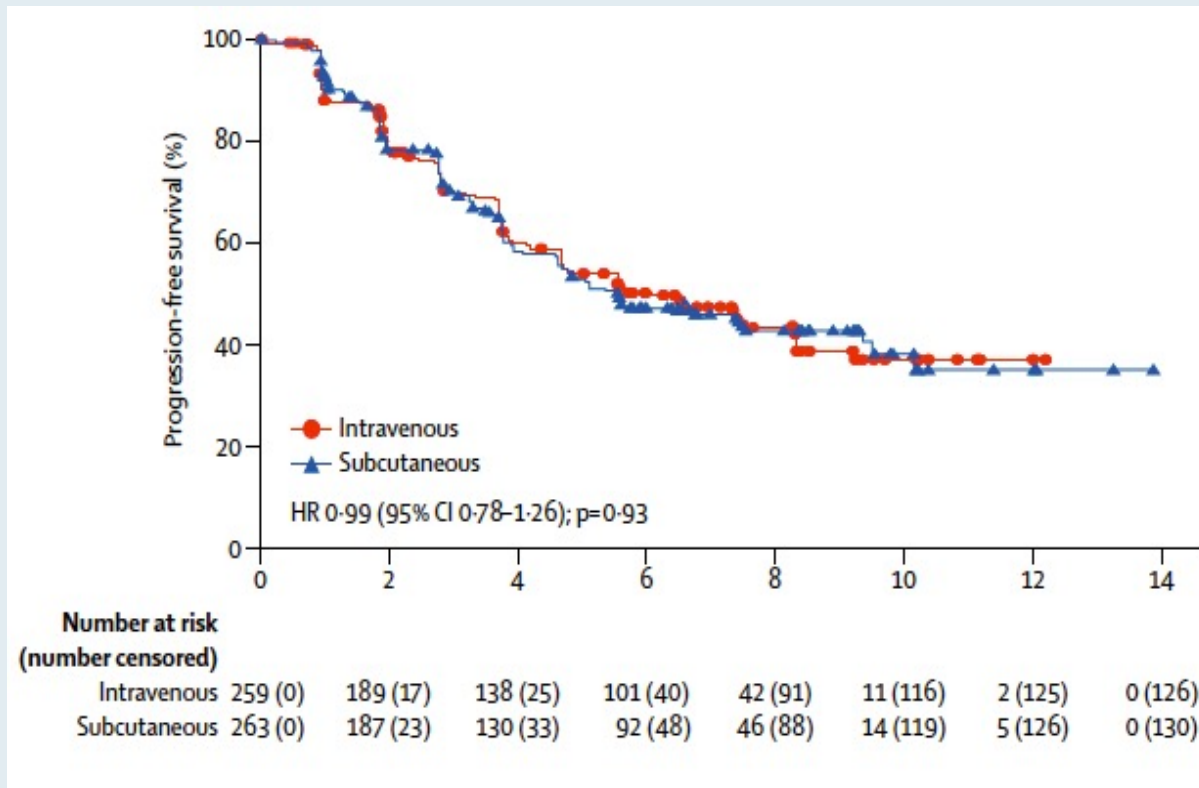


Subcutaneous versus intravenous daratumumab in patients with relapsed or refractory multiple myeloma (COLUMBA): a multicentre, open-label, non-inferiority, randomised, phase 3 trial

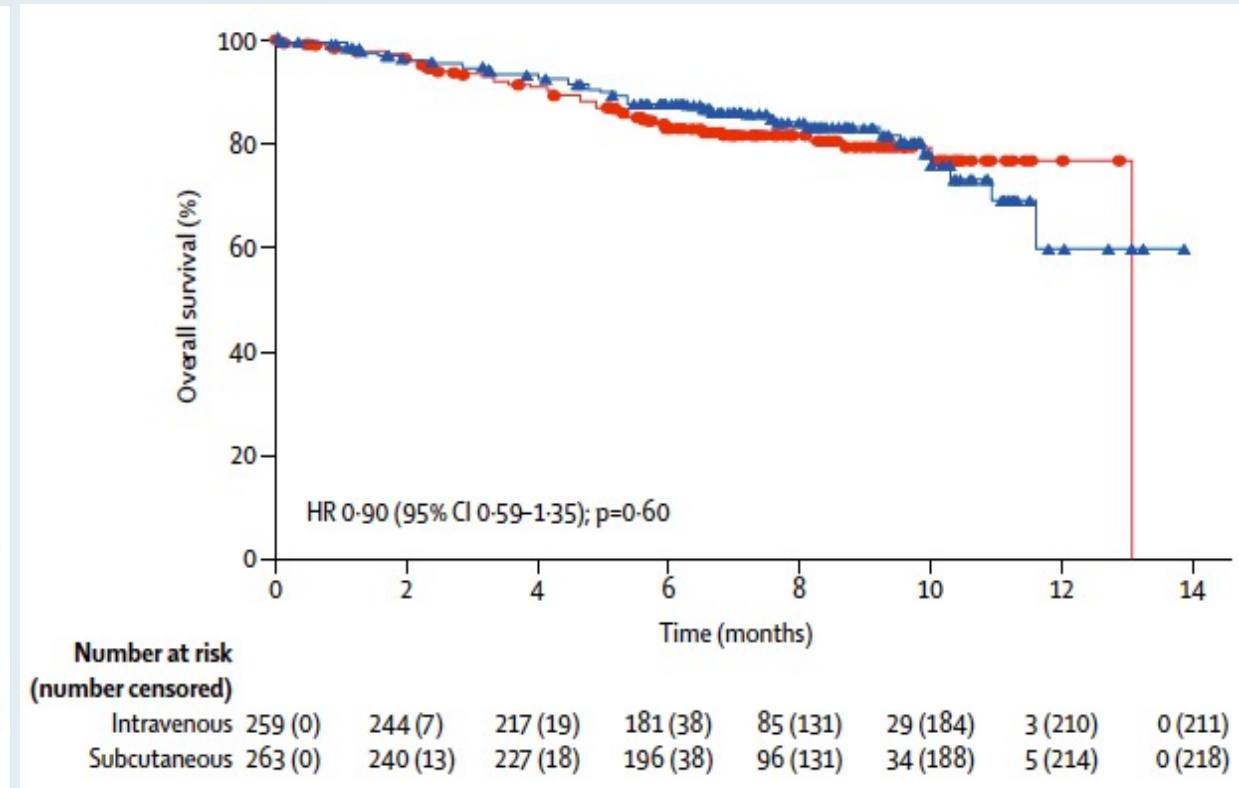
Maria-Victoria Mateos, Hareth Nahi, Wojciech Legiec, Sebastian Grosicki, Vladimir Vorobyev, Ivan Spicka, Vania Hungria, Sibirina Korenkova, Nizar Bahlis, Max Flogegard, Joan Bladé, Philippe Moreau, Martin Kaiser, Shinsuke Iida, Jacob Laubach, Hila Magen, Michele Cavo, Cyrille Hulin, Darrell White, Valerio De Stefano, Pamela L Clemens, Tara Masterson, Kristen Lantz, Lisa O'Rourke, Christoph Heuck, Xiang Qin, Dolly A Parasrampuria, Zhilong Yuan, Steven Xu, Ming Qi, Saad Z Usmani

COLUMBA: Subcutaneous versus Intravenous Daratumumab

Progression-Free Survival



Overall Survival



(Median follow-up 7.5 months)

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Module 2: Multiagent-Refractory Multiple Myeloma

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- Case 5 (Ms Mangan): A 77-year-old man with t(11;14) multiple regimen-relapsed multiple myeloma

Module 3: CAR T-Cell Therapy

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The primary safety concern with belantamab mafodotin is...

1. Renal toxicity
2. Hepatic toxicity
3. Ophthalmic toxicity
4. Peripheral neuropathy
5. I don't know

Case Presentation – A 78-year-old woman with t(11;14) multiple regimen-relapsed multiple myeloma (Part 1)



Ms Gleason

- Slowly progressing myeloma whose disease has progressed on several regimens, including venetoclax
- Treated with belantamab mafodotin on the DREAMM-4 clinical trial → 3-year response

Case Presentation – A 78-year-old woman with t(11;14) multiple regimen-relapsed multiple myeloma (Part 2)



Ms Gleason

- Slowly progressing myeloma whose disease has progressed on several regimens, including venetoclax
- Treated with belantamab mafodotin on the DREAMM-4 clinical trial → 3-year response
- ***Vision issues associated with belantamab mafodotin***

Case Presentation – A 77-year-old man with t(11;14) multiple regimen-relapsed multiple myeloma

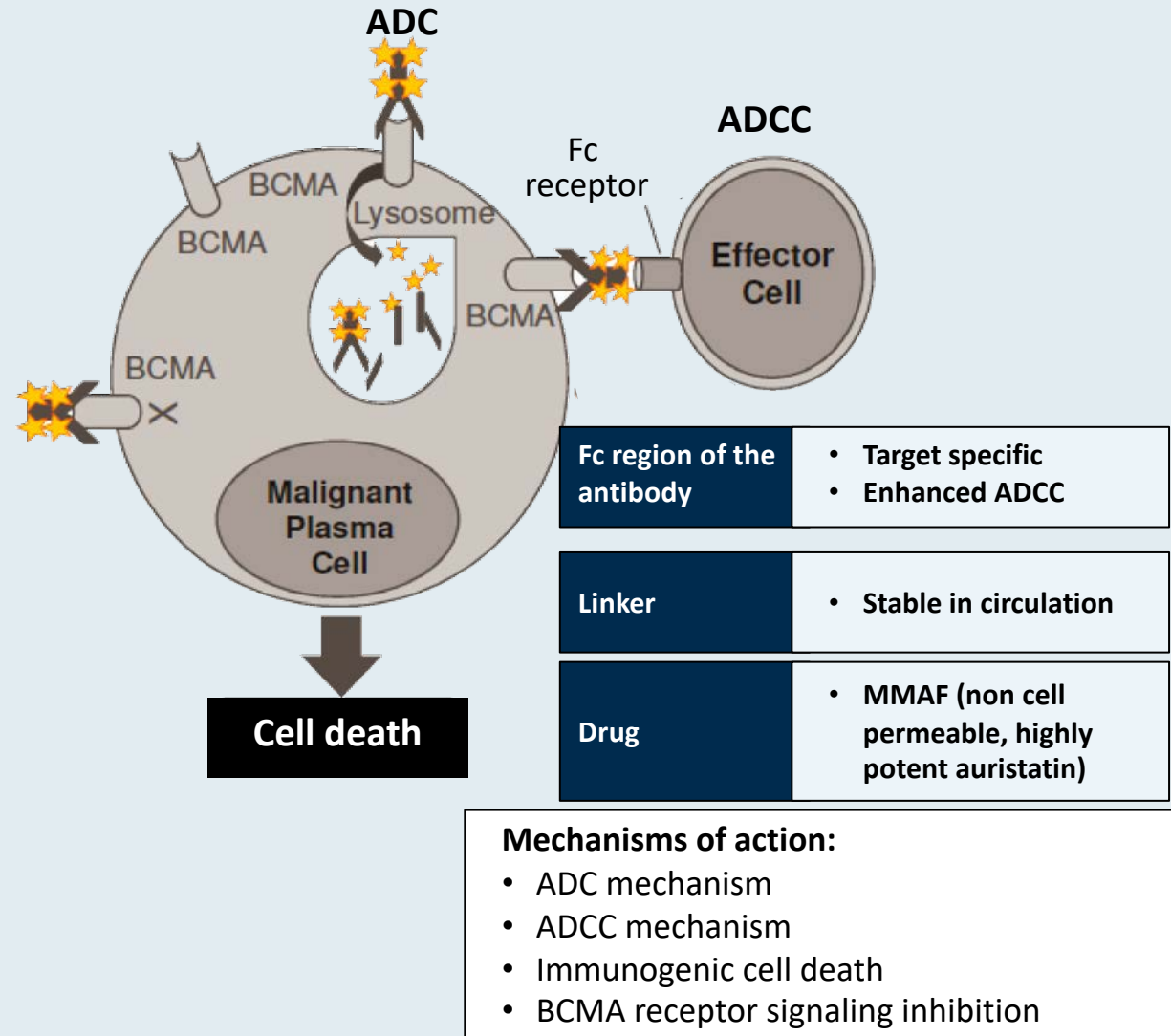


Ms Mangan

- Diagnosed with multiple myeloma 6 months after a CVA
- Front-line therapy: Bortezomib/dexamethasone → ASCT → Maintenance bortezomib
- Subsequent treatments: Lenalidomide/dexamethasone (Rd), Ixazomib/Rd, Ixazomib/pomalidomide/dexamethasone
- Venetoclax/carfilzomib/dexamethasone – t(11;14)
- Belantamab mafodotin, with rapid response
 - Ocular toxicity
 - Resolution of ocular toxicity, mild drop in platelets, transient fever

Belantamab Mafodotin: Anti-BCMA Antibody-Drug Conjugate

- B-cell maturation factor (BCMA) expression is restricted to B cells at later stages of differentiation and is required for survival of plasma cells
- BCMA is broadly expressed at variable levels on malignant plasma cells
- Belantamab mafodotin is a humanized, afucosylated IgG1 anti-BCMA antibody conjugated to microtubule disrupting agent MMAF via a stable, protease-resistant maleimidocaproyl linker



FDA Grants Accelerated Approval to Belantamab Mafodotin-blmf for Multiple Myeloma

Press Release – August 5, 2020

“The Food and Drug Administration granted accelerated approval to belantamab mafodotin-blmf for adult patients with relapsed or refractory multiple myeloma who have received at least 4 prior therapies, including an anti-CD38 monoclonal antibody, a proteasome inhibitor, and an immunomodulatory agent.

Belantamab mafodotin-blmf was evaluated in DREAMM-2 (NCT 03525678), an open-label, multicenter trial. Patients received either belantamab mafodotin-blmf, 2.5 mg/kg or 3.4 mg/kg intravenously, once every 3 weeks until disease progression or unacceptable toxicity.

Efficacy was based on overall response rate (ORR) and response duration, as evaluated by an independent review committee using the International Myeloma Working Group uniform response criteria. The ORR was 31%. Seventy-three percent of responders had response durations ≥ 6 months. These results were observed in patients receiving the recommended dose of 2.5 mg/kg.

The prescribing information includes a Boxed Warning stating belantamab mafodotin-blmf causes changes in the corneal epithelium resulting in alterations in vision, including severe vision loss and corneal ulcer, and symptoms, such as blurred vision and dry eyes. Ophthalmic exams at baseline, prior to each dose, and promptly for worsening symptoms should be conducted.”

DREAMM-2: Single-Agent Belantamab Mafodotin (Belamaf) in Patients with Relapsed/Refractory Multiple Myeloma (RRMM) – 1-Year Outcomes By Prior Therapies

Lonial S et al.

ASH 2020;Abstract 1417.

DREAMM-2: Single-Agent Belantamab Mafodotin Efficacy Outcomes

	Patients with 3-6 prior therapies (n = 47)	Patients with ≥7 prior therapies (n = 50)
ORR	34%	30%
Median DoR	11.0 mo	13.1 mo
Probability of DoR ≥6 months	63%	73%
Median PFS	2.9 mo	2.2 mo
Probability of PFS at 6 months	35%	30%

ORR = overall response rate; DoR = duration of response; PFS = progression-free survival

DREAMM-6: Safety, Tolerability and Clinical Activity of Belantamab Mafodotin (Belamaf) in Combination with Bortezomib/Dexamethasone (BorDex) in Relapsed/Refractory Multiple Myeloma (RRMM)

Popat R et al.

ASH 2020;Abstract 1419.

DREAMM-6: Belantamab Mafodotin + Vd Clinical Activity

- Response was evaluable in all patients:
 - ORR = 78%
 - VGPR = 50%
 - PR = 28%
 - SD = 17%
 - CBR = 83%
- Median DoR = not reached (median 18.2 weeks on treatment)

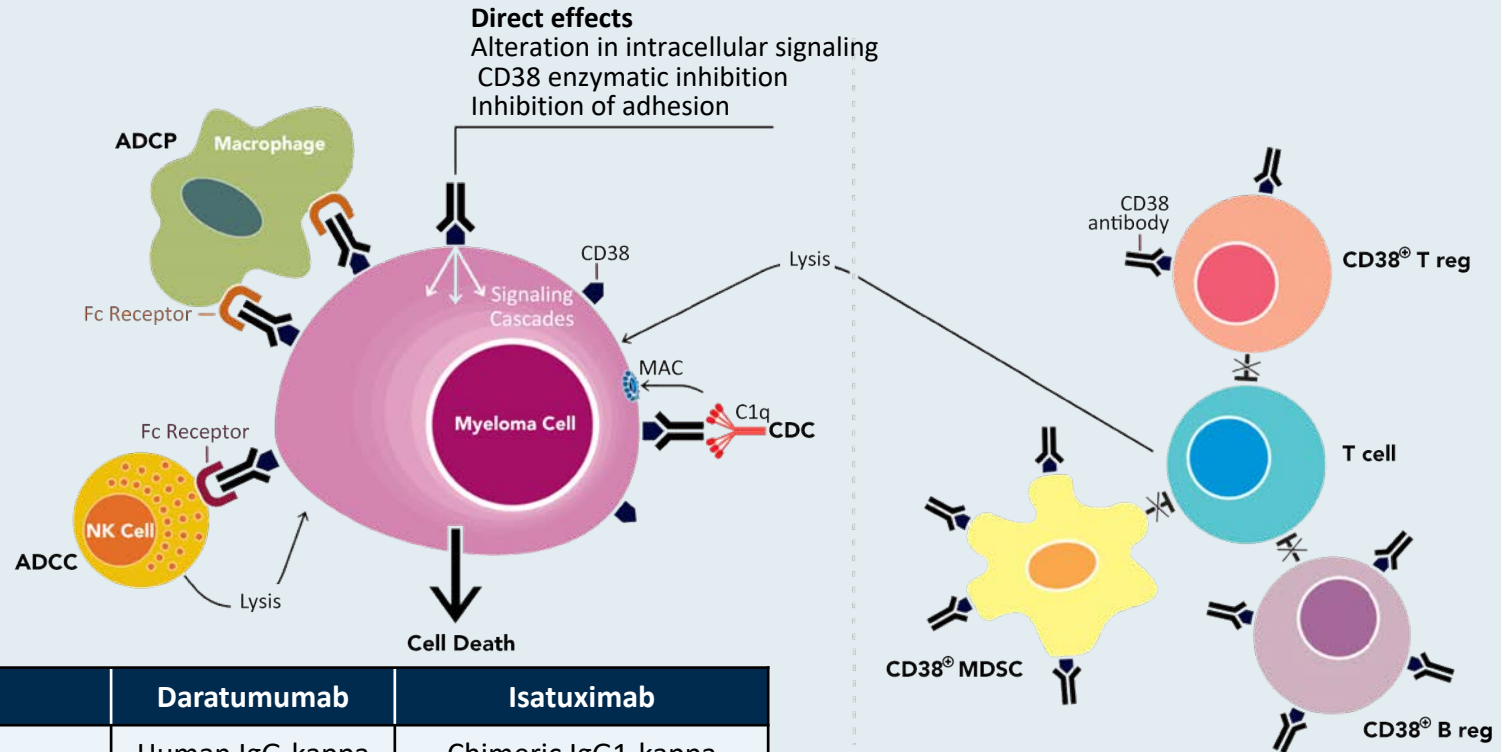
DREAMM-6: Overview of Adverse Events

Patients with AE, n (%)	Belantamab mafodotin 2.5 mg/kg single + Vd (N = 18)
AEs related to study treatment Grade 3/4 AE AEs leading to permanent discontinuation of a study treatment AEs leading to permanent discontinuation of belamaf	18 (100%) 16 (89%) 5 (28%) 0
AEs leading to dose reductions Corneal events Thrombocytopenia	13 (72%) 7 (39%) 6 (33%)
AEs leading to dose interruption/delay Corneal events Thrombocytopenia	18 (100%) 15 (83%) 7 (39%)
Any serious AE (SAE) Fatal SAE	12 (67%) 0
SAEs related to study treatment	5 (28%)

Anti-CD38 Antibodies: Mechanism of Action, Structural and Pharmacologic Similarities and Differences

Fc-dependent immune effector mechanisms and direct effects

Immunomodulatory effects

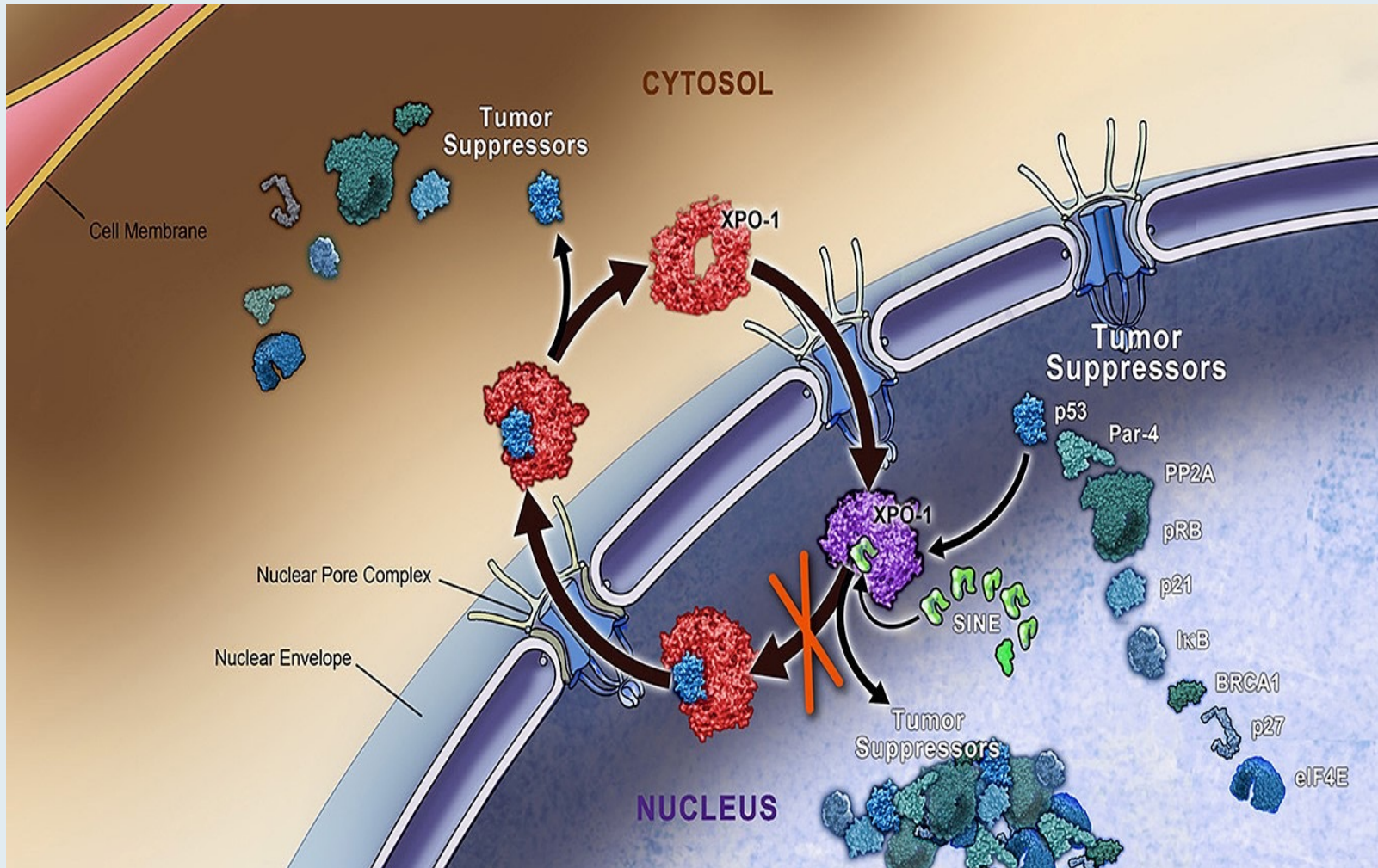


Mechanism of action	Daratumumab	Isatuximab
Origin, isotype	Human IgG-kappa	Chimeric IgG1-kappa
CDC	+++	+
ADCC	++	++
ADCP	+++	Not determined
PCD direct	—	++
PCD cross linking	+++	+++
Modulation ectoenzyme function	+	+++

Selinexor is associated with significant...

1. Cytopenias
2. Gastrointestinal side effects
3. Peripheral neuropathy
4. I don't know

Selinexor Mechanism of Action



- Exportin 1 (XPO1) is the major nuclear export protein for tumor suppressor proteins (TSPs), the glucocorticoid receptor (GR) and eIF4E-bound oncoprotein mRNAs (c-myc, BCL2, BCL-xL and cyclins).
- XPO1 is overexpressed in MM and its levels often correlate with poor prognosis.
- Selinexor is a first-in-class XPO1 inhibitor that induces nuclear retention and activation of TSPs and the GR in the presence of steroids and suppresses oncoprotein expression.

FDA Approves Selinexor in Combination with Bortezomib and Dexamethasone for Refractory or Relapsed Multiple Myeloma

Press Release – December 18, 2020

“The Food and Drug Administration approved selinexor in combination with bortezomib and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy.

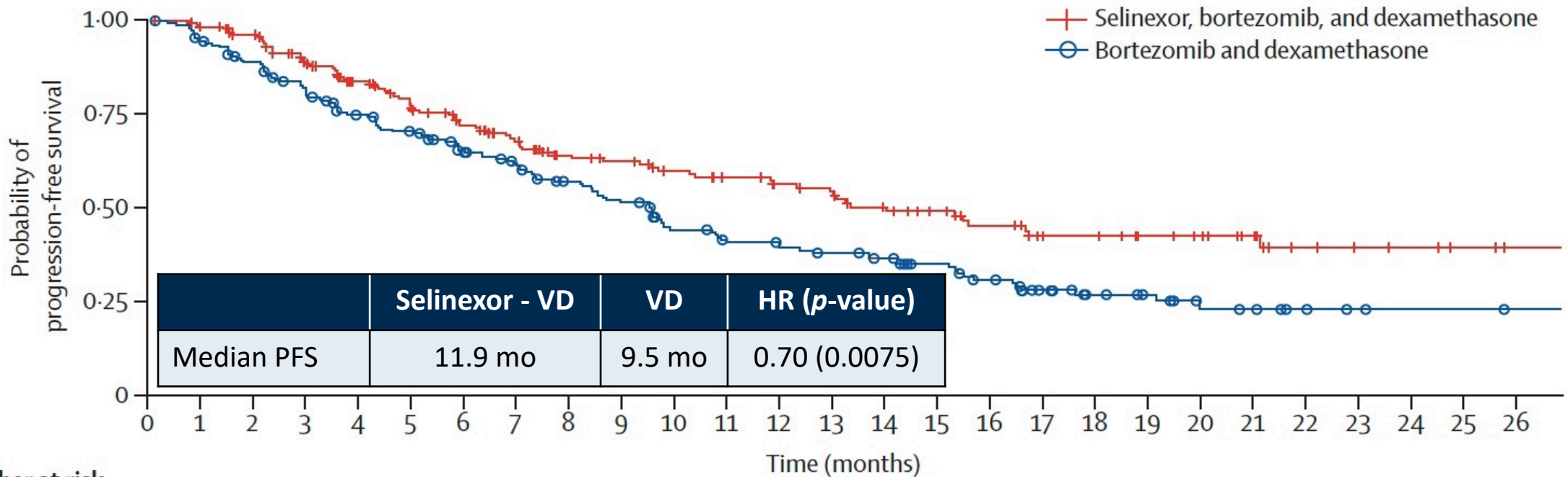
FDA granted selinexor accelerated approval in 2019 in combination with dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma (RRMM) who received at least four prior therapies and whose disease is refractory to at least two proteasome inhibitors, at least two immunomodulatory agents, and an anti-CD38 monoclonal antibody.

Efficacy of selinexor in combination with bortezomib and dexamethasone was evaluated in the BOSTON Trial (KCP-330-023, NCT03110562), a randomized (1:1) open-label, multicenter, active comparator-controlled trial in patients with RRMM who had previously received at least one and at most three prior therapies.”

Once-per-week selinexor, bortezomib, and dexamethasone versus twice-per-week bortezomib and dexamethasone in patients with multiple myeloma (BOSTON): a randomised, open-label, phase 3 trial

Sebastian Grosicki, Maryana Simonova, Ivan Spicka, Ludek Pour, Iryna Kriachok, Maria Gavriatopoulou, Halyna Pylypenko, Holger W Auner, Xavier Leleu, Vadim Doronin, Ganna Usenko, Nizar J Bahlis, Roman Hajek, Reuben Benjamin, Tuphan K Dolai, Dinesh K Sinha, Christopher P Venner, Mamta Garg, Mercedes Gironella, Artur Jurczyszyn, Pawel Robak, Monica Galli, Craig Wallington-Beddoe, Atanas Radinoff, Galina Salogub, Don A Stevens, Supratik Basu, Anna M Liberati, Hang Quach, Vesselina S Goranova-Marinova, Jelena Bila, Eirini Katodritou, Hanna Oliynyk, Sybiryina Korenkova, Jeevan Kumar, Sundar Jagannath, Phillipe Moreau, Moshe Levy, Darrell White, Moshe E Gatt, Thierry Facon, Maria V Mateos, Michele Cavo, Donna Reece, Larry D Anderson Jr, Jean-Richard Saint-Martin, Jacqueline Jeha, Anita A Joshi, Yi Chai, Lingling Li, Vishnuvardhan Peddagali, Melina Arazy, Jatin Shah, Sharon Shacham, Michael G Kauffman, Meletios A Dimopoulos, Paul G Richardson, Sosana Delimpasi**

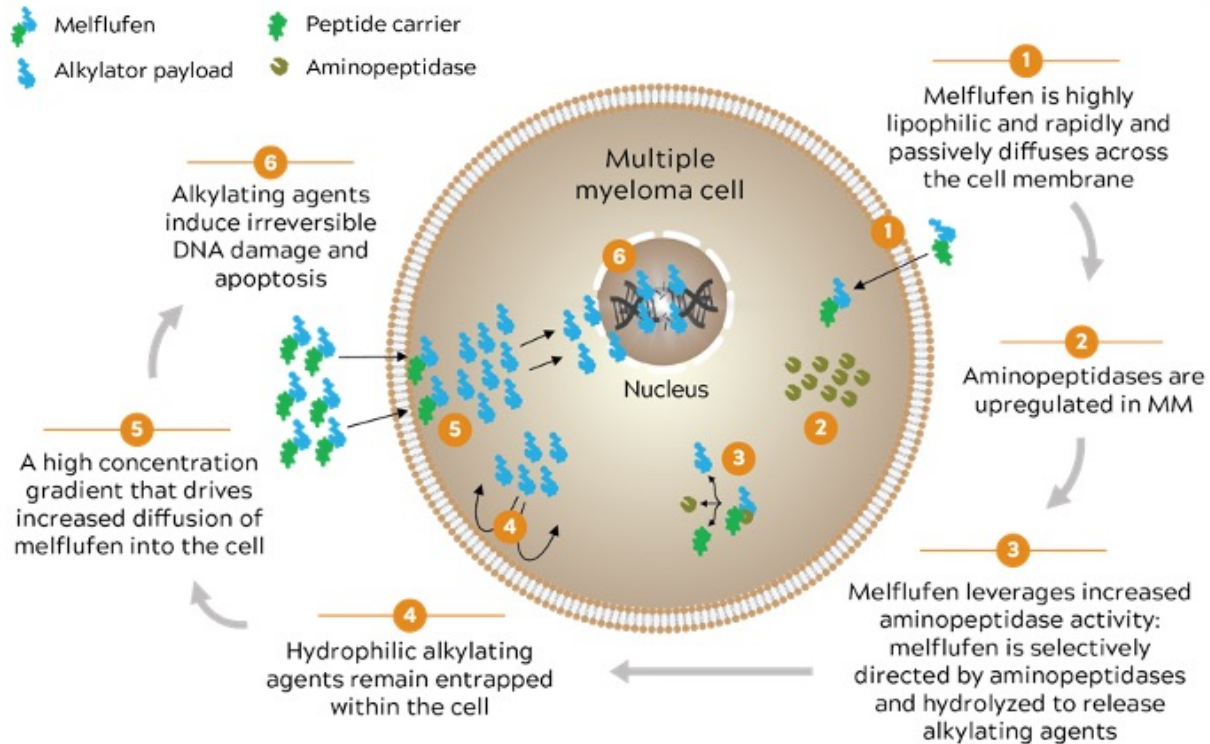
BOSTON: Progression-Free Survival (ITT)



	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26
Number at risk (number censored)																											
Selinexor, bortezomib, and dexamethasone	195 (0)	187 (5)	175 (12)	152 (21)	135 (31)	117 (37)	106 (42)	89 (50)	79 (57)	76 (59)	69 (63)	64 (66)	57 (71)	51 (73)	45 (76)	41 (80)	35 (83)	27 (89)	26 (90)	22 (94)	19 (97)	14 (102)	9 (106)	7 (108)	6 (109)	4 (111)	2 (113)
Bortezomib and dexamethasone	207 (0)	187 (8)	175 (10)	152 (15)	138 (20)	127 (22)	111 (29)	100 (32)	90 (37)	81 (37)	66 (41)	59 (43)	56 (44)	53 (45)	49 (47)	42 (52)	35 (55)	26 (60)	20 (65)	16 (69)	10 (73)	8 (75)	5 (78)	4 (79)	3 (80)	3 (80)	2 (81)

Melphalan Flufenamide (Melflufen): Mechanism of Action

Melflufen is an investigational first-in-class peptide-drug conjugate (PDC) that **targets aminopeptidases and rapidly releases alkylating agents into tumor cells.**¹⁻⁵



- In the pivotal phase 2 HORIZON study (OP-106), the activity of melflufen plus dexamethasone was further shown in heavily pretreated RRMM patients refractory to pomalidomide and/or anti-CD38 mAb therapy, with acceptable safety⁶
 - ORR was 29%; median PFS was 4.2 months, and median OS was 11.6 months
 - Grade 3/4 hematologic AEs were common (mainly neutropenia [79%], thrombocytopenia [76%], and anemia [71%]) but clinically manageable; nonhematologic AEs were infrequent

AE, adverse event; mAb, monoclonal antibody; ORR, overall response rate; OS, overall survival; PFS, progression-rate survival; RRMM, relapsed/refractory multiple myeloma.

FDA Grants Accelerated Approval to Melphalan Flufenamide for Relapsed or Refractory Multiple Myeloma

Press Release – February 26, 2021

“On February 26, 2021, the Food and Drug Administration granted accelerated approval to melphalan flufenamide in combination with dexamethasone for adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and one CD-38 directed monoclonal antibody.

Efficacy was evaluated in HORIZON (NCT02963493), a multicenter, single-arm trial. Eligible patients were required to have relapsed refractory multiple myeloma. Patients received melphalan flufenamide 40 mg intravenously on day 1 and dexamethasone 40 mg orally (20 mg for patients ≥ 75 years of age) on day 1, 8, 15 and 22 of each 28-day cycle until disease progression or unacceptable toxicity.

Efficacy was evaluated in a subpopulation of 97 patients who received four or more prior lines of therapy and were refractory to at least one proteasome inhibitor, one immunomodulatory agent, and a CD38-directed antibody. The main efficacy outcome measure was overall response rate (ORR) and duration of response (DOR) assessed by investigators according to the International Myeloma Working Group (IMWG) Criteria. The ORR was 23.7% (95% CI: 15.7, 33.4) and median DOR 4.2 months (95% CI: 3.2, 7.6).”

Agenda

Module 1: Newly Diagnosed Multiple Myeloma

- **Case 1 (Dr Richards): A 73-year-old woman who receives daratumumab, lenalidomide and dexamethasone**
- **Case 2 (Ms Gleason): A 78-year-old woman who receives kyphoplasty for newly diagnosed multiple myeloma**
- **Case 3 (Ms Mangan): A 66-year-old woman with newly diagnosed multiple myeloma and lytic lesions**

Module 2: Multiagent-Refractory Multiple Myeloma

- **Case 4 (Ms Gleason): A 78-year-old woman with t(11;14) multiple regimen-relapsed multiple myeloma**
- **Case 5 (Ms Mangan): A 77-year-old man with t(11;14) multiple regimen-relapsed multiple myeloma**

Module 3: CAR T-Cell Therapy

- **Case 6 (Dr Richards): A 56-year-old woman with multiple regimen-relapsed multiple myeloma**
- **Case 7 (Ms Gleason): A 62-year-old man with multiple regimen-relapsed multiple myeloma**

Case Presentation – A 56-year-old woman with multiple regimen-relapsed multiple myeloma



Dr Richards

- A woman with standard-risk myeloma and multiple regimen-relapsed disease
- Developed skin and pancreatic plasmacytomas
- Treated with idecabtagene vicleucel and developed Grade 2 CRS
- Complete resolution of skin plasmacytomas at 30-day response evaluation

Dr Richards: Patient education on receiving CAR T-cell therapy



Dr Richards: Quality of life benefits from remaining off therapy



Case Presentation – A 62-year-old man with multiple regimen-relapsed multiple myeloma (Part 1)



Ms Gleason

- Former flight attendant and volunteer firefighter with standard-risk myeloma that has relapsed on 5 prior regimens, including:
 - RVd → ASCT → maintenance lenalidomide
 - Pomalidomide/daratumumab/dexamethasone
 - Carfilzomib/cyclophosphamide/dexamethasone
 - V-DCEP (bortezomib/dexamethasone/cyclophosphamide/etoposide/cisplatin)
 - Pomalidomide/elotuzumab/dexamethasone
- Developed palpable plasmacytomas
- Treated with orvacabtagene autoleucel

Case Presentation – A 62-year-old man with multiple regimen-relapsed multiple myeloma (Part 2)



Ms Gleason

- Former flight attendant and volunteer firefighter with standard-risk myeloma that has relapsed on 5 prior regimens, including:
 - RVd → ASCT → maintenance lenalidomide
 - Pomalidomide/daratumumab/dexamethasone
 - Carfilzomib/cyclophosphamide/dexamethasone
 - V-DCEP (bortezomib/dexamethasone/cyclophosphamide/etoposide/cisplatin)
 - Pomalidomide/elotuzumab/dexamethasone
- Developed palpable plasmacytomas
- ***Caring for a patient through the highs and lows of their disease***

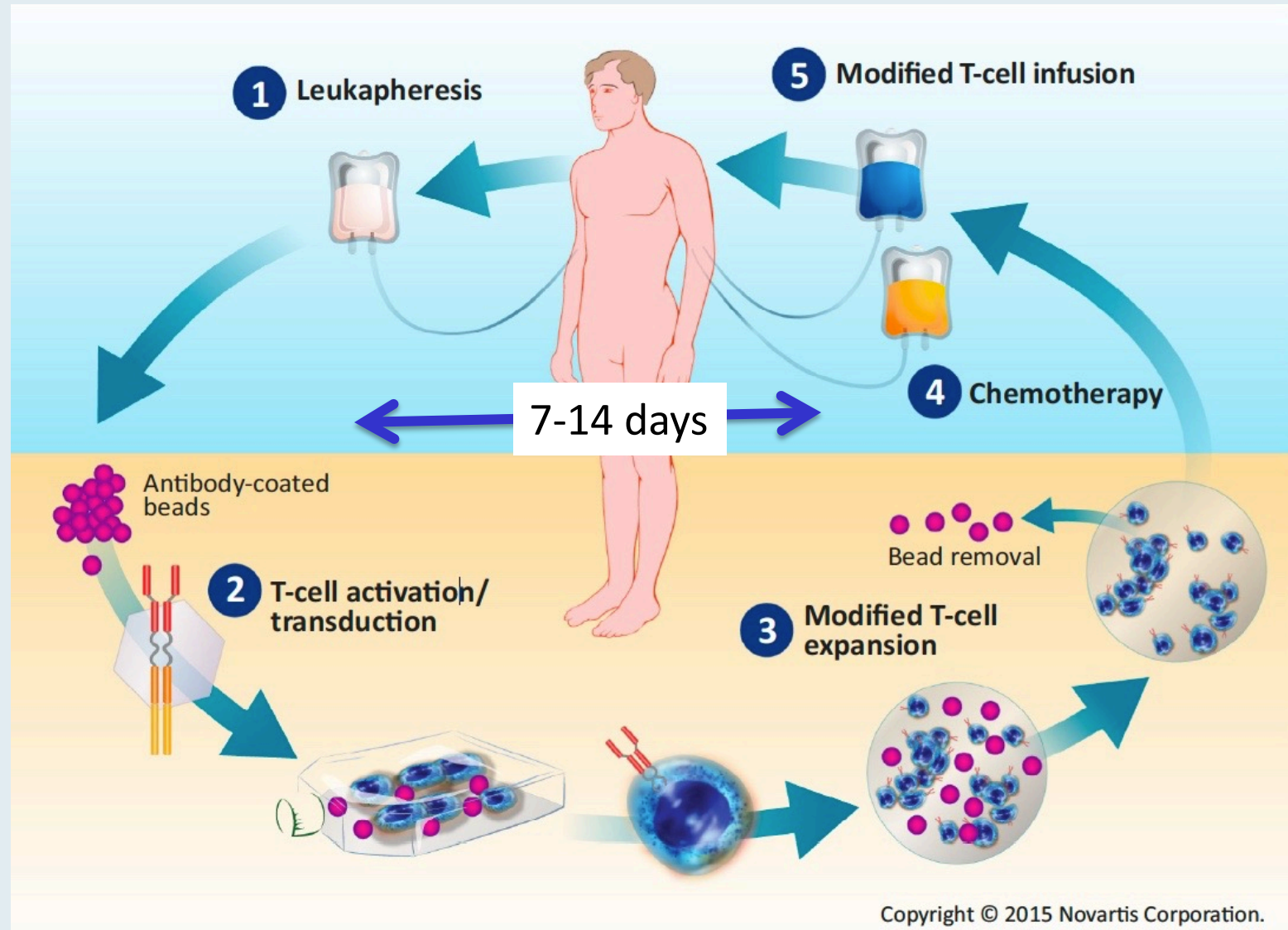
An early indicator of neurotoxicity from CAR T-cell therapy is...

1. Somnolence
2. Seizures
3. Altered handwriting
4. Hyperactivity
5. I don't know

At this point, responses to CAR T-cell therapy in patients with MM appear very similar to those seen with CD19-directed CAR T-cell therapy for diffuse large B-cell lymphoma...

1. Agree
2. Disagree
3. I don't know

Overview of CAR T-Cell Therapy



FDA Approves Idecabtagene Vicleucel for Multiple Myeloma

Press Release – March 26, 2021

“On March 26, 2021, the FDA approved idecabtagene vicleucel for the treatment of adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody. This is the first FDA-approved cell-based gene therapy for multiple myeloma.

Idecabtagene vicleucel is a BCMA-directed genetically modified autologous chimeric antigen receptor (CAR) T-cell therapy. Each dose is customized using a patient’s own T-cells, which are collected and genetically modified, and infused back into the patient.

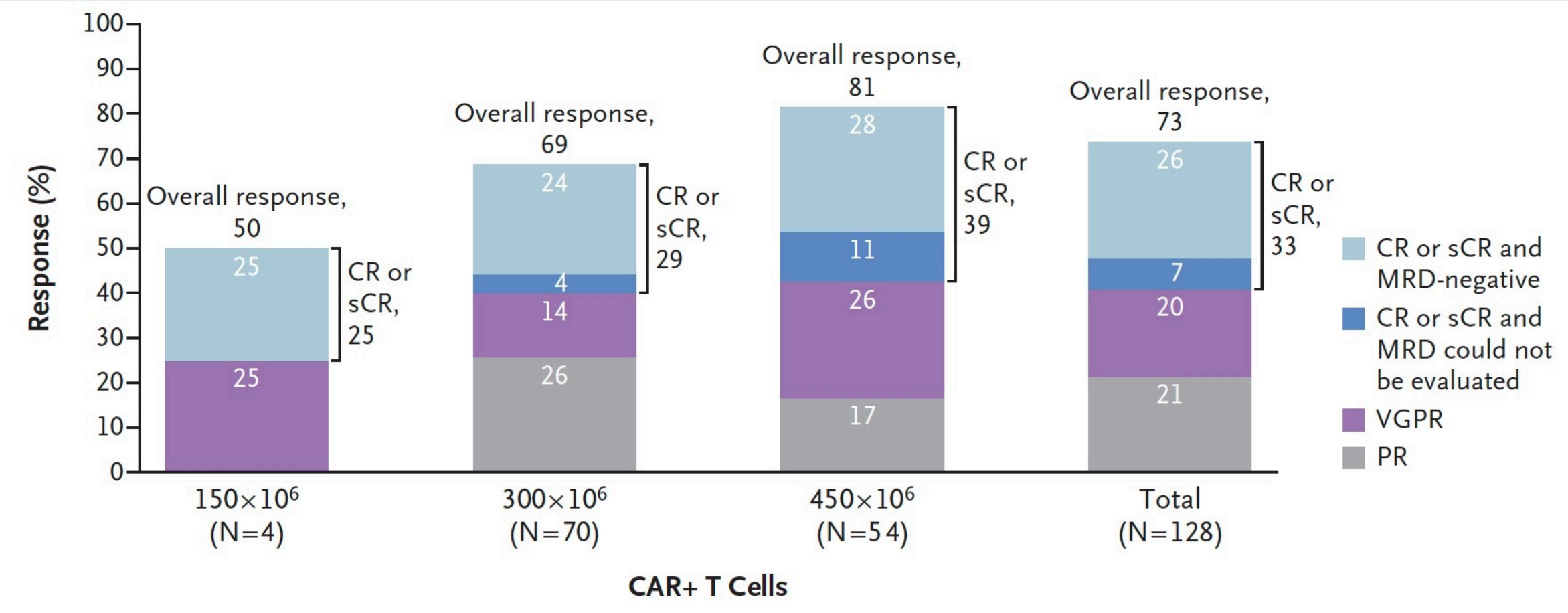
Efficacy was evaluated in 100 patients who received idecabtagene vicleucel in the dose range of 300 to 460 x 10⁶ CAR-positive T cells. Efficacy was established based on overall response rate (ORR), complete response (CR) rate, and duration of response (DOR), as evaluated by an Independent Response committee using the International Myeloma Working Group Uniform Response Criteria for Multiple Myeloma.”

ORIGINAL ARTICLE

Idecabtagene Vicleucel in Relapsed and Refractory Multiple Myeloma

Nikhil C. Munshi, M.D., Larry D. Anderson, Jr., M.D., Ph.D., Nina Shah, M.D., Deepu Madduri, M.D., Jesús Berdeja, M.D., Sagar Lonial, M.D., Noopur Raje, M.D., Yi Lin, M.D., Ph.D., David Siegel, M.D., Ph.D., Albert Oriol, M.D., Philippe Moreau, M.D., Ibrahim Yakoub-Agha, M.D., Ph.D., Michel Delforge, M.D., Michele Cavo, M.D., Hermann Einsele, M.D., Hartmut Goldschmidt, M.D., Katja Weisel, M.D., Alessandro Rambaldi, M.D., Donna Reece, M.D., Fabio Petrocca, M.D., Monica Massaro, M.P.H., Jamie N. Connarn, Ph.D., Shari Kaiser, Ph.D., Payal Patel, Ph.D., Liping Huang, Ph.D., Timothy B. Campbell, M.D., Ph.D., Kristen Hege, M.D., and Jesús San-Miguel, M.D., Ph.D.

KarMMa: Tumor Response, Overall and According to Target Dose



KarMMa: Select Adverse Events

	Any Grade	Grade 3 or 4
	<i>no. of patients (%)</i>	
Adverse event*		
Any	128 (100)	127 (99)
Hematologic		
Neutropenia	117 (91)	114 (89)
Anemia	89 (70)	77 (60)
Thrombocytopenia	81 (63)	67 (52)
Leukopenia	54 (42)	50 (39)
Lymphopenia	35 (27)	34 (27)
Febrile neutropenia	21 (16)	20 (16)
Cytokine release syndrome†	107 (84)	7 (5)
Neurotoxic effect‡	23 (18)	4 (3)

CARTITUDE-1: BCMA-Directed CAR-T Study Design

CARTITUDE-1: Phase 1b/2 Study Design

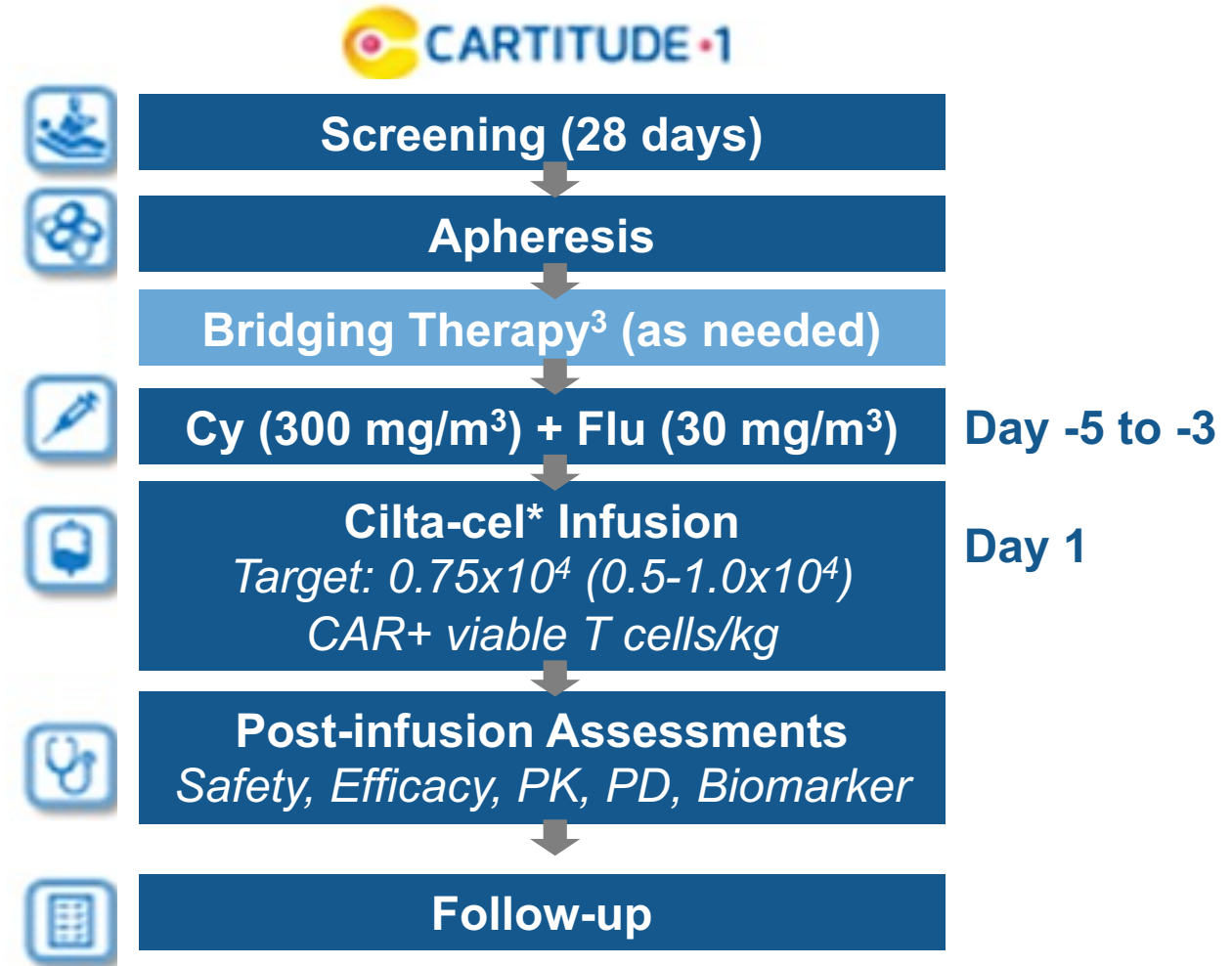
Primary Objectives

- **Phase 1b:** Characterize safety and confirm phase 2 dose as informed by LEGEND-2 study
- **Phase 2:** Evaluate efficacy of JNJ-4528

Key Eligibility Criteria

- Progressive MM per IMWG criteria
- ECOG PS ≤ 1
- Measurable disease
- Receive ≥ 3 prior therapies or double refractory
- Prior PI, IMiD, anti-CD38 therapy

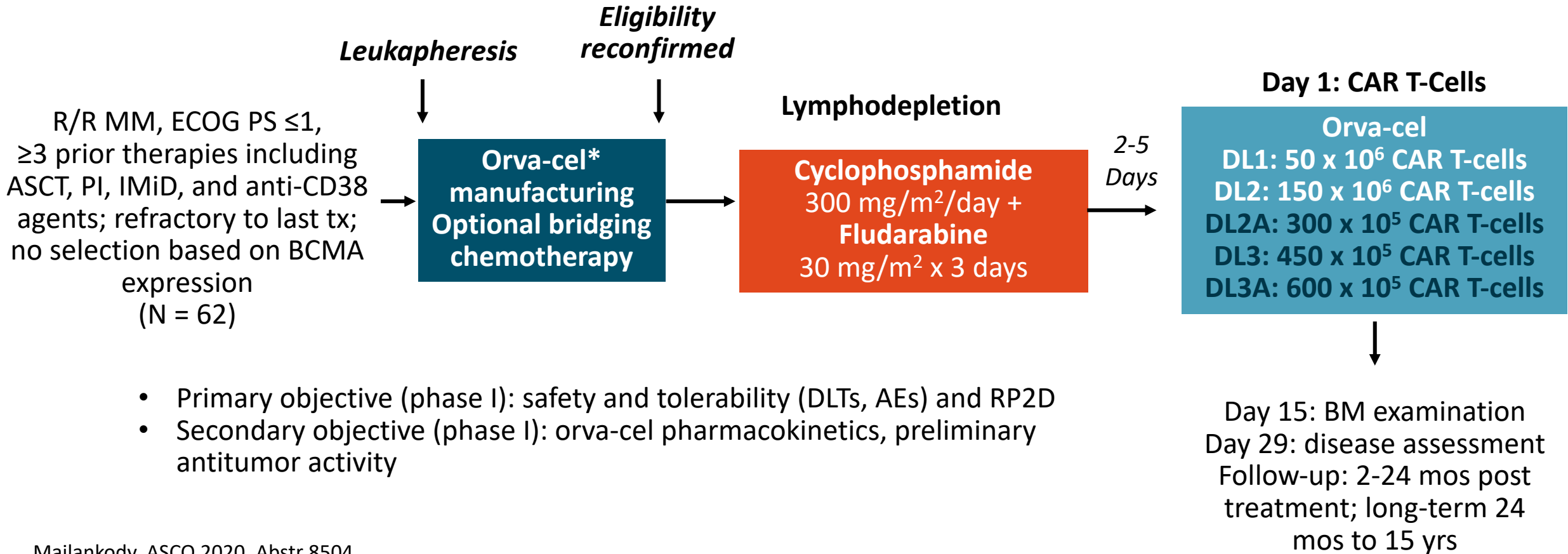
- Median administered dose - 0.73×10^5 (0.52 - 0.89×10^6) CAR+ viable T cells/kg
- Median follow-up at data cut-off – 6 mo (3-14)



* Ciltacabtagene autoleucel

EVOLVE: BCMA-Directed CAR-T Study Design

EVOLVE: Study Design



Mailankody. ASCO 2020. Abstr 8504.

* Orvacabtagene autoleucel

Courtesy of Edward A Stadtmauer, MD

ASCO 2020: 3 BCMA CAR-T Studies

Characteristics Summary

	KarMMa: idecabtagene vicleucel (n = 128)	EVOLVE: orvacabtagene autoleucel (n = 62)	CARTITUDE-1: ciltacabtagene autoleucel (n = 29)
Age	61 (33-78)	61 (33-77)	60 (50-75)
High-risk cytogenetics, %	35	41*	27
Tumor burden in BM, %	>50% PC = 51	—	≥60% PC = 24
Extramedullary PCs, %	39	23	10
Median prior line of therapy	6 (3-16)	6 (3-18)	5 (3-18)
Triple refractory, %	84	94	86
Bridging therapy, %	88	63	79
Unique properties	Human BCMA, 4-1BB, CD3z	Modified spacer, CD4: CD8 enriched for CM	Median cell dose 0.72x10 ⁶ cells/kg 2 BCMA single chain antibodies

* Included +1q21



Approved 3/26/2021

ASCO 2020: 3 BCMA CAR-T Studies

Safety

	KarMMa	EVOLVE	CARTITUDE-1
ANC \geq G3, % ↓	89	90	100
plts \geq G3, % ↓	52	47	69
CRS: all, \geq G3, %	84, 6	89, 3	93, 7
Med time to CRS, duration, days	1 (1-12) 5 (1-63)	2 (1-4) 4 (1-10)	7 (2-12) 4 (2-64)
ICANS: all, \geq G3, %	17, 3	13, 3	10, 3
HLH/MAS, %	—	5	? 7 (lfts)
Infections: all, \geq G3 %	69, —	40, 13	—, 19
Toci/steroid/ anakinra use, %	52/15/0	76/52/23	79/21/21

? This was not listed at MAS/HLH, I am just speculating → could this have been early MAS?

Efficacy

	KarMMa (n = 128)	EVOLVE (n = 62)	CARTITUDE-1 (n = 29)
ORR, %	73 (66-81)	92	100
sCR/CR, %	33	36	86
MRD neg $\geq 10^{-5}$, % (of evaluable)	94	84	81
PFS, DoR, months	8.8/10.7	NR*	NR**
Screened	150		35
Apheresed	140	—	35
Treated	128		29

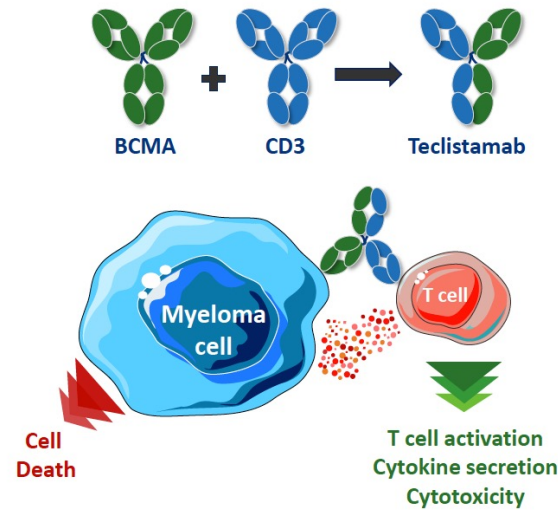
* 300 x 10⁶ cell dose cohort (lowest) = PFS 9.3 months, other med F/U = 8.8 and 2.3 month

** 9 mo PFS = 86%

Bispecific Antibodies for R/R MM

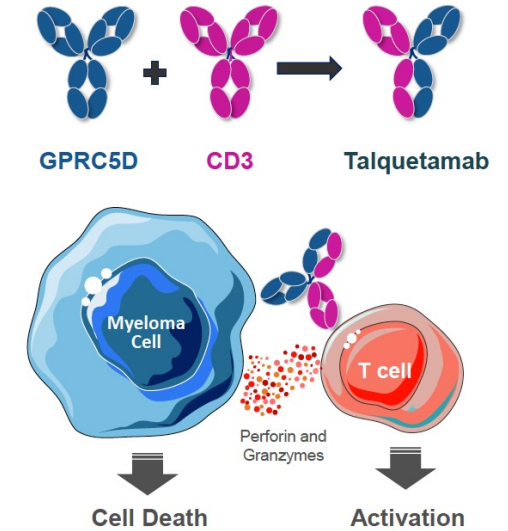
Teclistamab: BCMA x CD3 DuoBody® Antibody

- Prognosis is poor for patients who progress on available classes of therapies, with ORR ~30%, mPFS of ~3 months, and mOS between 6–11 months¹
- Teclistamab (JNJ-64007957)² is a humanized BCMA x CD3 bispecific IgG-4 antibody that redirects CD3⁺ T cells to BCMA-expressing myeloma cells
- Teclistamab induces T cell-mediated killing of myeloma cells from heavily-treated patients and in xenograft models²⁻⁴
- Updated results from an ongoing phase 1 study of teclistamab administered IV or SC in patients with RRMM (NCT03145181) are presented here⁵



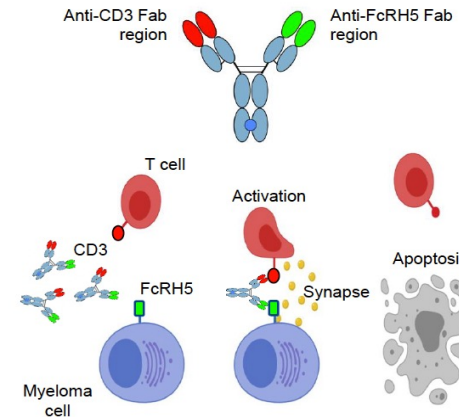
Talquetamab: GPRC5D x CD3 Bispecific Antibody

- Talquetamab is a first-in-class DuoBody® IgG4 PAA antibody that binds to both GPRC5D and CD3
- Talquetamab redirects T cells to GPRC5D-expressing myeloma cells to mediate cell killing
- Antitumor activity was demonstrated in primary myeloma cells and xenograft models of MM¹⁻³
- Talquetamab's pharmacokinetic profile presents an opportunity for less frequent SC dosing
- First-in-human phase 1 study is ongoing to evaluate talquetamab in patients with RRMM (NCT03399799)



Cevostamab: FcRH5xCD3 bispecific antibody

- Fc receptor-homolog 5 (FcRH5)
 - Expressed on myeloma cells with near 100% prevalence¹
 - Expression on myeloma and plasma cells > normal B cells¹
- Cevostamab
 - Humanized IgG-based T-cell-engaging bispecific antibody¹
 - Targets FcRH5 on myeloma cells and CD3 on T cells¹
- Ongoing Phase I dose-escalation and expansion trial (NCT03275103) is evaluating the safety and activity of cevostamab monotherapy in patients with RRMM²

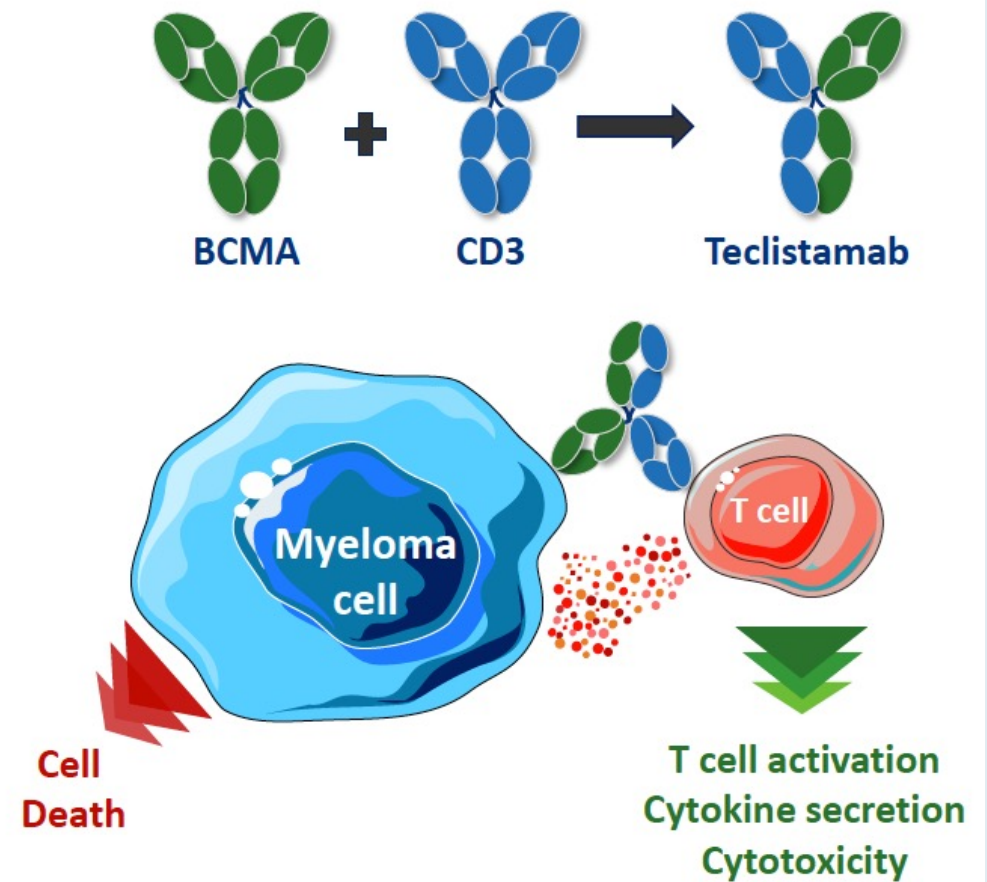


Garfall AL et al. ASH 2020;Abstract 180;
 Chari A et al. ASH 2020;Abstract 290;
 Cohen AD et al. ASH 2020;Abstract 292.

Bispecific Antibody: Teclistamab

Teclistamab: BCMA × CD3 DuoBody[®] Antibody

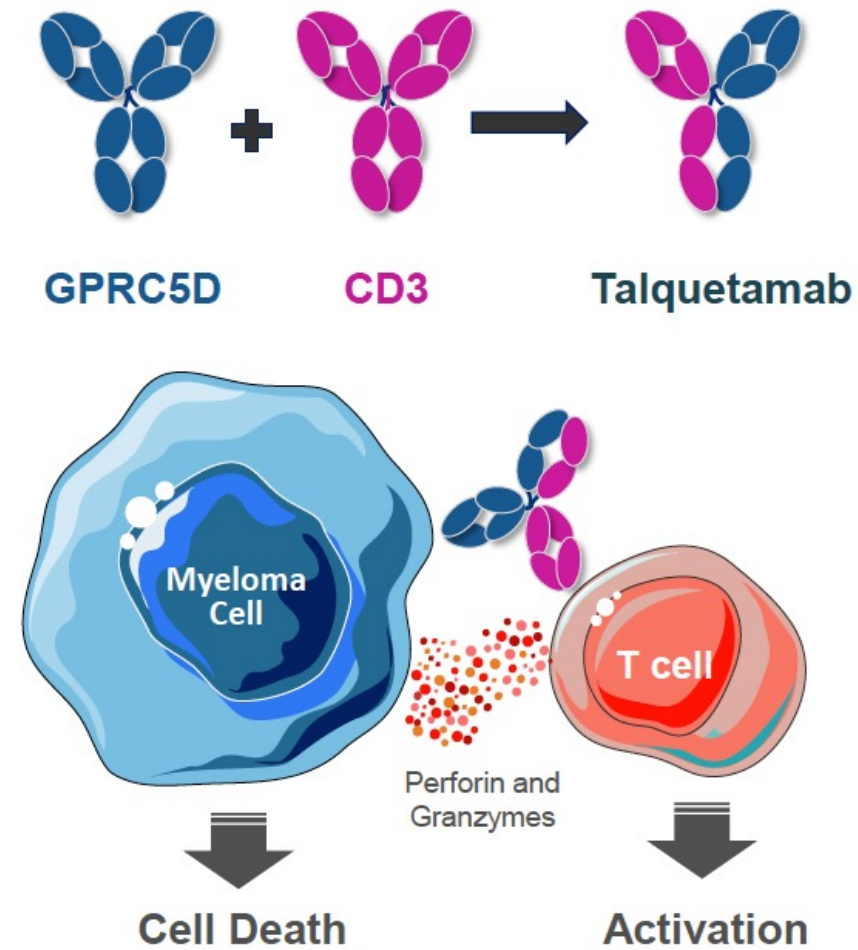
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Bispecific Antibody: Talquetamab

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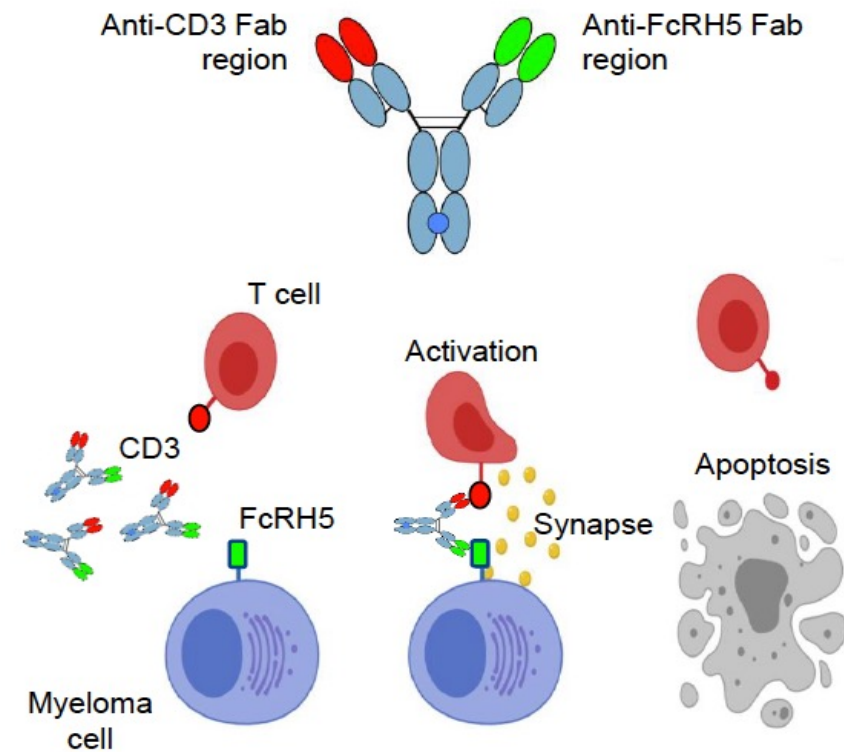
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Dr Richards: Reflections on being an oncology nurse practitioner



13th Annual Oncology Grand Rounds

*A Complimentary NCPD Live Webinar Series
Held During the 46th Annual ONS Congress*

Gynecologic Cancers

Tuesday, April 27, 2021

5:00 PM – 6:30 PM ET

Medical Oncologists

Robert L Coleman, MD

Thomas J Herzog, MD

Krishnansu S Tewari, MD

Oncology Nurse Practitioners

Paula J Anastasia, MN, RN, AOCN

Courtney Arn, CNP

**Kimberly A Spickes, MN, RN, APRN,
OCN, ACNP-BC**

Moderator

Neil Love, MD



Thank you for joining us!

***NCPD credit information will be emailed
to each participant shortly.***