Year in Review: Management of Multiple Myeloma

A CME/MOC-Accredited Live Webinar

Thursday, May 8, 2025 5:00 PM – 6:00 PM ET

Faculty

Meletios-Athanasios (Thanos) C Dimopoulos, MD Robert Z Orlowski, MD, PhD



Faculty



Meletios-Athanasios (Thanos) C Dimopoulos, MD

Professor and Chairman Plasma Cell Dyscrasias Unit Section of Hematology and Medical Oncology Department of Clinical Therapeutics School of Medicine National and Kapodistrian University of Athens Alexandra Hospital Athens, Greece



MODERATOR Neil Love, MD Research To Practice Miami, Florida



Robert Z Orlowski, MD, PhD Florence Maude Thomas Cancer Research Professor Department of Lymphoma and Myeloma Professor, Department of Experimental Therapeutics Vice Chair, Myeloma Translational Research Division of Cancer Medicine The University of Texas MD Anderson Cancer Center Houston, Texas



Commercial Support

This activity is supported by educational grants from GSK and Sanofi.



Dr Love — Disclosures

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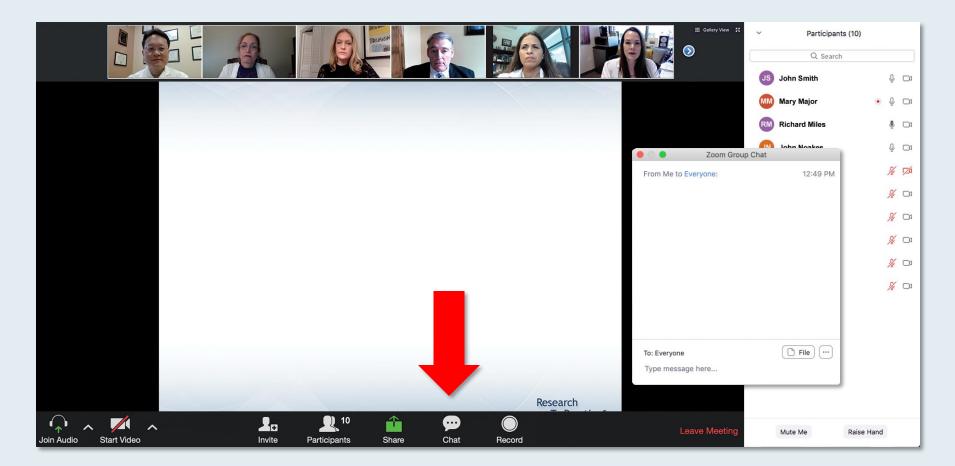
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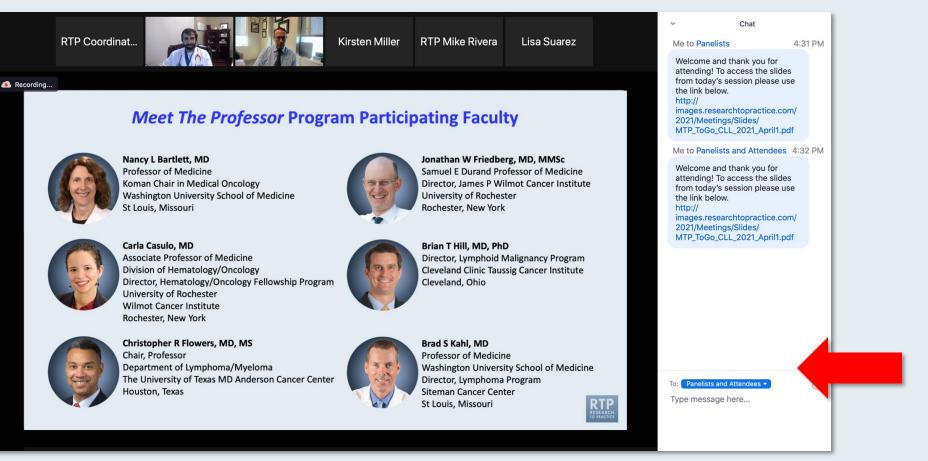


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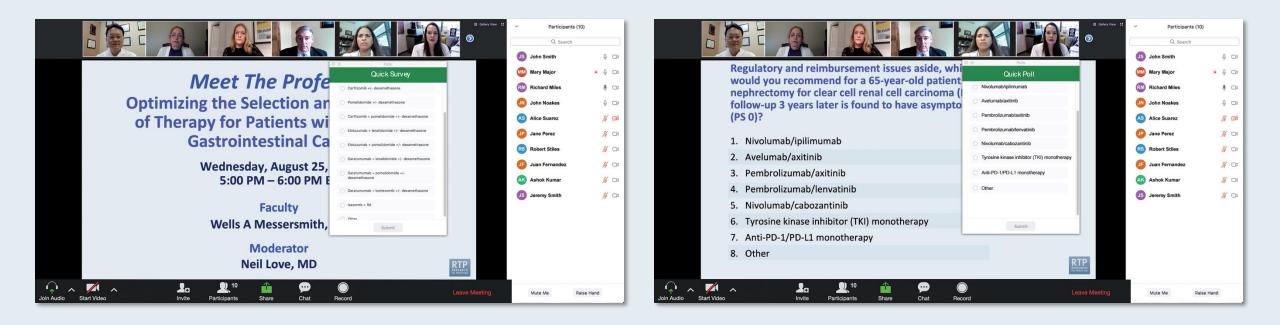
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ONCOLOGY TODAY WITH DR NEIL LOVE

Multiple Myeloma — An Interview with Dr Surbhi Sidana on Optimizing the Role of CAR T-Cell Therapy



DR SURBHI SIDANA









Dr Surbhi Sidana – Multiple Myeloma – Oncology Today with Dr Neil Love —

(15) (30)

Year in Review: Clinical Investigator Perspectives on the Most Relevant New Datasets and Advances in Oncology

Therapeutic Targets Beyond EGFR for Non-Small Cell Lung Cancer

A CME/MOC-Accredited Live Webinar

Thursday, May 15, 2025 5:00 PM – 6:00 PM ET

Faculty Jessica J Lin, MD Joel W Neal, MD, PhD



Practical Perspectives: Experts Review Actual Cases of Patients with Advanced Gastroesophageal Cancers

A CME/MOC-Accredited Live Webinar

Wednesday, May 21, 2025 5:00 PM – 6:00 PM ET

Faculty Geoffrey Y Ku, MD Zev Wainberg, MD, MSc



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MODULE 2: Belantamab Mafodotin

MODULE 3: CAR T-Cell Therapy

MODULE 4: Bispecific Antibodies

MODULE 5: Other Novel Agents



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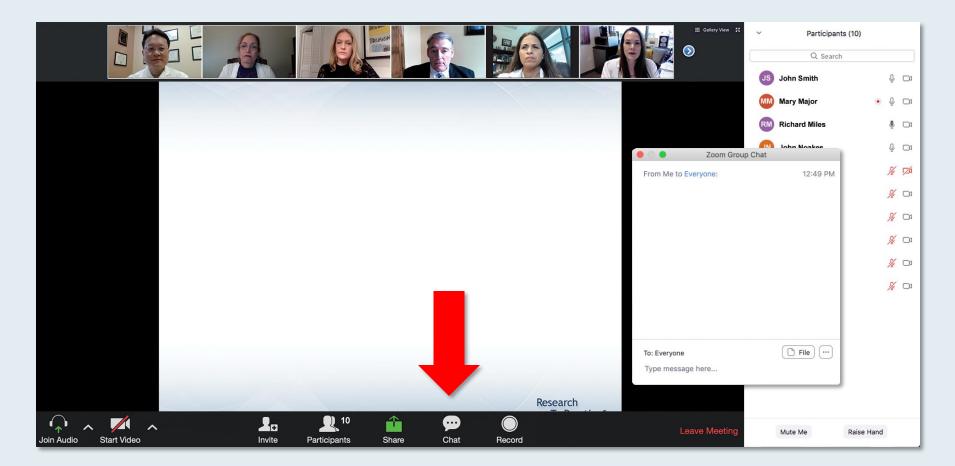
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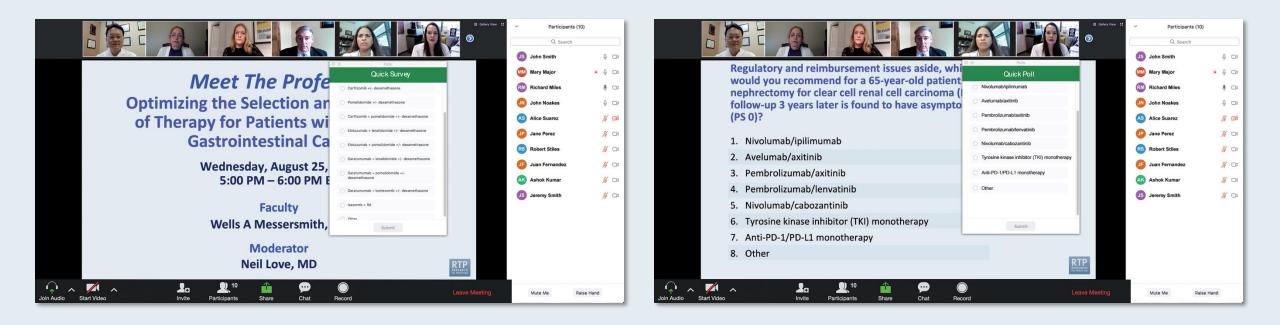
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Where Are We Heading in the Treatment of Multiple Myeloma Based on ASH 2024?

Robert Z. Orlowski, M.D., Ph.D.

Deputy Chair, Department of Lymphoma/Myeloma Florence Maude Thomas Cancer Research Professor Principal Investigator, High Risk Myeloma Moon Shot Chair, SWOG Myeloma Committee







Chimeric Antigen Receptor (CAR) T-Cell Therapy, Bispecific Antibodies and Antibody-Drug Conjugates (ADCs)



Meletios (Thanos) Dimopoulos, MD Professor of Hematology/Oncology, Director Plasma Cell Dyscrasias Unit, Department of Clinical Therapeutics, National and Kapodistrian University of Athens School of Medicine, Athens, Greece





Robert Z Orlowski, MD, PhD

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Robert Z Orlowski, MD, PhD (continued)

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Meletios-Athanasios (Thanos) C Dimopoulos, MD

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Meletios-Athanasios (Thanos) C Dimopoulos, MD (continued)

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INTRODUCTION: ASCO 2025 Preview

MODULE 1: Anti-CD38 Antibodies

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ASCO 2025 Oral Session June 3, 2025

9:45 AM CDT Abstract 7500

MRD-driven strategy following IsaKRD induction in transplant-eligible NDMM: Primary endpoints of the phase 3 MIDAS trial.

Aurore Perrot, MD, PhD

9:57 AM CDT Abstract 7501

Subcutaneous daratumumab (Dara) + bortezomib/lenalidomide/dexamethasone (VRd) with Dara + lenalidomide (DR) maintenance in transplant-eligible (TE) patients with newly diagnosed multiple myeloma (NDMM): Analysis of sustained minimal residual disease negativity in the phase 3 PERSEUS trial.

Philippe Moreau, MD

10:09 AM CDT Abstract 7502

Sustained MRD negativity in patients with newly diagnosed multiple myeloma treated with carfilzomiblenalidomide-dexamethasone with or without isatuximab (phase III IsKia trial).

Francesca Gay, MD, PhD



ASCO 2025 Oral Session June 3, 2025

10:21 AM CDT Abstract 7503

Randomized, multi-center study of carfilzomib, lenalidomide, and dexamethasone (KRd) with or without daratumumab (D) in patients with newly diagnosed multiple myeloma (NDMM): The ADVANCE clinical trial.

Carl Ola Landgren, MD, PhD

10:57 AM CDT Abstract 7504

Elranatamab in combination with daratumumab and lenalidomide (EDR) in patients with newly diagnosed multiple myeloma (NDMM) not eligible for transplant: Initial results from MagnetisMM-6 part 1.

Hang Quach, MD, FRACP, FRCPA

11:09 AM CDT Abstract 7505

First-in-human study of JNJ-79635322 (JNJ-5322), a novel, next-generation trispecific antibody (TsAb), in patients (pts) with relapsed/refractory multiple myeloma (RRMM): Initial phase 1 results.

Niels WCJ van de Donk, MD, PhD



ASCO 2025 Oral Session June 3, 2025

11:21 AM CDT Abstract 7506

Isatuximab (Isa) subcutaneous (SC) via an on-body delivery system (OBDS) vs Isa intravenous (IV), plus pomalidomide and dexamethasone (Pd) in relapsed/refractory multiple myeloma (RRMM): Results of the randomized, non-inferiority, phase 3 IRAKLIA study.

Xavier P Leleu, MD, PhD

11:57 AM CDT Abstract 7507

Long-term (≥5 year) remission and survival after treatment with ciltacabtagene autoleucel (cilta-cel) in CARTITUDE-1 patients (pts) with relapsed/refractory multiple myeloma (RRMM).

Peter M Voorhees, MD

12:09 PM CDT Abstract 7508

Safety and efficacy data from NEXICART-2, the first US trial of CAR-T in R/R light chain (AL) amyloidosis, NXC-201.

Heather Jolie Landau, MD



ASCO 2025 Rapid Oral Session June 2, 2025

8:00 AM CDT Abstract 7509

Isatuximab, carfilzomib, lenalidomide, and dexamethasone (Isa-KRd) for high-risk (HR) newly diagnosed multiple myeloma (NDMM): First-time report of the full cohort of transplant-eligible (TE) patients in the GMMG-CONCEPT trial.

Lisa B Leypoldt, MD

8:06 AM CDT Abstract 7510

Linvoseltamab (LINVO) + bortezomib (BTZ) in patients (pts) with relapsed/refractory multiple myeloma (RRMM): First results from the LINKER-MM2 trial.

Xavier P Leleu, MD, PhD

8:12 AM CDT Abstract 7511

Heterogeneity in the expression of GPRC5D between patients with multiple myeloma.

Harsh Parmar, MD



ASCO 2025 Rapid Oral Session June 2, 2025

8:30 AM CDT Abstract 7512

Belantamab mafodotin plus lenalidomide/dexamethasone in newly diagnosed intermediate-fit & frail multiple myeloma patients: Long-term efficacy and safety from the phase 1/2 BELARD clinical trial. Evangelos Terpos, MD, PhD

8:36 AM CDT Abstract 7513

Linvoseltamab (LINVO) + carfilzomib (CFZ) in patients (pts) with relapsed/refractory multiple myeloma (RRMM): Initial results from the LINKER-MM2 trial.

Salomon Manier, MD, PhD

8:42 AM CDT Abstract 7514

Phase 1, first-in-human study of ISB 2001: A BCMAxCD38xCD3-targeting trispecific antibody for patients with relapsed/refractory multiple myeloma (RRMM) — Dose escalation (DE) results. Hang Quach, MD, FRACP, FRCPA



ASCO 2025 Rapid Oral Session June 2, 2025

9:00 AM CDT Abstract 7515

Minimal residual disease (MRD) negativity (neg) in patients (pts) with relapsed or refractory multiple myeloma (RRMM) treated with belantamab mafodotin plus pomalidomide and dexamethasone (BPd) vs pomalidomide, bortezomib, and dexamethasone (PVd): Analysis from the DREAMM-8 trial.

Suzanne Trudel, MD

9:06 AM CDT Abstract 7516

Daratumumab plus bortezomib, lenalidomide, and dexamethasone (DVRd) in patients with newly diagnosed multiple myeloma (NDMM): Subgroup analysis of transplant-ineligible (TIE) patients in the phase 3 CEPHEUS study.

Saad Z Usmani, MD, MBA, FRCP, FASCO

9:12 AM CDT Abstract 7517

Isatuximab, bortezomib, lenalidomide, and dexamethasone (Isa-VRd) in newly diagnosed multiple myeloma (NDMM): Outcomes in patients with 1q21+ status in the phase 3 IMROZ study.

Robert Orlowski, MD, PhD



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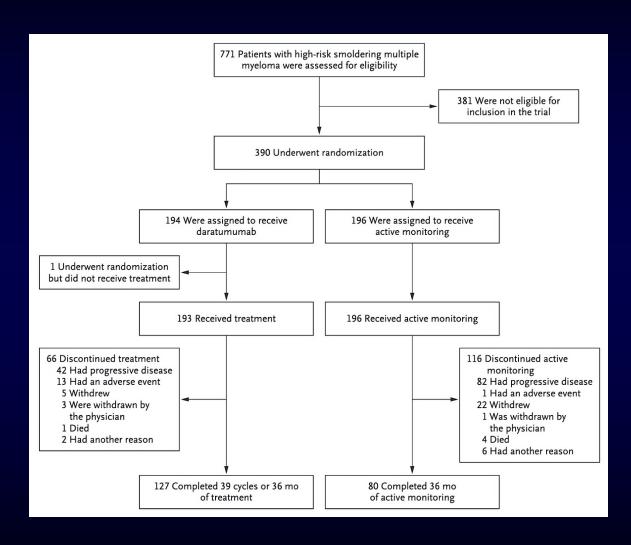
MODULE 3: CAR T-Cell Therapy

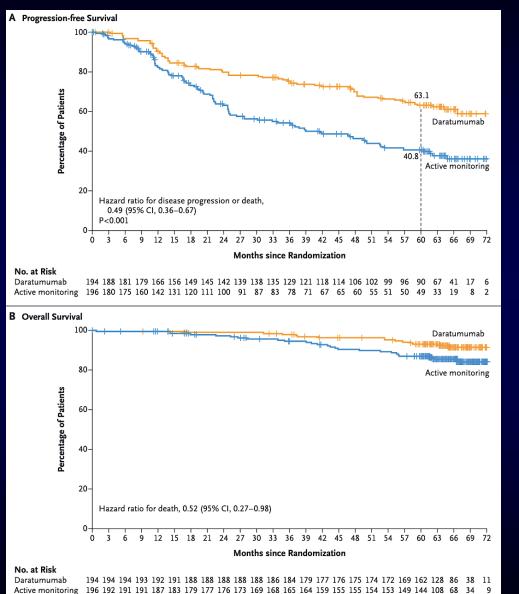
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MODULE 5: Other Novel Agents



Dara in Smoldering: Design & Outcomes





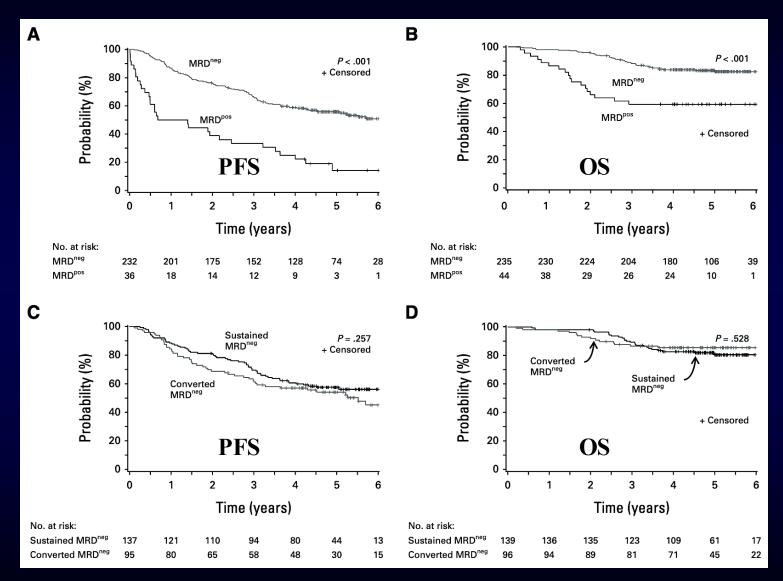
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Making Cancer History

Courtesy of Robert Z Orlowski, MD, PhD

Dimopoulos MA et al. N Engl J Med. 2024 Dec 9.

Value of MRD 1 Year Post-ASCT



Courtesy of Robert Z Orlowski, MD, PhD

Pasquini MC et al. J Clin Oncol. 2024 Aug 10;42(23):2757-2768.

MDAnderson Cancer Center

Making Cancer History

Anti-CD38 Antibody First-Line Indications

IV Daratumumab	Isatuximab
In combination with <u>lenalidomide and</u> <u>dexamethasone</u> for newly diagnosed patients who are ineligible for autologous stem cell transplant	In combination with <u>bortezomib</u> , <u>lenalidomide and</u> <u>dexamethasone</u> for adult patients with newly diagnosed multiple myeloma who are not eligible for autologous stem cell transplant
In combination with <u>bortezomib</u> , <u>melphalan and</u> <u>prednisone</u> for newly diagnosed patients who are <u>ineligible</u> for autologous stem cell transplant	
In combination with <u>bortezomib</u> , <u>thalidomide</u> , <u>and</u> <u>dexamethasone</u> for newly diagnosed patients who are <u>eligible</u> for autologous stem cell transplant	



New Isatuximab Subcutaneous Formulation Met Coprimary Endpoints in the IRAKLIA Phase III Study in Multiple Myeloma Press Release: January 9, 2025

"Results from the investigational, randomized, open-label IRAKLIA phase 3 study demonstrated that isatuximab administered at a fixed dose subcutaneously (SC) via an on-body delivery system (OBDS) in combination with pomalidomide and dexamethasone (Pd) met its co-primary endpoints of non-inferior objective response rate (ORR) and observed concentration before dosing (C trough) at steady state compared to intravenous (IV) isatuximab administered at a weight-based dose in combination with Pd in patients with relapsed or refractory multiple myeloma (R/R MM). Key secondary endpoints, including very good partial response (VGPR), incidence rate of infusion reactions and C trough at cycle 2 were also achieved. The study is ongoing, and the full results will be presented at a forthcoming medical meeting.

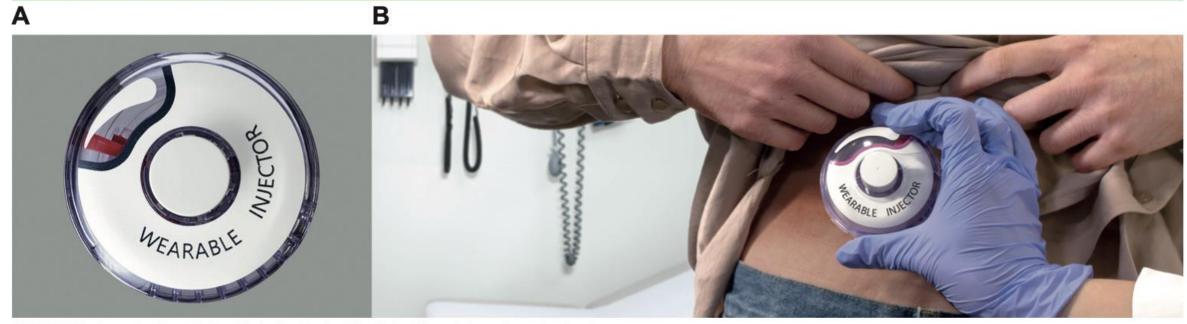
Additional studies evaluating isatuximab SC formulations across different combinations and lines of therapy are ongoing. The safety and efficacy of isatuximab SC [has] not been evaluated by any regulatory authority outside of [the] approved indications. Regulatory submissions in the US and in the EU are planned during the first half of 2025."



https://www.sanofi.com/en/media-room/press-releases/2025/2025-01-09-06-00-00-3006798

Subcutaneous Isatuximab Administration

Figure 1. SC Isa administration by on-body delivery system (OBDS). A) Wearable injector. B) Injector applied to the patient's abdomen*



*CAUTION – Investigational device. Limited by Federal (or United States) law to investigational use. Isa, isatuximab; SC, subcutaneous



Neil's Top 20 Questions



Is daratumumab a reasonable treatment option for patients with high-risk smoldering multiple myeloma?



Should patients generally receive an anti-CD38 monoclonal antibody (mAb) as part of induction treatment (transplant eligible and ineligible)?



What role, if any, do anti-CD38 mAbs play in maintenance treatment, and do MRD assays play a clinical role?



Currently how do you decide which anti-CD38 mAb to use in induction? Do you believe there are differences in efficacy and safety between them?



Is there a role for post-transplant MRD assessment?



How would you compare the patient experience with subcutaneous isatuximab versus subcutaneous daratumumab?



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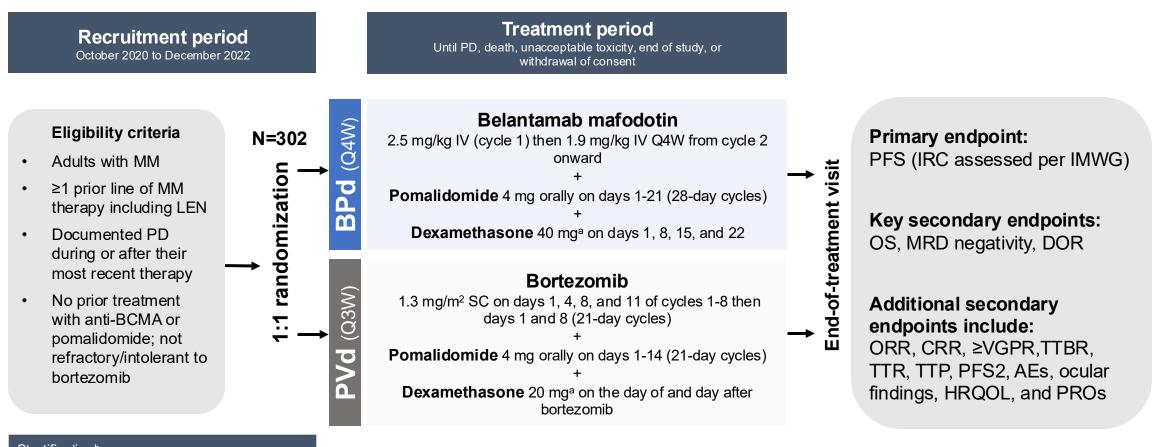
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DREAMM-8 Study: BelaPd vs PVd – Study Design



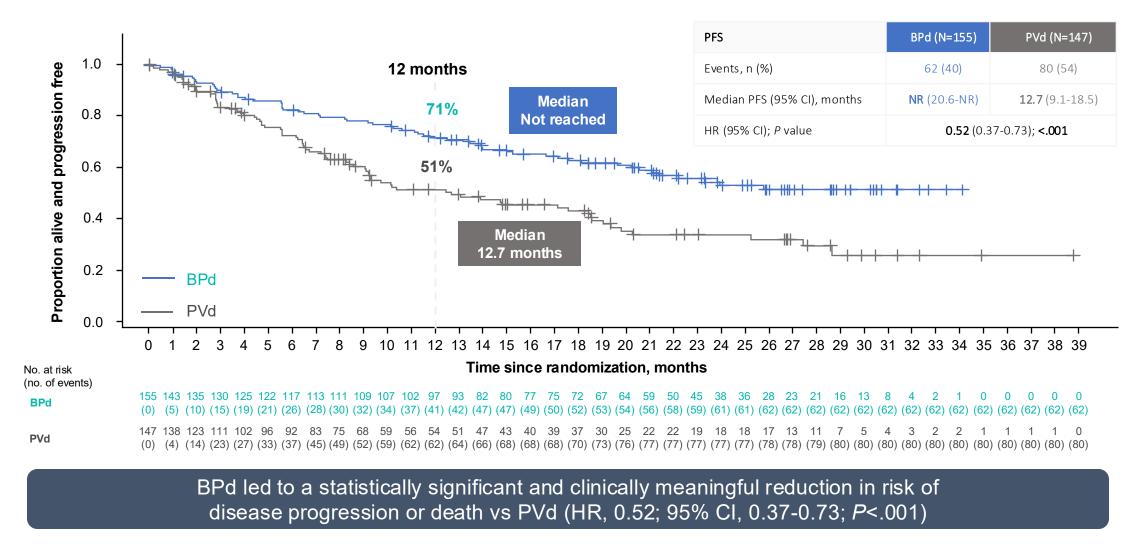
- Stratification^b:
- Prior lines of treatment (1 vs 2 or 3 vs \geq 4)
- Prior bortezomib (yes vs no)
- Prior anti-CD38 therapy (yes vs no)

DREAMM-8: Baseline Characteristics Were Balanced

Baseline characteristics	ITT population		
	BPd (N=155)	PVd (N=147)	
Age, median (range), years <65, n (%) 65 to <75, n (%) ≥75, n (%)	67 (40-82) 64 (41) 72 (46) 19 (12)	68 (34-86) 53 (36) 59 (40) 35 (24)	
Male/female, n (%)	99 (64)/56 (36)	82 (56)/65 (44)	
White/Black/Asian/Mixed race, n (%) ^a	133 (86)/0/20 (13)/1 (<1)	127 (87)/0/17 (12)/0	
ECOG PS ≤1, n (%) ^ь	146 (97)	140 (97)	
ISS stage at screening, n (%) I II III Unknown	93 (60) 39 (25) 22 (14) 1 (<1)	85 (58) 40 (27) 22 (15) 0	
Years since diagnosis, median (range)	4.04 (0.4-16.7)	3.43 (0.4-17.7)	
Cytogenetic abnormalities, n (%) Standard risk ^c High risk ^d Missing or nonevaluable Time to relapse after initiation of 1L	72 (46) 52 (34) 31 (20)	75 (51) 47 (32) 25 (17)	
treatment ≤12 months >12 months	22 (14) 133 (86)	20 (14) 127 (86)	
Extramedullary disease, n (%)	20 (13)	11 (7)	

Prior treatments, n (%)	ITT population			
	BPd (N=155)		PVd (N=147)	
Prior LOT				
1	82 (53)		77 (52)	
2 or 3	54 (35)		48 (33)	
≥4	19 (12)		22 (15)	
Prior ASCT	99 (64)		82 (56)	
Prior treatment	Exposed	Refractory	Exposed	Refractory
Prior proteasome inhibitor	140 (90)	40 (26)	136 (93)	35 (24)
Bortezomib	134 (86)	16 (10)	130 (88)	8 (5)
Carfilzomib	34 (22)	18 (12)	37 (25)	23 (16)
Ixazomib	11 (7)	8 (5)	15 (10)	11 (7)
Prior immunomodulatory drug ^a <u>Lenalidomide</u> Thalidomide	155 (100) <u>155 (100)</u> 49 (32)	127 (82) <u>125 (81)</u> 9 (6)	147 (100) 147 (100) 48 (33)	111 (76) 111 (76) 6 (4)
Prior anti-CD38 monoclonal antibody ^b Daratumumab Isatuximab	38 (25) 36 (23) 2 (1)	35 (23) 33 (21) 2 (1)	42 (29) 39 (27) 3 (2)	36 (24) 34 (23) 2 (1)

DREAMM-8: Significant PFS Benefit with BPd vs PVd



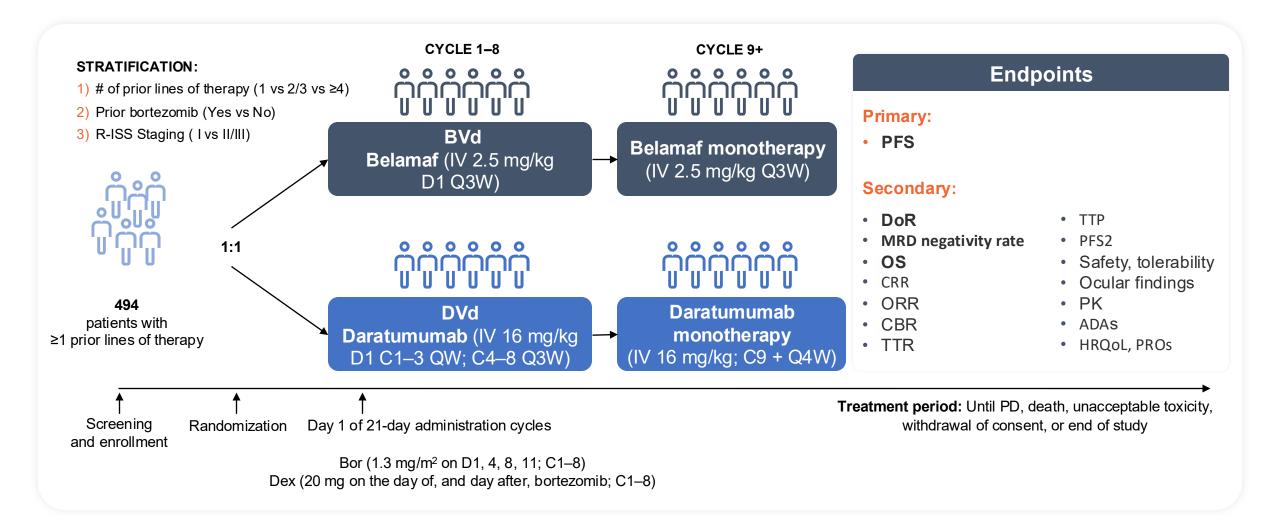
Median follow-up, 21.8 months (range, 0.03-39.23 months).

The treatment effect (HR and corresponding 95% CIs) was estimated using the stratified Cox proportional hazards model, and the P value was produced based on the 1-sided stratified log-rank test. Stratified analyses were adjusted

for number of prior lines of therapy and prior bortezomib use.

BPd, belamaf, pomalidomide, and dexamethasone; HR, hazard ratio; NR, not reported; PFS, progression-free survival; PVd, pomalidomide, bortezomib, and dexamethasone.

DREAMM-7: Bela-Vd vs Dara-Vd – Study Design



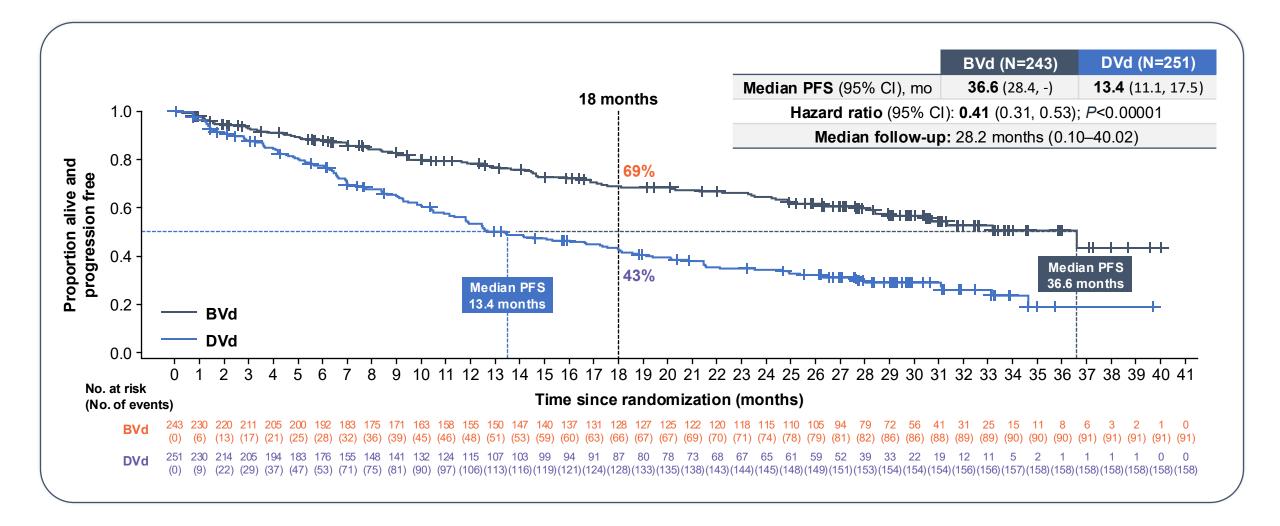
Courtesy of Thanos C Dimopoulos, MD

Hungria V, et al. N Engl J Med. 2024 Aug 1;391(5):393-407.

DREAMM-7 study – Patients Characteristics

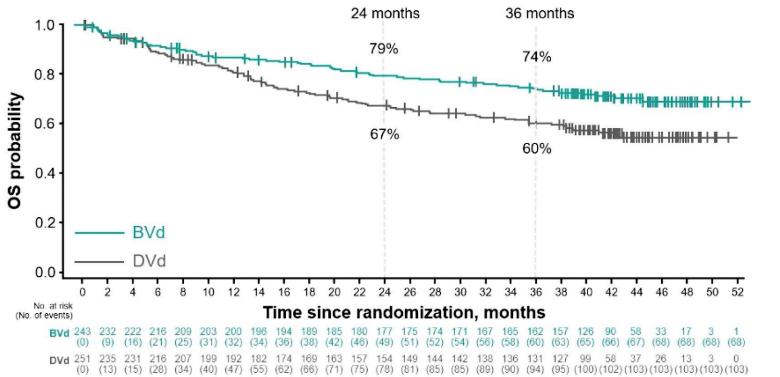
Demographics and baseline characteristics	BVd (N=243)	DVd (N=251)
Median age, years (range)	65 (34–86)	64 (32–89)
Standard/high risk cytogenetic abnormalities, n (%)	175 (72)/67 (28)	175 (70)/69 (27)
EMD present, n (%)	13 (5)	25 (10)
R-ISS Stage I/II/III, n (%)	102 (42)/130 (53)/9 (4)	103 (41)/132 (53)/14 (6)
Prior ASCT, n (%)	164 (67)	173 (69)
Prior LoT, 1/2 or 3/≥4, n (%)	125 (51)/88 (36)/30 (12)	125 (50)/99 (39)/27 (11)
Prior lenalidomide, n (%)	127 (52)	130 (52)
• Refractory to lenalidomide, n (%)	79 (33)	87 (35)
Prior daratumumab, n (%)	3 (1)	4 (2)

DREAMM-7 study – PFS



Updated and Additional Analyses From the Phase 3 DREAMM-7 Trial of BVd vs DVd in RRMM: OS

Median follow-up: 39.4 months (range, 0.1-52.3)

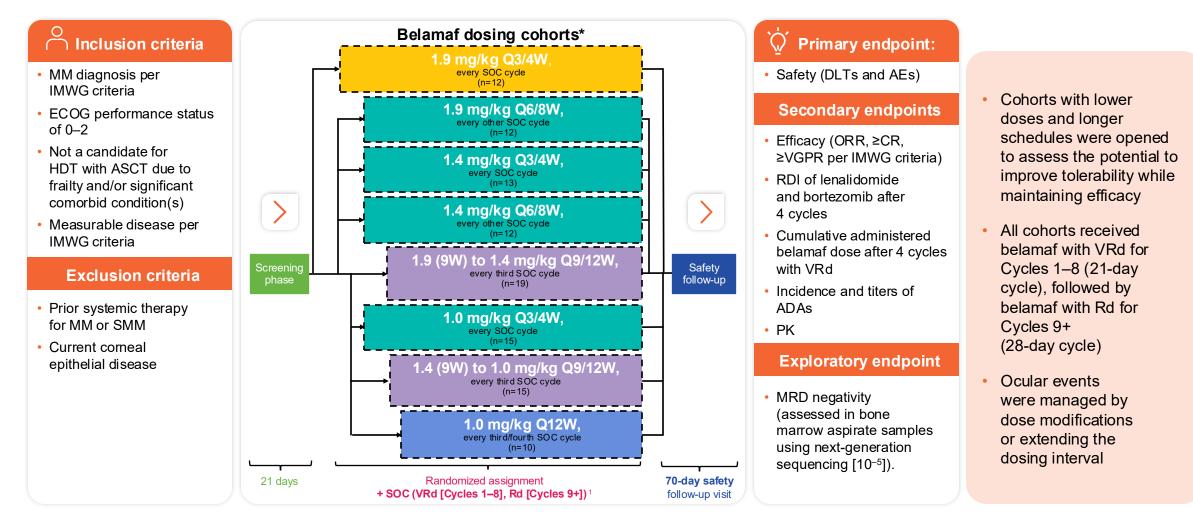


OS	BVd (n=243)	DVd (n=251)
Events, n (%)	68 (28)	103 (41)
Median OS (95% CI), months	NR (NR-NR)	NR (41.0-NR)
HR (95% Cl); <i>P</i> value	0.58 (0.43-0.7	9); <i>P</i> =0.00023
24-month OS, % (95% Cl)	79 (73-84)	67 (61-73)
36-month OS, % (95% Cl)	74 (68-79)	60 (54-66)

Median OS was not reached.

Predicted median OS based on modeling is 84 months with BVd and 51 months with DVd

DREAMM-9: Study design



*Cohorts of the same color opened at the same time. Cohorts with longer rectangles opened earlier.

ADA, anti-drug antibodies; AE, adverse event; ASCT, autologous stem cell transplant; belamaf, belantamab mafodotin; CR, complete response; DLT, dose-limiting toxicities; ECOG, Eastern Cooperative Oncology Group; HDT, high-dose chemotherapy; IMWG, International Myeloma Working Group; MM, multiple myeloma; MRD, minimal residual disease; ORR, overall response rate; PK, pharmacokinetics; PR, partial response; QxW, every x weeks; RDI, relative dose intensity; SMM, smouldering MM; SOC, standard of care; VGPR, very good partial response

DREAMM-9: Efficacy | ORR

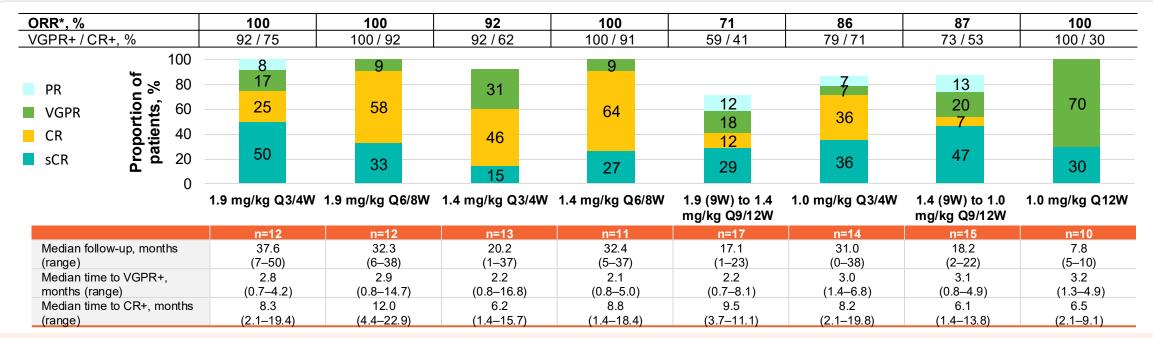
VGPR+ was 100% in 3 cohorts including those with lower doses and less frequent schedules



•

- Time to achieve VGPR+ was consistent across the cohorts (median 2.1–3.2 months) and response deepened over time
- In the first 4 cohorts, CR+ was 62–92%

ORRs ranged from 71% to 100%



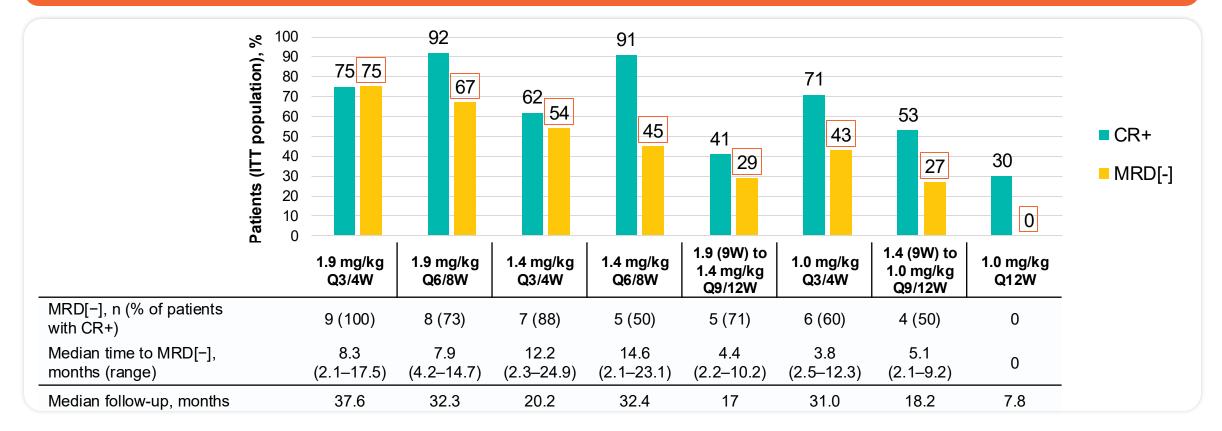
Median follow-up varied as cohorts opened at different times; some patients had not been treated for long enough to achieve response

Cl, confidence interval; CR+, complete response or better; ORR, overall response rate; PR, partial response; QxW, every x weeks; sCR, stringent complete response; VGPR+, very good partial response or better.

DREAMM-9: Efficacy | MRD-negativity rate*



Higher belamaf starting doses were associated with deeper and faster MRD[-] rates



*MRD[-] was measured by next-generation sequencing [10-5] in patients achieving CR+, and is shown as proportion of the ITT population.

belamaf, belantamab mafodotin; CR,+ complete response or better; ITT, intention-to-treat; MRD[-], minimal residual disease negativity; QxW, every x weeks.

DREAMM-9: Best corrected visual acuity

Dose and schedule affected the time to, and resolution of, BCVA decreases

- Extending the dosing interval between the 1.9 mg/kg or 1.4 mg/kg doses from Q3/4W to Q6/8W was associated with longer time to BCVA decrease to 20/50 or worse*
- Resolution of BCVA decreases was generally faster in cohorts with lower initial doses of belamaf



First occurrence of decrease in BCVA score from baseline (20/25 or better) to 20/50 or worse Number of patients, n (%) **Belamaf schedule** Time to onset Median (range), days 1.9 mg/kg Q3/4W 6 (50) 76 (42-439) 1.9 mg/kg Q6/8W 6 (50) 246 (106–472) 1.4 mg/kg Q3/4W 3 (23) 128 (113-409) 1.4 mg/kg Q6/8W 6 (50) 264 (92–546) Time to resolution 1.9 mg/kg Q3/4W 163 (36–230) 1.9 mg/kg Q6/8W 135 (29-246) 36 (22-85) 1.4 mg/kg Q3/4W 70 (43-421) 1.4 mg/kg Q6/8W 100 500 200 300 600 0 400 Days

*In the 4 cohorts shown, 2 patients had a BCVA change from 20/25 or better to 20/200 or worse. These patients both had bilateral cataracts. †Image adapted from Shi C, et al. bioRxiv. 2018;doi:doi.org/10.1101/328443. Copyright © 2018 the Author.

belamaf, belantamab mafodotin; BCVA, best corrected visual acuity; QxW, every x weeks.

In general, how would you compare the efficacy of belantamab mafodotin versus daratumumab as a component of combination therapy for patients with relapsed MM?



How do you manage the dose and schedule of belantamab mafodotin to maximize efficacy and minimize ophthalmic toxicity?



How do you approach prevention, screening and management of ophthalmic toxicity with belantamab mafodotin?

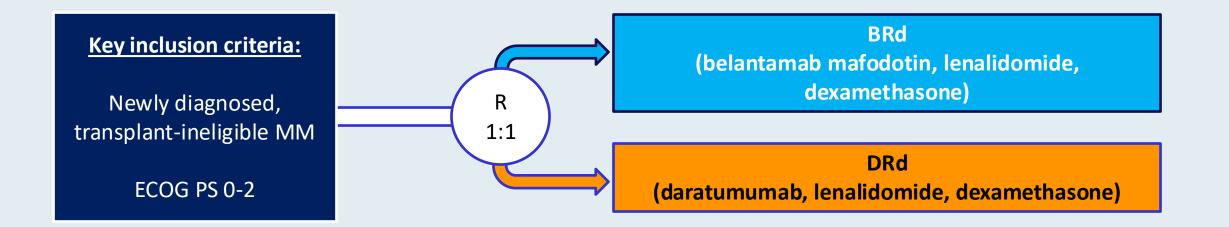


Do you have any predictions for what results of the DREAMM-10 trial will demonstrate?



DREAMM-10 Trial: Phase III Study of Belantamab Mafodotin with Lenalidomide and Dexamethasone (BRd) versus Daratumumab with Lenalidomide and Dexamethasone (DRd) in Transplant-Ineligible Newly Diagnosed MM

Trial identifier: NCT06679101 Estimated enrollment: 520





Lonial S et al. ASCO 2025; Abstract TPS7567; www.clinicaltrials.gov. NCT06679101. Accessed May 2025.

Would you recommend belantamab mafodotin for a patient with relapsed/refractory MM who has previously received both BCMA-directed CAR T-cell therapy and a BCMA-directed bispecific antibody (BS)?



AGENDA

Year in Review: Management of Multiple Myeloma

INTRODUCTION: ASCO 2025 Preview

MODULE 1: Anti-CD38 Antibodies

MODULE 2: Belantamab Mafodotin

MODULE 3: CAR T-Cell Therapy

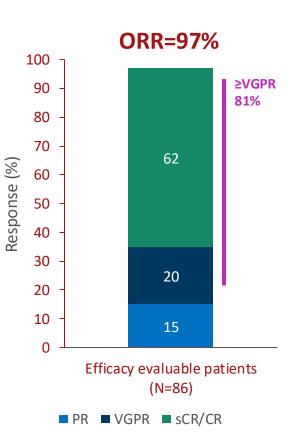
MODULE 4: Bispecific Antibodies

MODULE 5: Other Novel Agents



Phase 2 iMMagine-1: Anito-cel - Preliminary efficacy data for an anti-BCMA CAR T-cell therapy in RRMM

Patient characteristics	Safety evaluable (N=98)	Efficacy evaluable (N=86)
Median age (yrs)	65	65
Previous lines of therapy		
Lines of prior therapy, median (min-max)	4 (3-8)	4 (3-8)
3 prior lines of therapy	45 (46%)	37 (43%)
Triple refractory	85 (87%)	74 (86%)
Penta refractory	41 (42%)	37 (43%)
Prior ASCT	73 (75%)	64 (74%)
Bridging therapy	65 (66%)	61 (71%)
Outpatient administration	8 (8%)	5 (6%)
Median time since diagnosis (yrs)	7.2	7.5



• ORR: 97% and sCR/CR: 62% at 9.5 mos (median f/u)

- MRD –ve rate at 10⁻⁵ or lower: 93.1% (54/58)
- PFS rate at 6 mos: 93.3% and at 12 mos: 78.5%
- OS rate at 6 mos: 96.5% and at 12 mos: 96.5%

Anito-cel is an investigational product, currently not approved by any regulatory agency.

-ve, negative; Anito-cel, anitocabtagene autoleucel; ASCT, autologous stem cell transplant; CAR T, chimeric antigen receptor T cell; CR, complete response; f/u, follow up; mo, month; MRDng, minimal residual disease negativity rate; ORR, overall response rate; OS, overall survival; PFS, progression-free survival; PR, partial response; RRMM, relapse/refractory multiple myeloma; sCR, stringent CR; TEAE, treatment-emergent adverse event; VGPR, very good PR; yr, year.

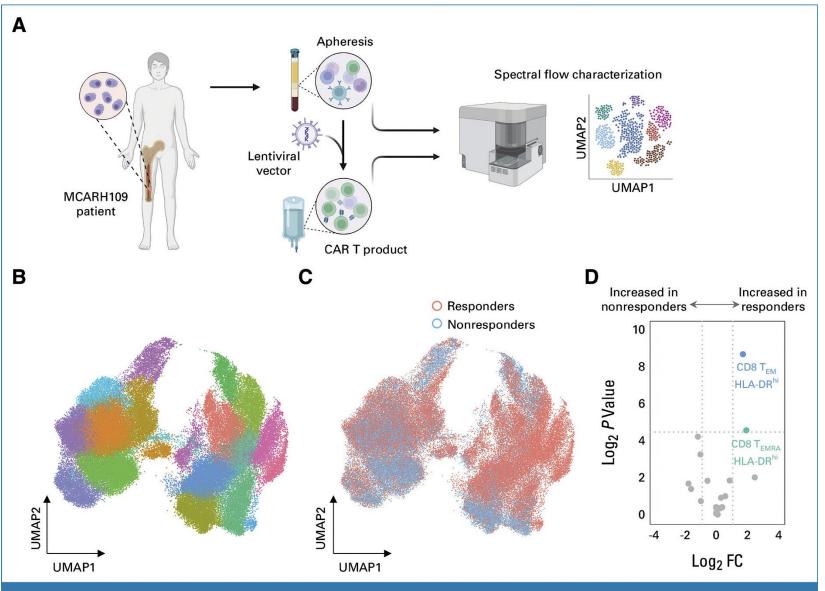
Courtesy of Thanos C Dimopoulos, MD

Phase 2 iMMagine-1: Anito-cel - Preliminary Safety Data in RRMM

Event	Safety evaluable (N=98)
CRS, any grade (%)	83
Median onset (days)	4
ICANS, any grade (%)	9
Median onset (days)	7
TEAEs (non-CRS/non-ICANS), Gr 3/4 after cell infusion (%)	
Neutropenia	54
Anemia	22
Thrombocytopenia	20

- 86% of patients with \leq Gr1 CRS
- 91% of patients with no ICANS
- No delayed or non-ICANS neurotoxicities to date
- Most common ≥Gr3 TEAEs: cytopenias
- 3 deaths due to TEAEs

Phase I Trial of MCARH109, a GPRC5D-Targeted Chimeric Antigen Receptor T-Cell Therapy for RR Multiple Myeloma

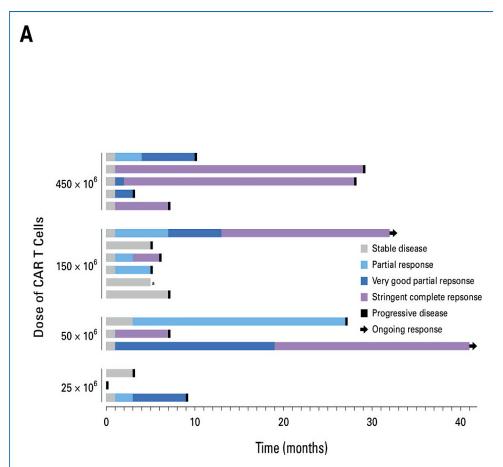


Jurgens EM, et al. J Clin Oncol 2025;43:498-504.

Courtesy of Thanos C Dimopoulos, MD

Phase I Trial of MCARH109 in RRMM: Efficacy Data

Characteristic	No Previous BCMA	Previous BCMA	Overall (N = 17)
	Therapy (n = 7)	Therapy (n = 10)	
Age, years Median (range)	57.9 (37.6-76.4)	63.8 (39.6-73.5)	59.6 (37.6-76.4)
High-risk cytogenetics, No. (%)			
Yes	5 (71.4)	8 (80.0)	13 (76.5)
No	2 (28.6)	2 (20.0)	4 (23.5)
Extramedullary plasmacytoma, No. (%)			
Yes	4 (57.1)	4 (40.0)	8 (47.1)
No	3 (42.9)	6 (60.0)	9 (52.9)
Previous lines of therapy			
Median (range)	5.0 (4.0-8.0)	6.50 (5.00-14.0)	6.00 (4.00-14.0)
Penta-exposed, No. (%)			
Yes	7 (100)	10 (100)	17 (100)
Triple-refractory disease, No. (%)			
Yes	7 (100)	9 (90.0)	16 (94.1)
No	0 (0)	1 (10.0)	1 (5.9)
Previous bispecific antibody			
Yes	0 (0)	2(20)	2 (11.8)
No	7 (100)	8(80)	15 (88.2)
Bridging therapy, No. (%)			
Yes	7 (100)	9 (90.0)	16 (94.1)
No	0 (0)	1 (10.0)	1 (5.9)
Responsive to bridging therapy			
Yes	0/7 (0)	1/9 (11.1)	1/16 (6.3)
No	7/7 (100)	8/9 (88.9)	15/16 (93.7)



Jurgens EM, et al. J Clin Oncol 2025;43:498-504. Courtesy of Thanos C Dimopoulos, MD

Is there a role for a second dose of CAR T-cell therapy, either as a consolidation of the first dose or in the form of maintenance given several months apart?



How would you compare the efficacy of anitocabtagene autoleucel (anito-cel) CAR T-cell therapy to ciltacabtagene autoleucel (cilta-cel) and idecabtagene vicleucel (ide-cel)?



How would you compare the toxicity of anito-cel CAR T-cell therapy to cilta-cel and ide-cel?



AGENDA

Year in Review: Management of Multiple Myeloma

INTRODUCTION: ASCO 2025 Preview

MODULE 1: Anti-CD38 Antibodies

MODULE 2: Belantamab Mafodotin

MODULE 3: CAR T-Cell Therapy

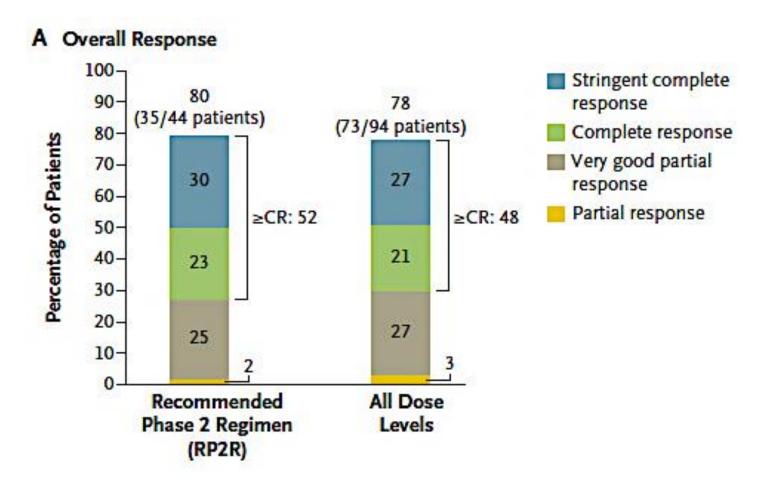
MODULE 4: Bispecific Antibodies

MODULE 5: Other Novel Agents



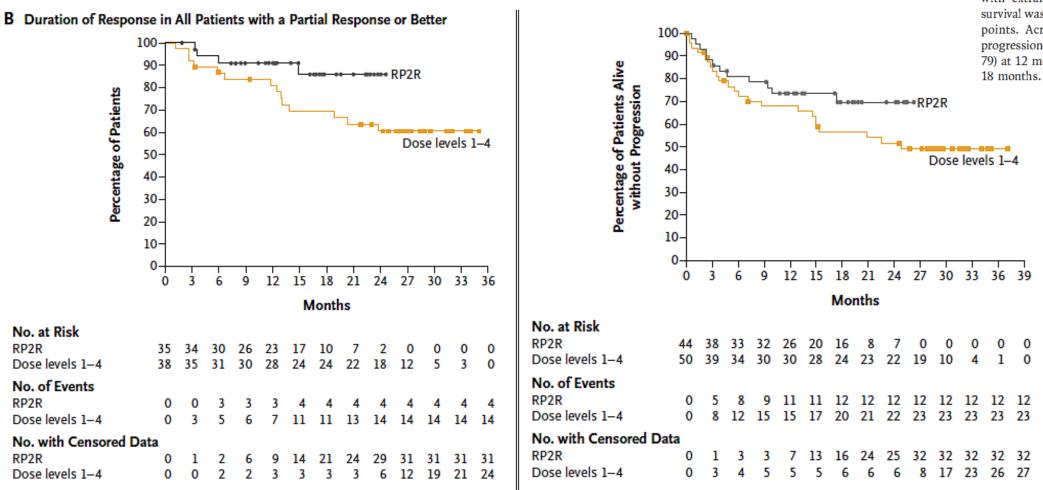
Phase Ib/II RedirecTT-1 Study: Teclistamab Plus Talquetamab in R/R Multiple Myeloma

- A Phase 1b/2 Dose Escalation and Expansion Study of the Combination of the Bispecific T Cell Redirection Antibodies Talquetamab and Teclistamab in Participants With Relapsed or Refractory Multiple Myeloma
 - Previous exposure to a PI, IMiD, and anti-CD38 mAb and refractory to last line of therapy
 - Median prior LOT: 4 (1-11); extramedullary plasmacytomas: 37.6%
- Primary endpoint: dose-limiting toxic effects;
- Secondary endpoints: overall response (partial response or better), dor, time to response, pharmacokinetics, pharmacodynamics, and immunogenicity.



Courtesy of Thanos C Dimopoulos, MD

Phase Ib/II RedirectTT-1 Study: Teclistamab Plus Talquetamab in R/R Multiple Myeloma – DoR and PFS



estimated progression-free survival was 74% (95% CI, 57 to 84) at 12 months and 70% (95% CI, 52 to 82) at 18 months (Fig. 3). Among patients with extramedullary disease, progression-free survival was 53% (95% CI, 28 to 73) at both time points. Across all dose levels, the estimated progression-free survival was 71% (95% CI, 60 to 79) at 12 months and 62% (95% CI, 51 to 72) at 18 months

Courtesy of Thanos C Dimopoulos, MD

Phase Ib/II RedirectTT-1 Study: Teclistamab Plus Talquetamab in R/R Multiple Myeloma – Safety

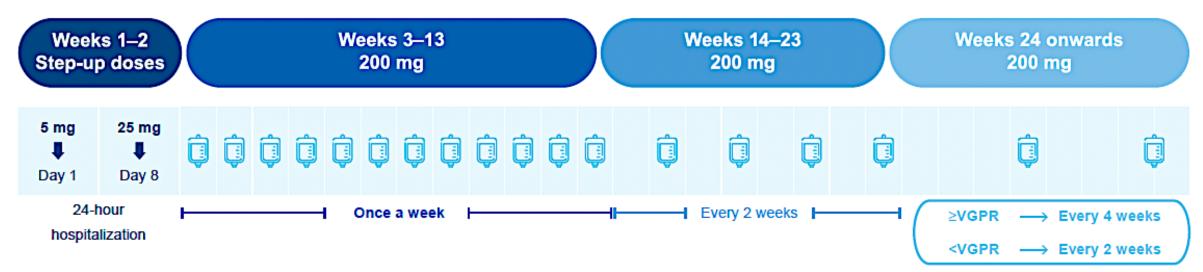
Table 2. Hematologic and Nonhematologic Adverse Events, According toGrade, in 94 Patients Who Received Talquetamab plus Teclistamab at AnyDose Level.*

Event	Any Grade	Grade 3 or 4
	number of pa	ntients (percent)
Any adverse event	94 (100)	90 (96)
Hematologic event		
Neutropenia	69 (73)	64 (68)
Anemia	53 (56)	36 (38)
Thrombocytopenia	40 (43)	28 (30)
Nonhematologic event		
Cytokine release syndrome	74 (79)	2 (2)
Taste changes†	61 (65)	NA
Nonrash skin adverse event‡	57 (61)	0
Nail-related adverse event§	49 (52)	0
Pyrexia¶	48 (51)	2 (2)
Diarrhea	45 (48)	3 (3)
Cough	42 (45)	1 (1)
Dry mouth	40 (43)	0
Covid-19	38 (40)	17 (18)
Rash adverse event	37 (39)	1 (1)
Pneumonia	34 (36)	19 (20)
Weight decrease	32 (34)	5 (5)
Fatigue	26 (28)	<mark>8 (</mark> 9)

Courtesy of Thanos C Dimopoulos, MD

Cohen YC, et al. N Engl J Med 2025;392:138-49.

LINKER-MM1 Update: Linvoseltamab in RRMM - Study Design

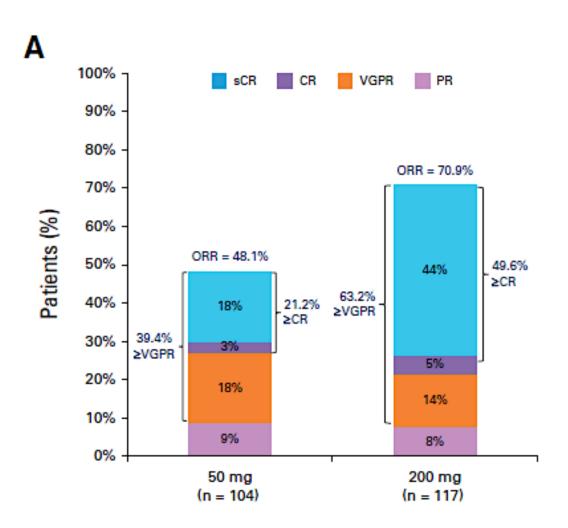


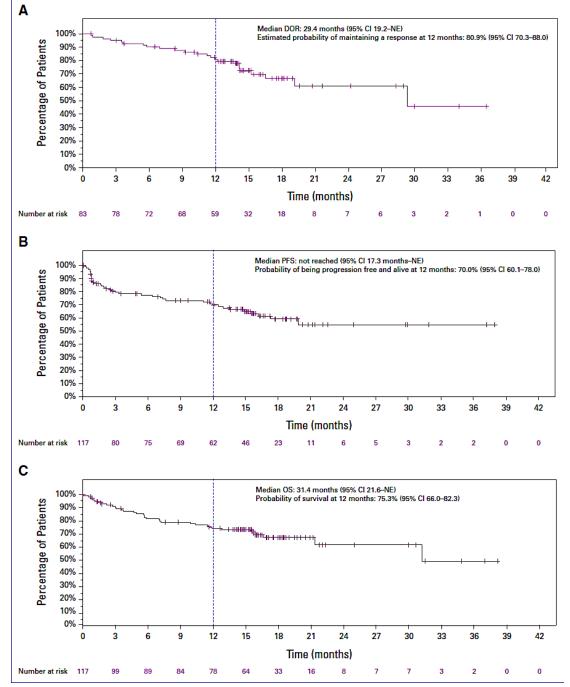
Linvoseltamab required two 1-day hospitalizations and allowed monthly dosing for patients who achieved ≥VGPR (Bumma et al., 2024)

Patient population (Suppl. Table 1) was heavily pretreated with high-risk features:

- Median age of 70 years; 26.5% ≥75 years of age
- Extramedullary plasmacytomas (≥2 cm) per IRC, 14.5%; ISS stage III, 17.9%

LINKER-MM1 Update: Efficacy





Courtesy of Thanos C Dimopoulos, MD

Shah MR, et al. ASH 2024; Abstract 3369; Bumma J Clin Oncol 2024

How does the PFS with bispecific antibodies (indirectly) compare to that with CAR T-cell therapy for patients with relapsed/refractory MM?



How do you typically sequence BS and CAR T-cell therapy in MM?



Other than tolerability issues with talquetamab, how would you compare schedule, method of administration and duration of treatment of the other approved BS and linvoseltamab?



What is the likely future role of BS and CAR-T as upfront therapy?



How much of a problem are infections in patients on BS, and how does the use of immunoglobulins impact infection risks? Should BS be given for a fixed duration?



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Year in Review: Management of Multiple Myeloma

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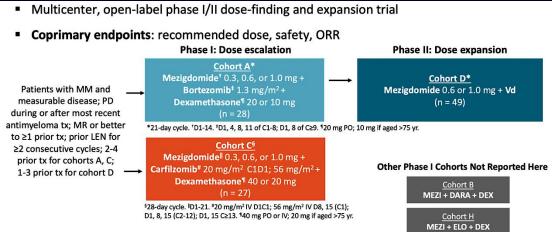
MODULE 3: CAR T-Cell Therapy

MODULE 4: Bispecific Antibodies

MODULE 5: Other Novel Agents



CC-92480-MM-02: MeziKd or MeziVd



MEZI + ELO + DEX			
Characteristic	Cohort A: MEZI-Vd	Cohort D: MEZI-Vd	Cohort C: MEZI-Kd
	(n = 28)	(n = 49)	(n = 27)
 Median previous therapies, n (range) Stem cell transplantation, n (%) Proteasome inhibitor, n (%) Bortezomib, n (%) Carfilzomib, n (%) Immunomodulatory agent, n (%) Anti-CD38 mAb, n (%) 	3 (2-4)	1 (1-3)	2 (2-4)
	17 (60.7)	35 (71.4)	19 (70.4)
	27 (96.4)	44 (89.8)	27 (100)
	23 (82.1)	36 (73.5)	27 (100)
	10 (35.7)	13 (26.5)	2 (7.4)
	28 (100)	49 (100)	27 (100)
	14 (50.0)	19 (38.8)	22 (81.5)
 Immunomodulatory agent refractory, n (%) Lenalidomide refractory, n (%) Pomalidomide refractory, n (%) 	24 (85.7)	31 (63.3)	24 (88.9)
	23 (82.1)	31 (63.3)	21 (77.8)
	13 (46.4)	0	12 (44.4)
 Proteasome inhibitor refractory, n (%) Ixazomib refractory, n (%) Bortezomib refractory, n (%) Carfilzomib refractory, n (%) 	14 (50.0)	8 (16.3)	14 (51.9)
	6 (21.4)	2 (4.1)	2 (7.4)
	3 (10.7)	1 (2.0)	13 (48.1)
	7 (25.0)	5 (10.2)	0
Anti-CD38 mAb refractory, n (%)	14 (50.0)	17 (34.7)	20 (74.1)
Triple-class refractory, n (%)	9 (32.1)	1 (2.0)	10 (37.0)

MDAnderson CancerCenter

Making Cancer History

Courtesy of Robert Z Orlowski, MD, PhD Sand

Sandhu I et al. ASH 2024; Abstract 1025.

MeziKd or MeziVd: Efficacy & Safety

MDAnderson

Making Cancer History

Efficacy Measure	Cohort A: MEZI-Vd (n = 28)				Cohort D: MEZI-Vd (n = 49)		Cohort C: MEZI-Kd (n = 27)	
Overall mPFS, mo	12.3				17.5		13.5	
ORR, % (95% CI)	75.0	(55.1-89.3	3)	85.7	(72.8-94.1)		85.2 (66.3-95.8	3)
Median DoR, mo (95% Cl)	10.9 (8.8-18.7)			19.	4 (9.7-NA)		11.9 (6.4-35.9)	
		t A: MEZI-Vd (n = 28)			Cohort D: MEZI-Vd (n = 49)		Cohort C: MEZI-Kd (n = 27)	
Efficacy Measure	•).6 mg (n = 9)	1.0 mg (n = 10)	0.6 mg (n = 11)	•	0.3 mg (n = 9)	0.6 mg (n = 9)	1.0 mg (n = 9)
mPFS, mo	13.4	11.2	12.3	20.8	16.6	11.7	13.5	13.8
ORR, % (95% CI)	NR	NR	60.0 (55.1-89.3)	NR	84.2 (68.7-94.0)	NR	NR	77.8 (40.0-97.2)
Median DoR, mo (95% CI)	NR	NR	11.6 (5.3-NA)	NR	19.4 (7.0-NA)	NR	NR	11.9 (0.2-NA)
		Cohort A: MEZI-V (n = 28)		ZI-Vd	Vd Cohort D: MEZI-Vo (n = 49)		Cohort C: MEZI-Kd (n = 27)	
Most Common* Grade 3/4 TEAEs of Interest, n (%)			0.6 mg = 18)	1.0 mg (n = 10)	0.6 mg (n = 11)	1.0 mg (n = 38)	0.3 + 0.6 mg (n = 18)	1.0 mg (n = 9)
Hematologic TEAEs Neutropenia Thrombocytopenia Anemia 		5 (2	•	7 (70.0) 1 (10.0) 1 (10.0)	8 (72.7) 2 (18.2) 0	23 (60.5) 11 (28.9) 3 (7.9)	6 (33.3) 1 (5.6) 2 (11.1)	6 (66.7) 3 (33.3) 2 (22.2)
Infections • COVID-19 • Pneumonia		•	27.8) 0 16.7)	0 0 0	2 (18.2) 1 (9.1) 1 (9.1)	14 (36.8) 3 (7.9) 9 (23.7)	6 (33.3) 4 (22.2) 0	3 (33.3) 1 (11.1) 1 (11.1)
 Neutropenia and concurrent infection Any neutropenia + grade 3/4 infection Grade 3/4 neutropenia + any infection *Occurring in ≥25% of patients. 		-	5.6) 5.6)	0 1 (10.0)	1 (9.1) 4 (36.4)	3 (7.9) 12 (31.6)	0 0	1 (11.1) 2 (22.2)

Courtesy of Robert Z Orlowski, MD, PhD

Sandhu I et al. ASH 2024; Abstract 1025.

How would you compare the efficacy and tolerability of mezigdomide, iberdomide and lenalidomide?



Year in Review: Clinical Investigator Perspectives on the Most Relevant New Datasets and Advances in Oncology

Therapeutic Targets Beyond EGFR for Non-Small Cell Lung Cancer

A CME/MOC-Accredited Live Webinar

Thursday, May 15, 2025 5:00 PM – 6:00 PM ET

Faculty Jessica J Lin, MD Joel W Neal, MD, PhD

> Moderator Neil Love, MD



Thank you for joining us!

Please take a moment to complete the survey currently up on Zoom. Your feedback is very important to us. The survey will remain open for 5 minutes after the meeting ends.

Information on how to obtain CME and ABIM MOC credit is provided in the Zoom chat room. Attendees will also receive an email in 1 to 3 business days with these instructions.

