

# SUSTAIN

Systematic Uptake and Standardization of Treatment  
Advances Through an Integrated Network for  
**BISPECIFIC ANTIBODY THERAPY**

Provided by  UK HealthCare

 The  
France  
Foundation

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- Ayman Qasrawi, MD has served as a consultant for Sanofi Pharmaceuticals. The financial relationship ended in June 2025.

All of the relevant financial relationships listed for these individuals have been mitigated.

The material presented in this course represents information obtained from the scientific literature as well as the clinical experiences of the speakers. In some cases, the presentations might include discussion of investigational agents and/or off-label indications for various agents used in clinical practice. Speakers will inform the audience when they are discussing investigational and/or off-label uses.

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A vertical decorative strip on the left side of the slide features a microscopic view of cells. The cells are primarily purple and blue, with some red and white elements, set against a pinkish-purple background. The cells appear to be in various stages of division or are different types of cells, possibly including a large cell with a prominent nucleus and smaller cells around it.

# Disclaimer

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## Educational Support

This activity is supported by an independent medical educational grant from Johnson & Johnson.

# Accreditation



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- **1.00 ACPE**

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This knowledge-based activity will award 1.00 contact hour(s) (0.100 CEUs) of continuing pharmacy education credit in states that recognize ACPE providers. Course JA-UAN Number: JA0000312-9999-26-031-L01-P

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This Live activity is designated for a maximum of 1.00 *AMA PRA Category 1 Credit™*. Physicians should claim only credit commensurate with the extent of their participation in the activity.

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- **1.00 IPCE**

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This activity was planned by and for the healthcare team, and learners will receive 1.00 Interprofessional Continuing Education (IPCE) credit(s) for learning and change.

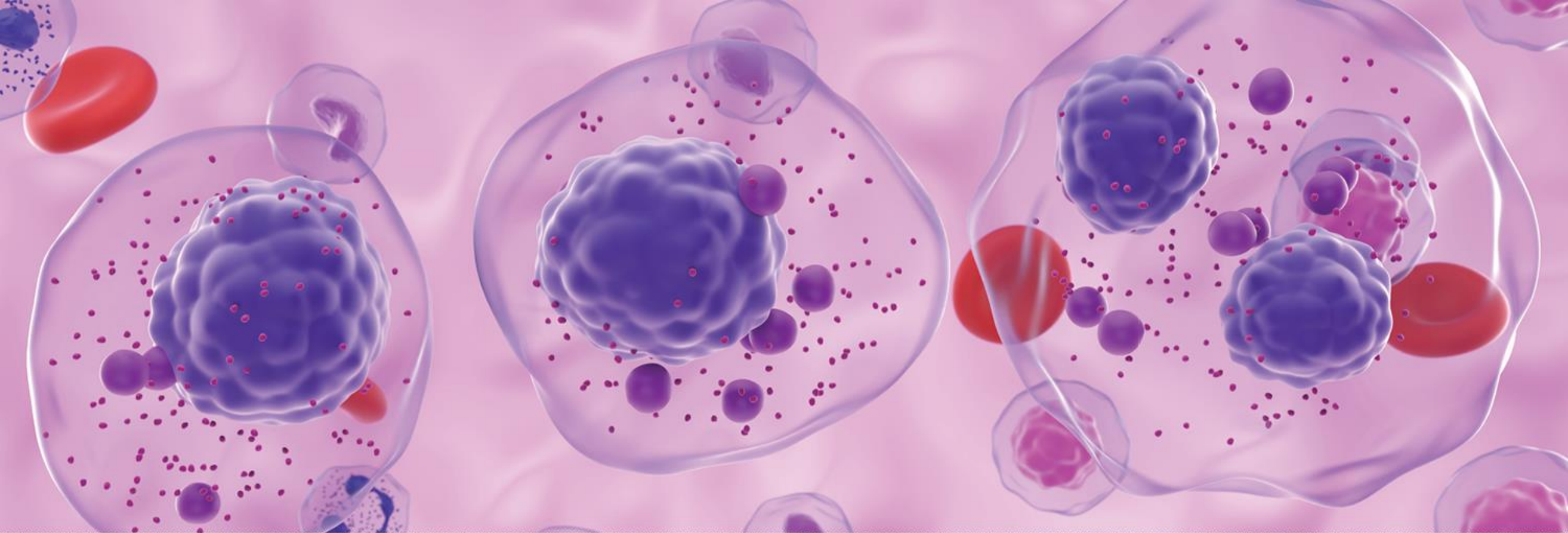
For full course  
information, visit:





# What is the preferred meeting day and time for these sessions going forward?

- A. Mondays, noon EST
- B. Tuesdays, 12:30 pm EST
- C. Wednesdays, 8:00 am EST
- D. Thursdays, 4:00 pm EST



**Session 1: Introduction to Bispecific  
Antibodies—Mechanism of Action and  
Clinical Evidence**



# Curriculum Learning Objective

- Develop and implement site-specific protocols for safe BsAb administration, including patient selection criteria, premedication regimens, dose escalation procedures, and post-infusion monitoring



# Session Objectives

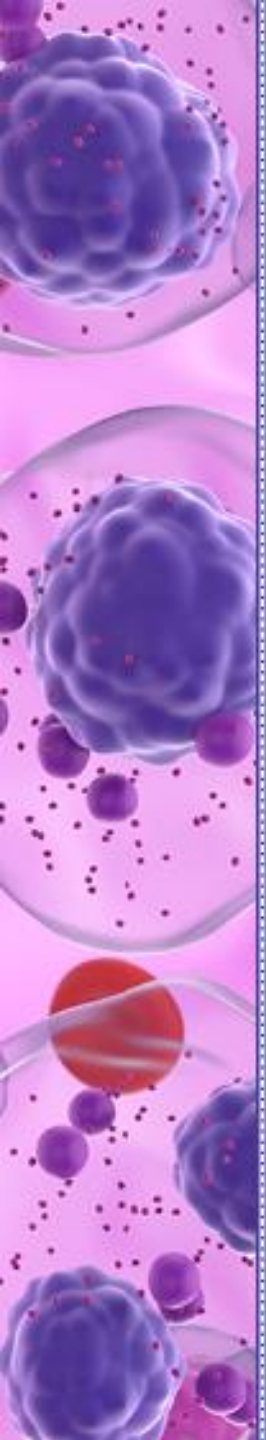
1. Describe the mechanism of action of BsAbs for the treatment of patients with relapsed or refractory multiple myeloma (R/R MM)
2. Explain the clinical indications for each approved BsAb for R/R MM
3. Discuss the clinical efficacy and safety of BsAbs for R/R MM

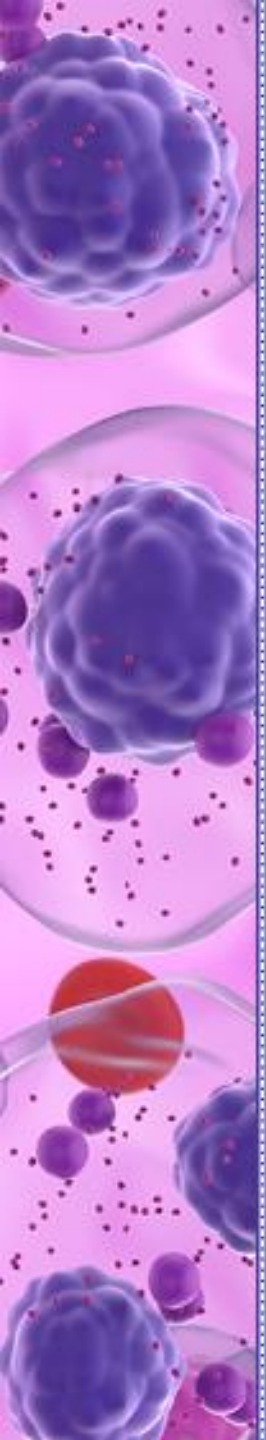
# What Do You Know?



Dysgeusia and nail and skin disorders are unique toxicities associated with which of the following BsAb targets?

- A. BCMA
- B. GPR5CD
- C. CD38
- D. CD3

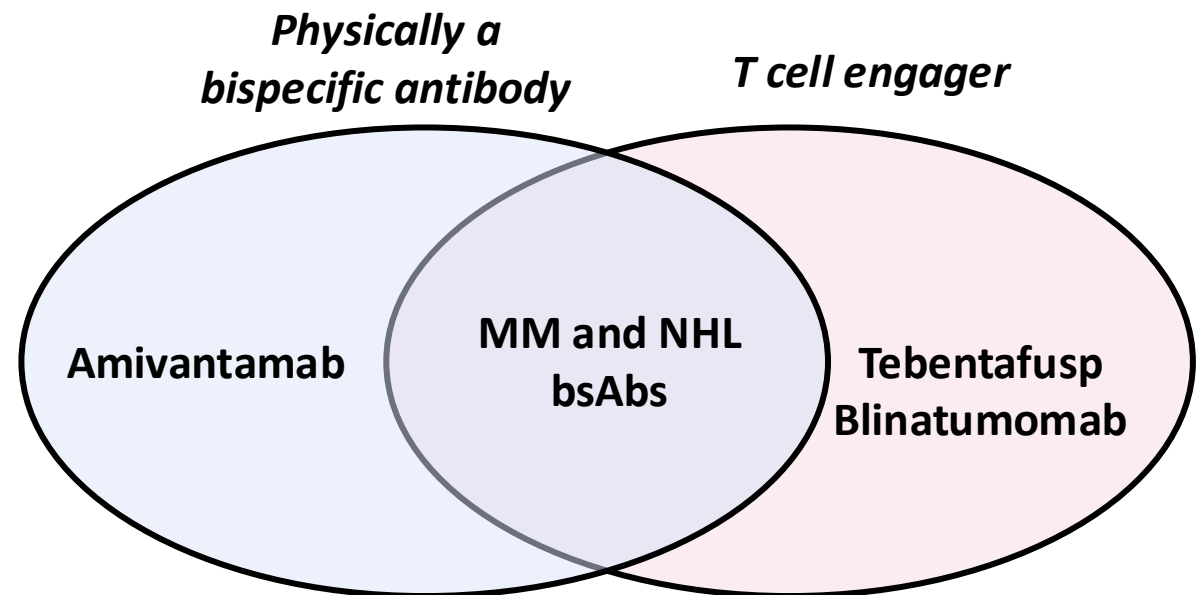




# Overview of Bispecific Antibodies

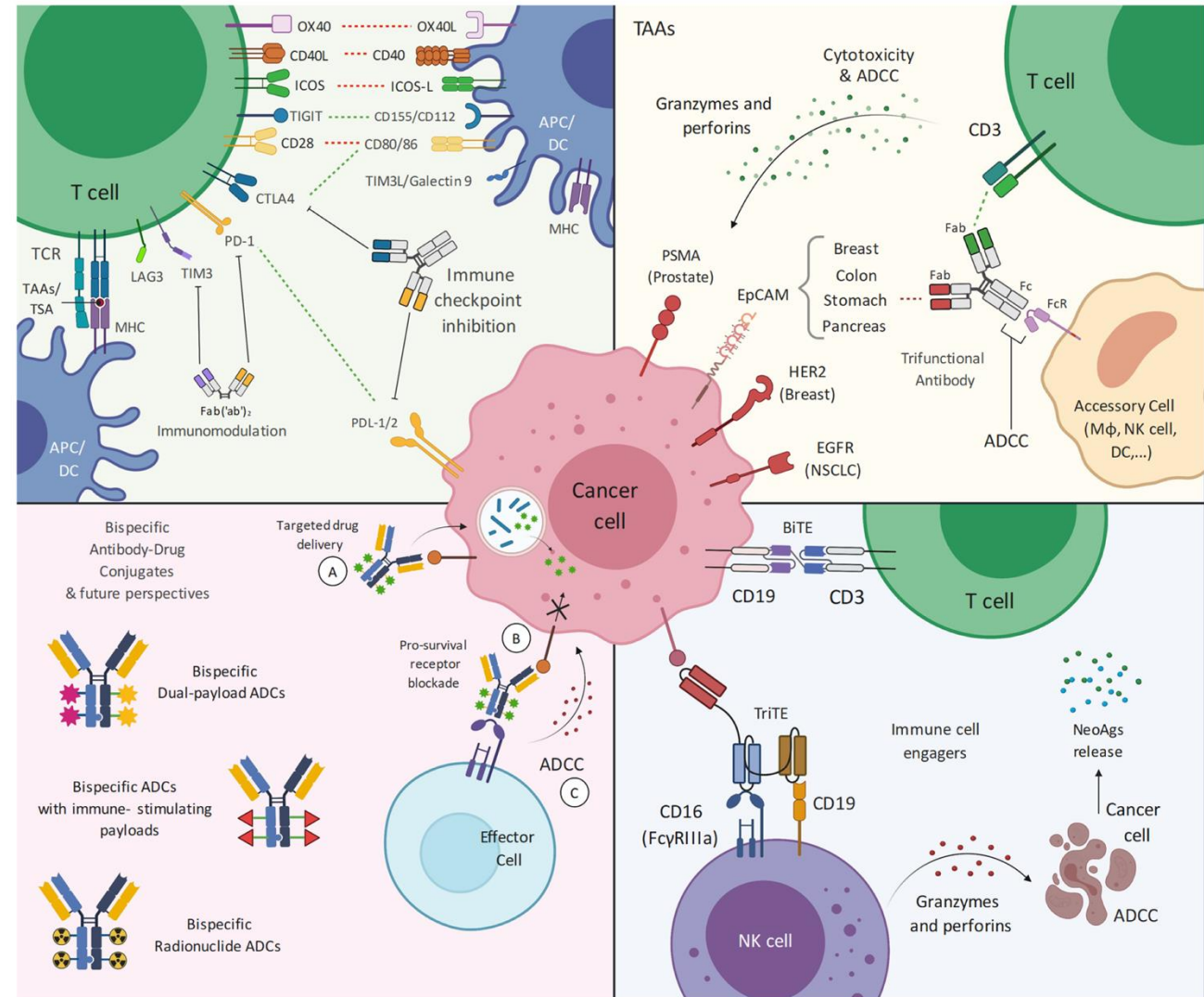
# What Is a Bispecific Antibody?

- An artificially created antibody with 2 unique binding sites that target different antigens or epitopes
- Here, we will focus on BsAbs in multiple myeloma that engage T cells. Similar bsAbs exist in non-Hodgkin's lymphoma (NHL) as well
  - MM: Teclistamab, talquetamab, elranatamab, linvoseltamab, *et al*
  - NHL: Glofitamab, epcoritamab, mosunetuzumab, *et al*
  - Blinatumomab (B-ALL), tebentafusp (uveal melanoma), and amivantamab (lung cancer) are not quite the same



# Clinical Applications of BsAbs

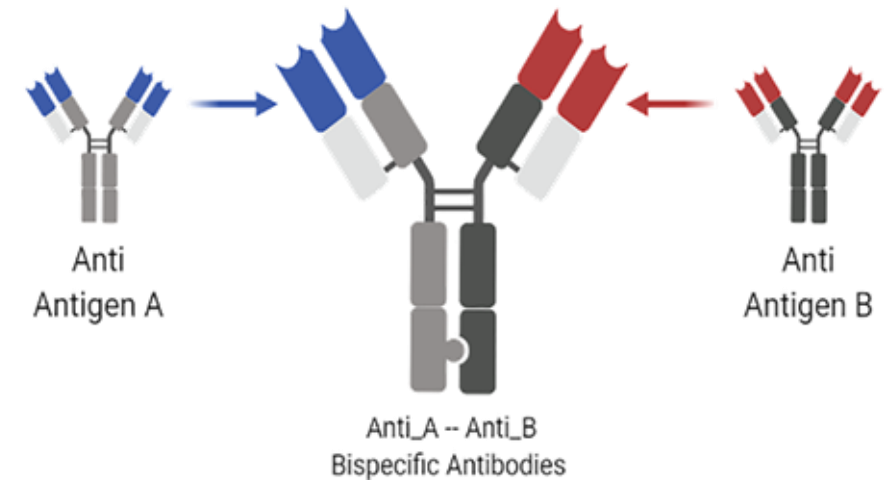
- Dual Immune Checkpoint Blockades
- Dual Tumor-Associated Antigens
- Bispecific Antibody-Drug Conjugates
- Immune Cell Engagers



OX40, Tumor necrosis factor receptor superfamily, member 4 or TNFRSF4; OX40L, OX40 ligand; ICOS, Inducible costimulator; ICOS-L, Inducible costimulator-ligand (ICOS-L); CD, cluster of differentiation; TIGIT, T cell immunoreceptor with Ig and ITIM domains; TIM3, T-cell immunoglobulin mucin 3; TIM3L, T-cell immunoglobulin mucin 3 ligand; CTLA-4, Cytotoxic T-Lymphocyte Antigen 4; PD-L1, Programmed death-ligand 1; PD-1, Programmed Death 1; TCR, T-cell receptor; LAG3, Lymphocyte-activation gene 3; MHC, Major Histocompatibility Complex; TAA, tumor-associated antigen; TSA, tumor-specific antigen; Fab, antigen-binding fragment; Fc, fragment crystallizable region; FcR, fragment crystallizable region receptor; APC, antigen-presenting cell; DC, dendritic cell; ADC, antibody-drug conjugates; ADCC, antibody-dependent cytotoxicity; PSMA, prostate-specific membrane antigen; BiTE, Bi-specific T-cell engager; TriTE, trispecific T-cell engager; EpCAM, Epithelial cell adhesion molecule; HER2, Human Epidermal Growth Factor Receptor 2; NK, natural killer cell; NeoAgs; neoantigens; FcγRIIIa, Fc Gamma Receptor IIIa; Mφ, macrophage; NSCLC, non-small cell lung cancer.

# How Are BsAbs for MM Designed?

- **Immune Cell Engagers:** Replace each of the two Fab regions with epitope-binding domains of one's choice
- **Antigen A** is typically CD3 (an important T-cell co-receptor for both CD4+ and CD8+ T cells)
- Options for **antigen B** in FDA-approved constructs:
  - BCMA: Teclistamab, elranatamab, linvoseltamab
  - GPRC5D: Talquetamab
  - *Others in development for these and other epitopes, eg FCrH5*

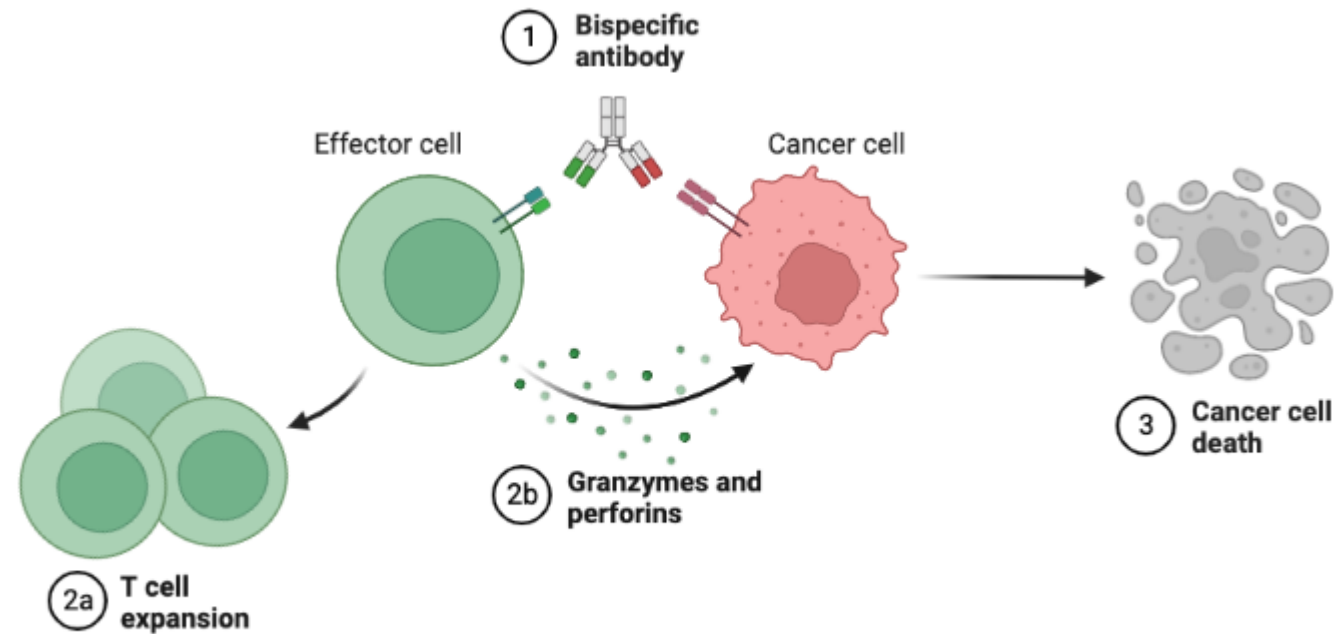


CD = cluster of differentiation; Fab = fragment antigen-binding; FCrH5 = Fc receptor-like protein 5; FDA = US Food and Drug Administration  
Khatib SE, Salla M. *Leuk Res Rep.* 2022;18:100335; Khosla AA, et al. *Pharmaceuticals (Basel).* 2023;16(10):1461.

# Mechanism of Action of BsAbs in Multiple Myeloma

The mechanism of action of BsAbs in MM involves the following steps:

1. BsAbs bind to a target antigen on the surface of myeloma cells, such as BCMA, FcRH5, or GPRC5D
2. BsAbs simultaneously bind CD3, a molecule present on the surface of T cells
3. This dual binding leads to the activation of T cells
4. Activated T cells then initiate the killing of myeloma cells via secretion of pro-apoptotic factors



# Approved BsAbs for R/R MM

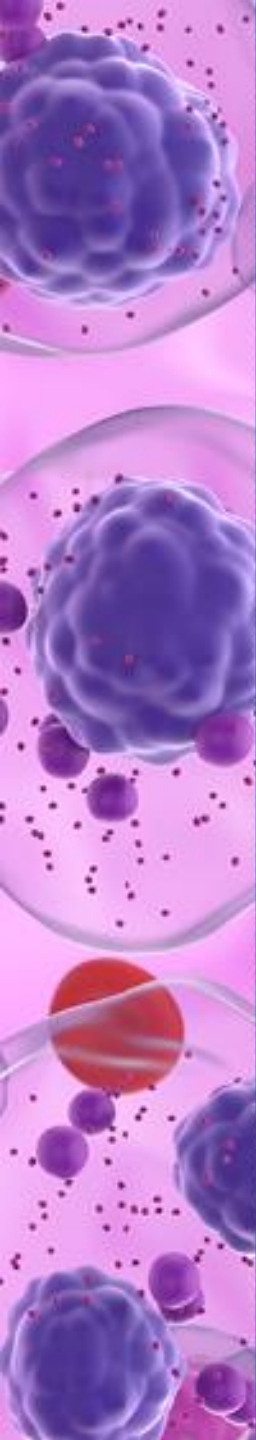
Teclistamab

Elranatamab

Talquetamab

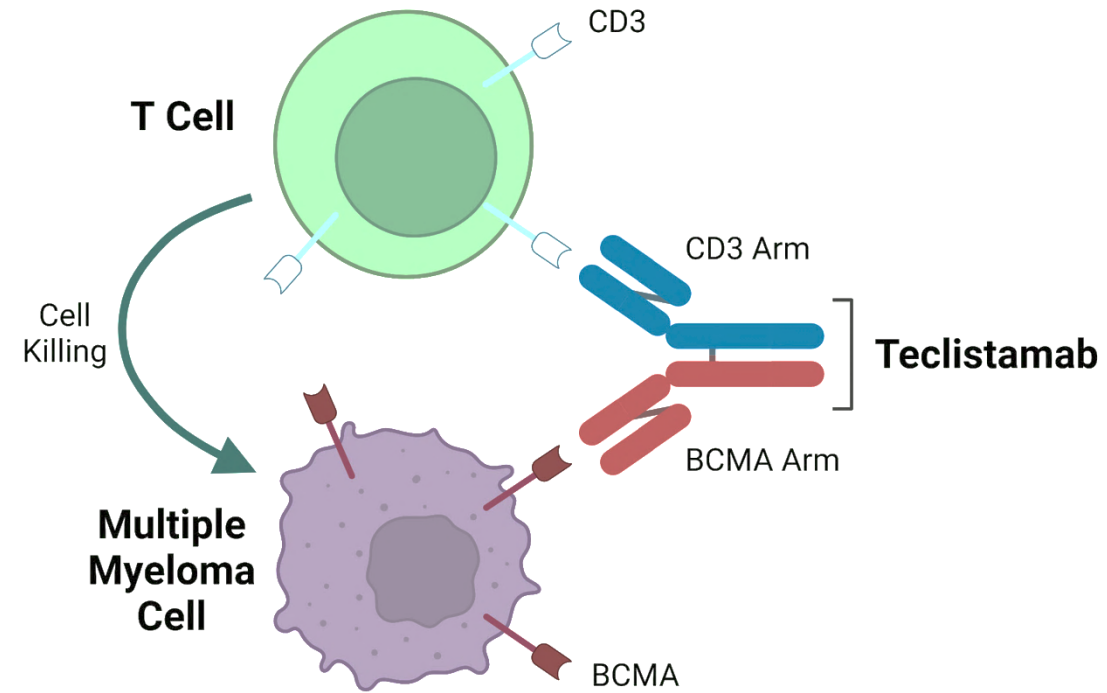
Linvoseltamab

You will learn more about patient eligibility criteria in ECHO Session #2!



# Teclistamab: Approval and Indication

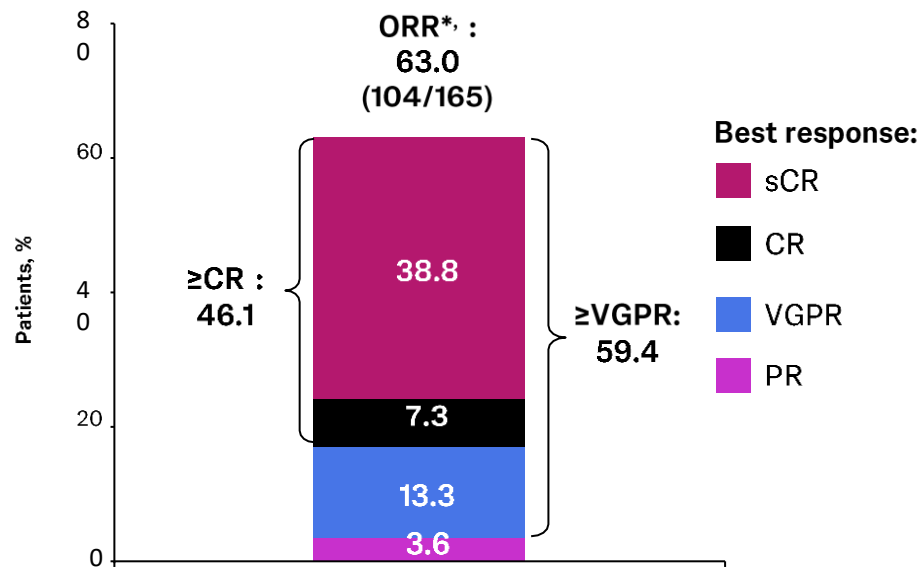
- Teclistamab is a BCMA x CD3 BsAb that was approved for use in 2022
- Indicated as a **single agent** for adult patients with R/R MM who have received **≥ 4 line(s) of therapy**, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody
- **March 2026 update:** Indicated in **combination with daratumumab/hyaluronidase** for adult patients with R/R MM who have received **≥ 1 line(s) of therapy**, including a proteasome inhibitor and an immunomodulatory agent



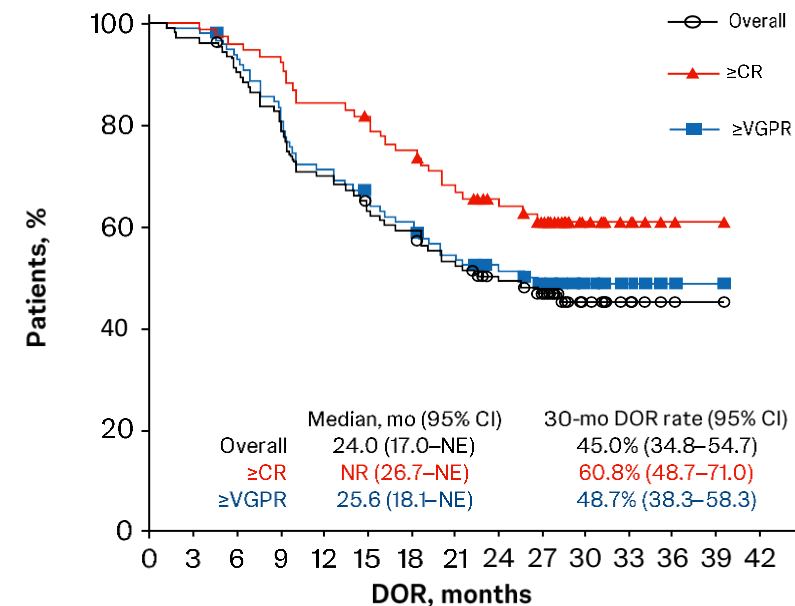
# Teclistamab: Primary Endpoint as a Monoagent

- Evaluated in MajesTEC-1, a single-arm, multicohort, open-label, multicenter study
  - Primary endpoint was overall response rate (ORR)
  - Secondary endpoints were duration of response (DOR), progression-free survival (PFS), and overall survival (OS)
- At a median follow-up of 30 months, the ORR was 63.0%, with 104 patients (46.1%) having a complete response (CR)

## Primary Endpoint: Overall Response Rate



## DOR



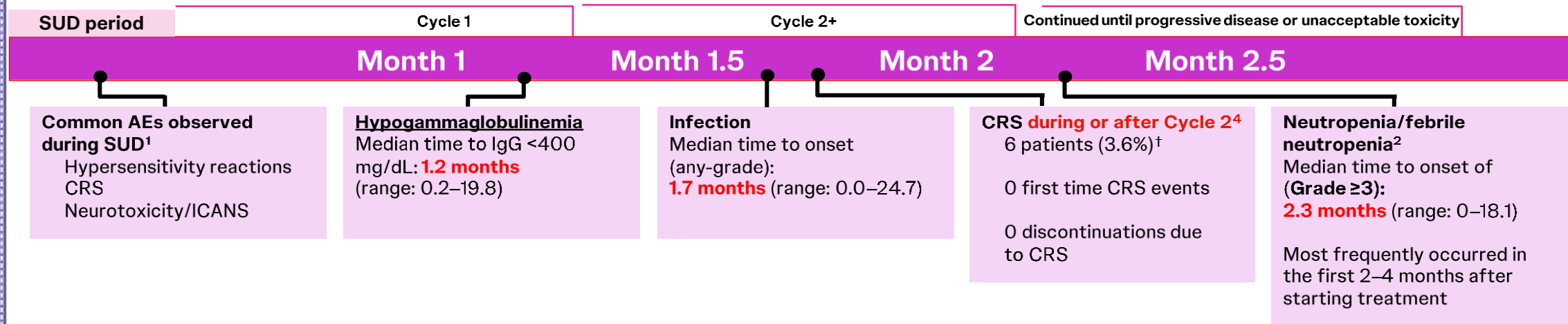
Patients at risk

Overall	104	101	93	83	72	64	60	53	46	39	16	8	3	1	0
≥CR	76	76	73	71	64	60	56	50	44	37	15	7	2	1	0
≥VGPR	98	97	90	80	69	62	58	51	45	38	16	8	3	1	0

CR = complete response; PR = partial response; sCR = stringent complete response; VGPR = very good partial response

Moreau P, et al. *N Engl J Med*. 2022;387(6):495-505; Sidana S, et al. *Hemasphere*. 2023;7(Suppl ):e62475d0; Garfall AL, et al. ASCO 2024. Poster presentation 7540

# Teclistamab: Safety as a Monoagent



You will learn more about how to manage adverse events in ECHO Sessions #3, #4, and #5!

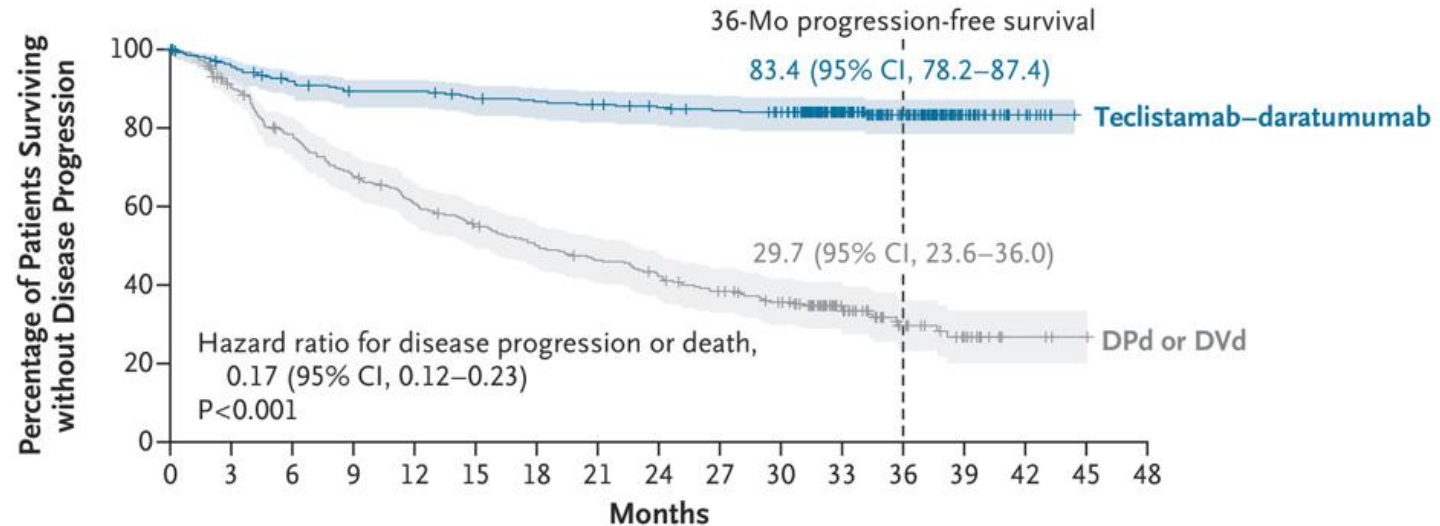
CRS = cytokine release syndrome; SUD = step-up-dose

Moreau P, et al. *N Engl J Med*. 2022;387(6):495-505; TECVAYLI® [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. March 2026; Nooka AK, et al. *Cancer*. 2024;130:886–900; Frerichs K, et al. Presented at the European Hematology Association Congress. June 2023. Frankfurt, Germany; Martin TG, et al. *Cancer*. 2023;129:2035–2046.

# Teclistamab: Primary Endpoint as Combination Therapy

- Evaluated in MajesTEC-3, a randomized, open-label study in combination with daratumumab and hyaluronidase in patients with R/R MM after one to three lines of therapy
  - Primary endpoint is PFS
  - Select secondary endpoints are OR, MRD, OS, DOR, and safety
- At a median follow-up of 34.5 months, estimated 36-month progression-free survival was 83.4% in those treated with daratumumab+teclistamab vs 29.7% in those treated with DPd, or DVd

Progression-free Survival



**No. at Risk**

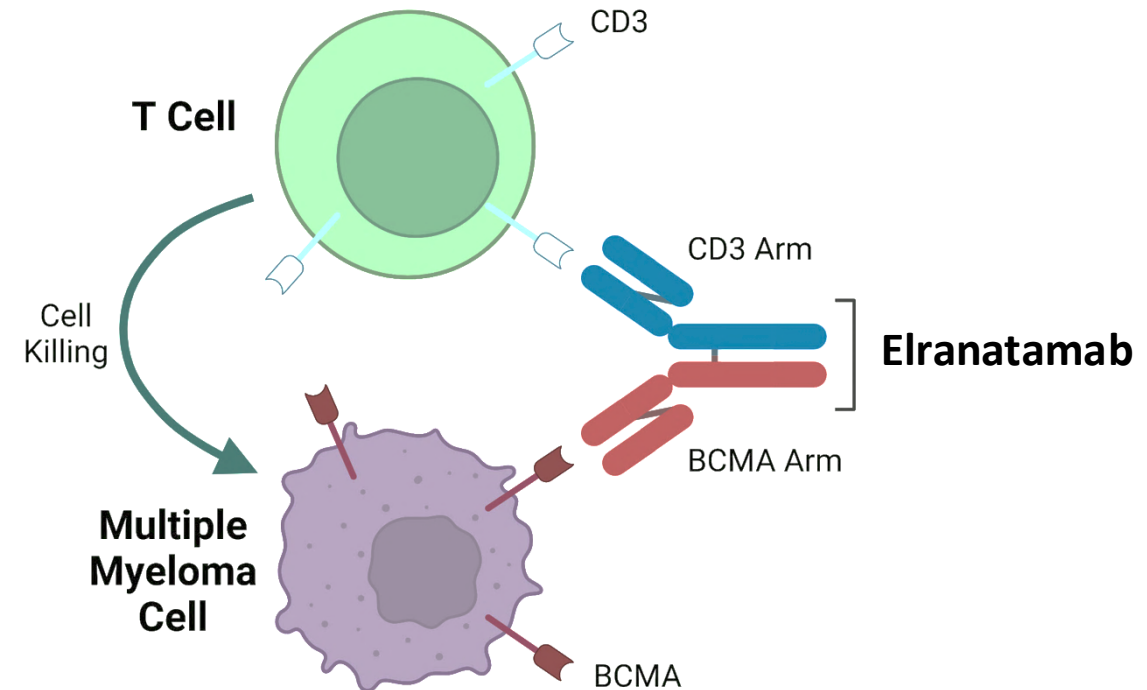
Teclistamab–daratumumab	291	262	249	240	240	233	230	227	222	218	214	142	89	34	9	0	0
DPd or DVd	296	254	218	188	167	149	135	124	112	99	87	52	26	14	3	1	0

# Teclistamab: Safety as a Combination Therapy

Adverse Event	Teclistamab–Daratumumab (N = 283)		DPd or DVd (N = 290)	
	Any Grade	<i>n</i> (%)	Any Grade	<i>n</i> (%)
<b>Any adverse event</b>	283	(100)	290	(100)
Hematologic				
Neutropenia	222	(78.4)	240	(82.8)
Anemia	111	(39.2)	103	(35.5)
Thrombocytopenia	103	(36.4)	126	(43.4)
Lymphopenia	63	(22.3)	50	(17.2)
Leukopenia	51	(18.0)	61	(21.0)
Nonhematologic				
Hypogammaglobulinemia	194	(68.6)	104	(35.9)
Cytokine release syndrome	170	(60.1)	0	
Diarrhea	147	(51.9)	89	(30.7)
Cough	136	(48.1)	66	(22.8)
Covid-19	124	(43.8)	97	(33.4)
Upper respiratory tract infection	115	(40.6)	88	(30.3)
Pyrexia	104	(36.7)	55	(19.0)
Pneumonia	65	(23.0)	53	(18.3)
Covid-19 pneumonia	34	(12.0)	12	(4.1)

# Elranatamab: Approval and Indication

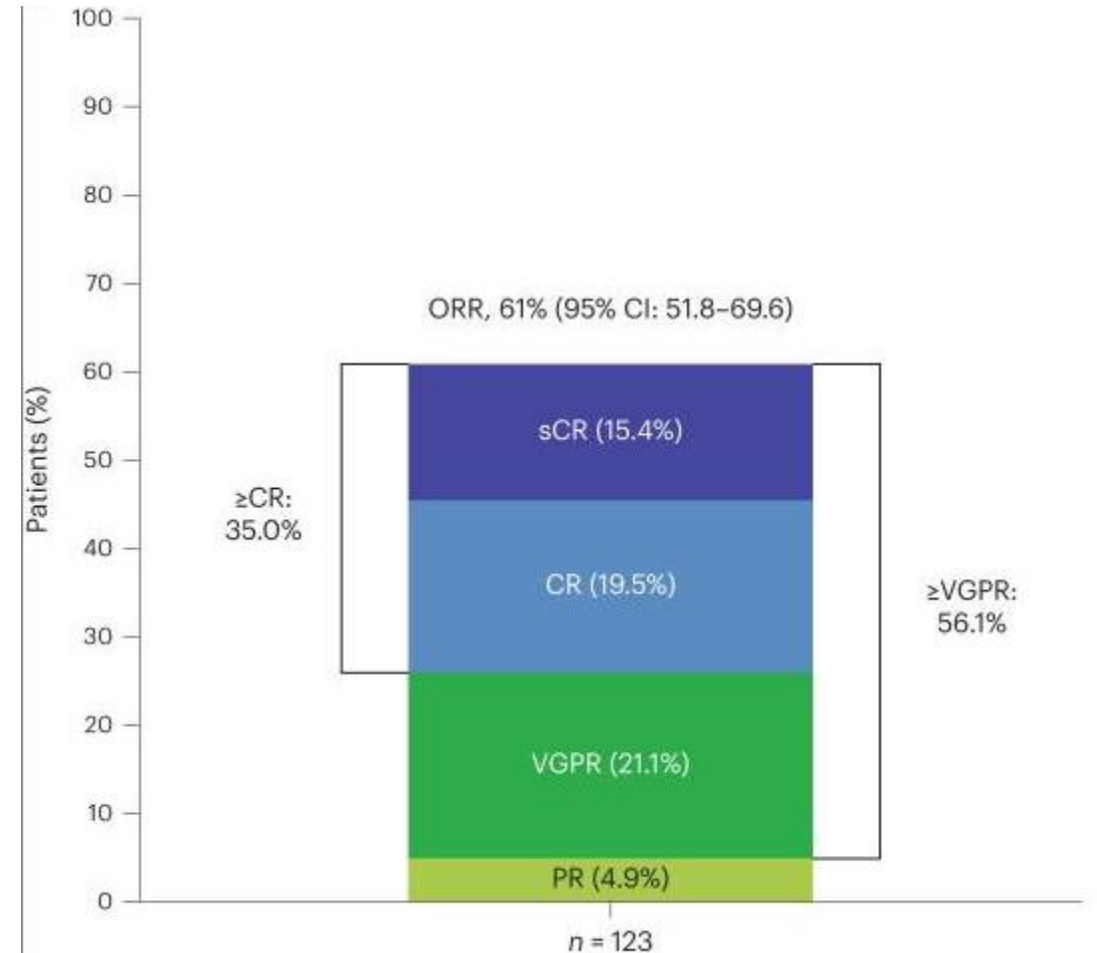
- Elranatamab is a BCMA x CD3 BsAb approved for use in 2023
- Indicated for adult patients with R/R MM who have received  $\geq 4$  lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody



# Elranatamab: Primary Endpoint

- Elranatamab was evaluated in MagnetisMM-3, an open-label, multicenter, multicohort non-randomized Phase 2 study
  - Primary endpoint was ORR
  - Secondary endpoints included DOR, PFS, OS, time to response (TTR), and minimal residual disease (MRD)
- At a median follow-up of 14.7 months, ORR was 61%, with 35% of patients achieving a CR

## Primary Endpoint: Overall Response Rate



# Elranatamab: Safety

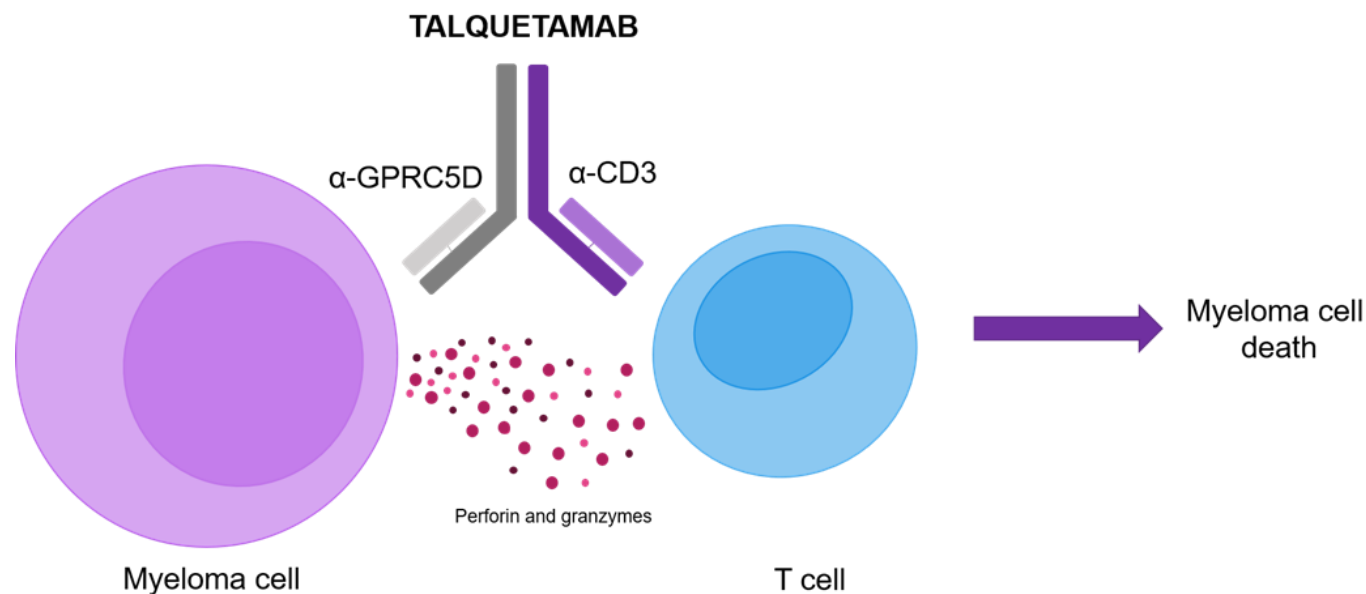
- The most common TEAEs were hematological, leading to dose reductions and interruptions in 28.5% and 77.2% of patients, respectively
- A total of 55 (44.7%) patients died while on study, with the majority due to disease progression
  - Four deaths were considered related to elranatamab by the investigator

You will learn more about how to manage adverse events in ECHO Sessions #3, #4, and #5!

Adverse Events With Elranatamab		
	N = 123	
	Any grade	Grade 3 or 4
<b>Any treatment-emergent adverse event</b>	123 (100)	87 (70.7)
<b>Hematologic</b>		
Anemia	60 (48.8)	46 (37.4)
Neutropenia	60 (48.8)	60 (48.8)
Thrombocytopenia	38 (30.9)	29 (23.6)
Lymphopenia	33 (26.8)	31 (25.2)
<b>Nonhematologic</b>		
Cytokine release syndrome	71 (57.7)	0
Diarrhea	52 (42.3)	2 (1.6)
Fatigue	45 (36.6)	4 (3.3)
Decreased appetite	41 (33.3)	1 (0.8)
Pyrexia	37 (30.1)	5 (4.1)
COVID-19 related	36 (29.3)	19 (15.4)
Injection site reaction	33 (26.8)	0
Nausea	33 (26.8)	0
Hypokalemia	32 (26.0)	13 (10.6)
Cough	31 (25.2)	0
Headache	29 (23.6)	0

# Talquetamab: Approval and Indication

- Talquetamab is a GPRC5D x CD3 BsAb approved for use in 2023
- Indicated for patients with R/R MM who have received  $\geq 4$  lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody



# Talquetamab: Primary Endpoint

- Talquetamab was evaluated in MMY1001 (MonumenTAL-1), a Phase 1/2, single-arm, open-label, multicenter study
- At median follow-ups of 11.7 months (405- $\mu\text{g}$  dose level) and 4.2 months (800- $\mu\text{g}$  dose level), 70% of patients (95% CI, 51-85) and 64% (95% CI, 48-78) had a response, respectively
- ORR was similar in patients with prior anti-BCMA CAR-T or BsAb therapy

## Primary Endpoint: Overall Response Rate

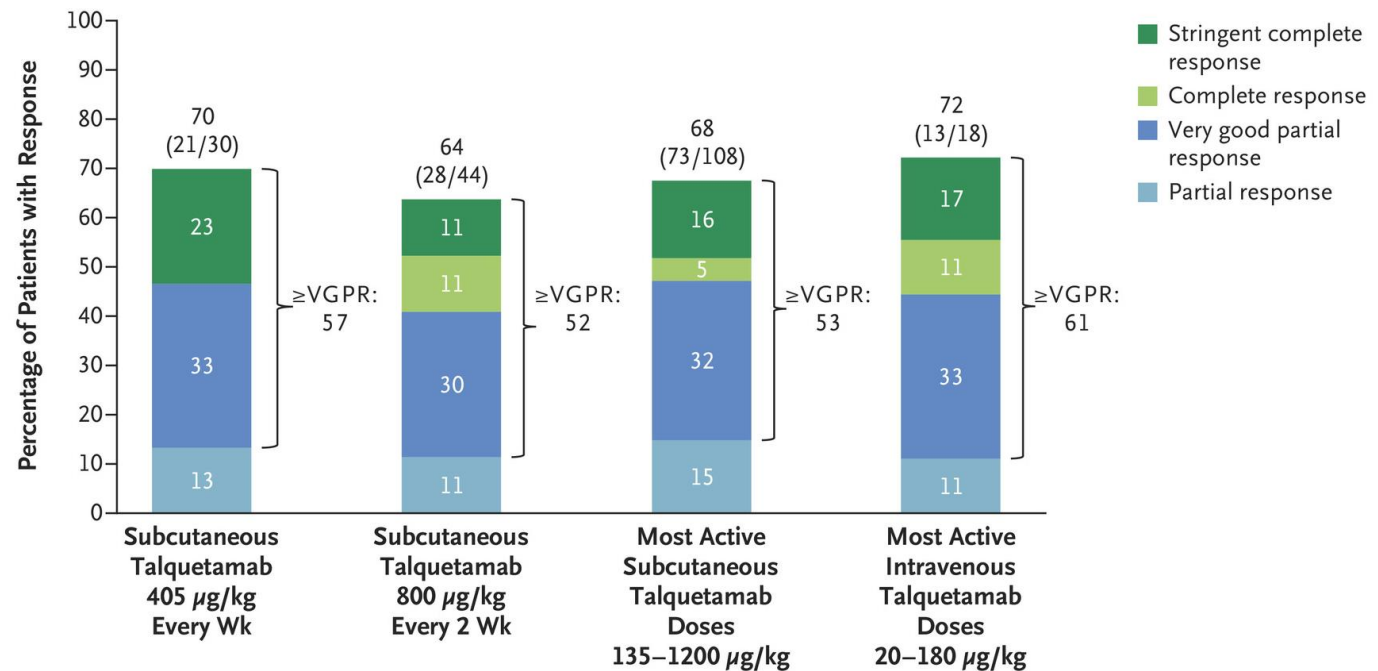


TABLE: ORR in patients with prior TCR

	Overall (N=70)	Prior BCMA CAR-T (n=48 <sup>a</sup> )	Prior BCMA BsAb (n=23 <sup>a</sup> )	Prior BCMA ADC and prior TCR (n=8)
ORR, n (%)	46 (65.7)	35 (72.9)	12 (52.2)	6 (75.0)

# Talquetamab: Safety

- **Serious AEs:** Occurred in 47% of participants; most common ( $\geq 2\%$ ) were CRS (13%), infections (including bacterial/sepsis, 8%), pyrexia (4.7%), ICANS (3.8%), COVID-19 (2.7%), and neutropenia (2.1%)
- **Fatal AEs:** Occurred in 3.2% of participants, including COVID-19, dyspnea, health deterioration, infections (bacterial/fungal), basilar artery occlusion, and pulmonary embolism
- **Discontinuations:** 9% discontinued

## Adverse Reactions Observed in $\geq 20\%$ of Clinical Trial Participants

Adverse Event	Any Grade (%)
Pyrexia	83
Fatigue	37
Cytokine release syndrome	76
Dysgeusia	70
Dry mouth	34
Dysphagia	23
Diarrhea	21
Nail disorder	50
Skin disorder	41
Rash	38
Xerosis	30
Pruritus	19
Musculoskeletal pain	43
Weight decrease	35
Upper respiratory tract infection	22
Hypotension	21
Headache	21



# GPRC5D-Related Toxicities

	All grade	Grade 3-4	Median onset
Skin-related event	69%	1%	24d
Rash-related event	36%	9%	21d
Dysgeusia	57%	N/A	13d
Nail-related events	29%	1%	50d
Dry mouth	46%	0%	-
Weight loss	32%	1%	-

**Rash:** often palmar/plantar, managed with emollients and topical steroids

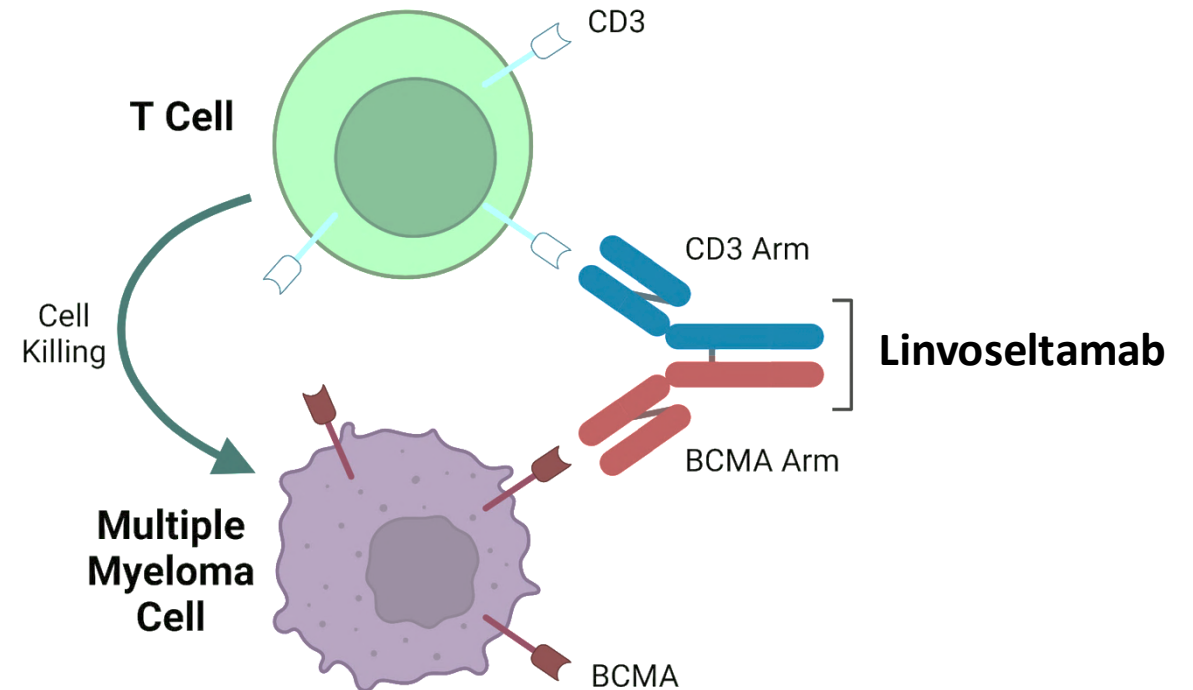
**Oral symptoms:** consider saliva substitute

Consider dose holds and reductions

You will learn more about how to manage adverse events in ECHO Sessions #3, #4, and #5!

# Linvoseltamab: Approval and Indication

- Linvoseltamab is a BCMA x CD3 bsAb approved for use in 2025
- Indicated for patients with R/R MM who have received  $\geq 4$  lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody



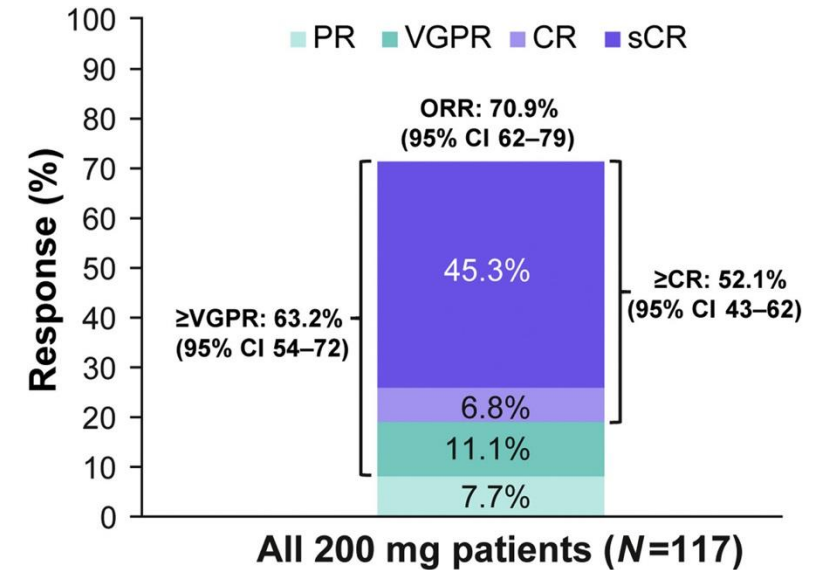
# Linvoseltamab: Primary Endpoint

- Linvoseltamab was evaluated in LINKER-MM1, a Phase 1/2, single-arm, open-label, multicenter study
- At the median survival follow-up of 21.3 months (range 0-45), the ORR was 70.9% (95% CI 62-79)
- Overall, 63.2% of patients achieved  $\geq$  VGPR and 52.1% achieved  $\geq$  CR
  - Responses were durable with a median DOR of 29.4 months (95% CI 20-NE) and median duration of  $\geq$  CR NR (95% CI 18.6-NE)

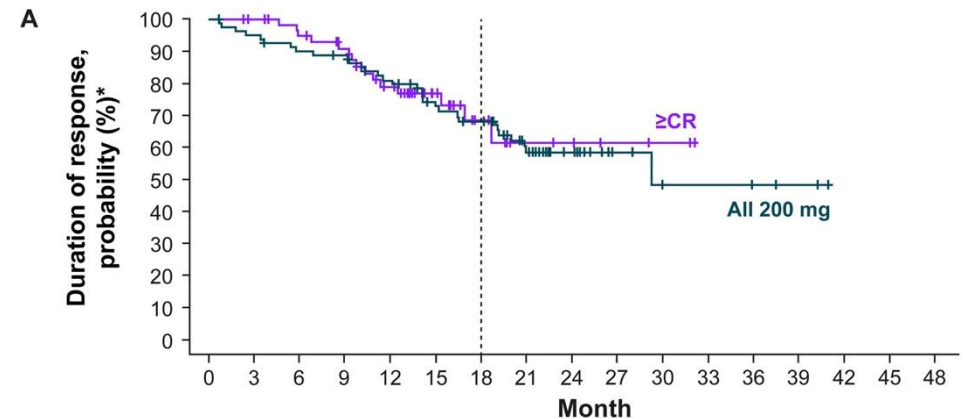
NE = not estimable

Lee HC, et al. *Clin Lymphoma Myeloma Leuk.* 2026;26(2):e201-e212.e8.

## ORR



## DOR



# Linvoseltamab: Safety

- All patients treated at the 200-mg dose experienced a TEAE
  - Grade  $\geq$  3 TEAEs occurred in 88% of patients
- 24 patients (21%) discontinued treatment due to TEAEs
  - Treatment-related events occurred in 11 (9%) patients

You will learn more about how to manage adverse events in ECHO Sessions #3, #4, and #5!

Event, n (%)	All Patients Who Received Linvoseltamab 200 mg (N = 117)	
	Any grade	Grade $\geq$ 3
Any adverse event	117 (100)	103 (88.0)
CRS	54 (46.2)	1 (0.9)
Neutropenia	51 (43.6)	50 (42.7)
Diarrhea	49 (41.9)	2 (1.7)
Anemia	47 (40.2)	36 (30.8)
Cough	47 (40.2)	0
Fatigue	40 (34.2)	1 (0.9)
Arthralgia	38 (32.5)	2 (1.7)
Headache	30 (25.6)	1 (0.9)
Hypokalemia	29 (24.8)	4 (3.4)
Nausea	28 (23.9)	0
Back pain	27 (23.1)	3 (2.6)
Dyspnea	27 (23.1)	1 (0.9)
COVID-19	26 (22.2)	14 (12.0)
Upper respiratory tract infection	25 (21.4)	2 (1.7)
Vomiting	25 (21.4)	0

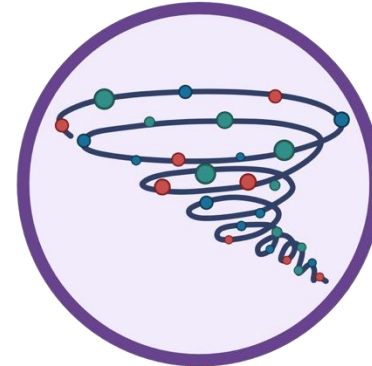
# BsAbs in MM: What Could Go Well?



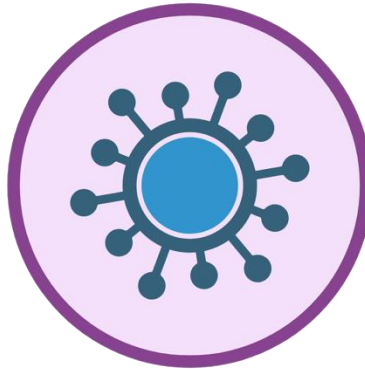
IEC-HC = immune effector cell-associated hemophagocytic lymphohistiocytosis-like syndrome; HLH = Hemophagocytic lymphohistiocytosis; ICANS = Immune effector cell-associated neurotoxicity syndrome  
Teclistamab-cqyv (Tecvayli) [prescribing information]. Janssen Biotech, Inc; March 2026; Elranatamab-bcmm (Elrexfio) [prescribing information]. Pfizer Inc; July 2025.; Linvoseltamab-gcpt (Lynozzyfic) [prescribing information]. Regeneron Pharmaceuticals, Inc; July 2025 ; Talquetamab-tgvs (Talvey) [prescribing information]. Janssen Biotech, Inc; August 2023.

# BsAbs in MM: What Could Go Wrong?

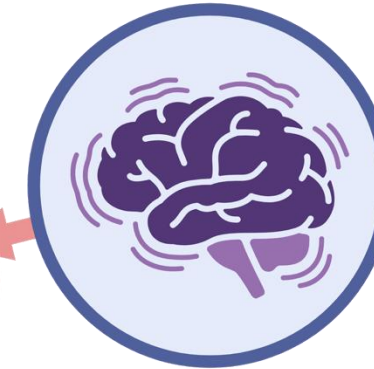
**Cytokine Release Syndrome**  
Fevers and possibly low blood pressure from systemic inflammation as bsAbs engage T-cells to destroy tumor cells



**Infections**  
A major issue with BCMA bsAbs is plasma cell depletion and T-cell redirection leading to increased infections



**ICANS (neurotoxicity)**  
Confusion, aphasia, or other neurological deficits related to systemic inflammation and possibly on-target toxicities



**Risks of Bispecific Antibodies**

**Dysgeusia and Skin Changes**  
Seen with GPRC5D bsAbs as an on-target toxicity



**'Time Toxicity'**  
BsAbs in R/R MM are typically dosed until progression, which can mean over a year of therapy every 1-2 weeks with some products



# Pipeline BsAbs

Bispecific Antibody	Target	Clinical Trials Identifier	Phase
Etentamig	BCMA x CD3	NCT06158841	Phase 3
Cevostamab	FcRH5 x CD3	NCT05535244	Phase 1/2
Alnuctamab	BCMA x CD3	NCT03486067	Phase 1
Forimtamig	GPRC5D x CD3	NCT04557150	Phase 1/2
F182112	BCMA x CD3	NCT07312188	Phase 2
ISB 1342	CD38 x CD3	NCT03309111	Phase 1
Ramantamig*	BCMA x GPRC5D x CD3	NCT07258511	Phase 3

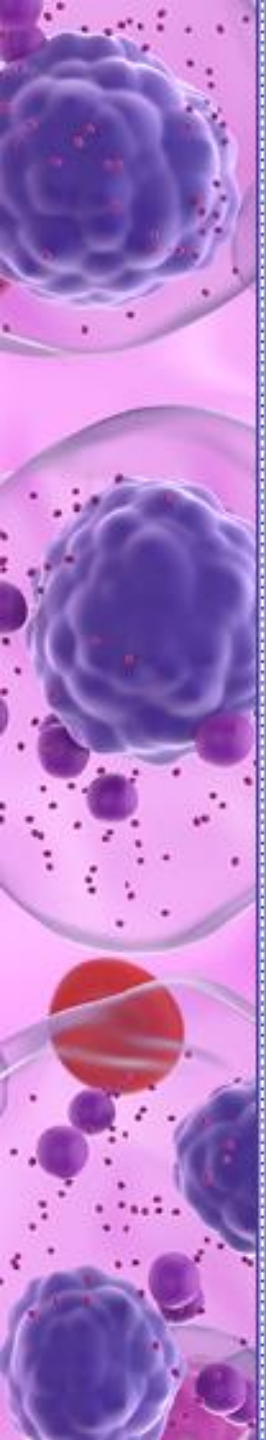
\*Ramantamig is a trispecific antibody

# What Did You Learn?



Dysgeusia and nail and skin disorders are unique toxicities associated with which of the following BsAb targets?

- A. BCMA
- B. GPR5CD
- C. CD38
- D. CD3





# Case Studies

Please come off mute or use the chat feature to discuss with your colleagues and ask questions about your patient cases.



# Case Study

- 64-year-old male patient with relapsed IgG kappa MM
  - 2018: Diagnosed with lytic lesions. Standard-risk cytogenetics
  - 2018: Received VRd then ASCT then lenalidomide maintenance
  - 2024: Biochemical relapse, received second-line Dara-Pd
  - 2025: Biochemical relapse, received third-line Kd doublet therapy
  - 2025: Had to stop Kd due to worsening dyspnea
  - 2025: Starts fourth-line Elo-Pd therapy
  - **2026: M-spike starting to rise on Elo-Pd (0.3 to 0.7 g/dL)**
- Current medications: Aspirin, acyclovir, statin
- Physical exam: Unremarkable

ASCT = autologous stem cell transplantation; Dara-Pd = daratumumab pomalidomide dexamethasone; Elo-Pd = elotuzumab pomalidomide dexamethasone; Kd = carfilzomib dexamethasone; VRd = bortezomib lenalidomide dexamethasone

A vertical strip on the left side of the slide shows a microscopic view of cells. The cells are stained in shades of purple and blue, with some showing distinct nuclei and cytoplasm. The background is a light pinkish-purple.

# What Else Might You Want to Know?

- **Disease/treatment factors**

- **Any evidence of t(11;14)?** If so, we can discuss other options
- **Any stem cells saved over?** Second transplantation is becoming rare in the US, but this patient had 5 years of ‘mileage’ from his first transplant
- **Adherence to pomalidomide?** Single-agent elotuzumab has little activity, and pomalidomide adherence can be tricky even for motivated patients
- **Disease tempo?** CAR-T therapy requires a 6-8 week manufacturing period

- **Patient factors and social history**

- **Caregiver?** At most centers, a caregiver is required for at least 4 weeks following CAR-T therapy to help monitor for CRS and ICANS
- **Driving distances?** While some bsAbs can likely be spaced out to every 4 weeks (currently off-label), they are often continued until progression

# Case Study # 2

- 69-year-old male with kappa free light chain MM
  - 2016: Diagnosed with jaw plasmacytoma, lytic lesions, 50%-60% plasma cells, cytogenetics with t8;14 and t11;14
  - 2016-2017: Received VRd then ASCT
  - 2017: Revlimid (rash) -> Velcade maintenance (d/c neuropathy)
  - 2019: Pomalidomide/Ixazomib/Dex (d/c neuropathy, altered mental status)
  - 2021: Daratumumab/Dex
  - 2021: Carfilzomib one dose (altered mental status vs. infection)
  - 2021-present: Venetoclax (current dose = 400 mg)
- Kappa light chain 550-649, K/L 157-202 (fluctuates)
- CAD s/p CABG 2018, peripheral arterial disease with iliac stents
- Hypogammaglobulinemia + history of recurrent infection on prn IVIG for IgG < 400 (q3-6 months)



# Key Takeaways

- BsAbs are artificially created antibodies with 2 unique binding sites that target different antigens on different cells
- BsAbs work by engaging CD3 on T cells and redirecting them to attack myeloma cells expressing antigens like BCMA or GPRC5D
- The 4 currently FDA-approved bsAbs in MM are teclistamab, elranatamab, talquetamab, and linvoseltamab
  - Many others are under investigation
  - Combination strategies are under investigation

# To Claim Credit

1. Go to <https://cme.cecentral.com/content/sustain-1-introduction-bispecific-antibodies—mechanism-action-and-clinical-evidence-may>

and “Take Course” then “Start Course”

2. Enter Attendance Code **QOBCUX** when prompted

3. Complete The Evaluation

4. Appropriate Credit will be issued automatically.

5. Download Certificate (Optional)

6. Complete Commitment to Change Survey (Optional)

For questions, please contact [support@cecentral.com](mailto:support@cecentral.com)

