Bispecific Antibodies in Plasma Cell Dyscrasias

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Disclosure

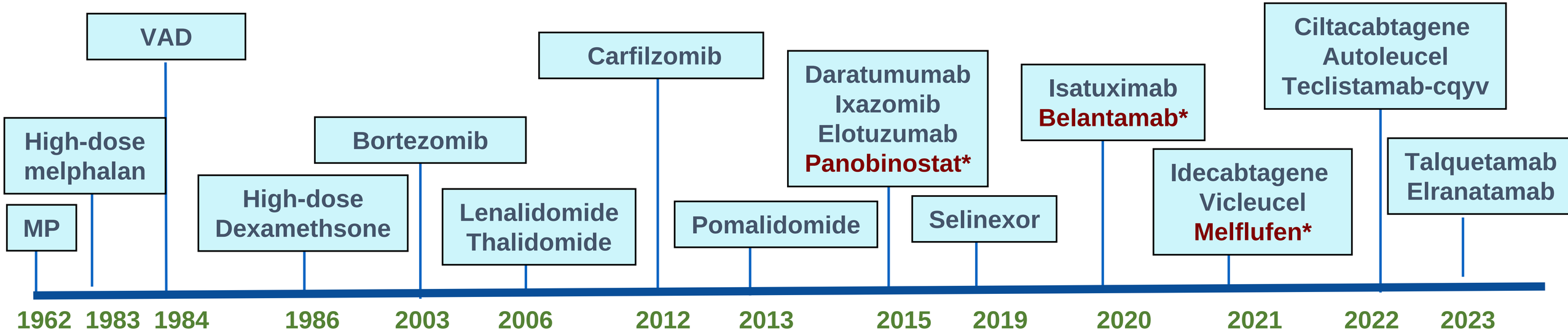
Consultancy: Janssen, Sanofi

Objectives

- **Bispecific antibodies in Multiple Myeloma (MM)**

  - Efficacy and Safety
  - Combination with novel agents and other bispecific antibodies
  - Sequencing of therapies
  - Access to Care- academic and community oncology partnerships

Drugs in Multiple Myeloma: A Golden Age



Doublet

Triplet

Quadruplet

MP: melphalan, prednisone
VAD: vincristine (V), doxorubicin (A), dexamethasone

***Withdrawn**

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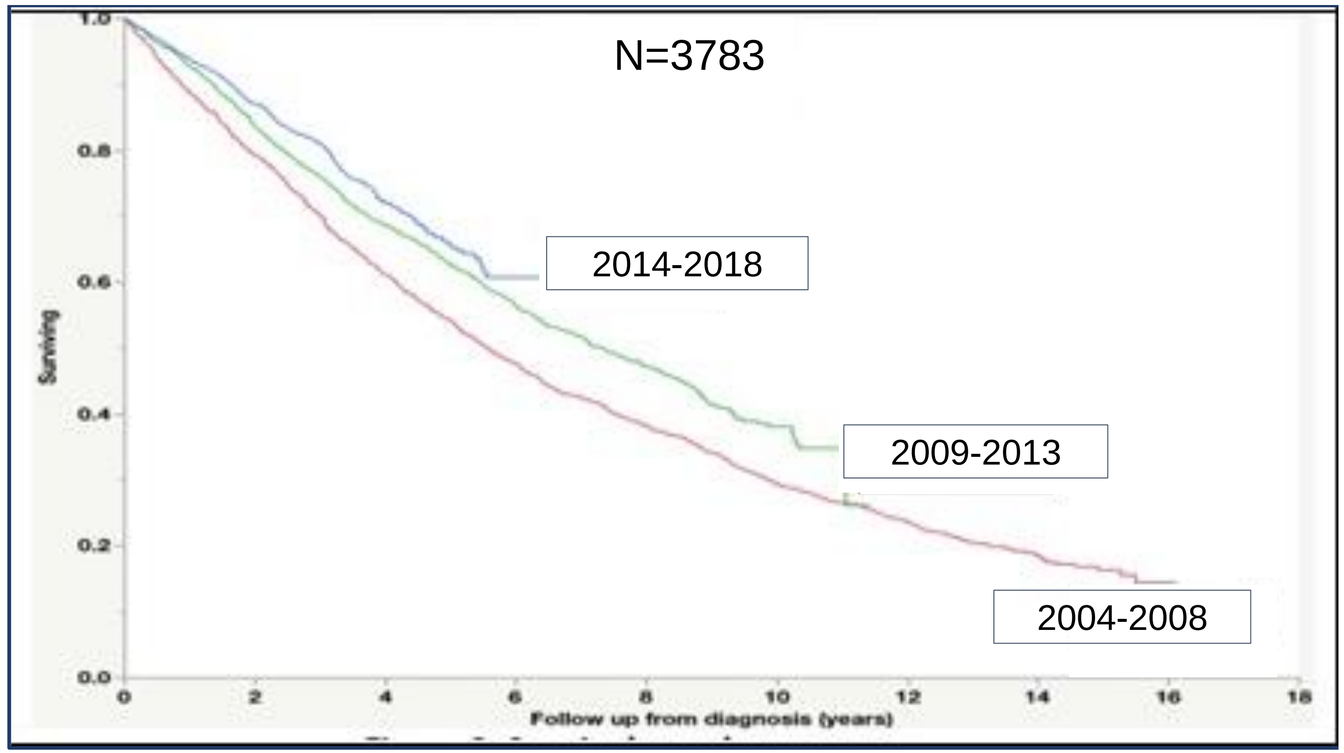
Survival in Multiple Myeloma

5-year relative survival rate: 58%

5-Year Relative Survival: Age <65: 63% | Age ≥65: 41%



Year	OS (years)	*P*
2014-2018	Not reached	0.0001
2009-2013	7.3	
2004-2008	5.5	

https://www.cancer.net/cancer-types/multiple-myeloma/statistics
SEER Cancer Statistics Review (CSR) 1975-2015
Nandkumar et al, ASH 2020

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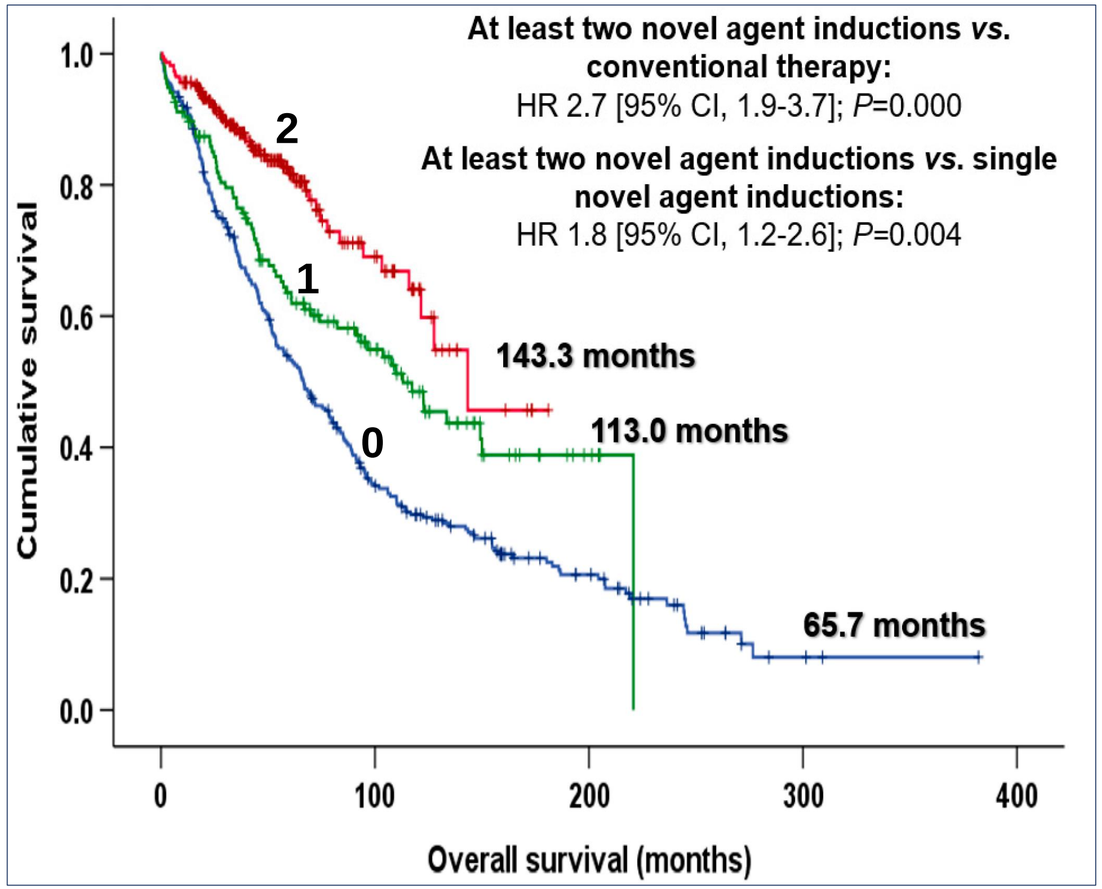
Use of Combinations of Novel Agents during Induction Improves Survival



Combinations of at least two novel agents improved response rates and overall survival in all patients, including >70-age group

Puertas et al. Cancers 2023, 15(5), 1558

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Treatment for Newly Diagnosed Multiple Myeloma

Proteasome Inhibitor (PI) or Immunomodulatory imid drug (IMiD)

Dexamethasone

Proteasome Inhibitor (PI)

Immunomodulatory imid drug (IMiD) /Alkylator

Dexamethasone

Proteasome Inhibitor (PI)

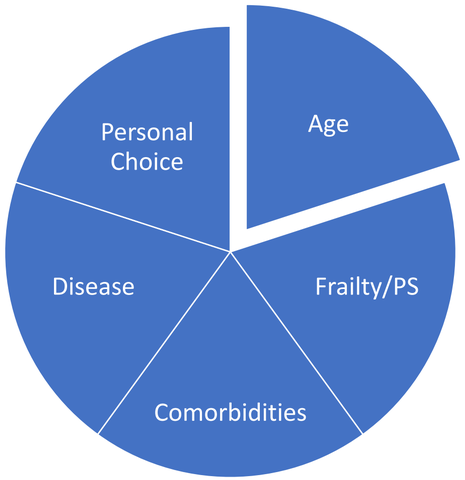
Immunomodulatory imid drug (IMiD)

Anti-CD38 monoclonal antibody

Dexamethasone

	RVd vs. Rd	KRd vs. RVd	DRd vs. Rd	D-VMP vs. VMP	D-VTd vs. VTd	D-RVd vs. RVd
Number	242/229	545/542	368/369	350/356	543/542	355/354
ORR (%)	82/72	86/83	93/82	91/74	93/90 (EOC)	97/91
≥CR (%)	24/12	17/15	51/29	46/25	39/26	88/70
PFS (mos)	43/30	33/32	62/34	36/19	NR/47	48 mo (%): 84/68
OS (mos)	75/64	3-yr OS%: 86/84	5-yr OS%: 66/53	42m OS%: 75/62	NR	NR
Ref	SWOG S0777 trial Durie et al, Lancet 2017	ENDURANCE trial Kumar et al, Lancet 2020	MAIA trial Facon et al. Lancet 2021	ALCYONE trial Mateos, NEJM 2018	CASSIOPEIA trial Moreau et al. Lancet 2021	Sonneveld, NEJM, 2024

TRANSPLANT?



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Treatment of Relapsed Multiple Myeloma: Factors in Decision-Making

Decision Making:
Prior Therapies
Treatment-free interval
Patient preference
Frailty
Disease
Organ function

Relapse → **1st** → **2nd** → **3rd** → **4th or more**

Anti-CD38 sensitive/naïve:
Anti-CD38 + IMid/PI

DRd
DKd
IsaKd
DPd
IsaPd

Anti-CD38 refractory:
Combinations of IMiD and PI
RVd
KRd
KPd
PVd
EloPd
EloKd

Lenalidomide refractory:
Cilta-cel

2 or more lines:
Ida-cel

BCMA-based therapies
CAR T
Bispecific antibodies

Others:
Selinexor

Choosing wisely

Better drug combinations

↓

Best response
Best progression-free survival
Improved overall survival

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Treatment at Relapse
Triplet Drug Regimen are better than Doublet

	POLLUX[1]		CASTOR[2]		CANDOR[3]		IKEMA[4]		APOLLO[5]		ICARIA[6]	
	DRd	p-value	**DVd**	p-value	**DKd**	p-value	**IsaKd**	p-value	**DPd**	p-value	**IsaPD**	p-value
ORR	93%	< 0.0001	85%	< 0.0001	84%	0.004	87%	0.19	69%	< 0.0001	63%	NA
≥ CR	57%	< 0.0001	29%	< 0.0001	29%	NA	40%	NR	25%	NR	9%	NA
PFS (mos)	44.5	< 0.0001	17	< 0.0001	28.6	0.0014	35.7	NA	12.4	0.0018	11.5	< 0.0001
MRD negativity (10^{-5})	30%	0.0001	14%	< 0.0001	14%	NA	30%	0.0004	9%	0.0102	5%	NA

[1]Bahlis, Leukemia, 2020; [2]Spencer, Haematologica, 2018; [3]Dimopoulos, Lancet, 2020; [4]Martin, ASH, 2020. Richardson. ASCO 2021

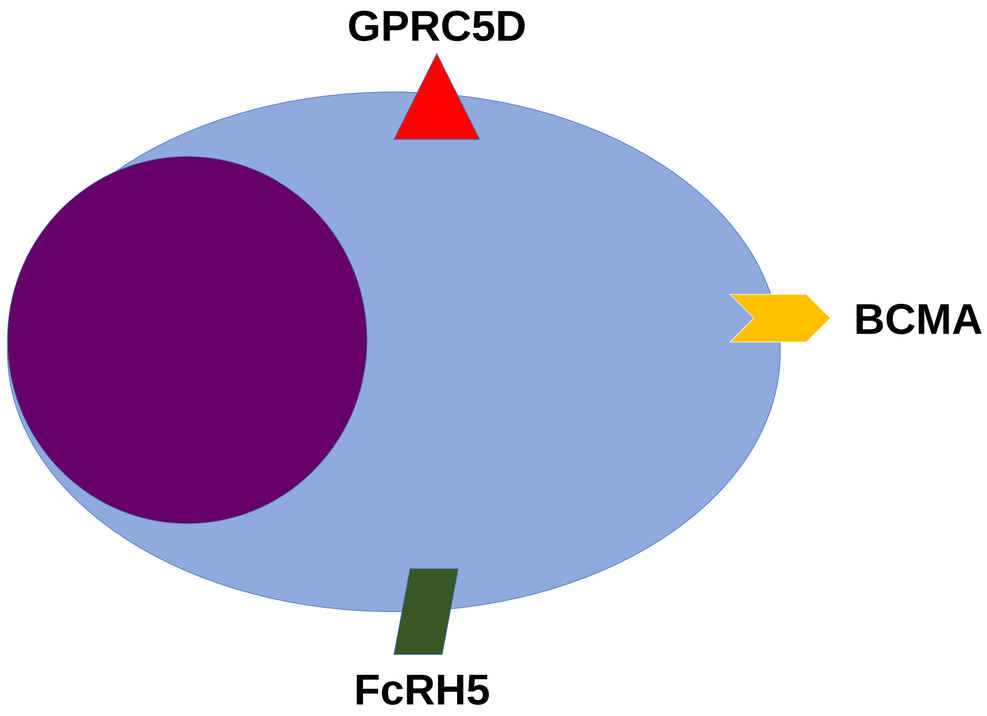
A B C of Immunotherapy in Multiple Myeloma

Bispecific T-Cell Engagers

Talquetamab

CAR T-Cell Therapies

MCARH109



Bispecific T-Cell Engagers

Cevostamab

Antibody–Drug Conjugates (A)

Belantamab mafodotin
MEDI2228
CC-99712

Bispecific T-Cell Engagers (B)

Teclistamab
TNB-383B
REGN-5458
Pavurutamab/AMG 701
Elranatamab

CAR T-Cell Therapies (C)

Idecabtagene vicleucel
Ciltacabtagene autoleucel
Zevor-cel (CT053)
P-BCMA-101
ALLO-715
FasTCAR-T GC012F
CART-ddBCMA

FDA approved

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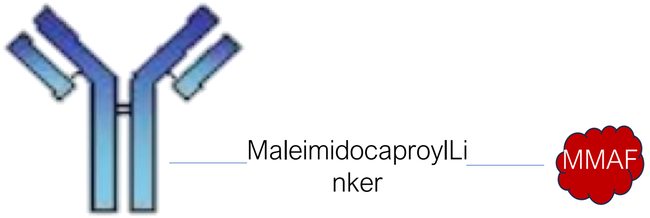
Life of an Antibody-Drug Conjugate and its Rebirth in MM

Belantamab mafodotin (Belamaf)



Humanized, afucosylated IgG1 anti-BCMA antibody conjugated to monomethyl auristatin (MMAF)

Internalized -> binds to tubulin -> induces G2/M cell cycle arrest

DREAMM 2[1]

> 3 prior lines & TCR, N = 196

- ORR 31-34%, ≥VGPR 19-20%
- mPFS 2.9-4.9 mos, DOR 11 mos

DREAMM 3[2]

>2 prior lines-PI and IMid, N=338

- ORR: Belamaf 41% vs. Pd 36%
- PFS: Belamaf 11.2 mos vs. 7 mos, NSS

No significant difference in PFS/OS

Belamaf withdrawn from US

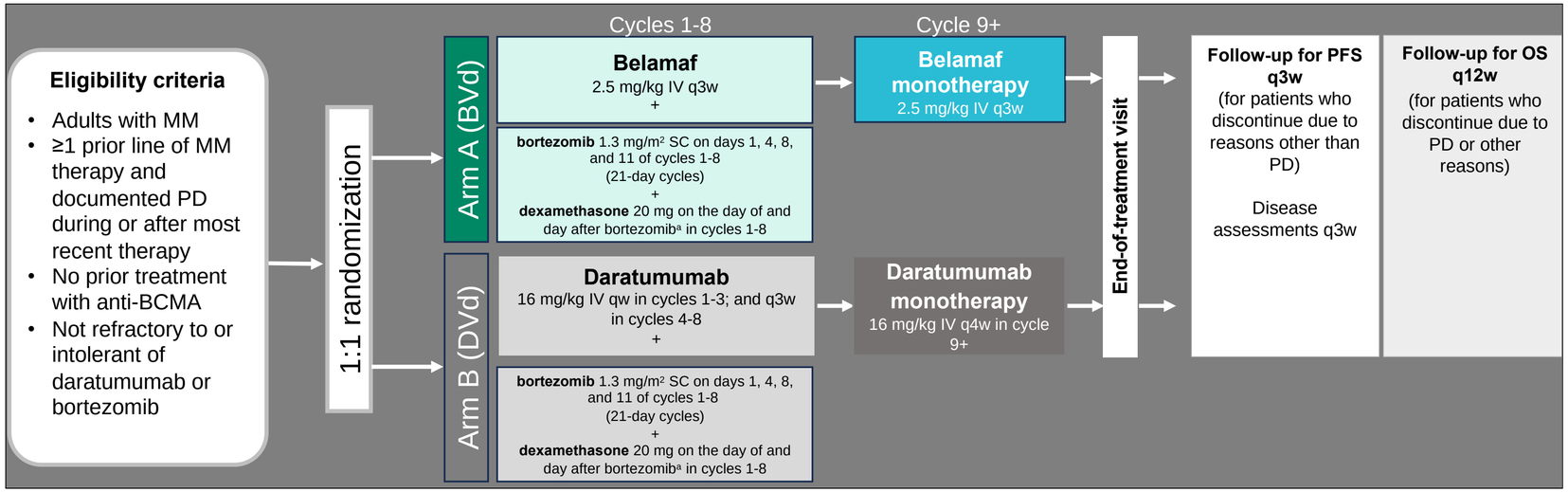
[1]Lonial et al. Lancet Oncology 2
[2]Dimopoulos et al, Lancet Hematolog

DREAMM-7 for in relapsed/refractory multiple myeloma

Belantamab mafodotin + bortezomib and dexamethasone (BVd)

vs.

Daratumumab, bortezomib and dexamethasone (DVd)



Phase 3, N= 494
Primary Endpoint: PFS

>80% with prior bortezomib exposure
~ 50% with prior lenalidomide exposure (~30% refractory)

Abstract # 7503, Maria-Victoria Mateos et al

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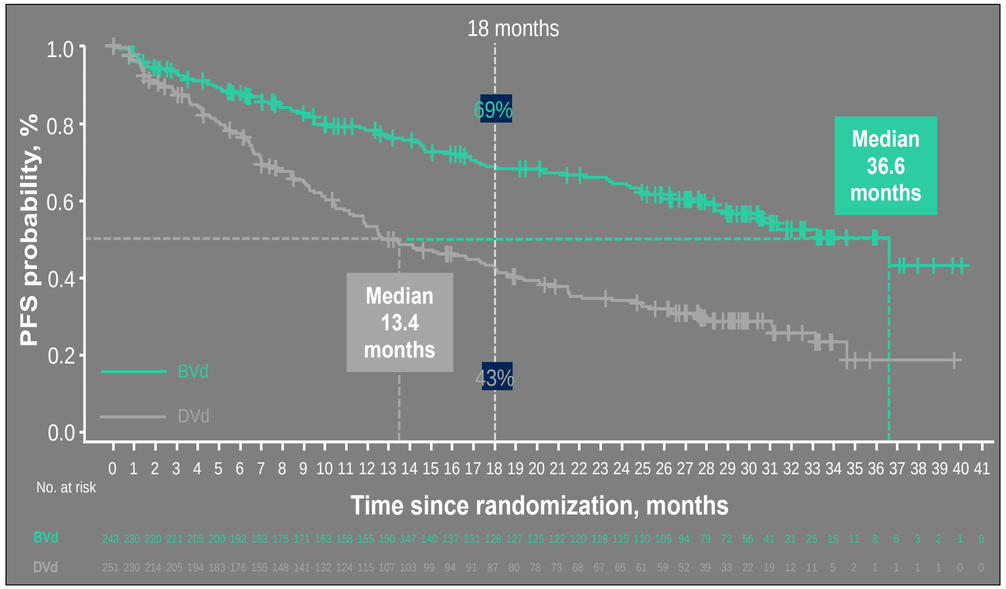
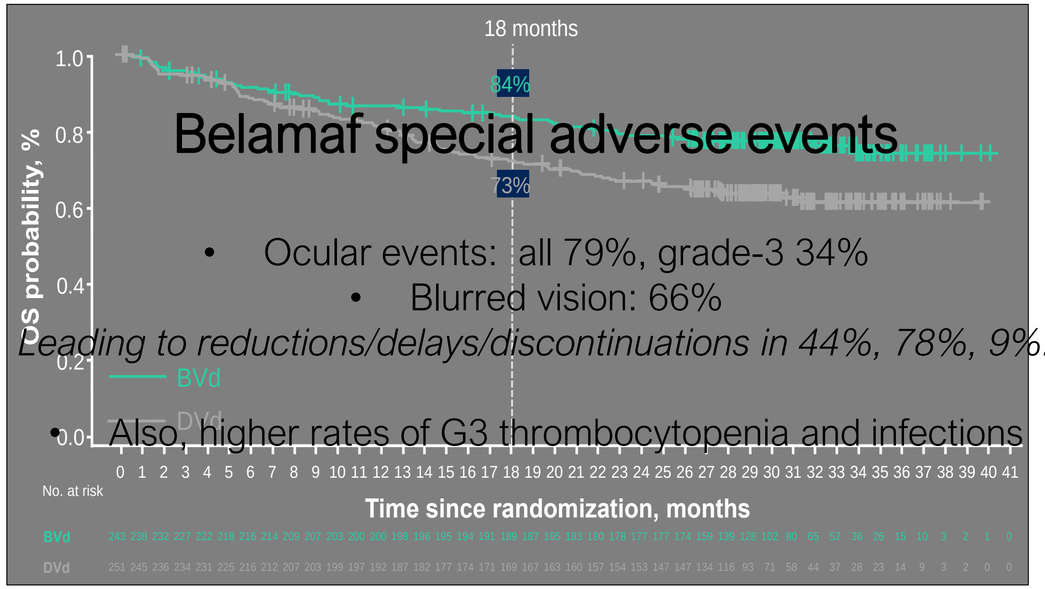
DREAMM 7: BVd vs. DVd in R/R Multiple Myeloma

More VGPR and CR seen with Belamaf, 31%/35% than DVd, 29%/17%
PFS benefit also seen in high-risk disease





Belamaf special adverse events

- Ocular events: all 79%, grade-3 34%
- Blurred vision: 66%

Leading to reductions/delays/discontinuations in 44%, 78%, 9%.

- Also, higher rates of G3 thrombocytopenia and infections

Longer median PFS of 37 mos with BVd vs. DVd 13 mos
HR: 0.41 (0.31-0.53), p <.00001

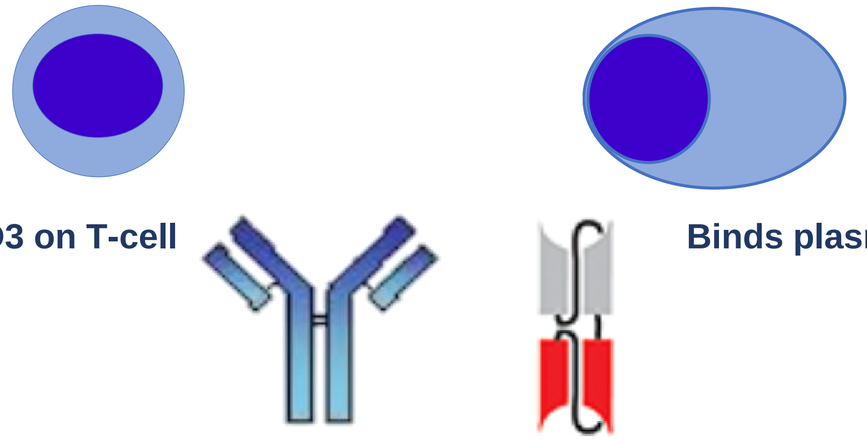
Trend favoring OS for BVd vs. DVd
HR: 0.57, (0.4-0.8), p .00049

Abstract # 7503, Maria-Victoria Mateos et al

Bispecific Antibodies/Bispecific T-cell Engagers in R/R MM

- Target CD3 on T cells and tumor-associated antigens on the surface of MM cells.
- Novel immunotherapeutic with high activity in heavily pre-treated multiple myeloma
- Therapy continued until progression.

T-Cell Activation and Degranulation
Release of Granzymes and Perforins
Apoptosis of MM Cell



Binds CD3 on T-cell

Binds plasma cell markers

Two single-chain variable fragments (scFv)

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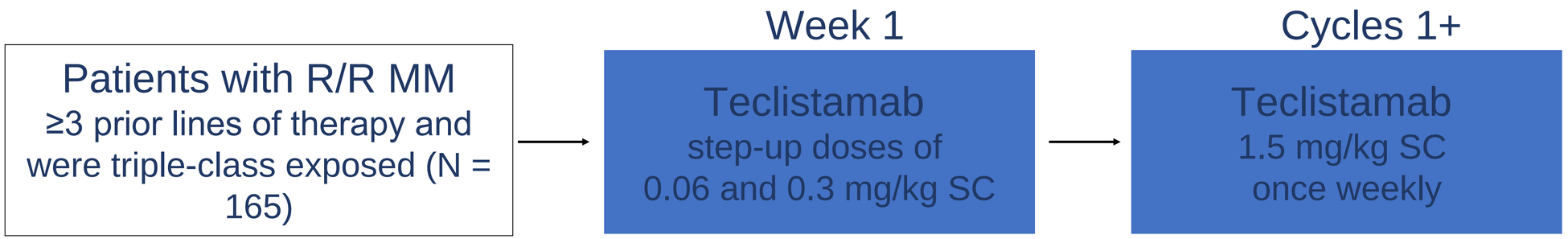
MajesTEC-1 trial
Teclistamab Monotherapy in R/R MM

- First-in-human, open-label, dose-escalation/dose-expansion phase I/II trial



Primary endpoint: ORR

Key secondary endpoints: DoR, MRD PFS, OS etc

P Moreau et al. N Engl J Med 2022;387:495-505.

MajesTEC-1 trial
Baseline Characteristics and Response

	N =165
Median age, yr (range)	64 (33-84)
Median prior lines of therapy, range	5 (2-14)
Male (%)	58
R-ISS stage (%) ▪ Stage I ▪ Stage II ▪ Stage III	 52 35 12
High-risk Cytogenetics (%)	26
Extramedullary disease (%)	17
Triple Refractory (%)	77
Penta Refractory (%)	30

Response	(%)
ORR	62
CR	7
≥ VGPR	58
MRD negativity assessment	(n = 150)
At 10^{-5}	25
At 10^{-6}	17

Median time to objective response was 1.2 months (range, 0.2-5.5)

P Moreau et al. N Engl J Med 2022;387:495-505.

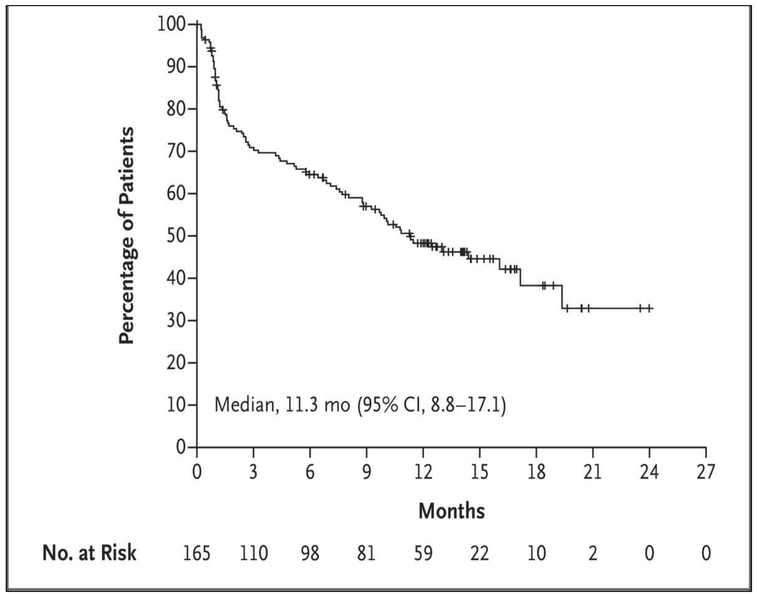
MajesTEC-1 Trial
Toxicity Profile: High rate of Infections

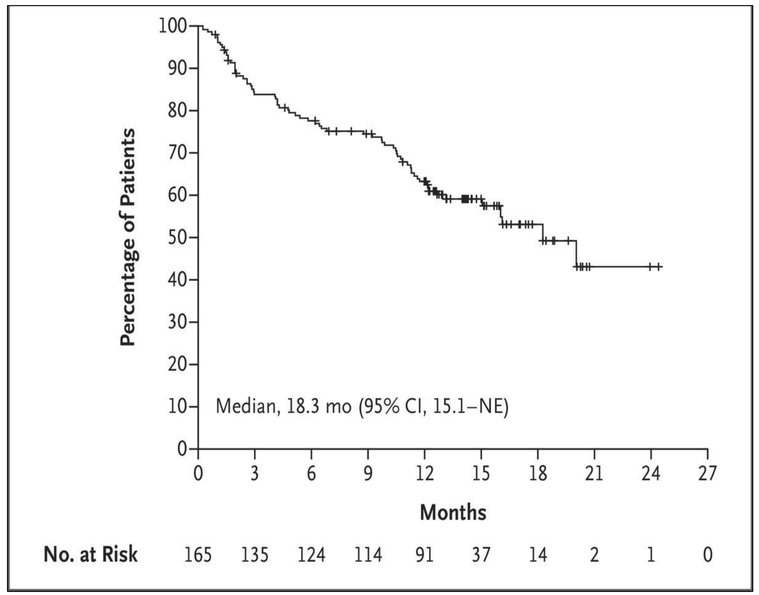
Toxicity	Any Grade (%)	Grade 3-4 (%)
Anemia	50	35
Neutropenia	66	57
Low platelets	38	21
Infections	63	35
Median Time to Onset 47 days (1-295)		
CRS	71	0.6
Median Time to Onset 2 days (1-6)		
ICANS	3	0
Median Time to onset 2.5 days (1-7)		

<u>9 Deaths due to AE</u>
7 COVID-19
1 pneumonia
1 hemoperitoneum

P Moreau et al. N Engl J Med 2022;387:495-505.

MajesTEC-1
Progression-Free Survival and Overall Survival





Median duration of response: 18.4 months (95% CI, 14.9-NR)
Median progression-free survival: 11.3 months (95% CI, 8.8-17.1)
Median Overall survival: 18.3 months (95% CI, 15.1-NR)

P Moreau et al. N Engl J Med 2022

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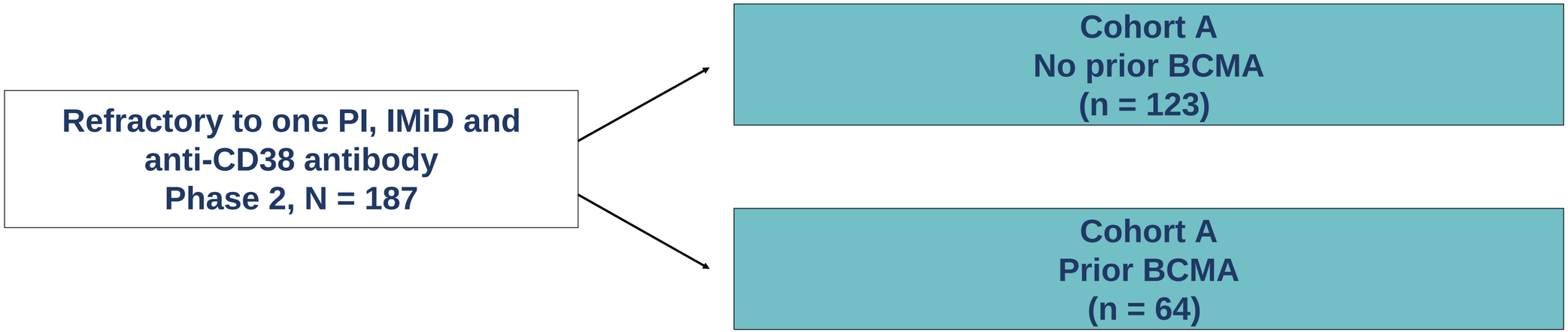
MagnetisMM-3 trial
Elranatamab Monotherapy in Triple Refractory MM

Elranatamab is a bispecific antibody targeting BCMA on MM cells and CD3 on T-cells



Elranatamab: 76 mg SC QW until cycle 6 and then Q2W
Primary endpoints: ORR
Secondary endpoints: DOR, PFS, CR, MRD etc

MagnetisMM-3 trial
Baseline Characteristics and Response

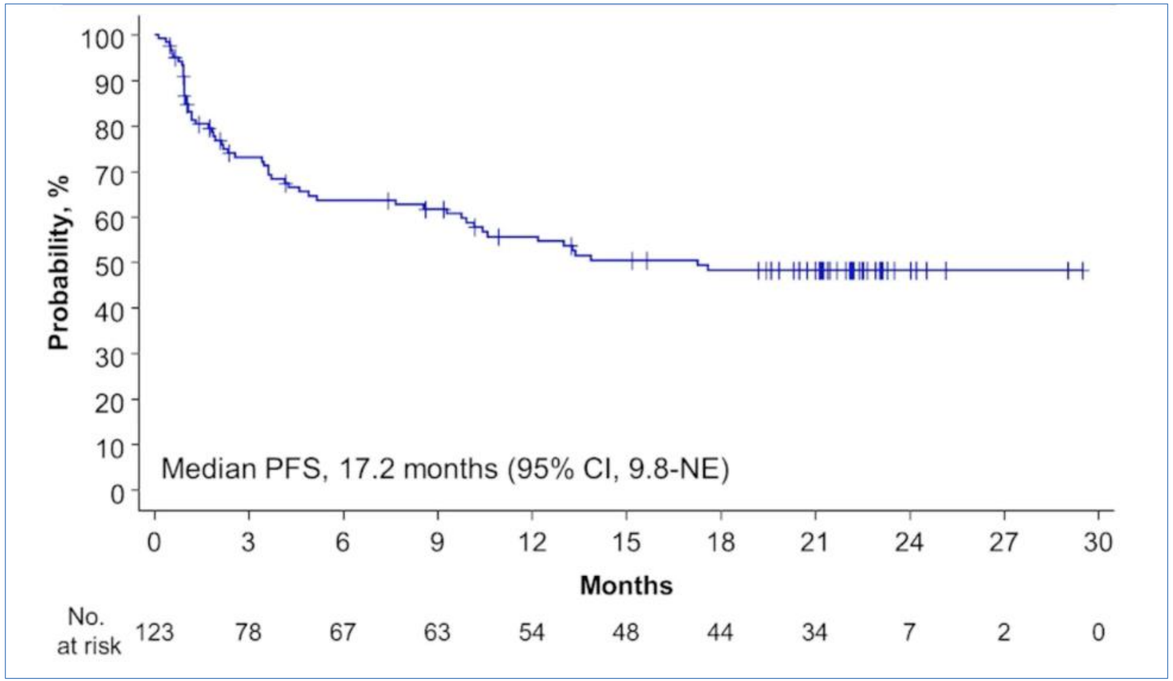
	N=123
Median age, yr (range)	68 (36-89)
Median prior lines of therapy, range	5 (2-22)
Male (%)	68
R-ISS stage (%) ▪ Stage I ▪ Stage II ▪ Stage III ▪ Not reported	 23 55 15 7
High-risk Cytogenetics (%)	25
Extramedullary disease (%)	32
Triple Refractory (%)	92
Penta Refractory (%)	42

Response	(%)
ORR	61
CR	15
≥ VGPR	55

Median time to objective response was 1.2 months (range, 0.9−6.9)

Bahlis. ASH 2022, Abs 159

MagnetisMM-3 trial
Progression Free Survival



DOR at 18 mos: 68%
OS: 21.9 mos (13.4-NE)

Treatment Discontinuation:
Progressive disease 32.5%
Adverse events 15%

Bahlis. ASH 2022, Abs 159

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MagnetisMM-3 trial
Toxicity Profile

Toxicity	Any Grade (%)	Grade 3-4 (%)
Anemia	48	36
Neutropenia	48	48
Low platelets	30	22
Infections	67	
Median Time to Onset 47 days (1-295)		
CRS	58	0
Median Time to Onset 2 days (1-9)		
ICANS	3.4	0
Median Time to onset 2.5 days (1-4)		

<u>25 Deaths</u>
11 Progressive disease
2 considered treatment related
FTT and Pseudomonal Pneumonia

Bahlis. ASH 2022, Abs 159

Bispecific Antibodies in R/R MM: Efficacy

Treatment	Target	Prior Lines n (range)	PFS (mos)	ORR, %	≥ VGPR, %
FDA Approved					
Teclistamab[1,2] N= 165	BCMA	5 (2-14)	11.3	63	59
Investigational Therapies					
Elranatamab[3] N= 123	BCMA	5 (2-22)	NR	61	55
ABBV-383[4] N= 124	BCMA	5 (3-15)	NA	57	
REGN5458[5] N = 68	BCMA	5 (2-17)	NA	73	
Talquetamab [SC 6] N=130	GPRC5D	6 (2-17)	NA	64-70	52-57
Cevostamab[7] N=161	FcRH5	6 (2-18)	NA	36-57	21-33

[1]Usmani, Lancet, 2021; [2]Moreau, ASH, 2021; [3]Sebag, ASH, 2021; [4]Kumar, ASH, 2021; [5]Zonder, ASH, 2021; [6]Berdeja. ASCO, 2021; [7]Trudel, ASH, 2021

Bispecific Antibodies in R/R MM: Toxicity

Treatment	Target	CRS, %	ICANS, %	Infection % All; Grade 3/4
FDA Approved				
Teclistamab[1,2] N= 165	BCMA	72 (0.6% grade 3)	3	76; 44.8
Investigational Therapies				
Elranatamab[3] N= 123	BCMA	56 (grade 1/2)	3	67; 35
ABBV-383[4] N= 124	BCMA	57 (grade ≥3 in 2%)	1.6 (overall)	41; --
REGN5458[5] N = 68	BCMA	38 (no grade 3)	4	47; 20
Talquetamab [SC 6] N=130	GPRC5D	77-80 (grade ≥3 in 3%)	5-10	34-47; 7
Cevostamab[7] N=161	FcRH5	77-80	14 (grade ≥3 in 0.6%)	40-45; -

[1]Usmani, Lancet, 2021; [2]Moreau, ASH, 2021; [3]Sebag, ASH, 2021; [4]Kumar, ASH, 2021; [5]Zonder, ASH, 2021; [6]Berdeja. ASCO, 2021; [7]Trudel, ASH, 2021

T-cell redirecting bispecifics – Early-phase trials

Trial	Follow-Up	N	mPrior (range)	TCR	ORR	≥VGPR	mDOR	mPFS
MajesTEC1/2[1]	14.1m	165	5 (2-14)	77.6%	63%	59%	24.0 m	12.5 m
MagnetisMM-3[2]	14.7m	123	5 (2-22)	96.7%	61%	56%	18 m 68.8%	17.2 m
ABBV-383B[3]	10.8m	124	5 (3-15)	82.0%	57%	43%	NR	10.4 m
LINKER-MM1[4*]	5.6m	117	5 (2-14)	73.5%	71%	59%	NR	NR
MonumenTAL-1[5*]	NR	143	5 (2-13)	74.1%	74%	59%	NR	NR
CAMMA[6]	6.1m	160	6 (2-18)	85.0%	55%	NR	15.6 m	NR

In phase I and II trials, heavily pretreated patients who were non-BCMA exposed had prolonged responses to bispecifics

[1]Moreau, NEJM, 2022; [2]Mohty, ASCO, 2023; [3]D'Souza, JCO, 2022; [4]Lee, ASCO, 2023; [5]Schinke, ASCO, 2023; [6]Trudel, ASH, 2021

Linvoseltamab – LINKER-MM1 study

Key eligibility criteria for Phase 2

- Active MM by IMWG criteria
- Progression on or after at least three lines of therapy, including an IMiD, a PI and an anti-CD38 Ab, or triple-refractory disease (refractory to at least one IMiD + one PI + one anti-CD38 Ab)

Key Phase 2 objectives

- Primary: to assess the antitumour activity as measured by ORR as determined by a blinded IRC (IMWG criteria)
- Secondary: ORR by investigator assessment, DOR, PFS, MRD status and OS

Linvoseltamab IV dosing schedule for Phase 2 expansion cohorts

	W1	W2	W3–14	W16–23	W24+
	Step-up doses		Cycles 1–3	Cycles 4–5	Cycle 6 onwards
50 mg cohort	5 mg	25 mg	50 mg QW†	50 mg Q2W	50 mg Q2W
200 mg cohort	5 mg	25 mg	200 mg QW	200 mg Q2W	≥VGPR → 200 mg Q4W <VGPR → 200 mg Q2W

Day 1 Day 8

24-hour hospitalisation

†Patients in the 50 mg cohort who progress within 4–12 weeks of treatment were allowed to escalate to 200 mg dosing.

Ab, antibody; CD, cluster of differentiation; DOR, duration of response; IMiD, immunomodulatory drug; IMWG, International Myeloma Working Group; IRC, independent review committee; IV, intravenous; MM, multiple myeloma; MRD, minimal residual disease; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; PI, proteasome inhibitor; QW, once every week; Q2W, once every 2 weeks; Q4W, once every 4 weeks; VGPR, very good partial response; W, week.

LINKER1-MM1: Linvoseltamab single agent

Inclusion

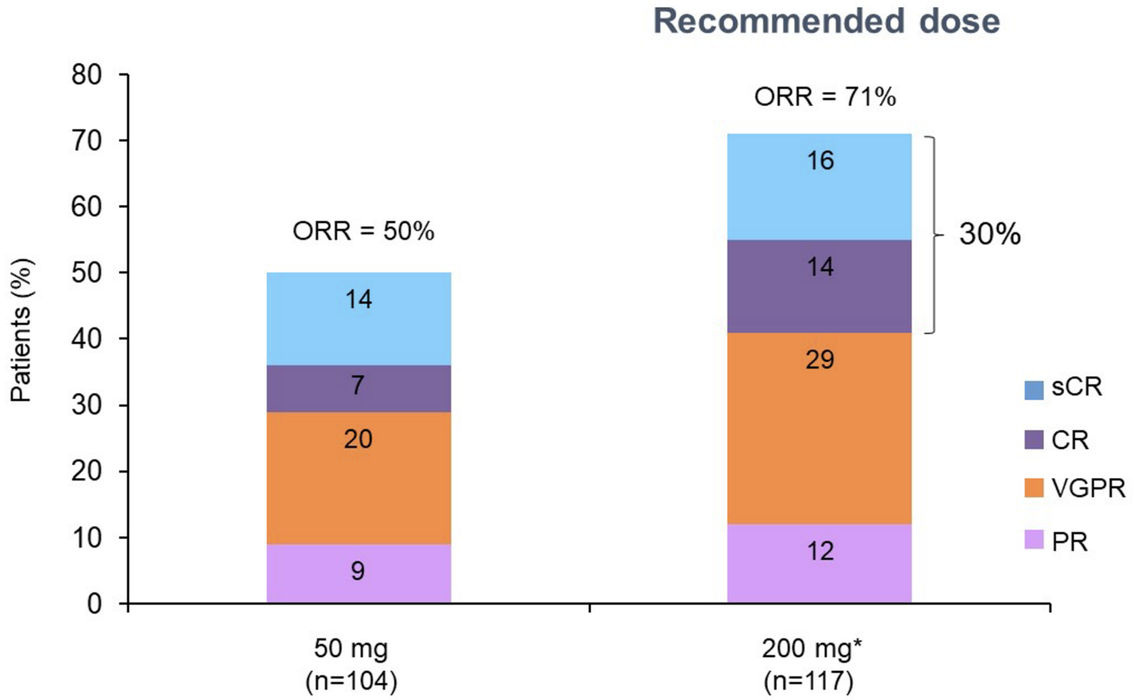
- RRMM ≥ 3 prior LOT including IMiD, PI, aCD38 mAb *or* TCR*

Patient characteristics

- Median prior lines 5 (2 – 14)
- Median duration of follow-up 5.6m (0.2 – 28.2)
- 14% EMD, 22% BMPCs ≥ 50%, 74% TCR, 24% PCR

Outcomes

- ORR 71%, ≥ VGPR 59%, ≥ CR 30%
- In those patients with ≥ CR with available MRD data – 54.3% MRD negative (10^{-5})
- ORR was ≥ 50% for all high-risk subgroups including EMD, hrFISH, high BMPCs
- Probability of maintaining response at 1 year: 79.2%



Similar mechanism of action, intravenous dosing, 200 mg target dose

*all data presented is for 200 mg dosing

Lee, ASCO, 2023; Lee, EHA, 2023

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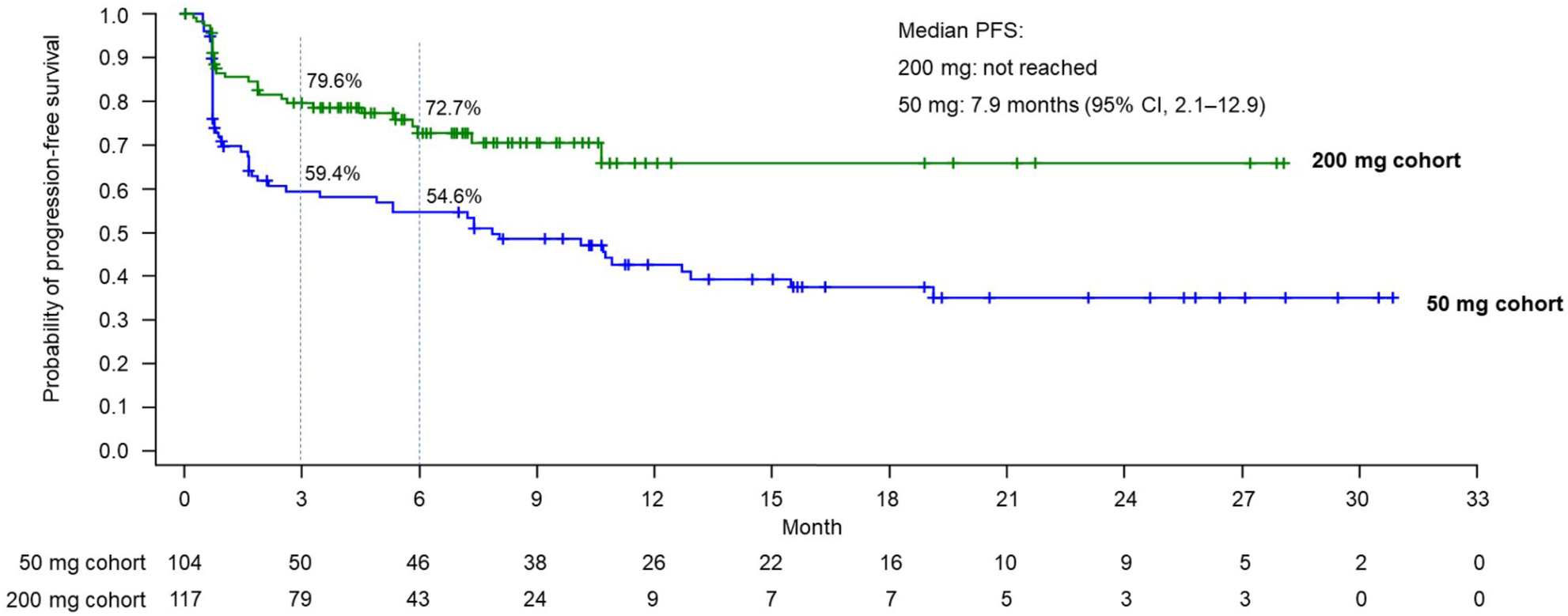
LINKER1-MM1: Linvoseltamab single agent



At a median follow-up of 5.6 months, the PFS was not reached in the 200 mg cohort and was 7.9 months in the 50 mg cohort (median follow-up 7.7 m (0.3 – 31.3))

Lee, ASCO, 2023; Lee, EHA, 2023

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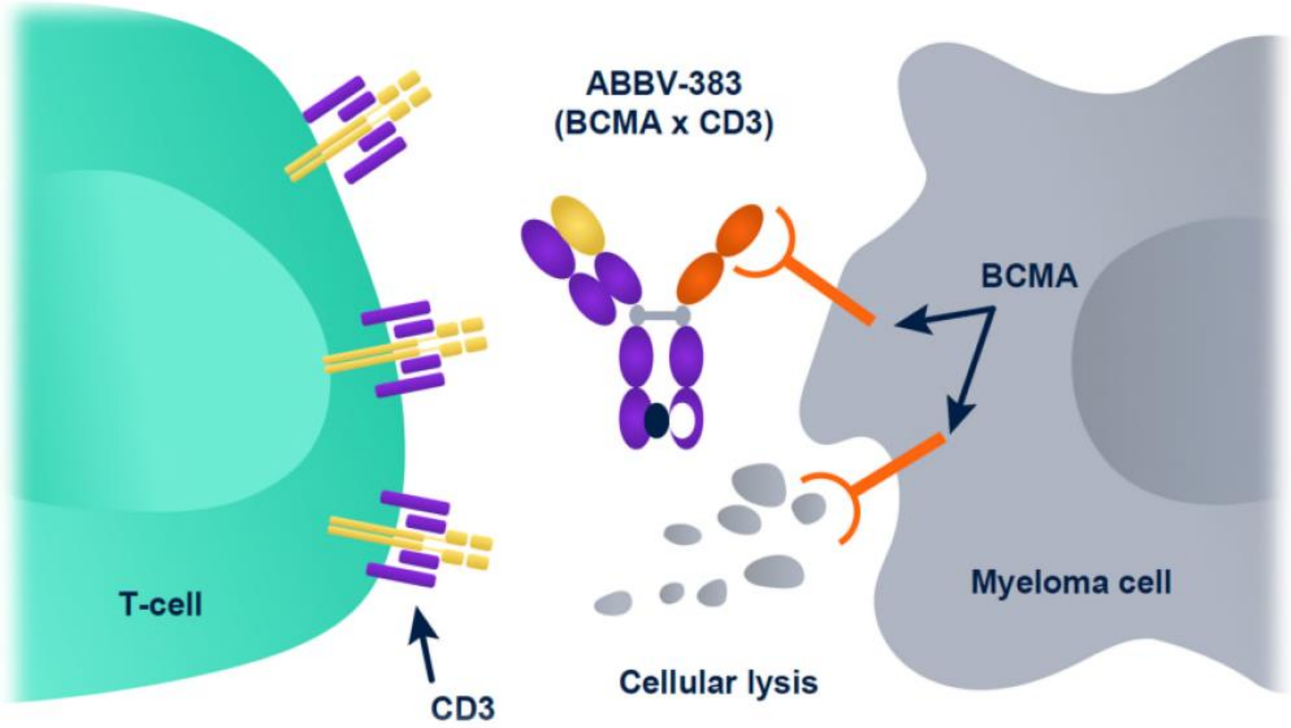
ABBV-383B: A BCMA bispecific T-cell engager

- Fully humanized IgG4 monoclonal antibody with low affinity CD3 binding
- Similar to other BCMA directed bispecifics, recruits CD3+ T-cells to BCMA+ MM cells and is supported by preclinical data in cell lines and xenograft models
- Specifically designed to evade systemic T-cell activation and minimize CRS through preferential activation of effector > regulatory T-cells



Kumar, ASH, 2021

ABBV-383B: Single agent phase 1 trial

Inclusion

- RRMM ≥ 3 prior LOT including IMiD, PI, aCD38 mAb
- Fixed q3w intravenous dosing

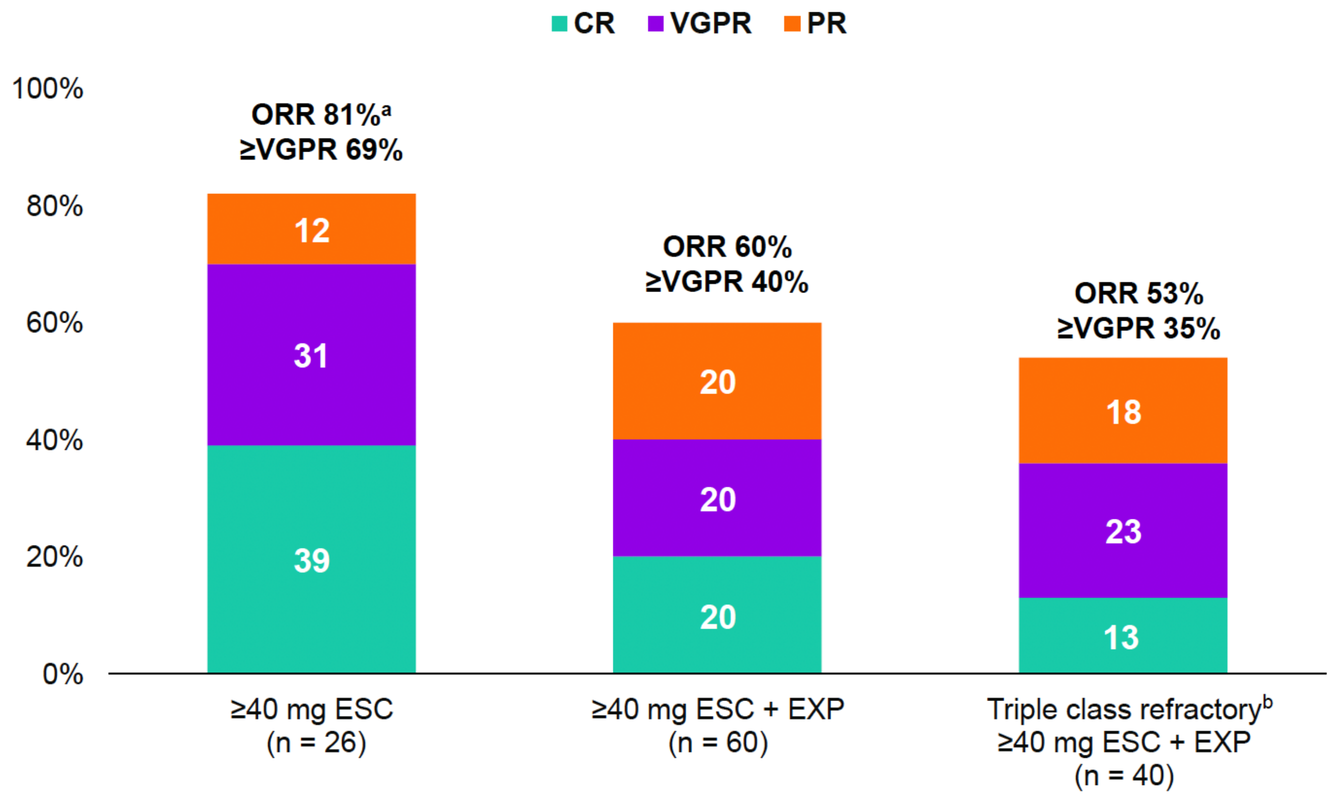
Patient characteristics (all; n = 124)[2]

- Median prior lines 5 (3 – 15)
- Median duration of follow-up 10.8 m (0.6 – 28.2)
- 82% TCR, 35% PCR, hrFISH 18%

Outcomes (all)

- ORR 57%, ≥ VGPR 43%, ≥ CR 28%
- mDOR NR, mPFS 10.4 m

Overall response rates at initial presentation[1]



[1]Kumar, ASH, 2021; [2]D'Souza, JCO, 2022

GPRC5D: G Protein-Coupled Receptor Family C Group 5 Member D

- **Expressed by:**
  - Malignant plasma cells > normal plasma cells
  - Cells that produce hard keratin
    - Hair shaft
    - Nails
    - Filiform papillae of the tongue
- Found in inferior olivary nucleus (in the medulla oblongata) – which relays motor and sensory signals from the spinal cord to the cerebellum, regulating motor coordination
  - Maybe related to ICANS

O'Neill, eJHaem, 2023

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Talquetamab (GPRC5d x CD3 Bispecific) - MonumenTAL-1 trial design

Phase 1: Progression on or intolerance to all established therapies; ECOG PS 0-1

Phase 2: ≥ 3 prior lines of therapy that included a PI, an IMiD, and an anti-CD38 antibody; ECOG PS 0–2

→ Talquetamab 0.4 mg/kg SC QW*
(n = 143)

→ Talquetamab 0.8 mg/kg SC Q2W*
(n = 145)

→ Prior T-Cell Redirection Group: Talquetamab
Either 0.4 mg/kg SC QW or 0.8 mg/kg SC Q2W
(n = 51)

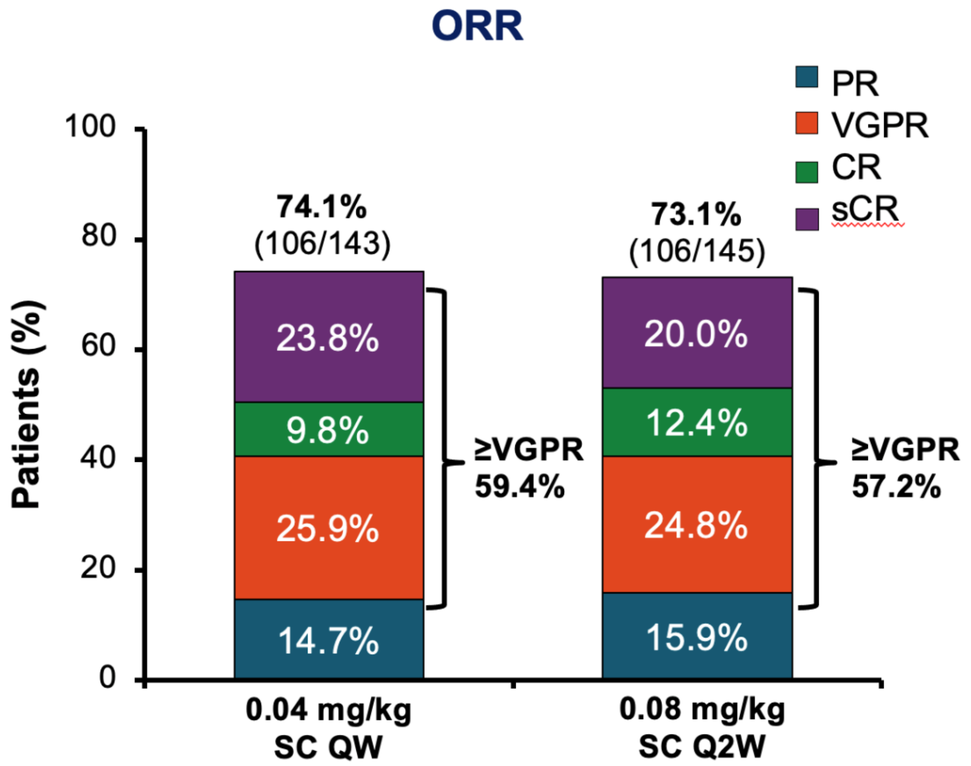
*Previous anti-BCMA therapy allowed; T-cell redirection therapy naive.

Chari, NEJM, 2022

MonumenTAL-1: Single-agent talquetamab (GPRC5D)

- IV: 405 µg/kg qwk/800 µg/kg q2wk
- ~70% TCR *and* PCR
- Median follow-up: 8.6 m (0.2–22.5)*
- Median time to response: 1.2 m*
- 800 cohort: ORR 64.0%, ≥VGPR 52.0%
- mDOR NR (10.6–NE)*
- mPFS 11.9 m (95% CI: 8.4–NE)*
- CRS 72.4% (1 G3), ICANS 10% (2 G3 events)*
- Skin AE (55.9%), nail AE (51.7%), dysgeusia (48.3%)
- Infections 50.3% (11.7% G3/4)

*800 mcg/kg cohort



Recommended dosing

SQ: 0.01 → 0.06 → 0.4 → 0.8 mg/kg d1,3,5 then q2week

MonumenTAL-1 is the first non-BCMA T-cell–redirecting bispecific antibody FDA approved for patients treated with at least 4 prior lines of therapy including IMiD, PI, and CD38 mAb

Chari, NEJM, 2022; Chari, ASH, 2022

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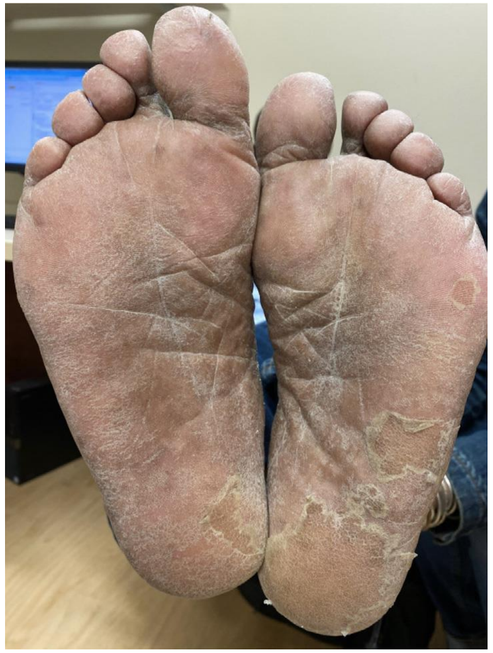
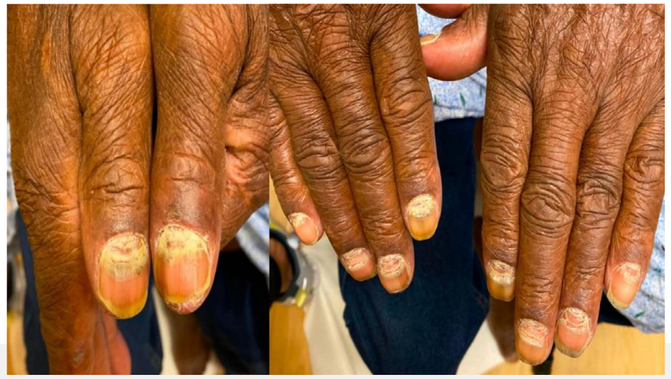
MonumenTAL-1: Nonhematologic Safety

AEs (≥30% in any cohort), n (%)	0.4 mg/kg SC QW (n=143)		0.8 mg/kg SC QW (n=145)		Prior TCR (n=51)	
	Any Grade	Grade 3/4	Any Grade	Grade 3/4	Any Grade	Grade 3/4
Nonhematologic AEs						
CRS	113 (79.0)	3 (2.1)	108 (74.5)	1 (0.7)	39 (76.5)	1 (2.0)
Dysgeusia	103 (72.0)	NA	103 (71.0)	NA	39 (76.5)	NA
Infections	84 (58.7)	28 (19.6)	96 (66.2)	21 (14.5)	37 (72.5)	14 (27.5)
Skin related	80 (55.9)	0	106 (73.1)	1 (0.7)	35 (68.6)	0
Nail related	78 (54.5)	0	78 (53.8)	0	32 (62.7)	0
Weight decreased	59 (41.3)	3 (2.1)	60 (41.4)	8 (5.5)	15 (29.4)	0
Rash related	57 (39.9)	2 (1.4)	43 (29.7)	8 (5.5)	18 (35.3)	2 (3.9)
Pyrexia	56 (39.2)	4 (2.8)	40 (27.6)	2 (1.4)	16 (31.4)	0
Dry mouth	38 (26.6)	0	58 (40.0)	0	26 (51.0)	0
Fatigue	35 (24.5)	5 (3.5)	40 (27.6)	1 (0.7)	23 (45.1)	1 (2.0)

Chari, Blood, 2022; Touzeau, EHA, 2023

Talquetamab Oral and Dermatologic AEs



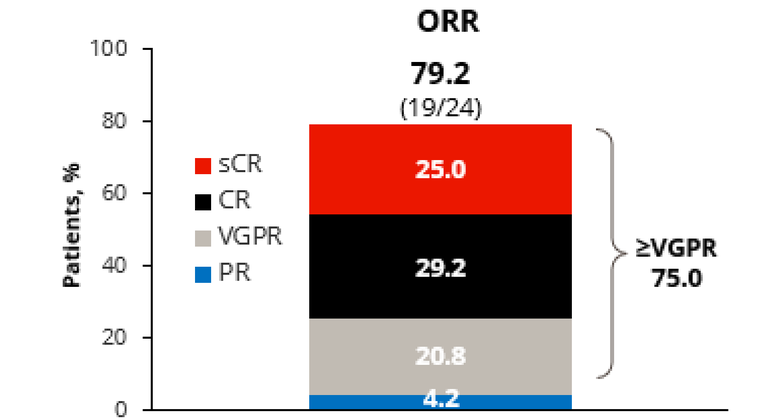


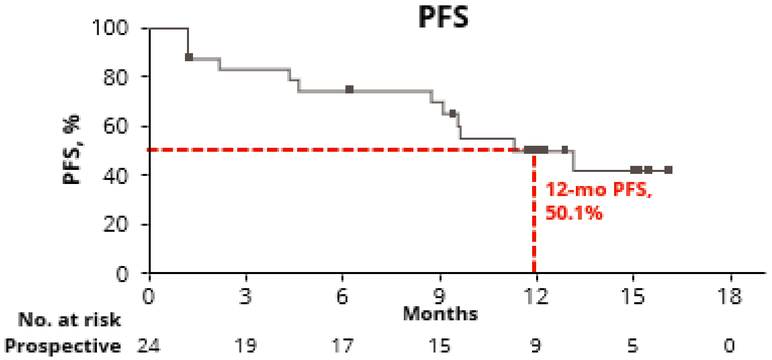
- Consider dose-reduction (0.8 mg/kg Q2W to 0.4 mg Q2W) or less frequent dose (0.8 mg/kg Q2W to 0.8 mg/kg Q4W) once attaining >= PR (Chari et al, *ASH* 2023)
- Management of toxicity includes moisturizers, topical or systemic steroids, saliva substitutes.

Chari. ASH 2022. Abstr 157.
Narayan, JAAD Case Rep, 2023; Chari, ASH, 2023

MonumenTAL-1: Response Maintained after Switch

- Patients with dose reductions had to be in response (n=19); dose reduction occurred at a median of 3.1 mo (range, 2.3–4.2) relative to treatment start





	Prospective (n=19)
Median follow-up, mo (range)[a]	13.2 (4.0+–16.1)
Median PFS, mo (95% CI)[a]	13.2 (8.8–NE)
12-mo PFS rate, % (95% CI)[a]	50.1 (27.9–68.7)
Median DOR, mo (95% CI)	NE (8.3–NE)

- In the 0.8 mg/kg Q2W registrational cohort (n=145)[1,b]
  - ORR: 71.7%
  - Median PFS: 14.2 mo (95% CI, 9.6–NE)
    - 12-mo PFS rate: 54.4%
  - Median DOR: NE (95% CI, 13.0–NE)

Data cut-off date: October 2, 2023. [a]Based on all patients included in the cohorts (N=24). [b]Data cut-off date: January 17, 2023. CR, complete response; DOR, duration of response; NE, not estimable; ORR, overall response rate; PFS, progression-free survival; PR, partial response; Q2W, every other week; sCR, stringent complete response; VGPR, very good partial response.

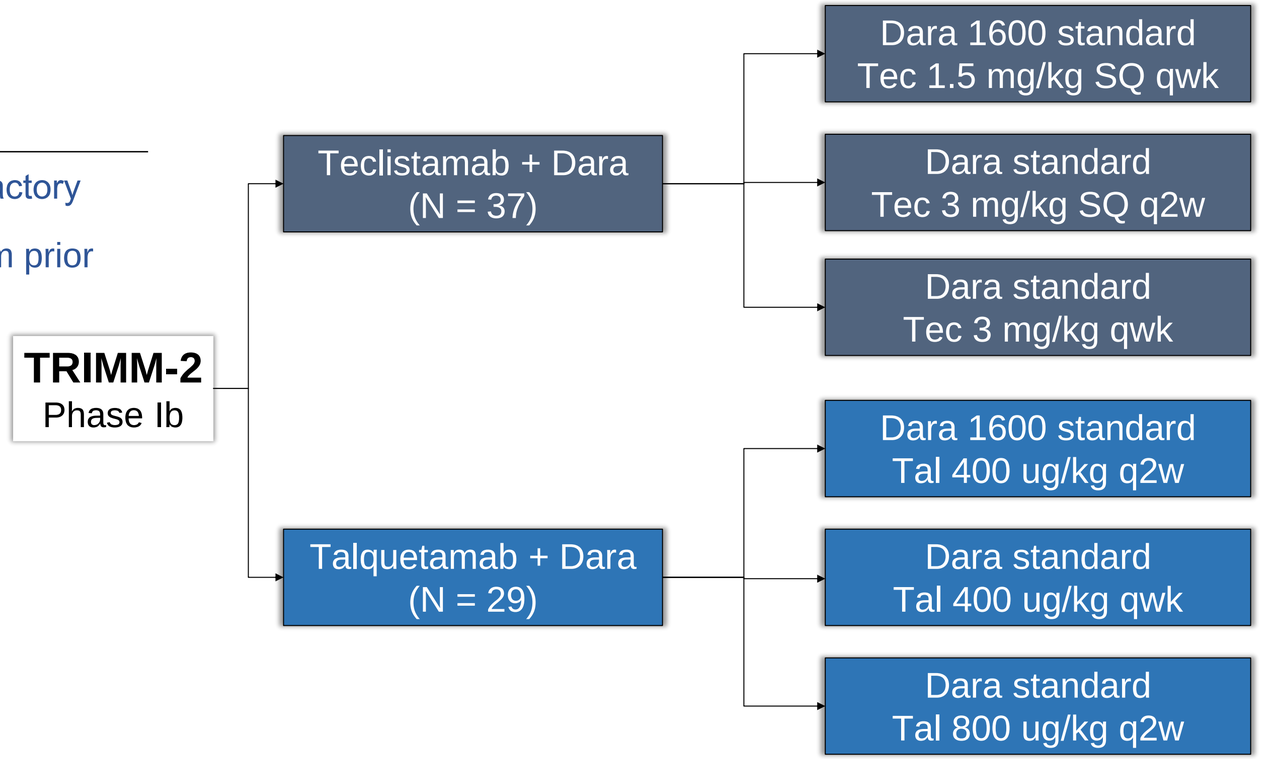
1. Touzeau C, et al. Presented at EHA; June 8–11, 2023; Frankfurt, Germany.

TRIMM-2: Combine daratumumab with Tec or Tal

Key eligibility criteria

≥3 prior lines or IMiD/PI double refractory

Prior dara (including refractory) >3 m prior

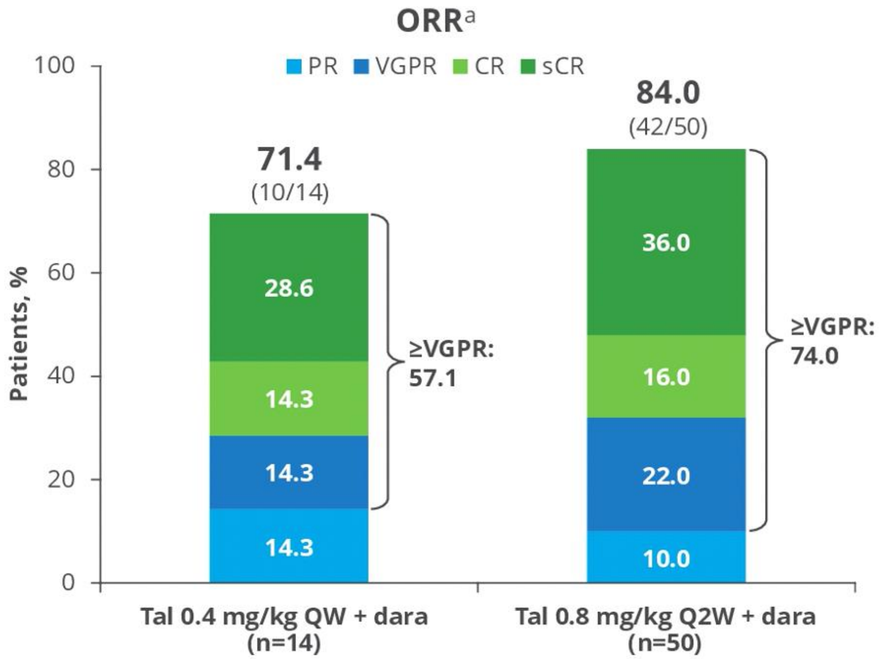


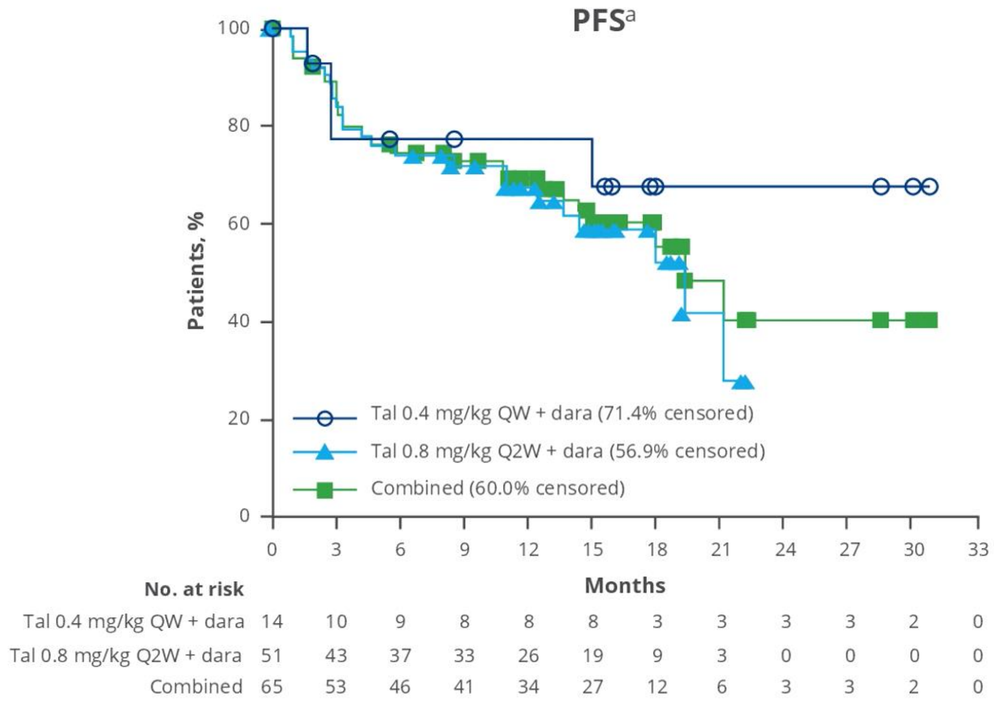
19% prior BCMA
76% prior aCD38 mAb
60% aCD38 mAb refractory
54% TCR
60% penta-exposed
19% penta-refractory

55% prior BCMA
79% prior aCD38 mAb
66% aCD38 mAb refractory
52% TCR
66% penta-exposed
31% penta-refractory

Chari, ASH, 2021; Rodriguez-Otero, ASH, 2021

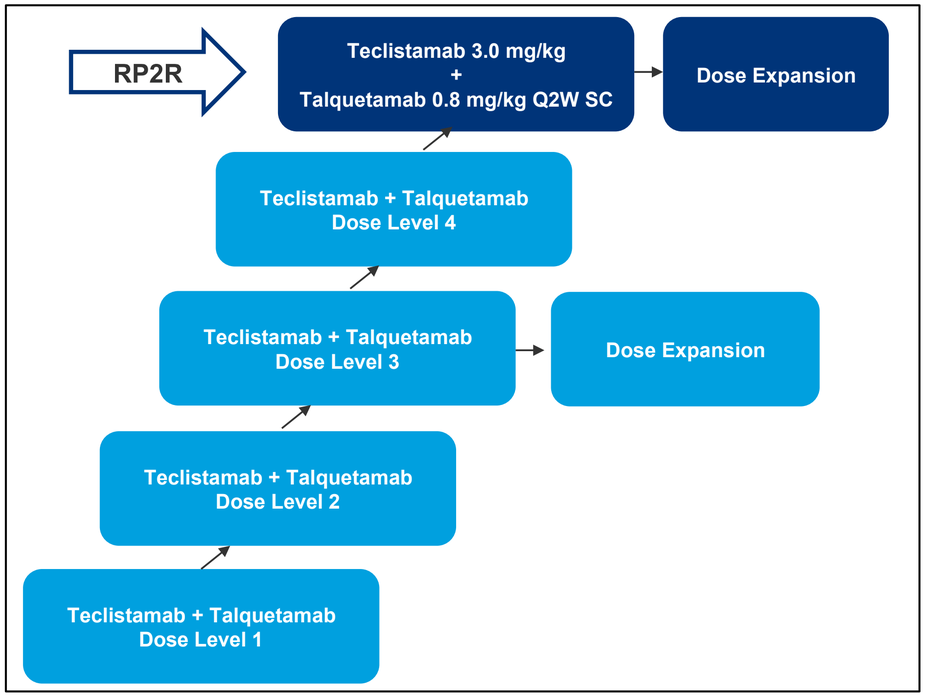
Talquetamab + Daratumumab (TRIMM-2)





Construct	mPrior	ORR (%)	≥VGPR	mDOR	mPFS
Talquetamab + Dara[2] Tal 800 ug/kg SQ q2w	5 (2-14)	84.0	74.0	20.3m	19.4m

RedirecTT-1: Phase 1b trial
Dual Targeting via Teclistamab + Talquetamab



- Triple refractory: 80%
- High –risk cytogenetics: 33%
- Extramedullary plasmacytoma, ≥1: 37.6%

Cohen et al, ASCO 2023

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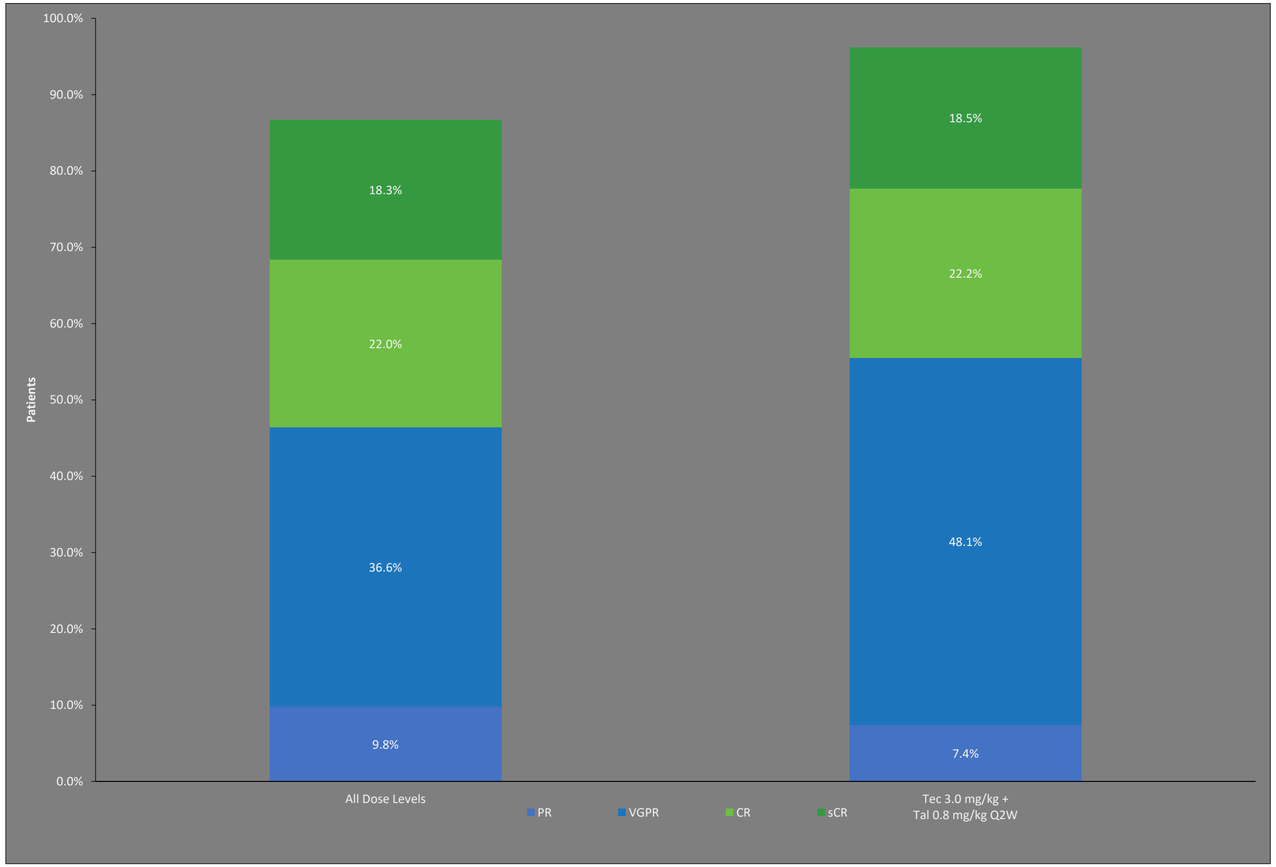
RedirecTT-1: Efficacy



All:
Median PFS: 20.9 (13.0–NE)

Extramedullary MM:
≥CR: 28.6%
DOR: NE (4.17–NE)

Cohen et al, ASCO 2023

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RedirecTT-1: Safety and Efficacy

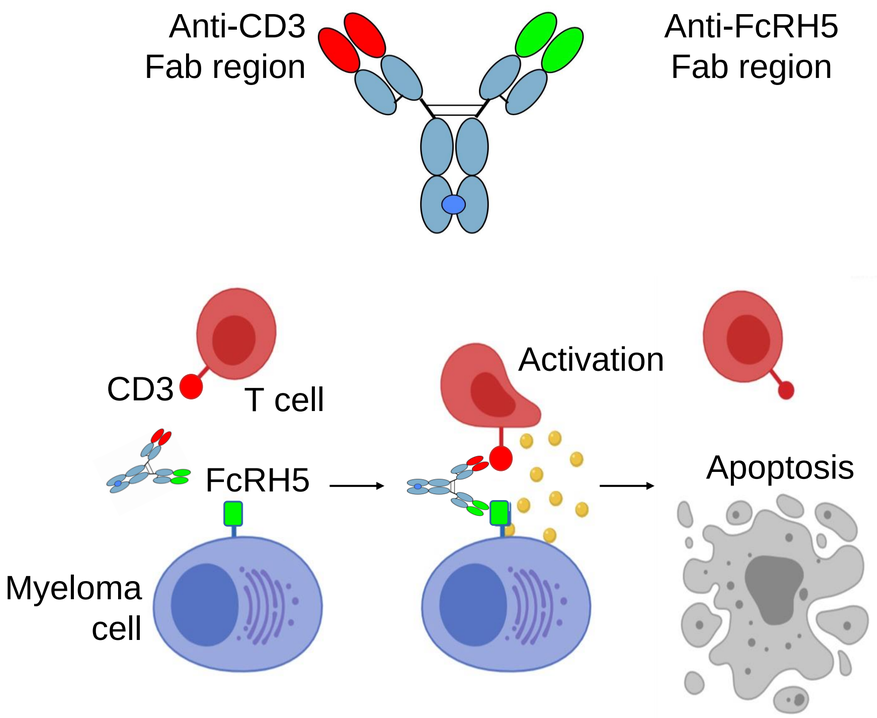
Patients, n (%)	All dose levels	Tec 3.0 mg/kg + Tal 0.8 mg/kg Q2W
	N=93	n=34
Any TEAE[a]	90 (96.8)	32 (94.1)
≥1 Grade 3/4 TEAE	82 (88.2)	27 (79.4)
Discontinuation due to drug-related TEAE	6 (6.5)	2 (5.9)
Death due to drug-related TEAE	6 (6.5)	1 (2.9)

TEAE[a] (≥25% overall), n (%)	All Dose Levels N=93		Tec 3.0 mg/kg + Tal 0.8 mg/kg Q2W n=34	
	Any Grade	Grade 3/4	Any Grade	Grade 3/4
Nonhematologic TEAEs				
CRS	71 (76.3)	3 (3.2)	25 (73.5)	0
Dysgeusia[b,c]	57 (61.3)	--	16 (47.1)	--
Pyrexia	47 (50.5)	2 (2.2)	13 (38.2)	1 (2.9)
Skin toxicity[d]	50 (53.8)	0	18 (52.9)	0
Nail disorders[e]	43 (46.2)	0	14 (41.2)	0
Diarrhea	38 (40.9)	2 (2.2)	14 (41.2)	1 (2.9)
Cough	36 (38.7)	0	8 (23.5)	0
Dry mouth	35 (37.6)	0	11 (32.4)	0
Rash[f]	32 (34.4)	1 (1.1)	10 (29.4)	1 (2.9)
COVID-19	31 (33.3)	9 (9.7)	14 (41.2)	1 (2.9)
Pneumonia	25 (26.9)	10 (10.8)	4 (11.8)	2 (5.9)
Fatigue	24 (25.8)	7 (7.5)	6 (17.6)	2 (5.9)

Cohen et al, ASCO 2023

Cevostamab: FcRH5 x CD3 bispecific antibody

- Fc receptor-homolog 5 (FcRH5)
  - Expressed exclusively in B-cell lineage (MM cells > normal B-cells)[1]
  - Near ubiquitous expression on MM cells[1,2]
  - Fc receptor-homolog 5 (FcRH5) located in the chromosomal breakpoint in 1q21
- Cevostamab bispecific antibody
  - Targets membrane-proximal domain of FcRH5 on MM cells and epsilon domain of CD3 on T-cells[1]
  - Dual binding results in T-cell directed MM cell killing[1]
- Previously reported phase 1 dose-finding experience (NCT03275103)[3]
  - Promising activity in patients with heavily pretreated RRMM
  - Manageable safety profile

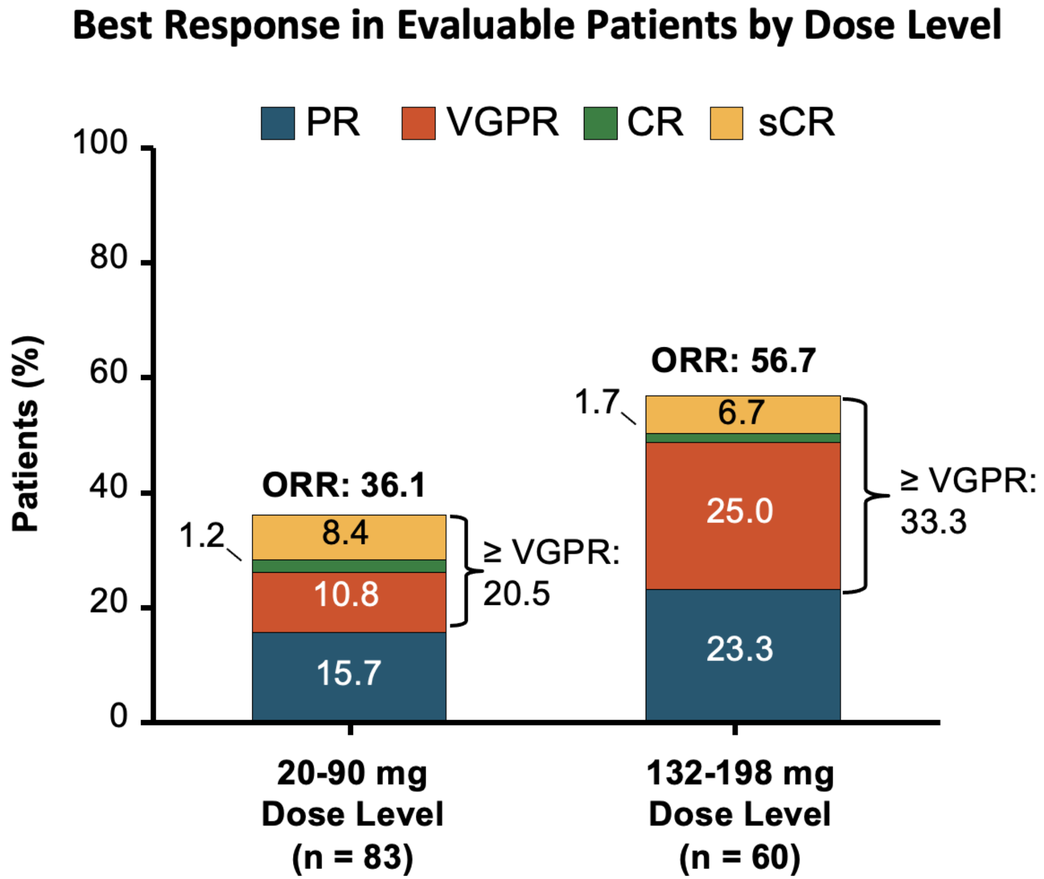


[1]Li, Cancer Cell, 2017; [2]Sumiyoshi, EAH, 2021; [3]Trudel, ASH, 2021

CAMMA: Single-agent cevostamab (FcRH5)

- IV: Step-up dosing day 1, 2, and 8 → q3wk
- Median prior lines 6 (2-18)
- 84.5% TCR, 68.3% PCR, 33.5% prior BCMA
- 70.5% hrFISH, 21.1% EMD
- CRS 70% (G3 ~1-2%)

Outcome	Cevostamab (N = 161)
Median time to response among responders, mo (range)	1.0 (0.7–5.9)
Median time to best response, mo (range)	2.1 (0.7–11.4)
MRD negativity at $<10^{-5}$ in patients with ≥VGPR, n/N (%)	7/10 (70)



T-cell directed therapies: Infections

Trial	N	Infections		Hypogammaglobulinemia
		Any grade (%)	Grade 3 – 4 (%)	Any grade (%)
KarMMA[1]	128	90 (70)	34 (27)	91 (94)
CARTITUDE-1[2]	97	40 (41)	16 (17)	91 (94)
MajesTEC-1[3]	165	95 (76)	56 (45)	123 (74.5)
ABBV-383B	124	51 (41)	NA	17 (14)
MagnetisMM-3[4]	123	86 (70)	49 (40)	43% received IVIG
LINKER-MM1[5*]	117	70 (60)	43 (37)	NR
Cevostamab[6]	160	68 (43)	30 (19)	NR
MonumenTAL-1	102	15 (34)	3 (7)	13 (71)

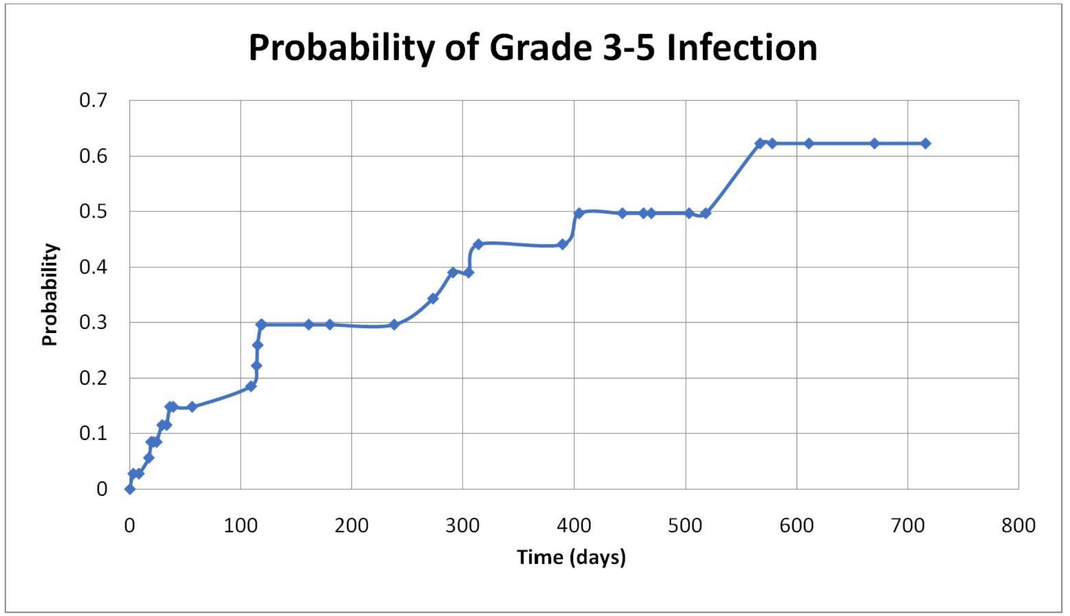
* 200 mg cohort

Infections are common, grade 3 or higher infections are more common in BCMA-directed bispecifics and hypogammaglobulinemia should be treated

[1]Munshi, NEJM, 2021; [2]Cohen, BCJ, 2022; [3]Moreau, NEJM, 2022; [4]Mohty, ASCO, 2023; [5]Lee, ASCO, 2023; [6]Trudel, ASH, 2021;

Prophylactic IVIG for Hypogammaglobulinemia

- **High incidence of hypogammaglobulinemia with bispecific therapy in multiple myeloma**
- Retrospective study of 37 patients receiving anti-BCMA bispecific therapies a single institute
- 100% incidence of severe hypogammaglobulinemia (IgG < 200 mg/dL), censoring for IVIG use if IgG used preemptively (5 patients)
  - Grade 3-5 infection rate while on IVIG was 0.25 per patient-year versus 1.23 per patient-year off IVIG (IRR 0.20, 95% CI [0.06-0.52], p<0.001)
    - Effect more pronounced with bacterial infections



Recommend IVIG if IgG < 400 mg/dL in myeloma patients receiving bispecific T-cell antibody therapy

Lancman, ASH, 2022

UTAH MULTIPLE MYELOMA

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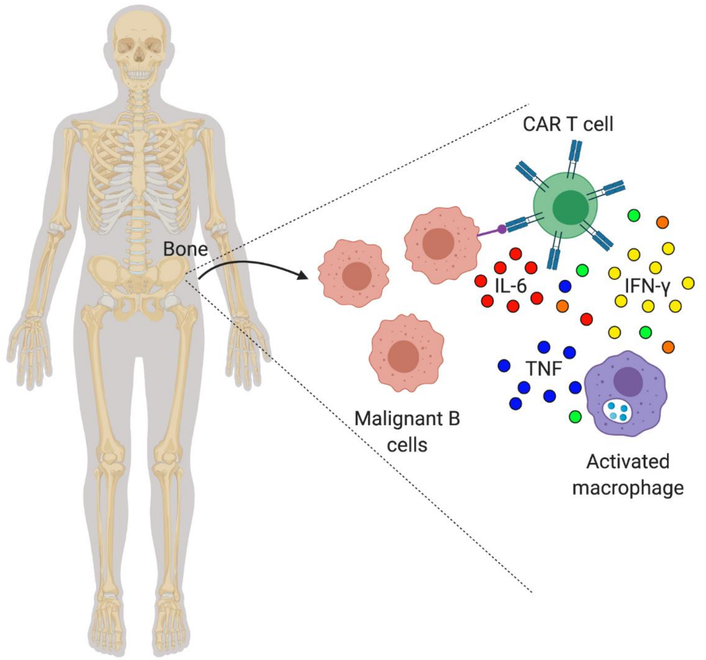
General T-cell directed therapy supportive care

Pathogen	Intervention	Indication/duration
Bacterial	Levofloxacin 500 mg daily. Consider alternatives: cefpodoxime 200 mg bid or augmentin 875 mg bid if allergy	CAR-T: Initiate when ANC < 500, continue until neutrophil recovery BsAb: Initiate when ANC < 500, continue until neutrophil recovery
	IVIG 400 mg/kg qmonth	CAR-T: Day +30 – +365 or until IgG > 400 BsAb: Start at 2nd month of therapy and continue, especially with BCMA-directed therapy
	Pneumococcus conjugated vaccine (PCV)	Start revaccination at 3-6 months after CAR-T. CDC recommends administration of 1 dose of PCV20 or 1 dose of PCV15 followed by 1 dose of PPSV23 at year 1
HSV/VZV	Acyclovir 400 – 800 mg PO twice daily or valacyclovir 500 mg PO once or twice daily	Universal and indefinite prophylaxis
CMV	Prophylaxis not recommended	Routine monitoring not recommended. Consider monitoring PCR viral load and CMV-directed therapy in patients with suspected CMV-related disease or unexplained fevers or in high-risk patients
COVID19	Immunization	Follow CDC guidelines
Influenza	Immunization	Seasonal
Hepatitis B	Entecavir or tenofovir	CAR-T or BsAbs: patients HBs Ag-positive, HBc Ab – IgG positive
Yeast and mold	Fluconazole 400 mg qday	Start when ANC < 500 and continue until neutrophil recovery, considering ongoing prophylaxis with mold coverage in high-risk patients
Pneumocystis jirovecii (PJP)	Trimethoprim 80 mg/sulfamethoxazole 400 mg qday or 160/800 mg 3x weekly (preferred) or dapsone 100 mg qday or atovaquone suspension 750mg/5mL – 1500 mg = 10 mL qday, or pentamidine 300 mg inhalation monthly	CAR-T: Start on day +30 through 6 months or until CD4 $\geq$ 200 BsAb: Start with therapy and continue for its duration or until CD4 $\geq$ 200

Adapted from Mohan, BJH, 2023

Cytokine Release Syndrome (CRS) Pathophysiology

- Bulk T-cell activation → massive release of inflammatory cytokines produced by CAR-T cells or other immune cells
- The cytokines released include IL-6, most notably, as well as TNF, IFN-g, IL-2, IL-8, and IL-10



IL, interleukin; IFN-γ, interferon gamma; TNF, tumor necrosis factor

Oluwole, JLB, 2016; Bruno, Blood, 2016; June, Science, 2018

CRS Recognition

Routine Monitoring

- Vital signs (temp, O2, etc)
  - q4 hours
- Review of systems/physical exam
  - Focus on cardiovascular, pulmonary, and neurologic systems
  - Survey for occult infection
- Labs
  - CRP
  - Cytokines
  - Ferritin
  - LDH

Focused Assessment Based Symptoms

- Fever
  - Sepsis protocol
  - Blood and urine culture
  - CXR
- Tachycardia
  - EKG
- Hypotension / persistent tachycardia
  - Echo

1. Brudno JN, Kochenderfer JN. Blood Rev. 2019;34:45-55. 2. Lee DW et al. Biol Blood Marrow Transplant. 2019;25:625-638.

STANDARD OF CARE

MM Bispecifics Cytokine Release Syndrome (CRS) Treatment Algorithm

CRS is the result of T cell cytokines and most often presents as fever progressing to systemic inflammatory response syndrome and end organ toxicity. Close monitoring of vitals before each dose and frequently when admitted is required.

SUPPORTIVE CARE FOR ALL GRADES

Initiate infection workup, start appropriate antibiotics, consider stopping anti-hypertensive agents, start antipyretics (e.g. acetaminophen), administer fluids if indicated for hypotension, initiate supplemental oxygen if indicated for hypoxia.

Grade severity* (Grade is determined by most severe adverse event)

Grade 1	Grade 2	Grade 3 / 4
Fever ≥ 38°C	SBP < 90 mmHg not requiring vasopressors OR SpO2 < 90% requiring O2 ≤ 6 L/min	SBP < 90 mmHg requiring vasopressors OR SpO2 < 90% requiring O2 > 6 L/min or mechanical ventilation
Grade 1 management: GIVE **dexamethasone** 16 mg PO x1 If fever persist for > 4 hours from dexamethasone dose or if CRS grade increases to ≥ grade 2 at any time, GIVE **tocilizumab** 8 mg/kg IV x1 (cap 800 mg)	**Grade 2 management:** GIVE **tocilizumab** 8 mg/kg IV x1 STAT (cap 800 mg) Notify attending; notify ICU of potential transfer; increase vitals monitoring to q2h	**Grade 3 and 4 management:** GIVE **tocilizumab** 8 mg/kg IV x1 STAT (cap 800 mg) CONSIDER **dexamethasone** 10 mg IV q6h at attending discretion Notify attending; transfer to the ICU; increase vitals monitoring to q2h

Symptoms improving > 8 hours after last tocilizumab dose:

Decrease vitals monitoring to q4h

Continue providing supportive care

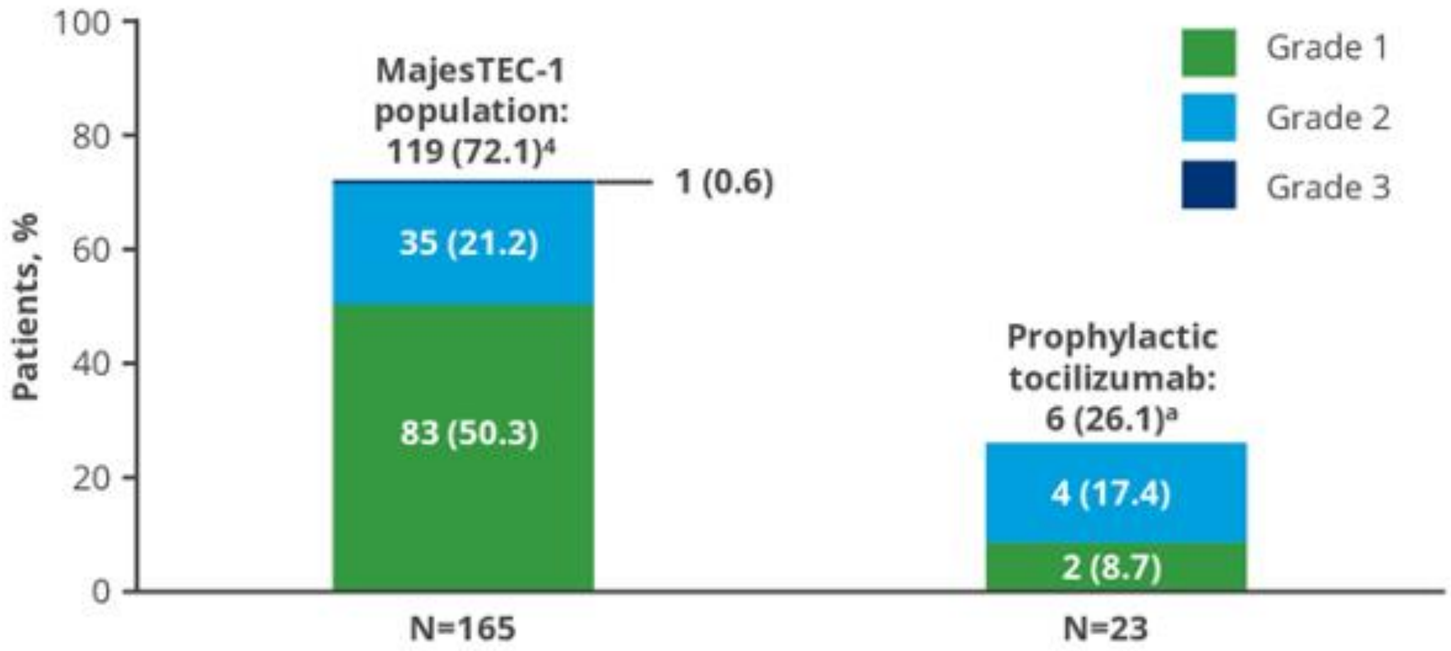
Stop or taper steroids per patient response

Symptoms NOT improving or worsening, consider:

Continue **tocilizumab** 8 mg/kg IV (cap 800 mg) q8h for up to 4 doses
Add **dexamethasone** 10 mg IV q6h if not done previously
Increase steroid **methylprednisolone** 1000 mg IV q24h
Add **anakinra** 100—400 mg/d SQ x 7 days

* per Lee et al. ASTCT criteria

BCMA bispecifics: Effect of prophylactic tocilizumab



Prophylactic tocilizumab primarily decreased grade 1 CRS but over 50% had high grade neutropenia

Van de donk, ASCO, 2023

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Neurological Assessment

ICE Score				
Orientation - Oriented to year, month, city, hospital: 1 point each, 4 points total				
Naming - Ability to name 3 objects: 1 point each, 3 points total				
Follow commands - Able to follow simple command: 1 point total				
Writing - Able to write a standard sentence: 1 point total				
Attention - Able to count backwards from 100 by 10’s: 1 point total				
Scoring				
10 No impairment	7-9 ICANS 1	3-6 ICANS 2	0-2 ICANS 3	0 ICANS 4

Neurologic Toxicity Recognition and Monitoring

Routine Monitoring and Follow-up

- Periodic review of neurologic system and full neuro exam according to institutional tools and guidelines[1]
  - If evidence of neurotoxicity, neurologic exam every 8 hours[2]
- Imaging[1]
  - Head CT
  - MRI
- Lumbar puncture, when feasible[2]
- Neurology consultation[2]

Monitoring Following Discharge to Home

- Patient/caregiver counseling, particularly regarding encephalopathy[1]

CRS and neurologic toxicity can occur simultaneously[2]

Brudno, Blood Rev, 2019; Brudno, Blood, 2016; Lee, BBMT, 2019

Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) Treatment Algorithm

If both CRS and ICANS, then follow the CRS algorithm.
If Clinical Trial, then follow study toxicity management protocols.

ICANS may be the result of CAR T cell cytokine release (IL6, etc.) and most often presents as global encephalopathy, but may also include headache, insomnia, dysphagia, ataxia, palsy, tremor, hallucinations, or seizure. Vigilant neuro checks are required for at least the first 7 days, but may also present several weeks later. It may present concurrently with CRS or separately.

Grade Severity* (Grade is determined by most severe event)

Mild (ICANS Grade 1)

ICE score 7-9; awakens spontaneously.

Always treat with:

- Symptomatic therapy / Supportive care PRN
- Aspiration precautions
- Nursing neuro exams every 8 hours
- Rule out other causes (e.g. infection, ammonia level, etc)
- Start **Levetiracetam 500 mg PO BID** prophylaxis, until day 30 and ICANS grade 0
- **Dexamethsone 10 mg IV q24**, stop when ICANS resolved for 24hrs
- Consider treating as grade 2 if persistent for > 72hrs

Moderate (ICANS Grade 2)

ICE score 3-6; awakens to voice but may have slowed responses.

Treat as Mild, plus:

- **Dexamethasone 10 mg IV q6h**
- Notify ICU about patient in case transfer needed
- Notify BMT attending on-call
- Nursing neuro exams every 4 hours
- Consider MRI brain w/wo contrast
- Consider LP with opening pressure, cultures, protein, IL6, oligoclonal bands, and cell count (if able as inpatient)
- Consider Initial 30 min EEG
- For seizures: increase anti-epileptic(s) from prophylactic doses to treatment doses

Severe (ICANS Grade 3 or 4)

ICE score 0-2, awakens to tactile stimulus **OR** unarousable, seizure, paralysis, decerebrate, decorticate posturing, CN VI palsy, papilledema, Cushing's triad, or cerebral edema.

Treat as Mild and Moderate, plus:

- Ensure mild/moderate orders are ordered
- Admit to ICU, if not already transferred
- Nursing neuro exams every 1 hour
- Consider airway protection
- Notify BMT attending on-call
- Consult neurology
- Consider Continuous EEG
- Consider stopping anti-coagulation (discuss with BMT attending)

Symptoms improving >24 hours after Dexamethasone?

No →

Symptoms Not Improving/Worse

- **Methylprednisolone 1000 mg IV q24h x3 days** without Tocilizumab (and stop dexamethasone)

Yes ↓

Symptoms Improving

- Continue to monitor
- Provide supportive care as in Mild-Moderate
- **Continue steroids** until event ≤ Grade 1 and a minimum of 3 days, then:
  - Taper steroids over 3 days or as clinically appropriate
  - Monitor for adrenal insufficiency

Symptoms improving 1-3 days after Methylprednisolone?

Yes ←

No →

Symptoms Not Improving/Worse

Consider adding: **Anakinra SQ/IV 100-400 mg/day x7 days**, continue steroid (SQ preferred; IV may be necessary for edematous patients)

If after 7 days, not improving:
Consider: **Siltuximab 11 mg/kg IV** over 1 hour STAT (maximum 1200 mg) (Please note: use within these guidelines does NOT require medical director approval), continue steroids

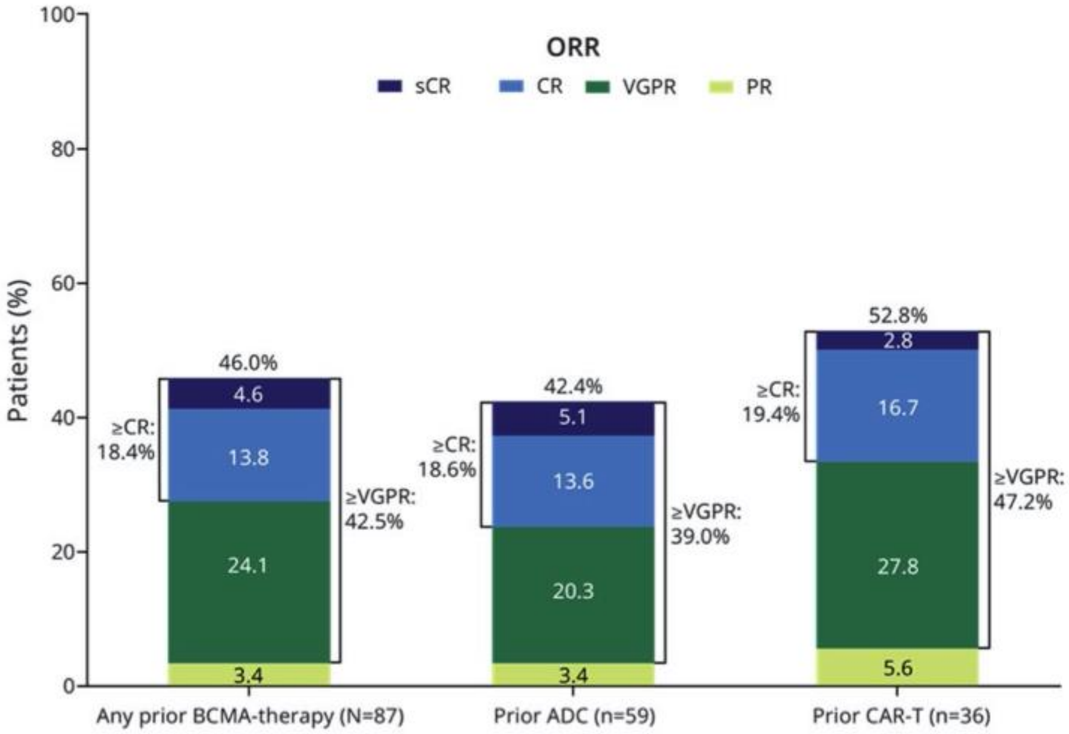
If after 2-3 days, still not improving:
Consider: **IT Methotrexate 12-15 mg** and repeat LP work-up (to r/o other causes)

Lastly consider: T-cell ablation with **Cyclophosphamide 1.5 g/m2 IV**

*Lee, D et al. ASTCT Concensus Grading for Cytokine Release Syndrome and Neurologic Toxicity Associated with Immune Effector Cells. Biol Blood Marrow Transplant. 25 (2019) 625-638.

Sequencing BCMA-Directed Immunotherapies CART and/or ADC → Bispecific

Pooled Analysis of Elranatamab in MagnetisMM-1, MagnetisMM-2, MagnetisMM-3, MagnetisMM-9 studies



Median PFS: 5.5 months
Prior ADC PFS: 3.9 months
Prior CAR-T PFS: 10.0 months

Median DOR: 17.1 months
Prior ADC DOR: 13.6 months
Prior CAR-T DOR: NE

Nooka, ASCO, 2023

Sequencing: BsAb perform with prior BCMA exposure

Trial	Follow-Up	N	mPrior (range)	ORR	≥VGPR	mDOR
Teclistamab[1]	104 d	18	NR	56.0%	NR	NR
Elrantamab[2]		87	7 (3-19)	46.0%	42.5%	17.0 m
Talquetamab[3]	14.8 m	51	6 (3-15)	64.7%	54.9%	11.9 m
Tal + Dara[4*]	15.0 m	19	5 (2-14)	78.9%	NR	NR
CAMMA-2[5]	Ongoing					

Even in patients previously treated with BCMA-directed bispecifics or CAR T, bispecifics may still be highly effective

Firestone, ASCO, 2023; Nooka, ASCO, 2023; Schinke, ASCO, 2023; Dholaria, ASCO, 2023; Kumar, ASCO, 2023

T-cell redirecting bispecific antibodies - Summary

- **ADVANTAGES**
  - “**Off-the-shelf”** format provides immediate **ACCESS** to patients in immediate need of therapy (rapidly progressing disease, community practice)
  - **Strong efficacy** comparable to some autologous CART products
- **DISADVANTAGES**
  - **Continuous dosing (vs. CART)**
  - **Adverse events**
    - CRS common; Grade 3/4 CRS and neurotoxicity rare; severe CRS is be mitigated by step-up dosing strategy (still requires inpatient monitoring)
    - Drug- or target-specific AEs
      - Infection risk particularly with BCMA targeted bispecifics
      - GPRC5D: dysgeusia, skin exfoliation, nail disorders

Slide courtesy of Hans Lee, MD

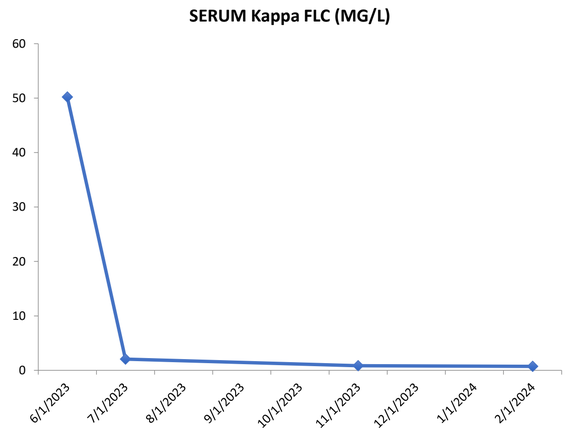
Bispecific Antibody Practical Considerations

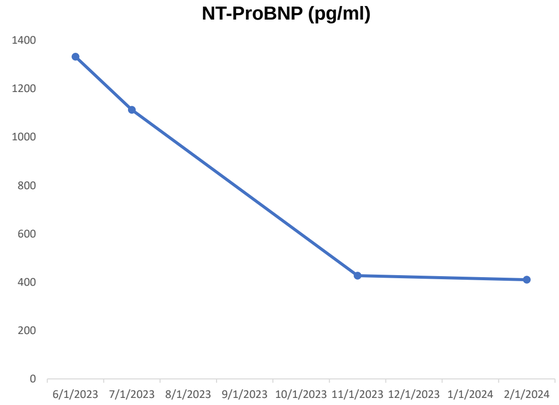
- **When to use?**
  - ≥ 4 prior lines of therapy with exposure to PI, IMiD, and anti-CD38 antibody
  - Earlier use being studied in clinical trials
- **Factors of which bispecific antibody to use?**
  - Target (BCMA, GPRC5D, FcRH5, etc.) and previous exposures
  - Step-up dosing schedule and hospitalization requirements
- **Adverse event management**
  - CRS/ICANS
    - Most CRS grade 1 (i.e. fever), some grade 2, rare grade 3 or 4 events
    - ICANS less common
  - Infection prophylaxis/surveillance (BCMA > non-BCMA)
    - Anti-viral and PJP prophylaxis
    - IVIG if IgG < 400 mg/dL
  - Dermal/nail/taste AEs with GPRC5d-targeting therapies

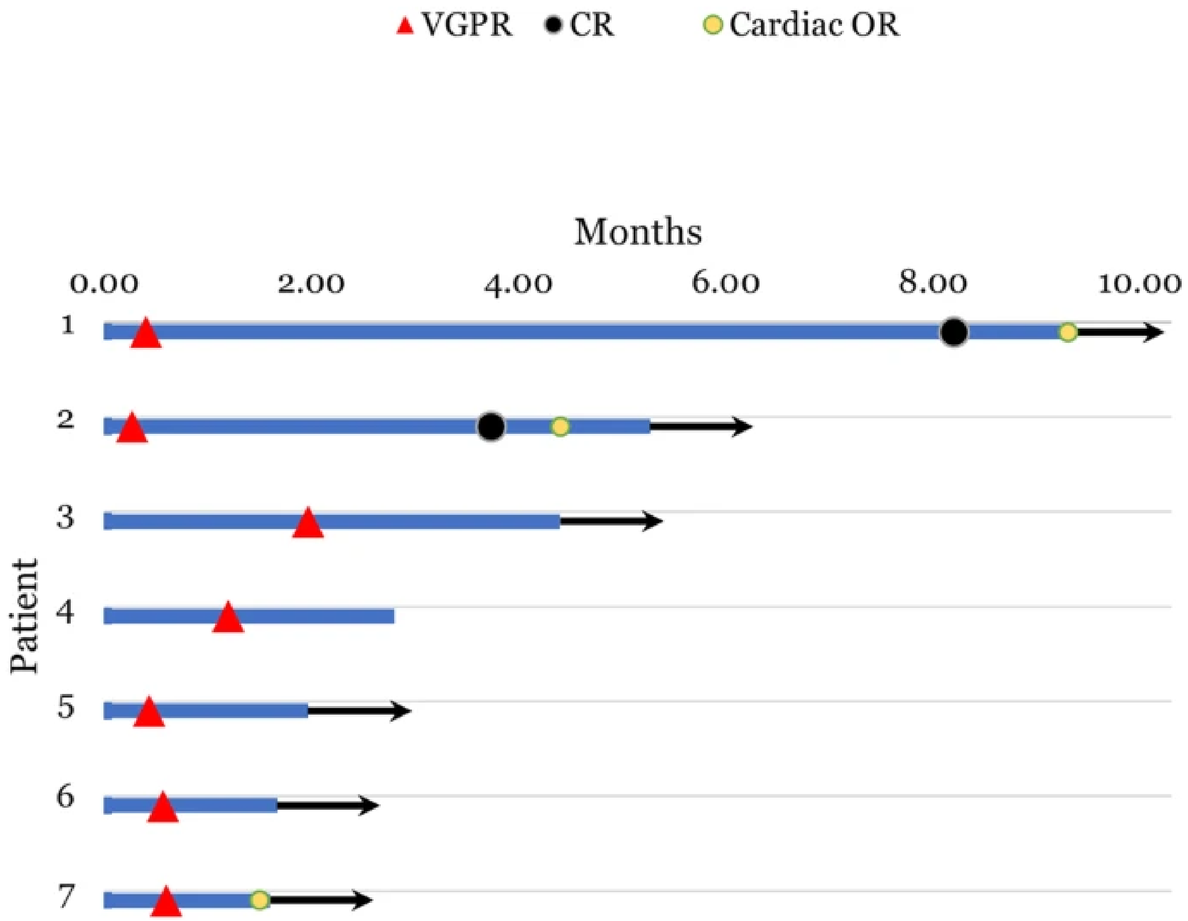
Slide courtesy of Hans Lee, MD

Bispecific Antibodies in AL amyloidosis

73 YOF with AL Amyloidosis (cardiac, renal, hepatic and pulmonary involvement) and 5 prior LOT







Chakraborty et al, BCJ 2023

MONTANA STATE ONCOLOGY SOCIETY

Care Transition Document

CARE PLAN TO COMMUNITY PROVIDER FOR BISPECIFIC ANTIBODY THERAPY

DEMOGRAPHICS AND BISPECIFIC ANTIBODIES TREATMENT OVERVIEW:

Name: **DOB:**

Insurance: **Language:**

Caregiver:

SOC/Clinical Trial: **Manufacturer/Product:**

Teclistimab: subq
Dosing schedule: Test dose #1 -> 0.06mg/kg given on day 1, test dose #2 -> 0.3mg/kg day 4 (no CRS)
Treatment dose -> 1.5mg/kg day 7 (no CRS)
Premeds for test doses: dex 16mg PO, benadryl 50mg PO, acetaminophen 650mg PO
Talquetamab
Elranatamab

Initiation of treatment/infusion:

Line of therapy: 4 or __

TREATMENT COURSE:

Admit day: inpatient v outpatient

Complications: from latest progress note, overview of treatment, issues, adverse events (if applicable)

CRS: most commonly occurs as grade 1-3 within 48hrs of initial 3 doses

ICANS/Neurotox:

IL-6 inhibitor/IL inhibitor/steroid doses and dates:

Referrals during treatment: pain management, dietician, home health, etc.

IMMUNOSUPPRESSION PROPHYLAXIS:

Antibiotic prophy:
Bacterial: Levaquin 500mg QD (duration TBD based on CBC)
Fungal: Fluconazole 400mg QD (duration TBD based on CBC)
Viral: Acyclovir 800mg BID indefinitely
PJP (SMX-TMP or pentamidine): initiated at discharge until CD4 >200 for two months consecutively, or 6 months (whichever is longer)

CD4 & CMV PCR/quant NAAT labs:

Infectious complications:

Remaining stem cells:

IVIG: including product, auth, last dose, reaction Y/N

Ongoing infusions monthly for IgG < 400 or recurrent/chronic infections

Immunization schedule (attached)

CYTOPENIAS:

Transfusion parameters: Hgb<8, Plts<11

COAG PROPHYLAXIS:

d/c anticoagulation when PLT < 50k or if CRS

ONGOING MONITORING SCHEDULE (see attached)

Lab monitoring: **Line Access:**

BMBx MRD: **Imaging notes:** Whole body PET, MRIs needed

Notable cytogenetics:

Social considerations:

Outpatient care model

- Partnership with Huntsman at Home
  - Patients will wear temperature biometric device
  - Step-up dosing monitoring occurs in clinic and "at home"
- Step-up dosing care algorithms
  - CRS/ICANS
  - Outpatient workflow
- Patients will need caregiver and proximity to HCI

Thank you

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Ghulam Mohyuddin

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