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BLENREP (belantamab mafodotin) for Patients with Relapsed Refractory Multiple Myeloma (RRMM)

Oncologic Drugs Advisory Committee

July 17, 2025

GSK

BLENREP (belantamab mafodotin) Introduction

Hesham A. Abdullah, MD, MSc, RAC

Senior Vice President

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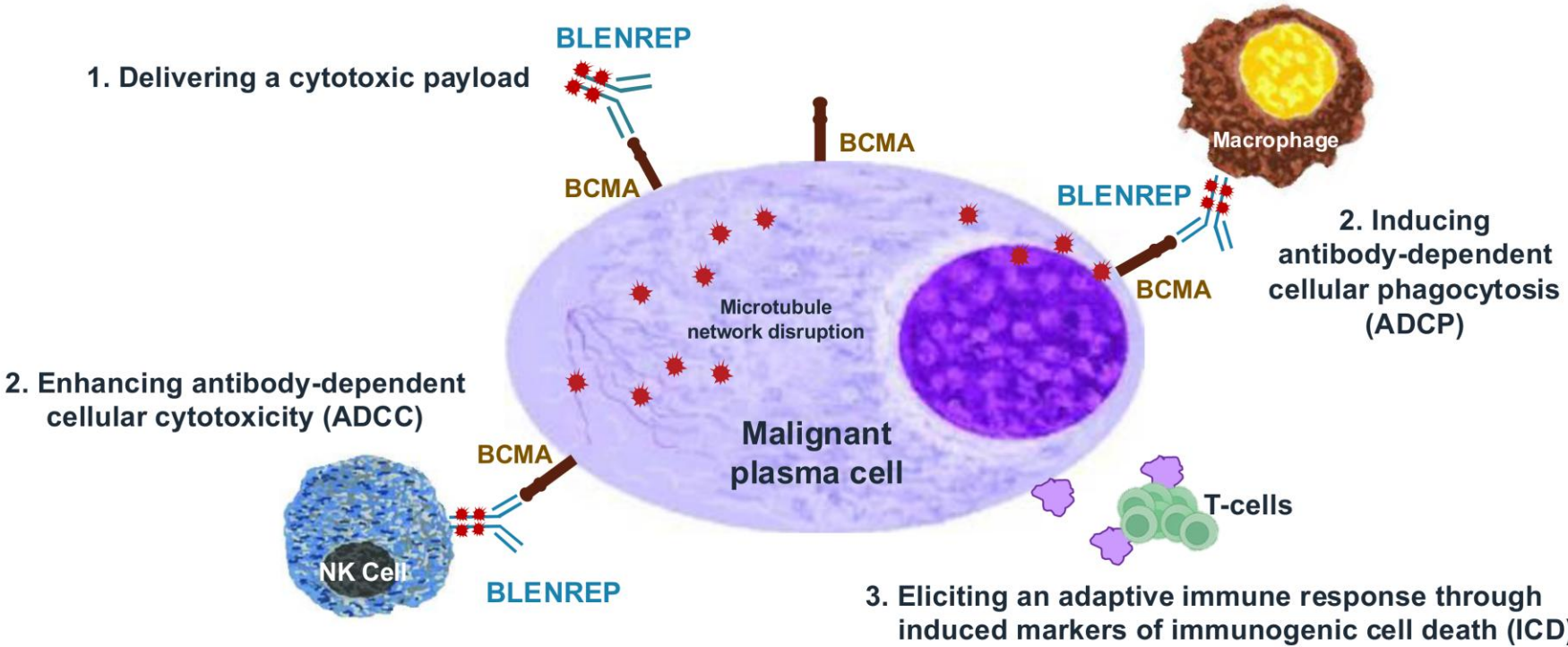
GSK

BLENREP Offers a Novel and Multi-Modal Mechanism of Action Targeting Myeloma

First-in-class afucosylated MMAF-based anti-BCMA IgG1 antibody-drug conjugate (ADC)



BLENREP Development Program for Patients with RRMM with ≥ 1 Prior Line of Therapy

Phase 3 Studies	
DREAMM-7	**DREAMM-8**
Open-Label, Randomized, Active-Controlled Study	**Open-Label, Randomized, Active-Controlled Study**
(BLENREP + Bortezomib/Dex vs Daratumumab* + Bortezomib/Dex)	(BLENREP + Pomalidomide/Dex vs Bortezomib + Pomalidomide/Dex)
RRMM with ≥ 1 prior line of therapy	RRMM with ≥ 1 prior line of therapy (including lenalidomide)

*Daratumumab is recognized in guidelines as a gold standard for treatment of MM; dex = dexamethasone

Proposed Indications

Belantamab mafodotin is indicated for the treatment of adults with multiple myeloma

- In combination with bortezomib and dexamethasone in patients who have received at least 1 prior therapy
- In combination with pomalidomide and dexamethasone in patients who have received at least 1 prior therapy including lenalidomide

Recommended dose as per dosing schedule used in DREAMM-7 and DREAMM-8 protocol
Approved in UK, Switzerland, Japan, UAE, and Positive EU opinion

BLENREP Provides Positive Benefit-Risk in Patients with RRMM

Unmet Need

- MM is incurable
- Disease will ultimately relapse, despite treatment options
- Only one BCMA-targeted treatment with improved OS
- Need for effective, accessible therapies with novel MOA to extend survival

Efficacy

- Consistent benefit across endpoints in two positive Phase 3 studies
  - ~2-year improvement in mPFS
  - 42% reduction in risk of death (DREAMM-7); positive trend in OS (DREAMM-8)
  - 20–25% absolute increase in ≥ VGPR
  - Doubling of CR/sCR and DoR
  - MRD negativity 2.5-5-fold
- Benefit across all subgroups

Safety

- Safety consistent with known and well-characterized profile
- Ocular events reversible with time; effectively managed with dose modifications
- Proposed risk management enables patients to access treatment while ensuring safe use
- Allows administration in out-patient setting

ODAC Discussion Topics

FDA Comment	GSK Position
Dose Exploration	
ORR (≥ PR) rates comparable and tolerability may be improved with lower doses	▪ Extensive exploration in ~400 patients ▪ Higher starting dose/more frequent schedule associated with deep (VGPR, CR/sCR) responses, and resulting PFS and OS ▪ Lower starting dose and/or less frequent schedule improves tolerability but with significant loss in efficacy
Ocular Toxicity and Tolerability	
Ocular toxicity is unique for MM Analyzed outcome of last Grade 2+ KVA	▪ Well-characterized pathophysiology supports reversibility ▪ Ocular events common across doses, transient, reversible over time ▪ Clinically meaningful changes in vision occur in ~1/3 of patients; resolve with dose modifications and do not appear to impact overall QoL ▪ Ocular events monitorable and manageable with dose modifications

Agenda

Unmet Need	**Paul Richardson, MD*** Clinical Program Leader and Director of Clinical Research Jerome Lipper Multiple Myeloma Center Dana-Farber Cancer Institute, Boston, MA RJ Corman Professor of Medicine Harvard Medical School
BLENREP Dose Rationale and Clinical Efficacy	**Pralay Mukhopadhyay, PhD** Vice President Medicine Development Leader, Oncology, GSK
Characterization of Ocular Safety and Monitoring	**Natalie Afshari, MD** Stuart I. Brown MD Chair in Ophthalmology in Memory of Donald P. Shiley Professor of Ophthalmology Chief of Cornea & Refractive Surgery Shiley Eye Institute, University of California, San Diego
BLENREP Clinical Safety Results	**Zeshaan Rasheed, MD, PhD** Senior Vice President Head of Oncology Clinical Development, GSK
Clinical Perspective	**Sagar Lonial, MD*** Chair and Professor and Chief Medical Officer Winship Cancer Institute Emory University School of Medicine

*Not compensated for time

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Unmet Needs in Relapsed and/or Refractory Multiple Myeloma (RRMM)

Paul Richardson, MD

Clinical Program Leader

Director of Clinical Research

Jerome Lipper Multiple Myeloma Center

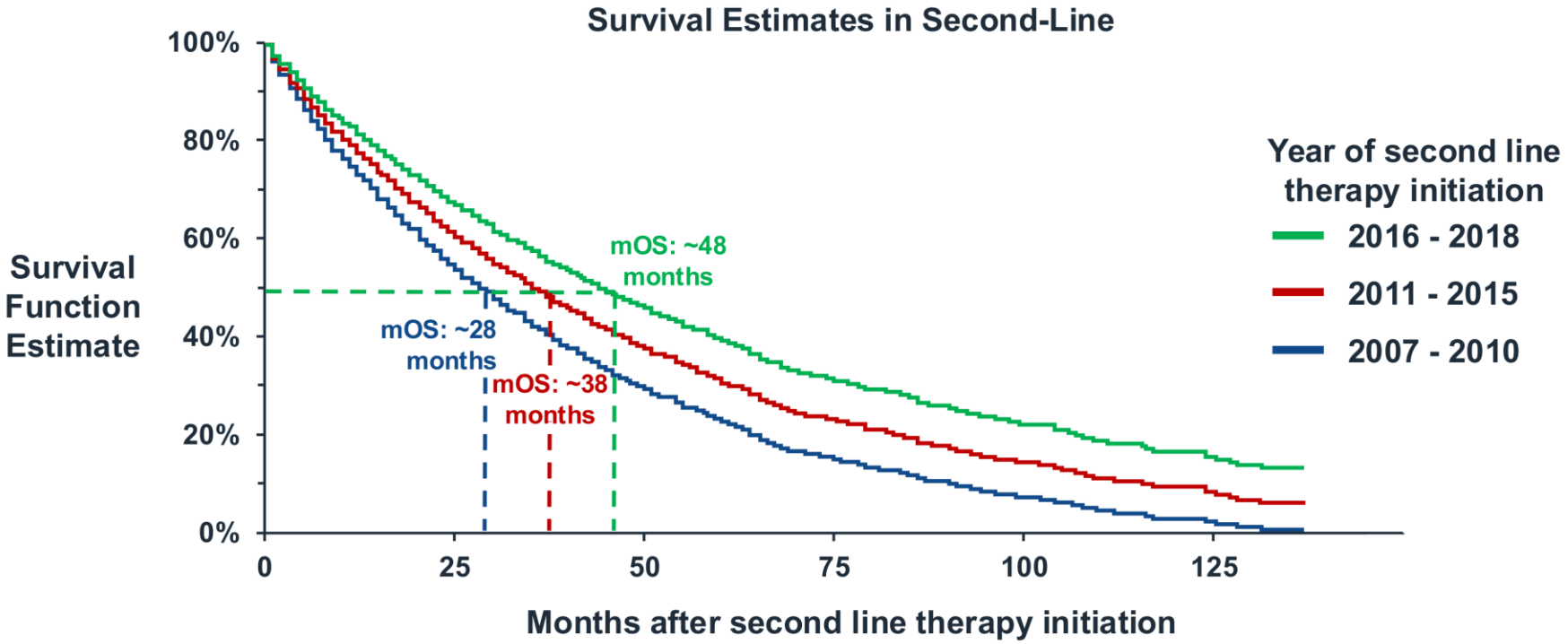
Dana-Farber Cancer Institute, Boston, MA

RJ Corman Professor of Medicine

Harvard Medical School

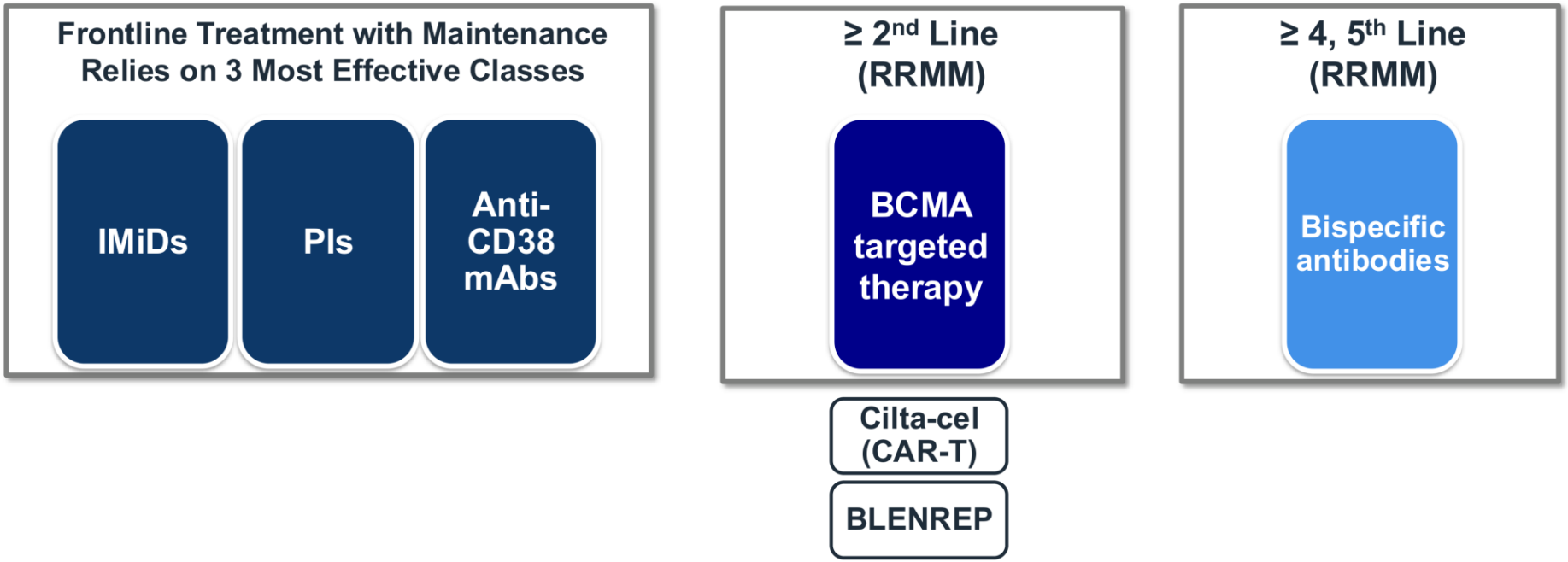
Not compensated for time

Survival has Improved, But Multiple Myeloma Remains an Incurable Disease



Leblanc et al., 2024

Treatment of MM in 2025: Critical Need for Novel MOAs, Targeting BCMA



IMiDs: immunomodulatory drugs (lenalidomide), PIs: proteasome inhibitors (bortezomib, carfilzomib), mAbs: CD38 monoclonal antibodies (daratumumab, isatuximab)
Adapted from Richardson, JSH 85th Annual Meeting, October 2023. Moreau, Lancet Oncol, 2021.

Only One Approved Option with OS Benefit in Second Line RRMM (2025)

Regimen	Indication: RRMM
DaraRd, DaraVd, IxaRd, Seli Vd, Kd	≥ 1 prior line
DaraPd	≥ 1 prior line, lenalidomide and PI
Ciltacabtagene-autoleucel	≥ 1 prior line, PI and IMID, refractory to lenalidomide
DaraKd, KRd, IsaKd, EloRd, Kd	1 to 3 prior lines of therapy
EloPd, IsaPd, Pd	≥ 2 prior lines, lenalidomide and PI
Idecabtagene-vicleucel	≥ 2 prior lines, IMID, PI and anti-CD38 mAb
Daratumumab	≥ 3 prior lines, PI and IMID or double refractory to a PI and IMID
Teclistamab, Talquetamab, Elranatamab, Linvoseltamab-gcpt	≥ 4 prior lines, IMID, a PI and an anti-CD-38 mAb
Seli-d	≥ 4 prior lines, ≥ 2 PIs, ≥ 2 IMIDs, and an anti-CD38 mAb

Updated and Adapted from FDA's BD Table 1; PI=Proteasome Inhibitor: V=bortezomib, K=carfilzomib, I=ixazomib. IMID=Immunomodulatory Drug: R=lenalidomide, P=pomalidomide. Anti-CD38 Monoclonal Antibodies: Dara=daratumumab, Isa=isatuximab. AntiSLAMF7 Monoclonal Antibody: Elo=elotuzumab. XPO1 Inhibitor: Seli=selinexor. Chimeric Antigen Receptor T-cell Therapies: ciltacabtagene autoleucel, idecabtagene vicleucel. Bispecific CD3 T-cell Engagers: teclistamab, elranatamab, talquetamab, linvoseltamab-gcpt. Other: d=dexamethasone.

CAR-Ts Show OS Improvement but Come with Significant Limitations

- **CAR-Ts in RRMM are not universally accessible or appropriate**[1,2]
  - Administered at specialized centers: < 20% of patients have access
  - Requires individual manufacturing
    - ~15% of patients in CAR-T trials did not receive infusions prior to progression or death[3]
- **Requires a fit younger patient who can tolerate lymphodepletion and potential complications**
- **Safety considerations**[4]: CRS, acute & late neurotoxicity (including ICANs, Parkinsonism), enterocolitis, infections and secondary malignancies;

  Real world non-relapse mortality ~10%[5]

ICANS = immune Effector Cell-Associated Neurotoxicity Syndrome; CRS = Cytokine Release Syndrome

1. Haslam, 2024; Gajra, 2022; 3. Wallington, 2025; 4. FDA Label for CAR-T products; 5. Sidana, 2025

Application of BLENREP to Real-World Practice: Important Considerations

- **Unique MOA**, including immunogenic cell death
- Need to consider **ease of administration,** availability, and **access for patients**, with community outreach
- **Delivery to community practice,** without need for hospitalization
- True **"off-the-shelf"** capability
- **Ease of integration** into current treatment paradigms
- **Profound efficacy** of BLENREP in patients with RRMM (including lenalidomide-refractory, CD-38 exposed and/or refractory, high-risk cytogenetics)

MOA: Mechanism of Action; Richardson, Blood Cancer Journal, 2020; Palwyn, Blood Cancer Journal, 2025; Richardson, Blood Cancer Journal, 2018

Dose Rationale and DREAMM-7 and DREAMM-8 Efficacy

Pralay Mukhopadhyay, PhD

Vice President

Medicine Development Leader, Oncology

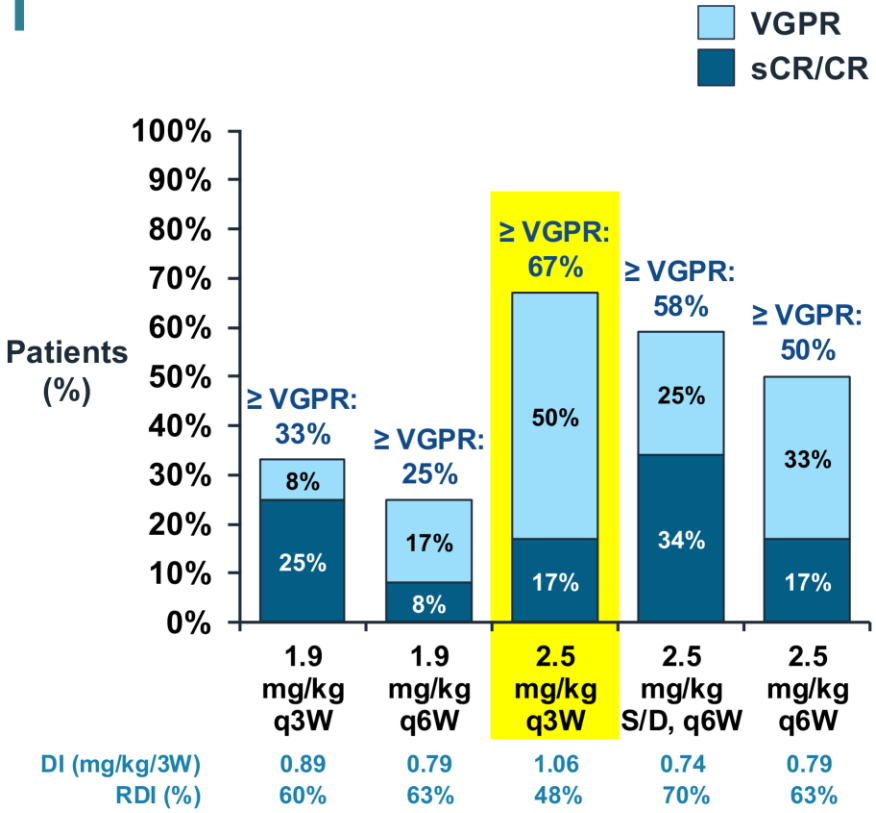
GSK

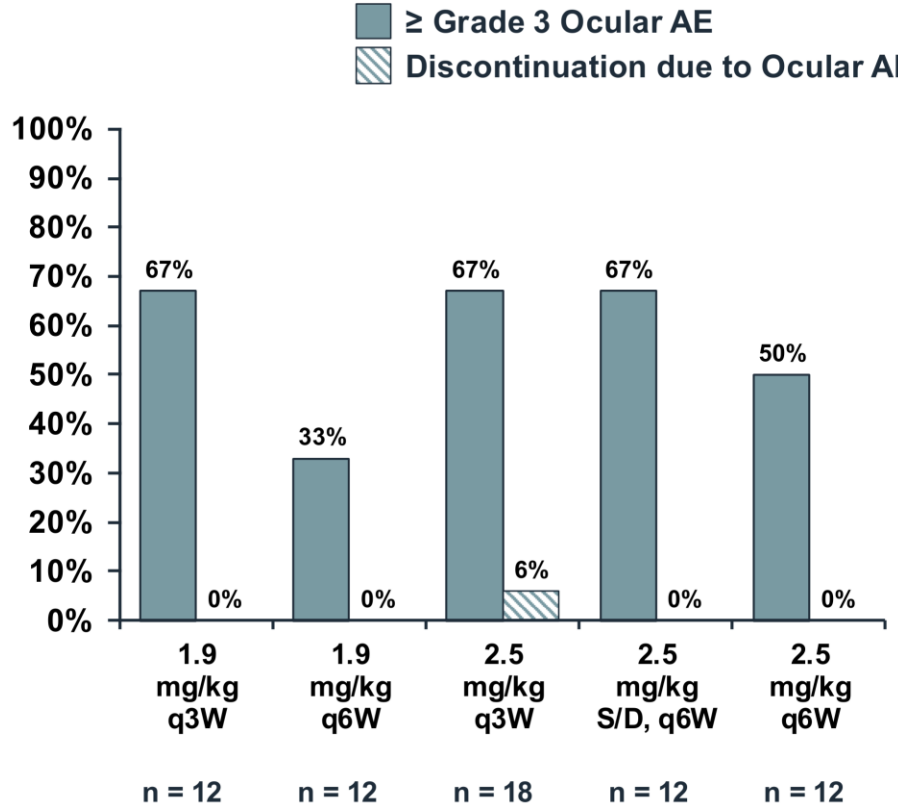
BLENREP Starting Dose and Schedule Extensively Assessed in RRMM (N=399*)

Exploration	Tested	Conclusions	Recommendation
Different starting doses	1.9 mg/kg 2.5 mg/kg 3.4 mg/kg	1.9 mg/kg lower efficacy with limited safety gain 3.4 mg/kg worse safety	2.5 mg/kg starting dose
Different starting schedules	D1 / D8, Q3 / 4W Q3 / 4W Q6 / 8W Q12W	Starting Q6W+ substantial loss in efficacy with modest safety improvement	Q3 / 4W selected
Proactive step down	Step to 1.9 mg/kg after Cycle 1	Similar efficacy and safety profile	2.5 mg/kg with or without proactive step down are viable options

*DREAMM-6, DREAMM-14, Algonquin

DREAMM-6: Higher Starting Dose and Frequency Support Deep Response

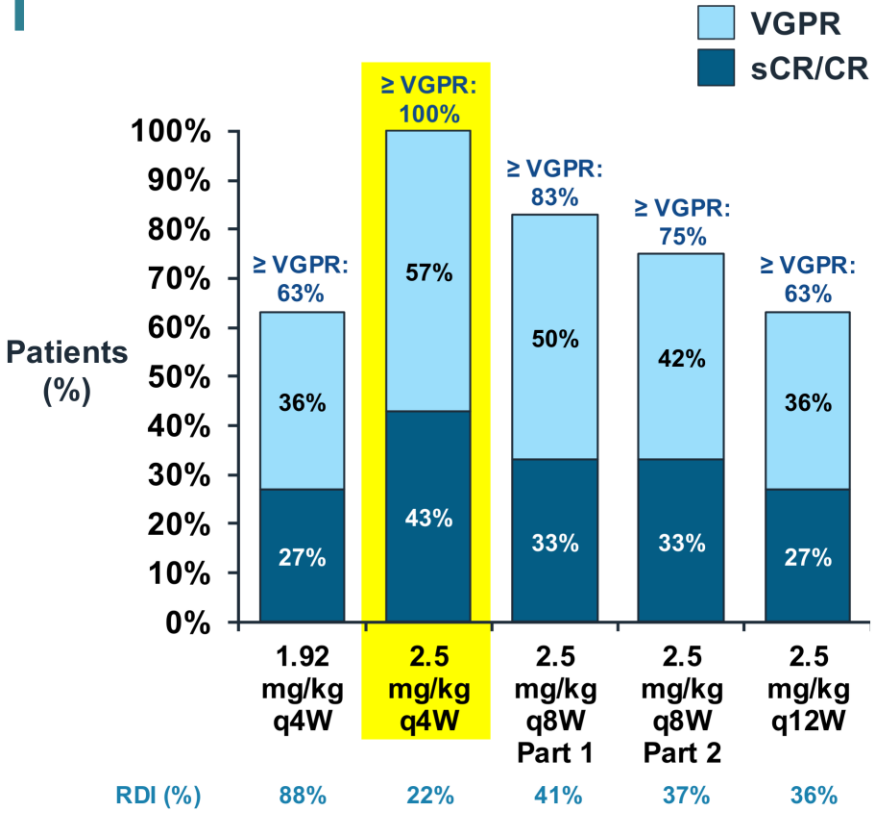


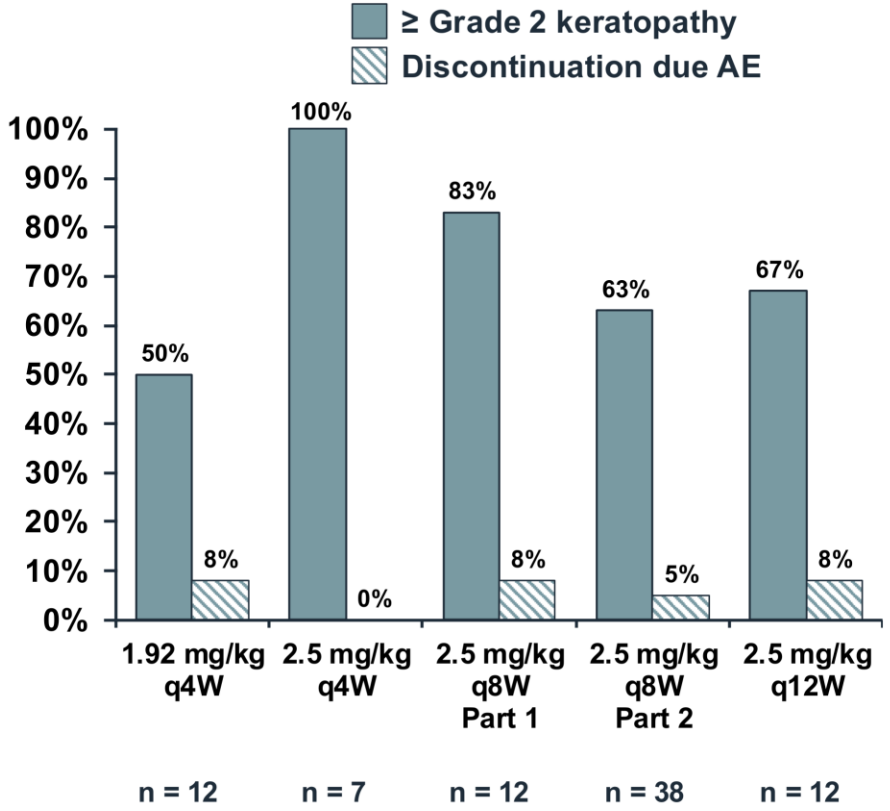


S/D = split dose; RDI = relative dose intensity; DI = dose intensity

All doses are +Vd

ALGONQUIN: Consistent Findings Supporting Deep Response with 2.5 mg/kg Starting Dose and Q4W Schedule

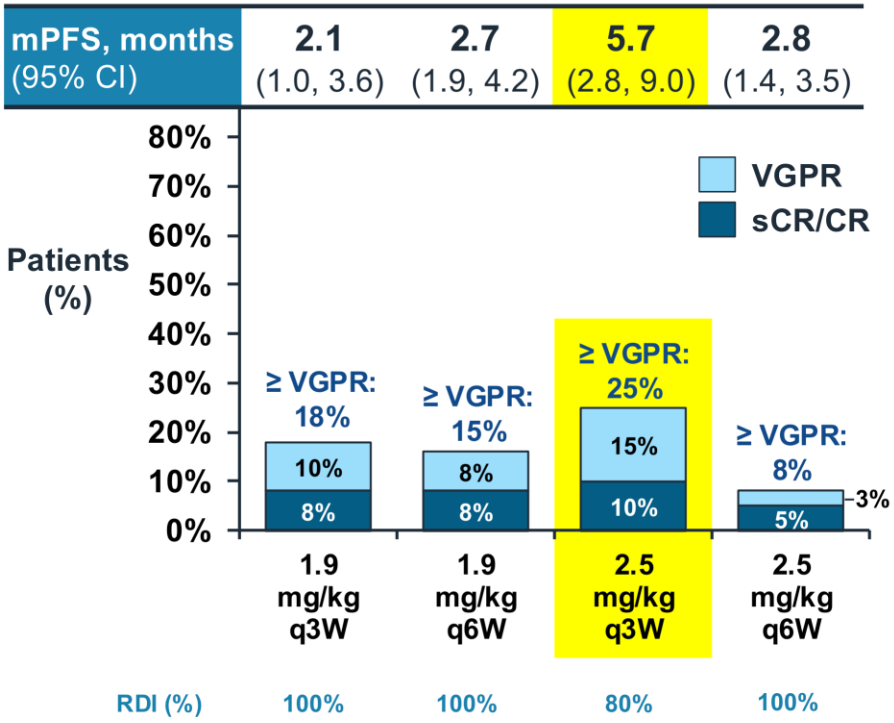


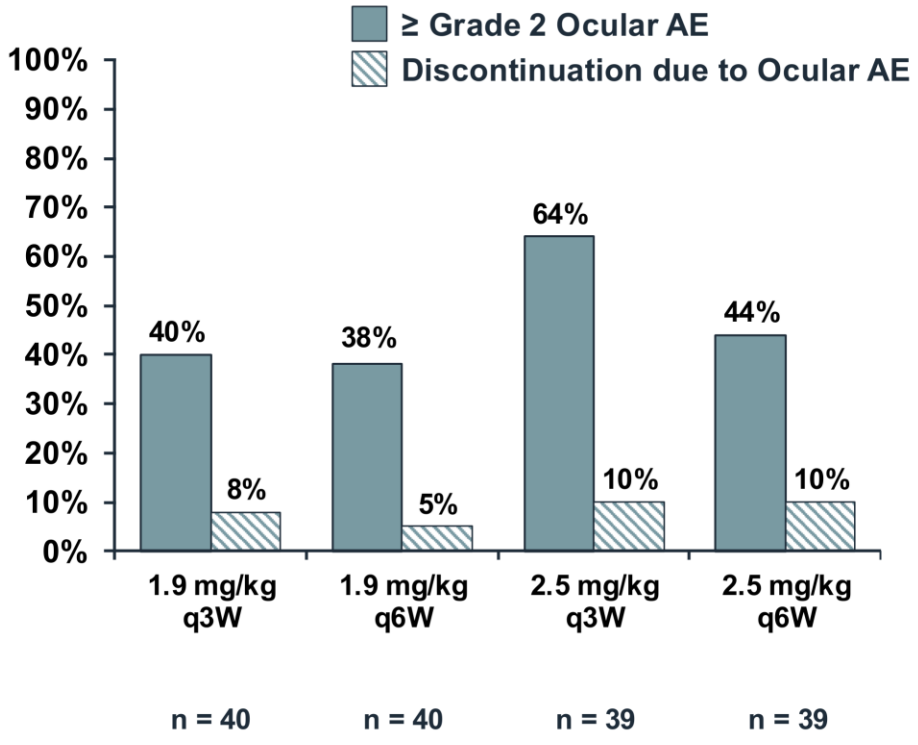


Trudel S, et al. Nature Med, 2023

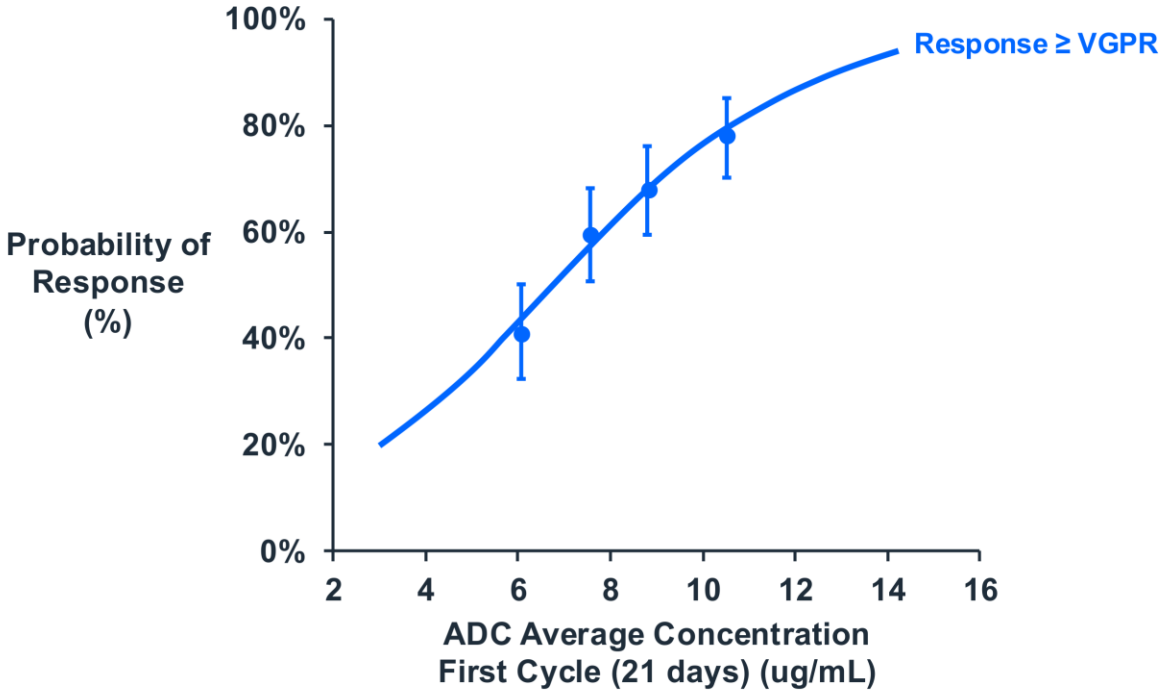
All doses are +Pd

DREAMM-14 (4L+): Continues to Show Same Trends Supporting Efficacy of 2.5mg/kg Q3W Dose and Schedule





Exposure-Response Supports 2.5 mg/kg as Optimal Starting Dose to Gain Deep Response

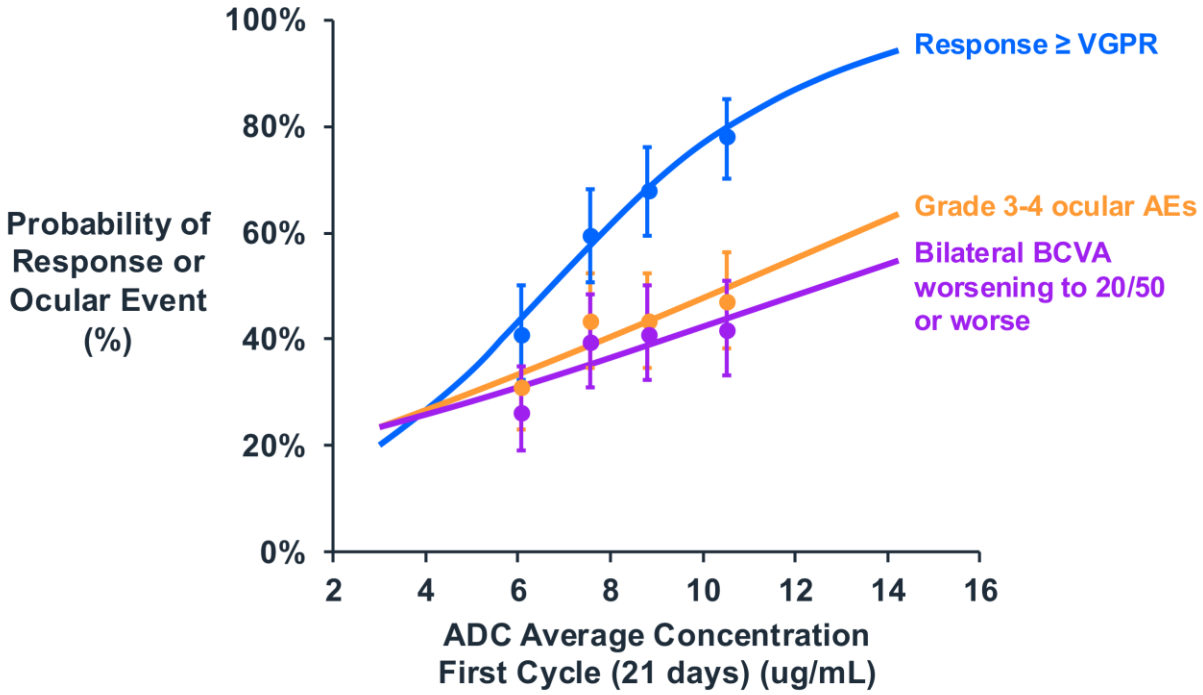


Multivariate Model Prediction
adjusted for baseline disease factors

Probability	1.9 mg/kg	2.5 mg/kg
VGPR+ response	54%	70%

Includes DREAMM-6, DREAMM-7, DREAMM-8

Lower Starting Doses Do Not Lessen Risk for Grade ≥ 3 Ocular Events

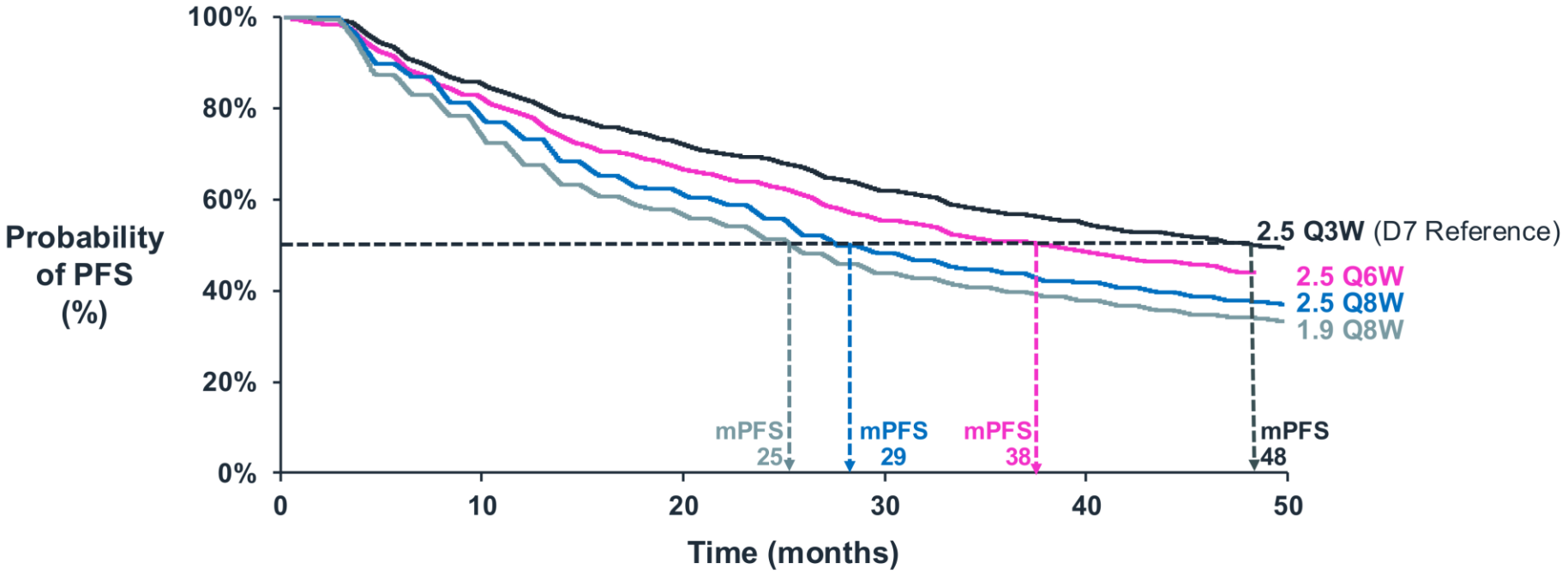


Multivariate Model Prediction
include effect of disease factors

Probability	1.9 mg/kg	2.5 mg/kg
VGPR+ response	54%	**70%**
Gr 3+ Ocular AEs	52%	52%
Bilateral BCVA worsening to 20/50 or worse	28%	33%

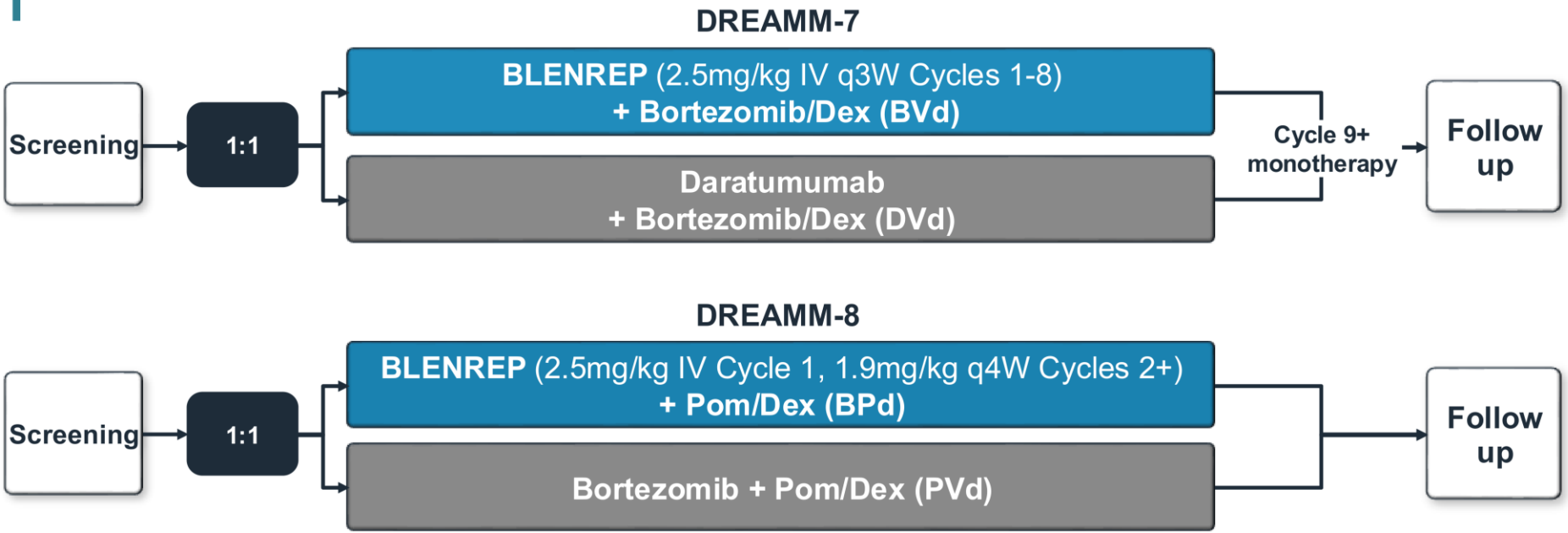
Includes DREAMM-6, DREAMM-7, DREAMM-8

Dose Simulations with Modifications Support DREAMM-7/-8 Doses: Meaningful Loss in PFS with Lower Starting Doses / Less Frequent Schedules



DREAMM-7 and DREAMM-8

DREAMM-7 and -8 Design



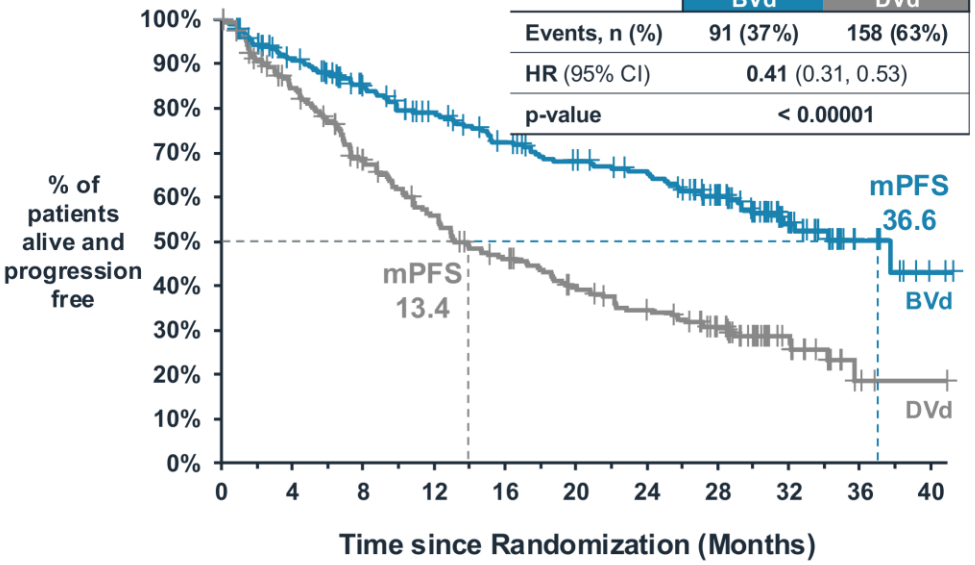
- **Primary: PFS**
- **Key Secondary: OS, DOR, MRD (CR/sCR)**
- **Others: PFS2, MRD (≥ VGPR), CRR, ORR, CBR, TTR, TTP, PROs**

DREAMM-7 and -8: PFS Primary Endpoint Met

DREAMM-7

~ 24-month improvement in mPFS

	BVd	DVd
Events, n (%)	91 (37%)	158 (63%)
HR (95% CI)	0.41 (0.31, 0.53)	
p-value	< 0.00001	



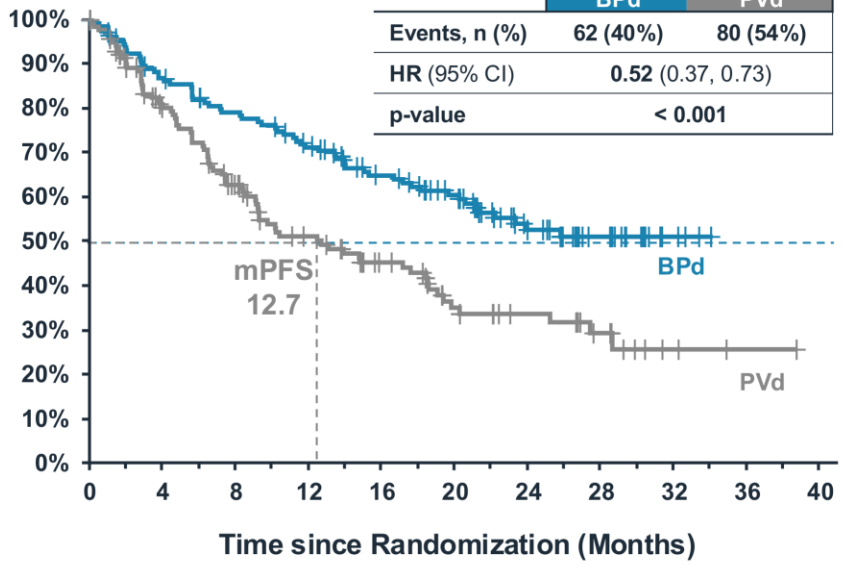
No. at Risk

BVd	243	205	175	155	137	125	115	79	31	8	1
DVd	251	194	148	115	94	78	65	39	12	1	0

DREAMM-8

mPFS NR at primary; mPFS 33-months at updated FU

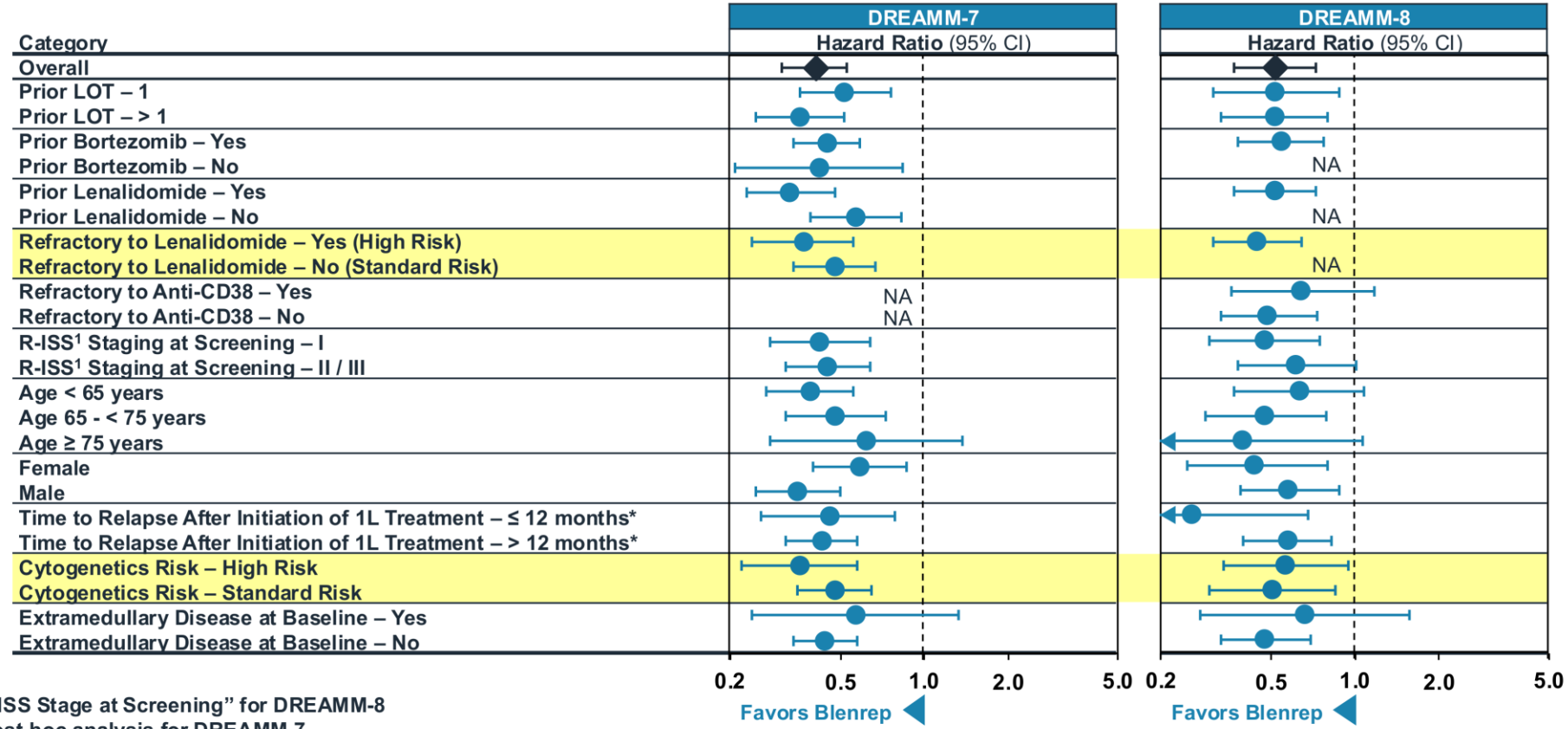
	BPd	PVd
Events, n (%)	62 (40%)	80 (54%)
HR (95% CI)	0.52 (0.37, 0.73)	
p-value	< 0.001	



BPd	155	125	111	97	77	64	38	21	4	0	0
PVd	147	102	75	54	40	25	18	11	3	1	0

BVd: BLENREP + Bortezomib/Dex; DVd: Daratumumab + Bortezomib/Dex; BPd: BLENREP + Pomalidomide/Dex; PVd: Bortezomib + Pomalidomide/Dex

PFS Benefit Seen Across Pre-Specified Subgroups

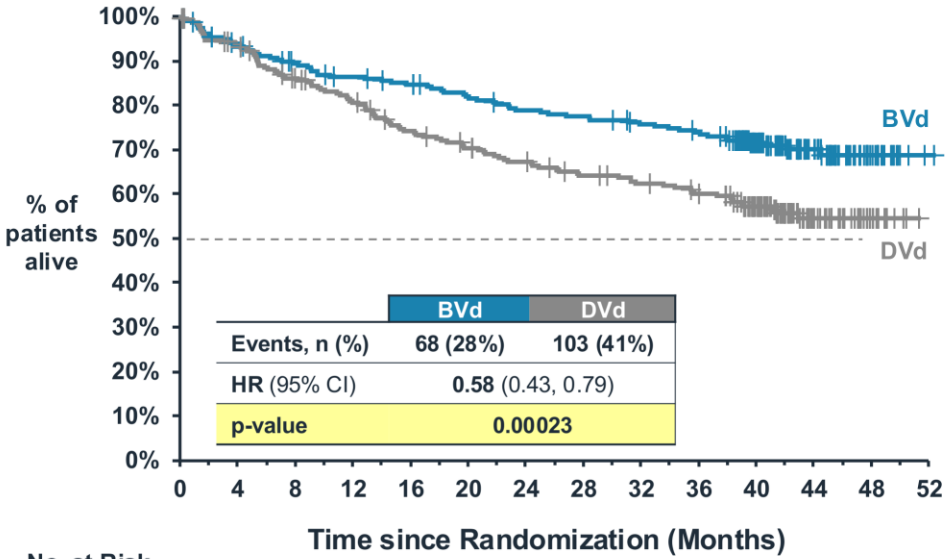


1."ISS Stage at Screening" for DREAMM-8
*Post-hoc analysis for DREAMM-7

Robust Overall Survival Improvements Favor BLENREP

DREAMM-7 (Interim Analysis 2)

Statistically Significant OS



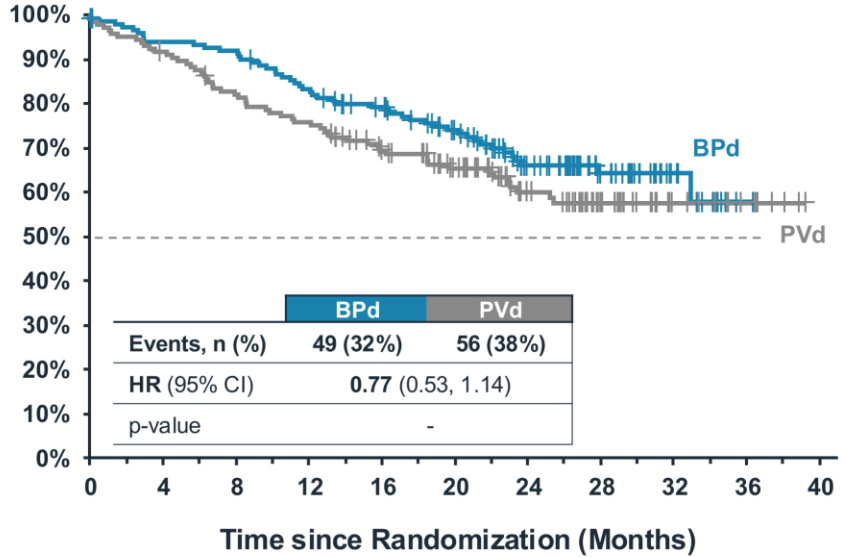
	BVd	DVd
Events, n (%)	68 (28%)	103 (41%)
HR (95% CI)	0.58 (0.43, 0.79)	
p-value	0.00023	

No. at Risk

BVd	243	222	209	200	194	185	177	174	167	162	126	58	17	1
DVd	251	231	207	192	174	163	154	144	138	131	99	37	13	0

DREAMM-8 (Interim Analysis 1)

Positive trend, follow-up ongoing



	BPd	PVd
Events, n (%)	49 (32%)	56 (38%)
HR (95% CI)	0.77 (0.53, 1.14)	
p-value	-	

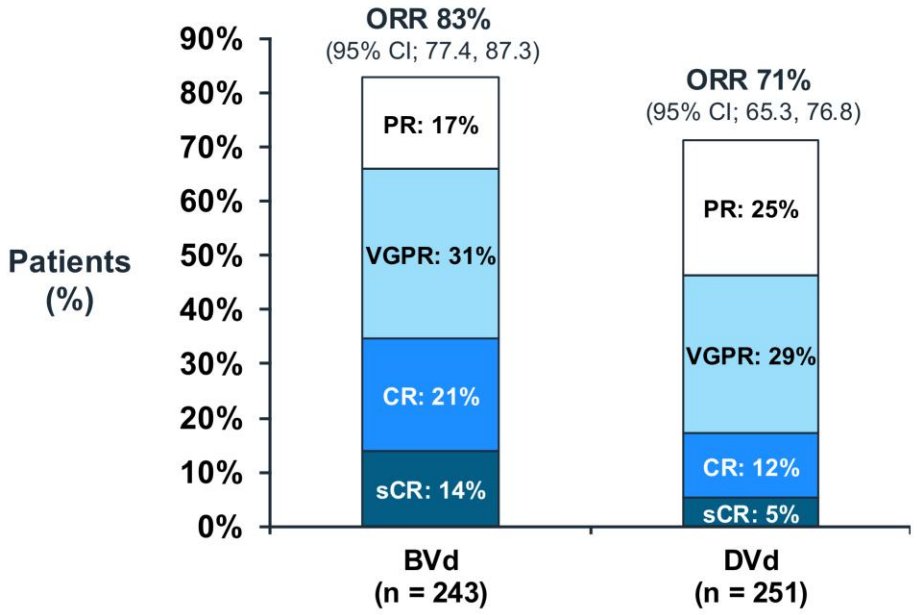
BPd	155	142	139	125	112	93	63	35	13	1	0
PVd	147	134	119	110	93	75	50	31	13	7	0

Median follow-up: DREAMM-7: 40.2 mo (BVd), 38.2 mo (DVd); DREAMM-8: 28.8 mo (BPd), 27.5 mo (PVd)

Improved ORR with BLENREP

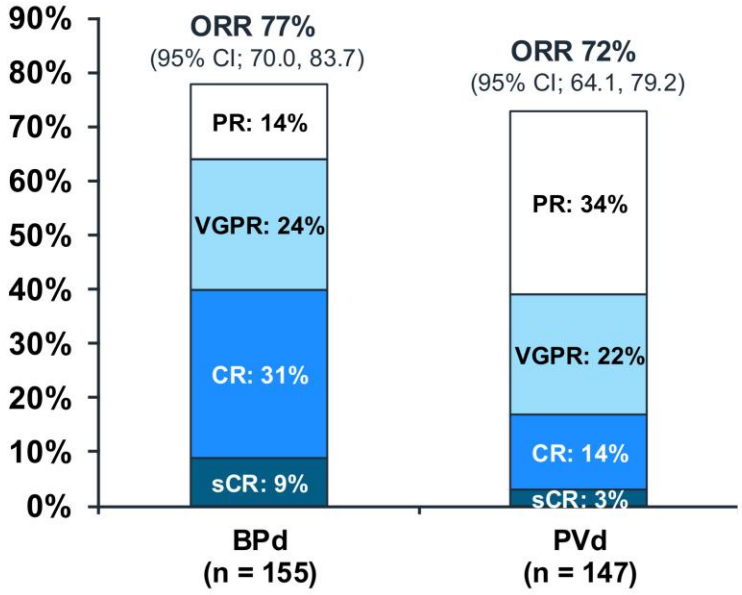
DREAMM-7

+12% Improvement in ORR



DREAMM-8

+5% Improvement in ORR

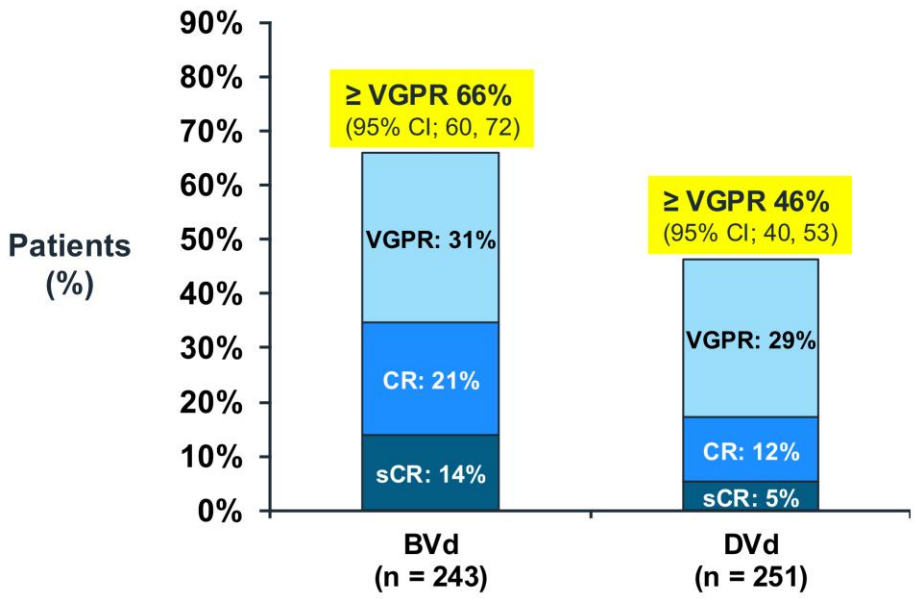


BVd: BLENREP + Bortezomib/Dex; DVd: Daratumumab + Bortezomib/Dex; BPd: BLENREP + Pomalidomide/Dex; PVd: Bortezomib + Pomalidomide/Dex

Deeper Response (≥ VGPR) with BLENREP Support PFS and OS Results[1]

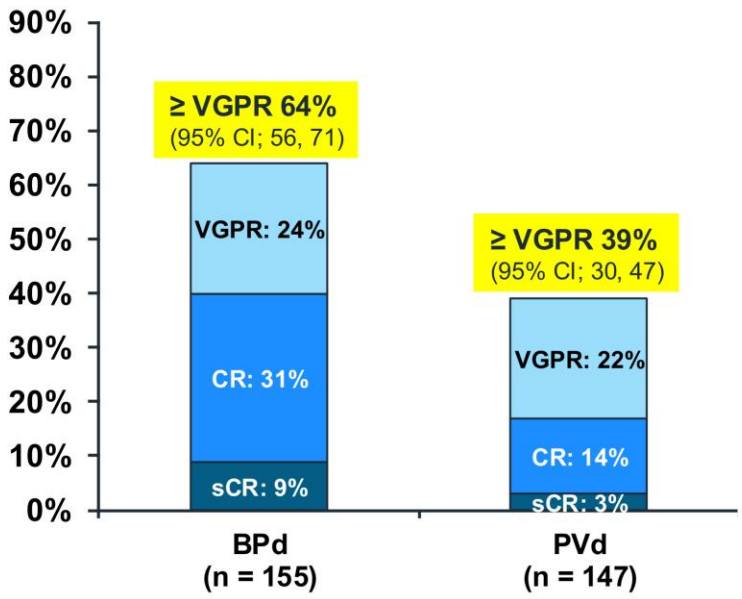
DREAMM-7

20% Absolute Increase in ≥ VGPR



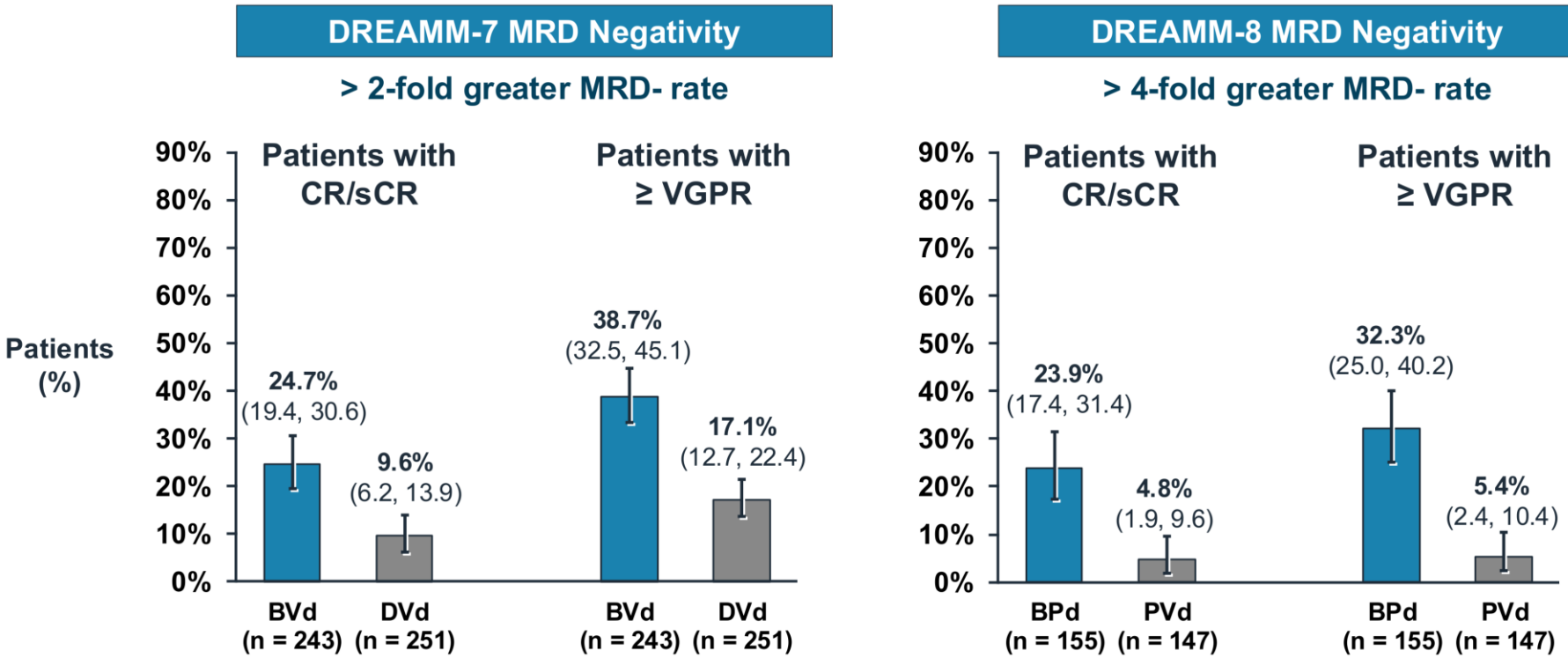
DREAMM-8

25% Absolute Increase in ≥ VGPR



1. Mangal, 2018 (VGPR+ drives PFS)
2. BVd: BLENREP + Bortezomib/Dex; DVd: Daratumumab + Bortezomib/Dex; BPd: BLENREP + Pomalidomide/Dex; PVd: Bortezomib + Pomalidomide/Dex

MRD-Negativity Favors BLENREP, Confirming Importance of Depth of Response



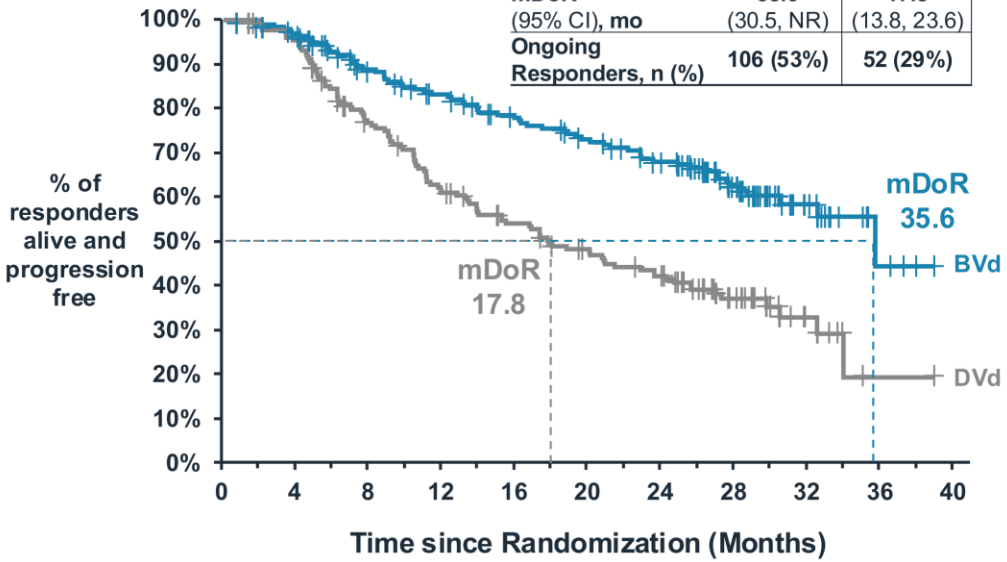
1. Munshi, 2020 (MRD negativity supports PFS and OS)

BVd: BLENREP + Bortezomib/Dex; DVd: Daratumumab + Bortezomib/Dex; BPd: BLENREP + Pomalidomide/Dex; PVd: Bortezomib + Pomalidomide/Dex

BLENREP Demonstrated Durable Responses Double that of Comparators

DREAMM-7

	BVd	DVd
Events, n (%)	68 (34%)	105 (59%)
mDoR (95% CI), mo	35.6 (30.5, NR)	17.8 (13.8, 23.6)
Ongoing Responders, n (%)	106 (53%)	52 (29%)

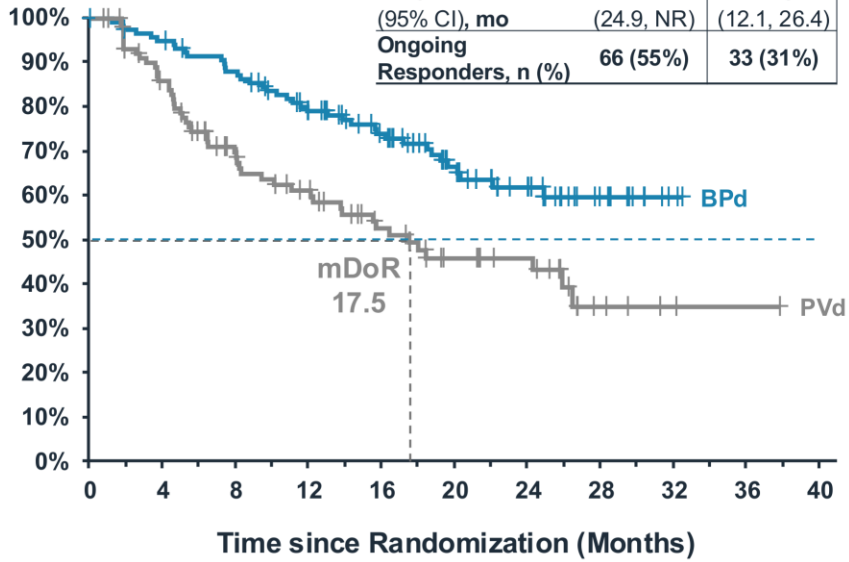


No. at Risk

BVd	201	189	160	145	130	119	104	67	23	4	0
DVd	179	168	128	101	85	72	61	31	9	1	0

DREAMM-8

	BPd	PVd
Events, n (%)	39 (33%)	49 (46%)
mDoR (95% CI), mo	NR (24.9, NR)	17.5 (12.1, 26.4)
Ongoing Responders, n (%)	66 (55%)	33 (31%)



No. at Risk

BPd	120	112	102	84	69	47	33	14	2	0	0
PVd	106	83	58	47	34	22	18	5	2	1	0

NR = Not Reached

DREAMM-7 and -8: Superior and Clinically Meaningful Efficacy Benefit

- Starting dose 2.5 mg/kg along with dose modifications resulted in robust efficacy

	~2-year improvement in mPFS ~3-year projected improvement in mOS			~20-month improvement in mPFS Positive OS trend		
	DREAMM-7		HR (95% CI)	DREAMM-8		HR (95% CI)
	BVd	DVd		BPd	PVd	
mPFS (months)	**36.6** (28.4, NR)	**13.4** (11.1, 17.5)	**0.41** (0.31, 0.53)	**NR** (20.6, NR)	**12.7** (9.1, 18.5)	**0.52** (0.37, 0.73)
mOS (months)	**NR**	**NR** (41.0, NR)	**0.58** (0.43, 0.79)	**NR** (33.3, NR)	**NR** (25.2, NR)	**0.77** (0.53, 1.14)

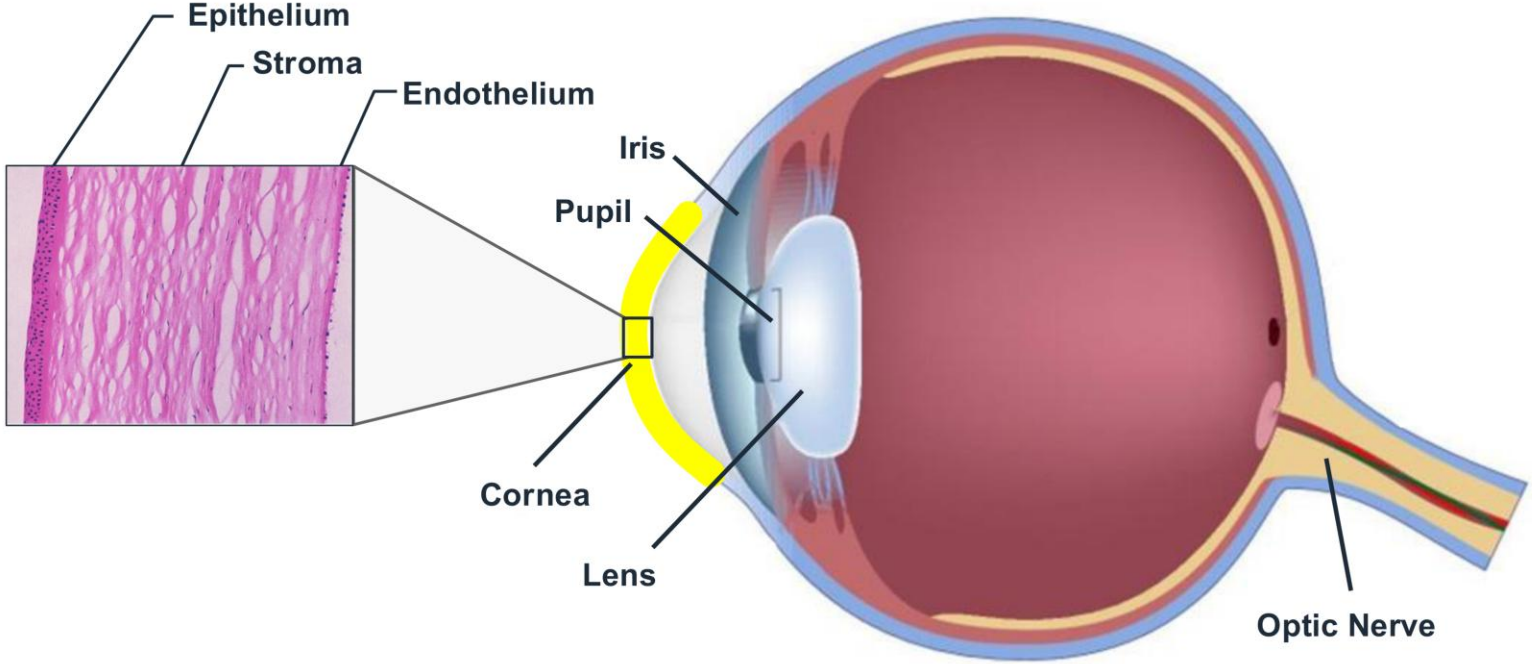
BVd: BLENREP + Bortezomib/Dex; DVd: Daratumumab + Bortezomib/Dex; BPd: BLENREP + Pomalidomide/Dex; PVd: Bortezomib + Pomalidomide/Dex

Characterization of Ocular Events and Safety Monitoring

Natalie Afshari, M.D.

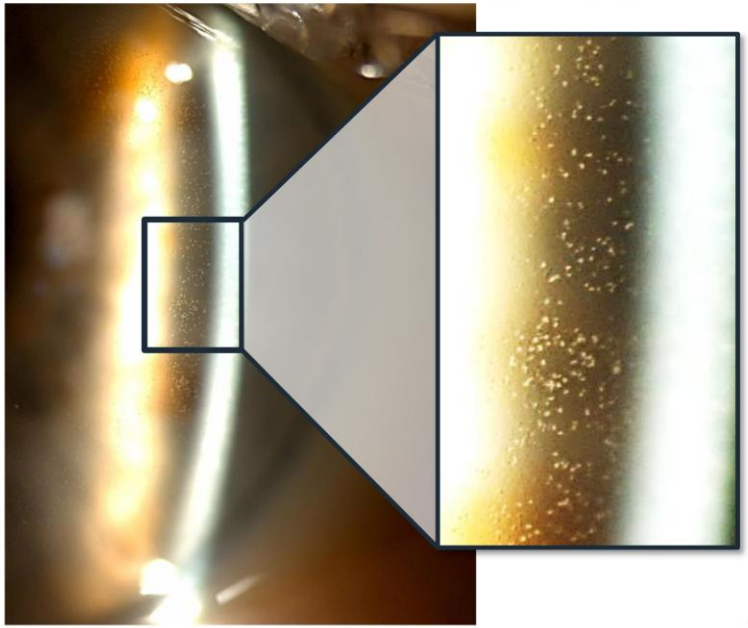
Stuart I. Brown MD Chair in Ophthalmology
in Memory of Donald P. Shiley
Professor of Ophthalmology
Chief of Cornea & Refractive Surgery
Shiley Eye Institute
University of California, San Diego

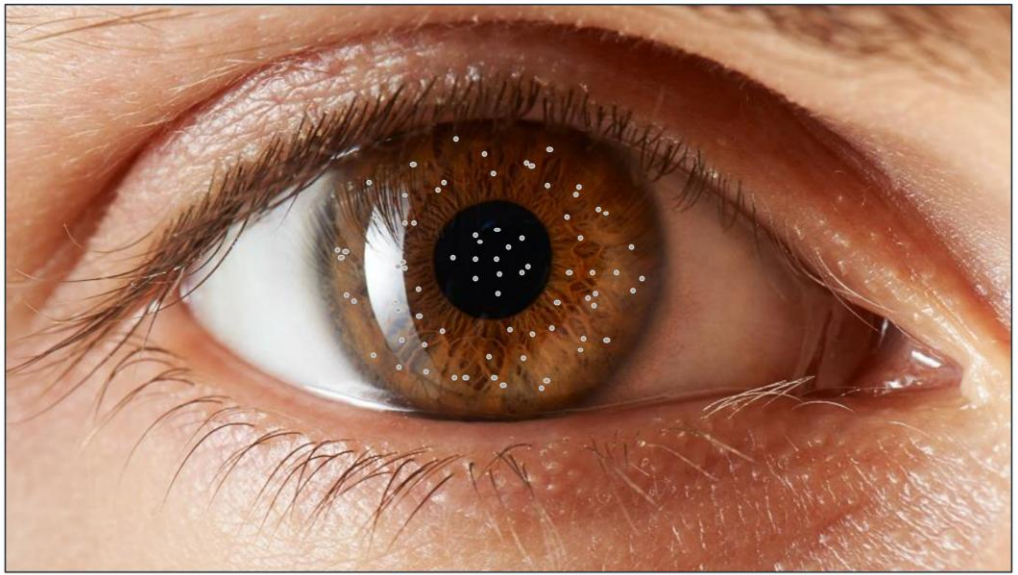
Anatomy of the Eye: Epithelium is Naturally Regenerating and Events Often Self-Limiting



Pathophysiology Supports Resolution of Ocular Events Associated with BLENREP

Side view of eye under slit lamp showing microcyst-like epithelial changes (MECs)[1]

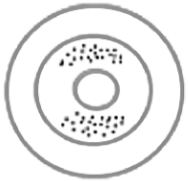
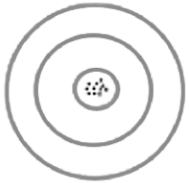
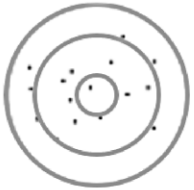
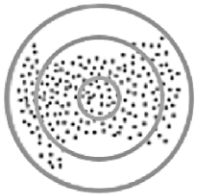




Microcyst-like deposits larger for representation, not to scale. Schematic example

1. Image from Shaohui Liu, MD, PhD

Keratopathy and Visual Acuity (KVA) Scale Created to Grade Both Slit Lamp Exam Findings and BCVA Results for Worse Eye

	KVA Grade 1	KVA Grade 2	KVA Grade 3	KVA Grade 4
Snellen Visual Acuity Scale	Decline of 1 line from baseline	Decline of 2 or 3 lines from baseline (not worse than 20/200)	Decline of >3 lines from baseline (not worse than 20/200)	Worse than 20/200
Slit Lamp Exam	Mild superficial keratopathy	Moderate superficial keratopathy Patchy microcyst-like deposits Peripheral subepithelial haze New peripheral stromal opacity	Severe superficial keratopathy Diffuse microcyst-like deposits Central subepithelial haze New central stromal opacity	Corneal epithelial defect (erosion or ulcer)
Slit Lamp Location In Eye				
Slit Lamp Concentration in Eye				

BCVA = best corrected visual acuity

Ocular Events Associated with BLENREP are Easily Identified

- Eye care providers routinely identify and manage ocular events
  - Also common with other ADCs
  - Easily identified on exam
- Eyes are unilaterally tested (one eye at a time)
- Bilateral vision (function of both eyes together) is most impactful to a patient
- Sponsor's KVA scale uses worst grade finding of worse eye to trigger dose modifications
- Reversible with time off drug allowing epithelium to heal

Clinical Safety Results

Zeshaan Rasheed, MD, PhD
Senior Vice President
Head of Oncology Clinical Development
GSK

Overview of Safety Profile

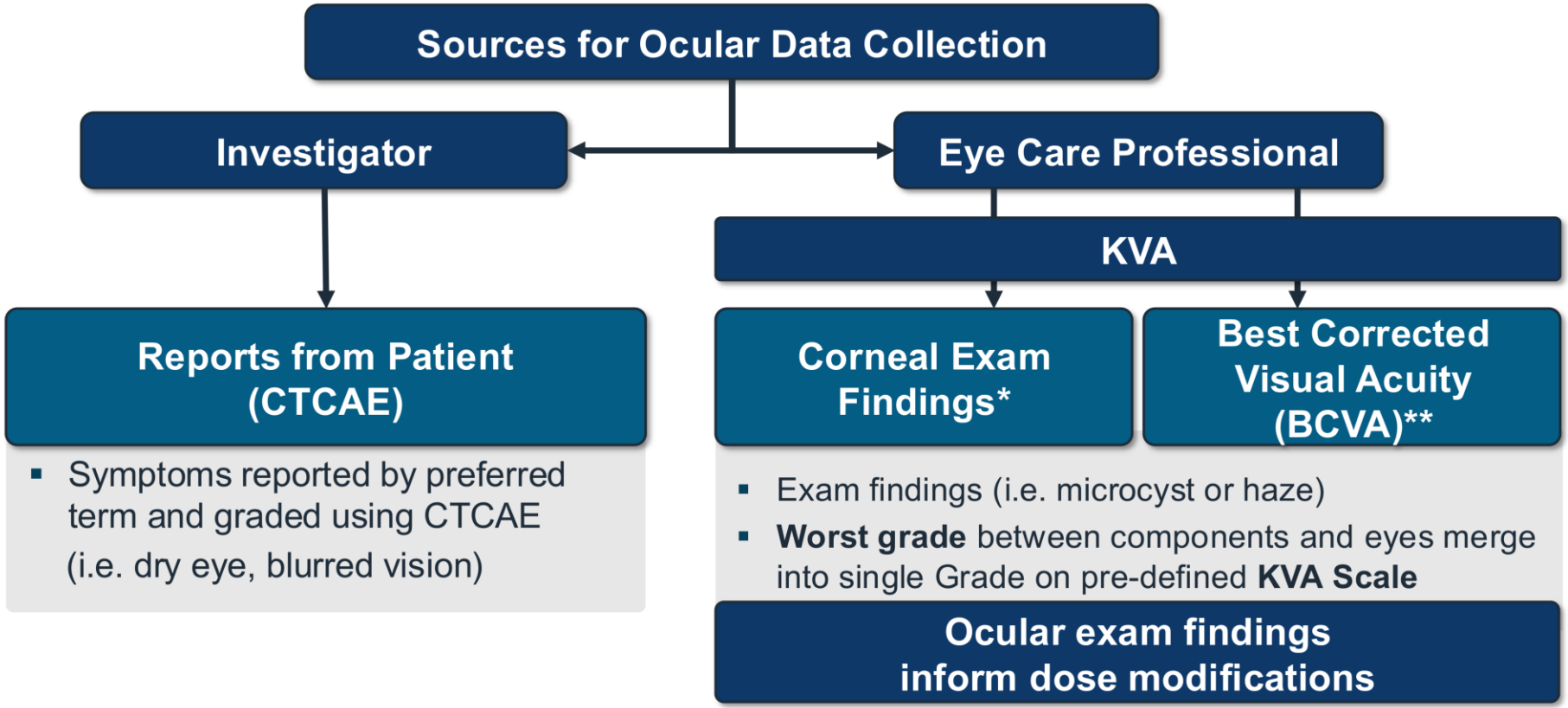
	Percent of Patients				Exposure-Adjusted Rates[1]			
	DREAMM-7		DREAMM-8		DREAMM-7		DREAMM-8	
	BVd N = 242	DVd N = 246	BPd N = 150	PVd N = 145	BVd N = 242	DVd N = 246	BPd N = 150	PVd N = 145
Any AE	100%	100%	99%	97%	60.2	71.7	59.8	91.3
Grade 3/4 AE	85%	72%	82%	66%	51.0	51.3	49.4	61.9
SAE	53%	38%	67%	47%	32.1	27.4	40.5	44.3
AEs leading to discontinuation of treatment	32%	19%	19%	14%	19.1	13.7	11.2	13.7
AEs leading to modification of treatment	98%	89%	91%	86%	58.9	64.2	55.0	81.5
Fatal SAEs	11%	8%	13%	12%	6.5	5.8	7.6	11.7

120-Day Update

BVd: BLENREP + Bortezomib/Dex; DVd: Daratumumab + Bortezomib/Dex; BPd: BLENREP + Pomalidomide/Dex; PVd: Bortezomib + Pomalidomide/Dex

1. Exposure-adjusted rates = total # of patients with event divided by total patient-years (per 100 PY). Total is sum of all exposure (last dose - first dose + 1) / 365.25

Comprehensive Assessments of Ocular Events



*Patients had to undergo routine slit lamp exams prior to every dose; **Captured by Snellen or equivalent score

Ocular-Related Dose Modifications Using Sensitive KVA Tool to Gain Timely Intervention

Patients with dose modification Type of modification	DREAMM-7 BVd N = 242	DREAMM-8 BPd N = 150
Dose modification due to ocular AE and/or KVA event*	**83%**	**84%**
Drug interrupted / delayed	78%	83%
Dose reduced	43%	59%
Study treatment withdrawn	10%	11%

- Median duration of dose hold: 8 weeks

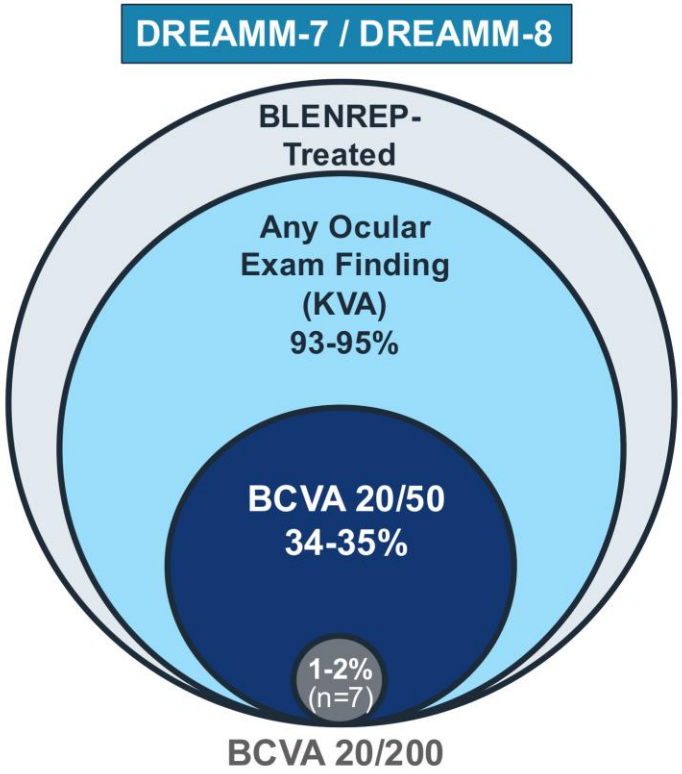
120-Day Update; *KVA based on ocular exam findings
BVd: BLENREP + Bortezomib/Dex; DVd: Daratumumab + Bortezomib/Dex; BPd: BLENREP + Pomalidomide/Dex; PVd: Bortezomib + Pomalidomide/Dex

DREAMM-7: Grade ≥ 2 KVA Recurrences Common with Consistent Pattern of Resolution

Occurrence, KVA Grade 2+	% Patients with Grade ≥ 2 KVA Finding[1] (N = 242)	% Occurrences Resolved to Grade ≤ 1 (N = 242)	Time to Resolution to Grade ≤ 1 (days)[2] Median (IQR) (N = 242)
1st	**88%**	**80%**	**117** (64, 294)
2nd	**60%**	**92%**	**96** (45, 148)
3rd	**48%**	**93%**	**102** (64, 134)
4th	**38%**	**95%**	**85** (47, 109)
5th	**33%**	**89%**	**97** (64, 117)
	All Occurrences 5,315 exams 899 occurrences	**87% Resolved** **13% Ongoing** 5% treatment ongoing 3% follow-up ongoing 5% withdrew/died	**85** (47, 127)

1. Based on all treated patients; 2. Based on patients with Grade ≥ 2 KVA event

Not All Ocular Exam Findings Result in Clinically Meaningful Vision Changes with BLENREP



BCVA 20/50

BCVA 20/200

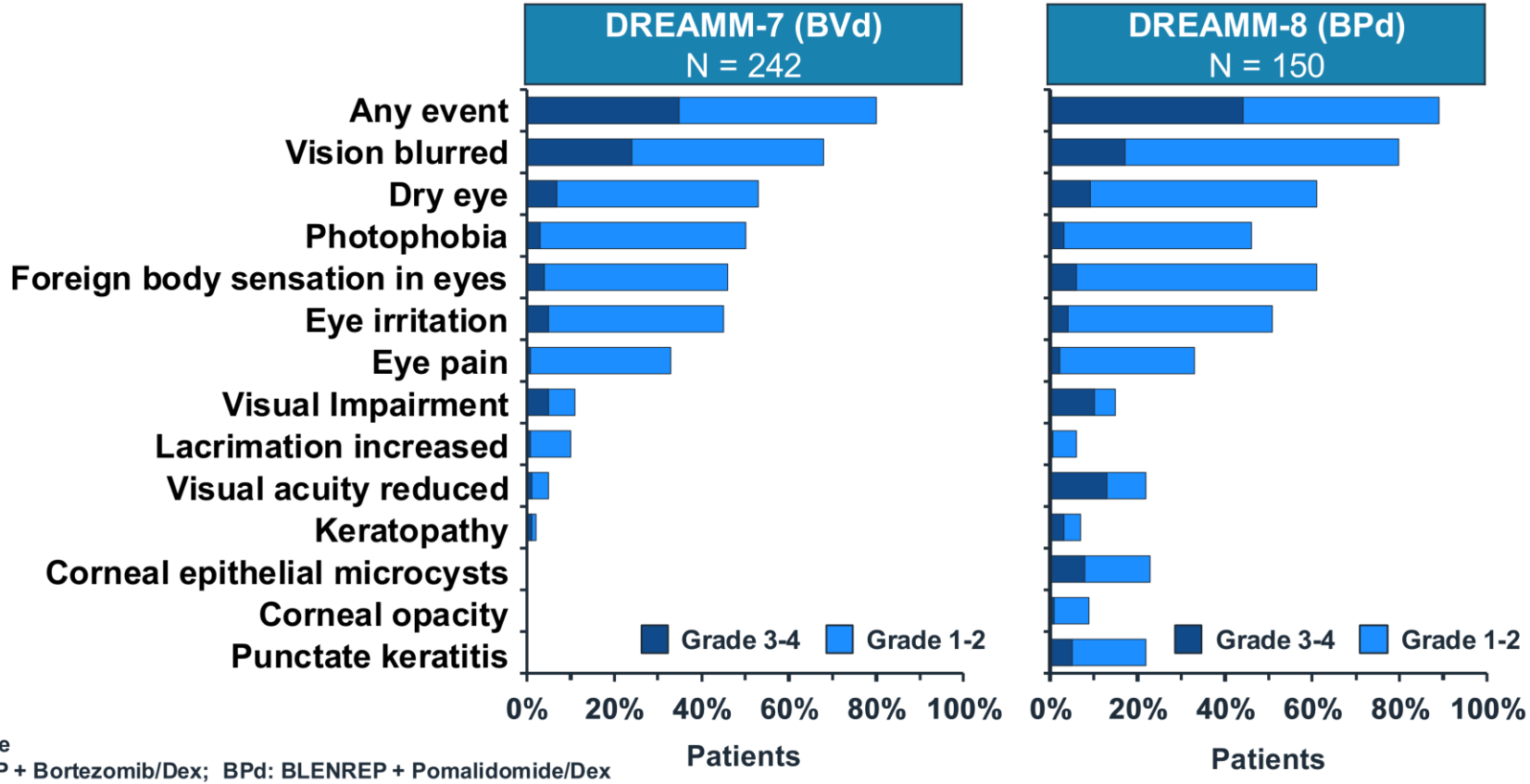
120-Day Update, visual acuity change for patients with normal baseline (20/25 or better) = 20/50 or worse in better seeing eye

DREAMM-7: Bilateral BCVA Changes Resolve with Time

	BVd N = 242	
First event	**20/50 or worse**	**20/200 or worse**
n **(%)**	84 **(35%)**	5 **(2%)**
Time to onset, days median (IQR)	**79** (45, 184)	**105** (93, 249)
Improvement*, %	**96%**	**100%**
Time to improvement (no longer 20/XX in at least one eye), days, median (IQR)	**22** (22, 33)	**19** (13, 22)
Resolution, %**	**93%**	**80%**
Time to resolution (20/25 or better in at least one eye), days, median (IQR)	**64** (33, 101)	**87** (51, 144)

Reason for unresolved BCVA: Patient still on treatment/in follow-up (possible future resolution), or died or withdrew (no future resolution data)
120-Day Update, BCVA 20/50 in patient with normal (20/25 or better baseline), *no longer bilateral 20/XX in ≥ 1 one eye, **resolved to 20/25 or better in ≥ 1 eye

Ocular CTCAE Reporting Rates Across Studies (> 5% of Patients within BVd/BPd arm)



120-Day Update
BVd: BLENREP + Bortezomib/Dex; BPd: BLENREP + Pomalidomide/Dex

PROs Informative to Understand Overall Patient Experience and Tolerability of BLENREP

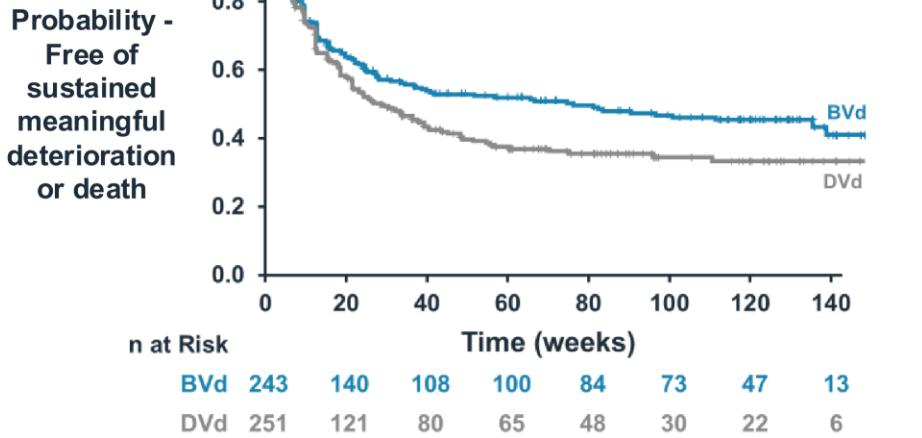
PRO Tool	Conclusions
PRO-CTCAE (Includes severity and interference of blurry vision in last 7 days)	• Consistent with known safety profile, more BLENREP patients reported interference with blurry vision or limitations with vision-related activities (reading, driving at night)
OSDI (Includes frequency of reading or driving at night limitations in last 7 days)	• Overall symptom bother was small but numerically higher than the comparator
FACT-GP5 (Bother of treatment side effects overall in last 7 days)	• Across scales, severity and impacts of blurry vision and treatment burden peaked around month 4, and then improved • Likely due to use of dose delay or reduction and supportive care
EORTC- QLQ-C30 / MY20 (General and disease-specific QoL)	• Overall quality of life was maintained and comparable between arms • Clinically meaningful delay in time to deterioration of physical functioning and time to worsening of disease-specific symptoms in BLENREP patients

DREAMM-7: Longer Time to Sustained Meaningful Deterioration in Physical Functioning and Disease Symptoms in BVd Arm

Physical Functioning

Strenuous activities, walking, self care

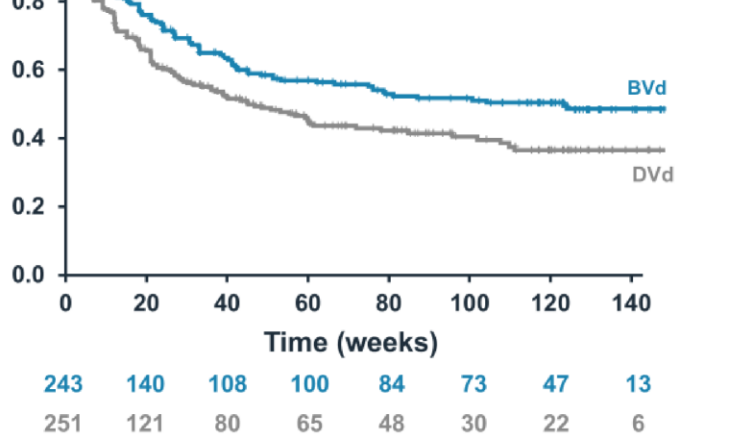
	BVd	DVd
Median time to event, months	18.6	6.7
HR (95% CI)	**0.74** (0.58, 0.94)	



Disease Symptoms

Bone aches, pain in back, arm/shoulder pain, hip pain, chest pain, pain with increase activity

	BVd	DVd
Median time to event, months	28.4	10.8
HR (95% CI)	**0.67** (0.51, 0.86)	



Meaningful change from baseline in the PRO score greater than or equal to predefined meaningful within-patient deterioration defined as 13.3 for Physical Functioning and 11.1 for Disease Symptoms. Sustained from baseline is observed at least in two consecutive assessments.

Ocular Risk Management Strategy Enables Patients to Access Treatment While Ensuring Safe Use

- Clinical trial and real-world experience in > 7500 patients has highlighted a consistent safety profile
- Totality of data characterizes AE profile, including ocular events, to best inform patients and healthcare professionals
- Physicians and patients educated prior to BLENREP treatment
- Patients receive ocular exams as part of BLENREP treatment as per labeling
  - Prescriber confirmation of ocular exams
  - Clinician to hold/reduce therapy based on exam findings

Dose Modification Guidance for Treatment with BLENREP

Ocular Exam Evaluation (Slit Lamp + BCVA)	Recommended Actions for Oncologist
Grade 1: Mild superficial keratopathy or BCVA decline of 1 line	• Continue BLENREP at current dose
Grade 2: Moderate superficial keratopathy, patchy microcyst-like deposits or BCVA decline of 2 lines	• Withhold BLENREP until both corneal exam finding and BCVA change become Grade 1, then resume at reduced dose
Grade 3: Severe superficial keratopathy, diffuse microcyst-like deposits or BCVA decline of ≥ 3 lines	
Grade 4: Corneal epithelial defect or ulcer or BCVA worse than 20/200	• Consider BLENREP discontinuation • If continuing treatment, hold BLENREP until Grade 4 becomes Grade 1, then resume at reduced dose

Abridged version of proposed USPI grading of pre-dosing severity from ocular exam (KVA); Based on guidance used in DREAMM-7 and -8

BLENREP Safety Profile is Well-Characterized and Manageable

- Ocular events are common; can be easily identified and are reversible
- Dose modifications allow patients to stay on treatment and continue to derive benefit
- No confirmed permanent bilateral vision loss
- Patients' overall QoL maintained from baseline, despite transient impacts to vision-related function
- GSK has developed a comprehensive ocular risk management strategy to support safe use of BLENREP in clinical practice

Clinical Perspective

Sagar Lonial, MD, FACP

Chair and Professor

Department of Hematology and Medical Oncology

Anne and Bernard Gray Family Chair in Cancer

Chief Medical Officer

Winship Cancer Institute

Emory University School of Medicine

Not compensated for time

Patients with RRMM Need Effective Therapies with Novel MOA

- MM is incurable, disease will ultimately progress
- Mortality remains high
- Every treatment has side effects to be communicated to patients for shared decision making
- All available options carry benefits and risks
  - Patients deserve options for personalized care
- Need to take advantage of new targets and new MOAs

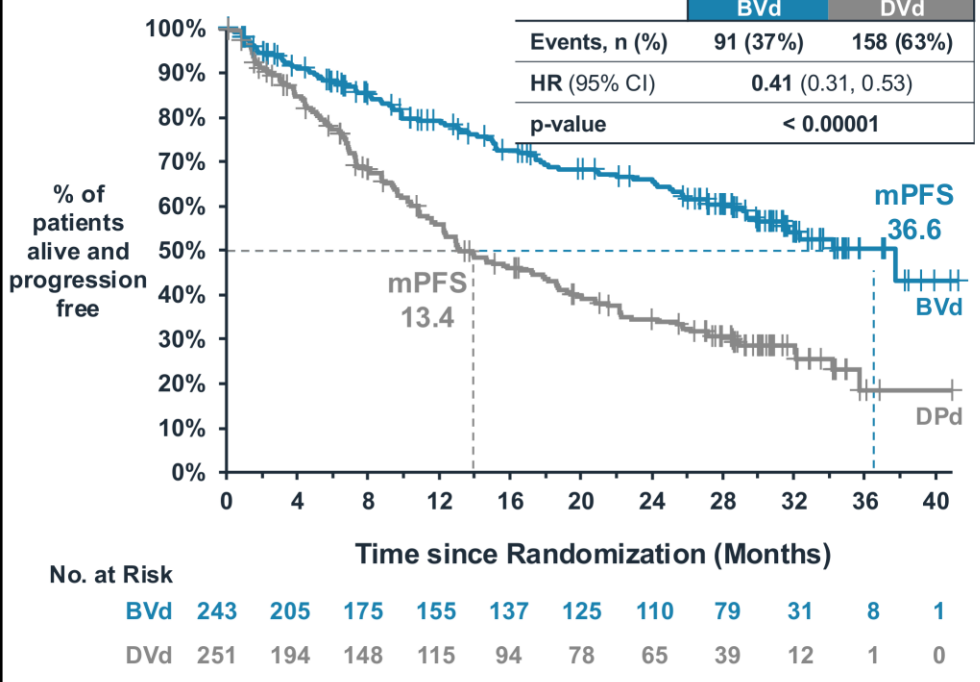
Contextualizing Benefit-Risk

- Is the efficacy observed meaningful?
- Are safety events manageable?
  - What is the impact of ocular events on the patient?
  - How to use individualized dosing to manage toxicity?
- How does the benefit-risk profile compare with other options in the same space?

Does the benefit outweigh the risk?

Transformative PFS in DREAMM-7 and -8 Using Recommended Dose Schedule and Modifications

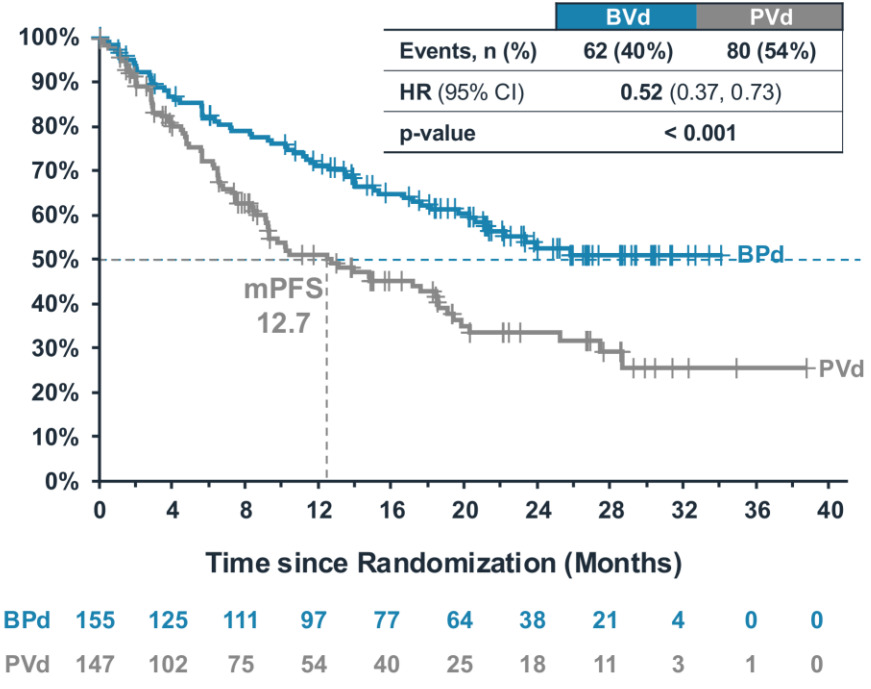
DREAMM-7



No. at Risk

BVd	243	205	175	155	137	125	110	79	31	8	1
DVd	251	194	148	115	94	78	65	39	12	1	0

DREAMM-8

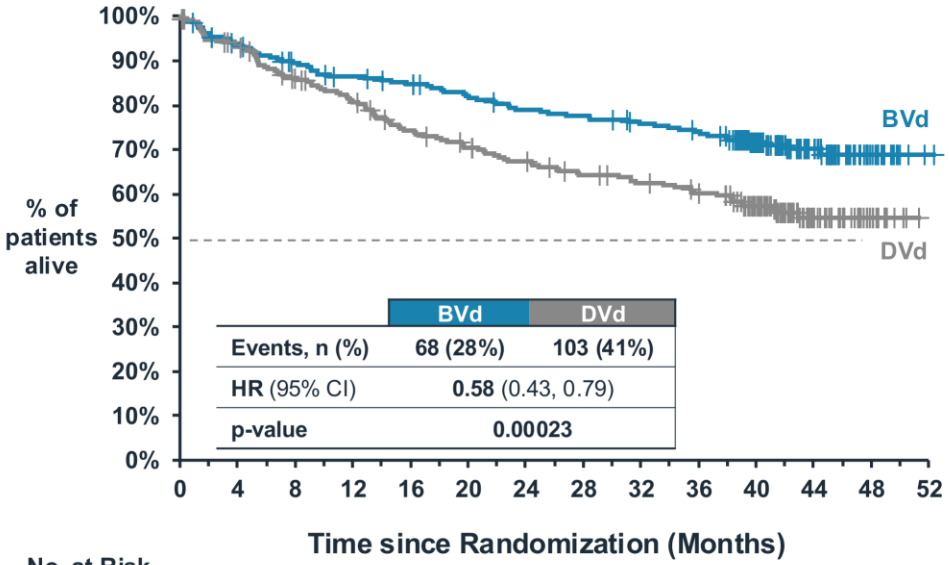


BPd	155	125	111	97	77	64	38	21	4	0	0
PVd	147	102	75	54	40	25	18	11	3	1	0

BVd: BLENREP + Bortezomib/Dex; BPd:BLENREP + Pomalidomide/Dex; DPd: Daratumumab + Bortezomib/Dex; PVd: Bortezomib + Pomalidomide /Dex

Transformative OS in DREAMM-7, Positive Trend in DREAMM-8 Using Recommended Dose Schedule and Modifications

DREAMM-7*

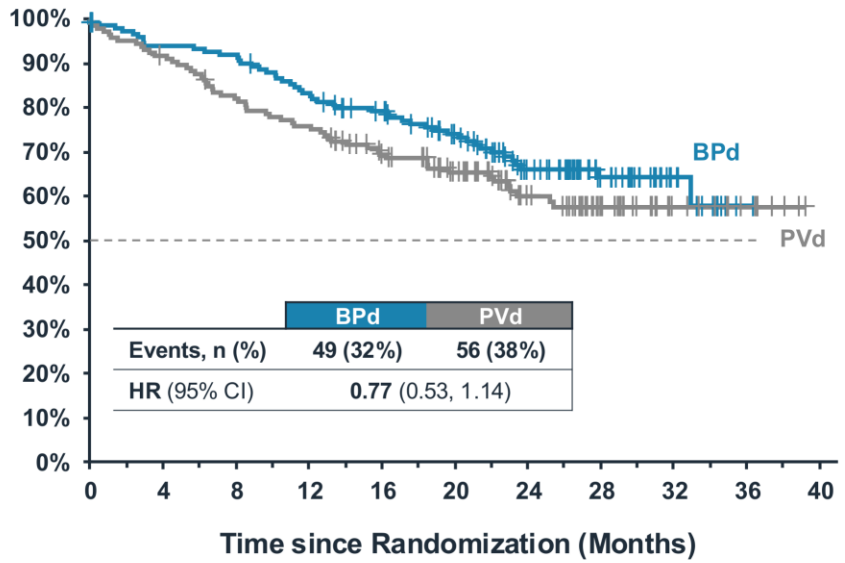


	BVd	DVd
Events, n (%)	68 (28%)	103 (41%)
HR (95% CI)	0.58 (0.43, 0.79)	
p-value	0.00023	

No. at Risk

BVd	243	222	209	200	194	185	177	174	167	162	126	58	17	1
DVd	251	231	207	192	174	163	154	144	138	131	99	37	13	0

DREAMM-8



	BPd	PVd
Events, n (%)	49 (32%)	56 (38%)
HR (95% CI)	0.77 (0.53, 1.14)	

BPd	155	142	139	125	112	93	63	35	13	1	0
PVd	147	134	119	110	93	75	50	31	13	7	0

*DREAMM-7 IA2

Ocular Events Can be Managed with Dose Modifications

- Ocular events common, well understood
- Visual acuity changes with BLENREP are transient
  - ~70% of patients free from meaningful changes
  - Patients' vision returns to baseline with sufficient follow-up
  - No permanent bilateral vision loss
- Clear guidance on dose modifications, allows for continued therapy without impacting efficacy

Contextualizing the BLENREP Efficacy Data

Efficacy	BLENREP (BVd) DREAMM-7	BLENREP (BPd) DREAMM-8	Cilta-Cel CART-4
12-month PFS	**78%**	**71%**	**76%**[a]
HR (95% CI)	**0.41** (0.31, 0.53)	**0.52** (0.37, 0.73)	**0.41** (0.30, 0.56)[b]
12-month duration of response (DOR)	**83%**	**79%**	**85%**[a]
24-month survival (OS)	**79%**	**NC***	**79%**[c]
HR (95% CI)	**0.58** (0.43, 0.79)	**0.77** (0.53, 1.14)	**0.55** (0.39, 0.79)[d]

Safety	BLENREP	Cilta-Cel
Toxicity profile	Ocular events, cytopenias, infections	Neurotoxicity, CRS, Parkinsonism, infections, enterocolitis, secondary malignancies

Excerpted from published pivotal studies and USPI; NC: not computed; * Follow-up for OS ongoing
a.) San-Miguel et al., NEJM 2023; b.) Cilta-Cel USPI; c.) ODAC briefing document, 15 March 2024; d.) Mateos et al., IMS presentation 2024

BLENREP Data Supports a Positive Benefit-Risk

Risk	Benefit
Patients likely to experience an ocular event	**Patients likely to experience a meaningful response**
▪ Well-characterized safety profile ▪ Events managed with dose modifications ▪ Objective ocular exam findings do not often correlate with meaningful changes in vision ▪ Visual changes reversible with time	▪ BCMA most specific target for MM ▪ Meaningful PFS and OS ▪ Deep, durable responses driven by initial dosing ▪ Improvements in MRD ▪ Ease of administration

BLENREP fulfills unmet need as a novel, effective, manageable, BCMA targeting agent that is easily accessible for patients with 2L+ RRMM

BLENREP (belantamab mafodotin) for Patients with Relapsed Refractory Multiple Myeloma (RRMM)

Oncologic Drugs Advisory Committee

July 17, 2025

GSK

End of Presentation

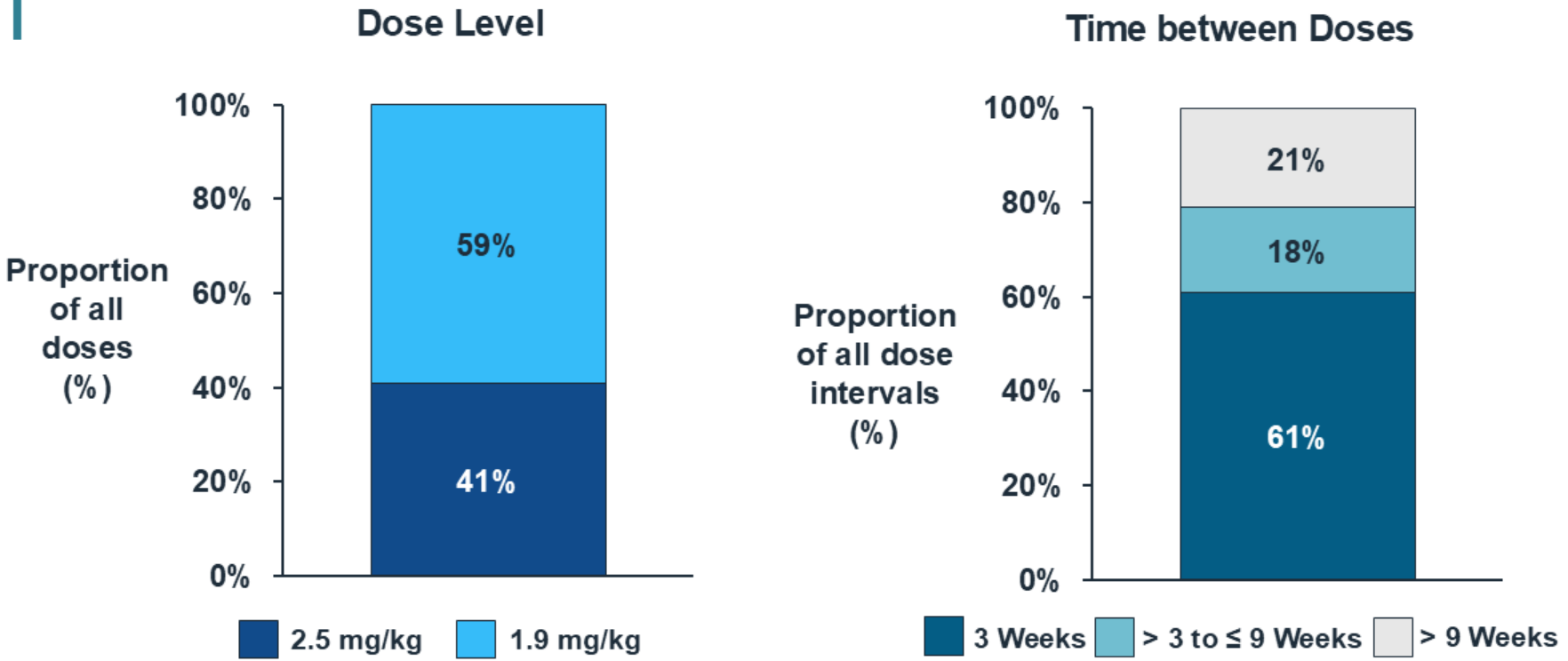
Backup Slides Shown During Question & Answer

DREAMM-7 & DREAMM-8: BLENREP Dose Intensity Over Time

	DREAMM-7 (BVd)		DREAMM-8 (BPd)	
Dose intensity (mg/kg/cycle*)	**N**	**Median** (IQR)	**N**	**Median** (IQR)
Overall	**242**	**1.27** (0.72, 2.22)	**150**	**1.04** (0.68, 1.8)
0 - ≤ 6 months	**242**	**1.91** (1.36, 2.48)	**150**	**1.61** (1.03, 2)
> 6 - ≤ 12 months	**162**	**1.71** (0.96, 1.91)	**109**	**0.66** (0.46, 1.3)
> 12 months	**132**	**0.7** (0.46, 1.43)	**82**	**0.71** (0.57, 0.9)
Relative dose intensity, %	**N**	**Median** (IQR)	**N**	**Median** (IQR)
Overall	**242**	**51** (29, 89)	**150**	**52** (34, 91)
0 - ≤ 6 months	**242**	**77** (55, 99)	**150**	**78** (48, 99)
> 6 - ≤ 12 months	**162**	**68** (38, 76)	**109**	**35** (24, 68)
> 12 months	**132**	**28** (18, 57)	**82**	**37** (30, 47)

*Q3W for DREAMM-7, Q4W for DREAMM-8

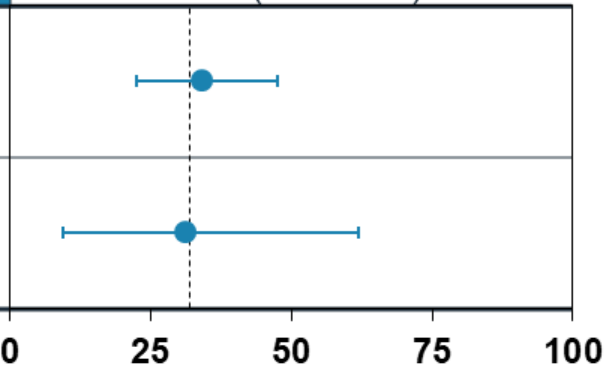
DREAMM-7: BLENREP Dose Level and Time Between Doses Through Study Duration



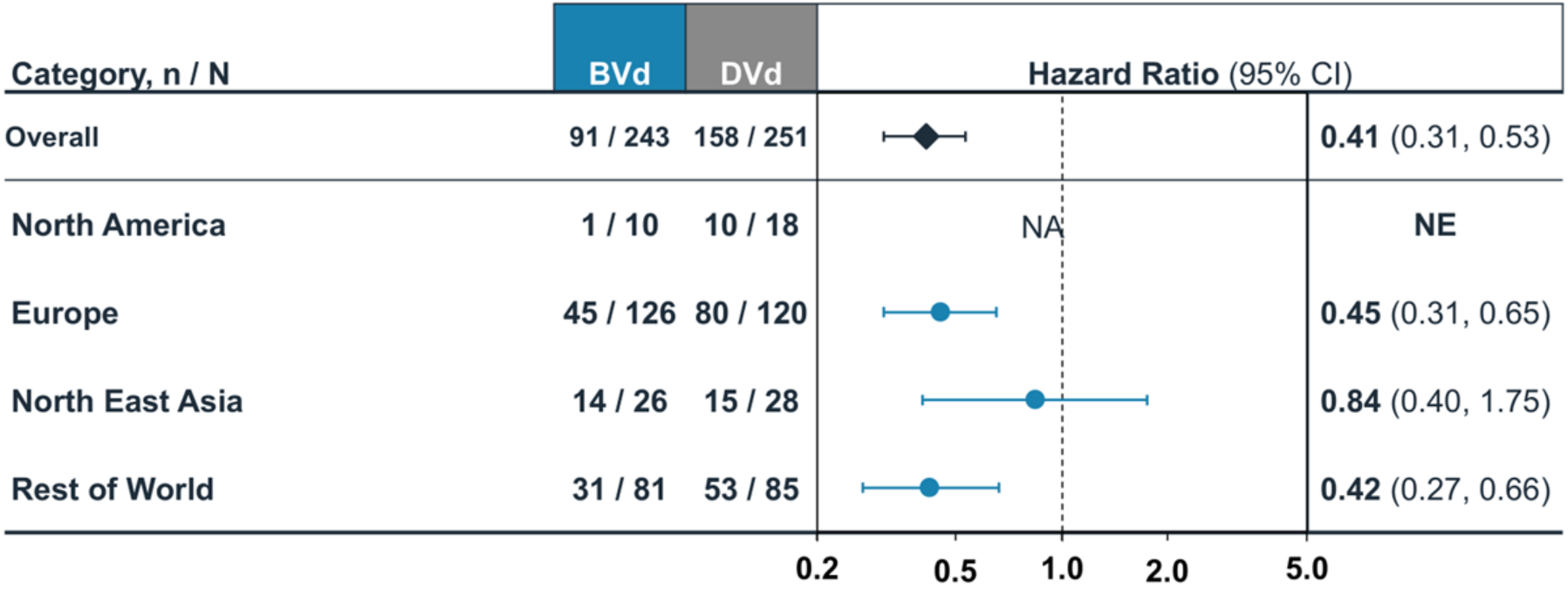
Median (IQR) **days to step-down (to 1.9 mg/kg): 105** (63, 176)

DREAMM-2: No Difference in Outcomes Between Black and White Patients

Ethnic Background	n / N	ORR	(97.5% CI)
White	26 / 76	34.2%	(22.4, 47.6)
Black	5 / 16	31.3%	(9.3, 62.0)



DREAMM-7: PFS HR Favored BLENREP vs SoC Triplet in Patients Across Geographical Regions

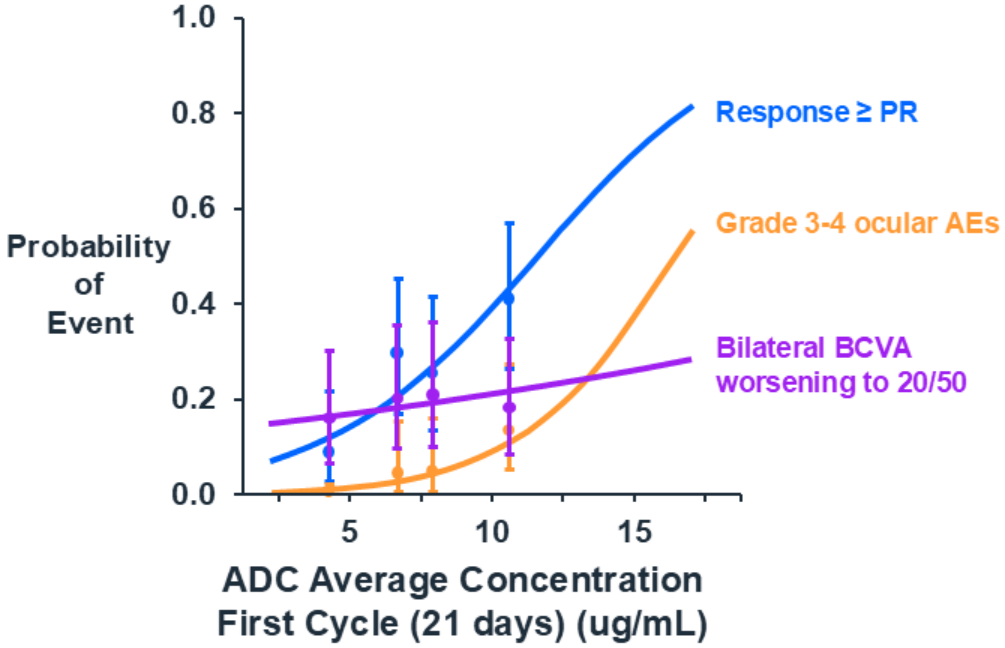


DREAMM-7: OS Benefit Observed Despite Use of Effective Post-Study Antimyeloma Therapies in Comparator Arm

Subsequent antimyeloma therapy, n (%)[b]	BVd N = 87	DVd N = 130
Steroids	**77** (89%)	**107** (82%)
Anti-CD38 antibodies	**61** (70%)	**14** (11%)
Proteasome inhibitor	**46** (53%)	**80** (62%)
Carfilzomib	**26** (30%)	**54** (42%)
Immunomodulator	**60** (69%)	**92** (71%)
Pomalidomide	**41** (47%)	**47** (36%)
BCMA-targeting therapy[c]	**9** (10%)	**34** (26%)
Non-BCMA BiTEs[d]	**5** (6%)	**5** (4%)
Transplant	**3** (3%)	**2** (2%)
T/NK cell therapy	**1** (1%)	**3** (2%)

[b] Since multiple categories per patient are possible, the total percentage may be >100%. [c] Bispecific antibodies that target BCMA included teclistamab (BVd, n=6; DVd, n=5), TNB 383B (BVd, n=0; DVd, n=5), elranatamab (BVd, n=1; DVd, n=1), HPN217 (BVd, n=0; DVd, n=1), and linvoseltamab (BVd, n=0; DVd, n=1). Bispecific antibodies that have other targets include talquetamab (BVd, n=1; DVd, n=2), cevostamab (BVd, n=3; DVd, n=0), investigational antineoplastic agent (BVd, n=0; DVd, n=2), and forimtamig (BVd, n=0; DVd, n=1).

DREAMM-14: Exposure-Response Analyses in Monotherapy Dose Optimization – Higher Exposure Associated with Higher Response Rate



Number of Patients Studied at Different Doses/Schedules During Dose Exploration

Studies	Number of Participants	Doses and Schedules Evaluated
DREAMM-14 (B in 4L+, IA)	160	1.9 and 2.5 mg/kg Q3W and Q6W
DREAMM-6 Arm A (B-Rd in 2L+)	45	1.9 and 2.5 mg/kg D1/D8 Q4W, Q4W, Q8W
DREAMM-6 Arm B (B-Vd in 2L+)	107	1.9, 2.5 and 3.4 mg/kg D1/D8 Q3W, Q3W, Q6W, S/D Q6W
ALGONQUIN (B-Pd in 2L+)	87	1.9, 2.5 and 3.4 mg/kg D1/D8 Q4W, Q4W, S/D Q4W, Q8W, Q12W

B = belantamab mafodotin; Pd = pomalidomide + dexamethasone; Rd = lenalidomide + dexamethasone; Vd = bortezomib + dexamethasone