BLENREP
belantamab mafodotin-blmf
for injection 70 mg

3x mPFS vs a daratumumab-based triplet

For adults with multiple myeloma who have received at least 2 prior lines of therapy[1]

Elevate the Outcome. Transform the Journey

Their ticket to 3x mPFS vs a daratumumab-based triplet is within reach

PFS (HR=0.31 [95% CI: 0.21-0.47]); mPFS was 31.3 months (95% CI: 23.5-NR) for BVd (N=108) vs 10.4 months (95% CI: 7-13.4) for DVd (N=109).

The data are based on exploratory post hoc analysis of a subgroup (N=217) and are not designed to detect a statistical difference.

INDICATION

BLENREP is indicated in combination with bortezomib and dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least two prior lines of therapy, including a proteasome inhibitor and an immunomodulatory agent.

IMPORTANT SAFETY INFORMATION

WARNING: OCULAR TOXICITY

- **BLENREP causes changes in the corneal epithelium resulting in changes in vision, including severe visual impairment, and symptoms such as blurred vision and dry eyes. In the clinical study, corneal ulcers, including cases with infection, also occurred.**
- **Conduct ophthalmic exams at baseline, before each dose, promptly for new or worsening symptoms, and as clinically indicated. In the clinical study, 83% of patients required a dosage modification due to ocular toxicity. Withhold BLENREP until improvement and resume or permanently discontinue, based on severity.**
- **Because of the risk of ocular toxicity, BLENREP is available only through a restricted program called the BLENREP Risk Evaluation and Mitigation Strategy (REMS).**

Please see Important Safety Information continued throughout and click to see full Prescribing Information, including Boxed Warning for BLENREP.

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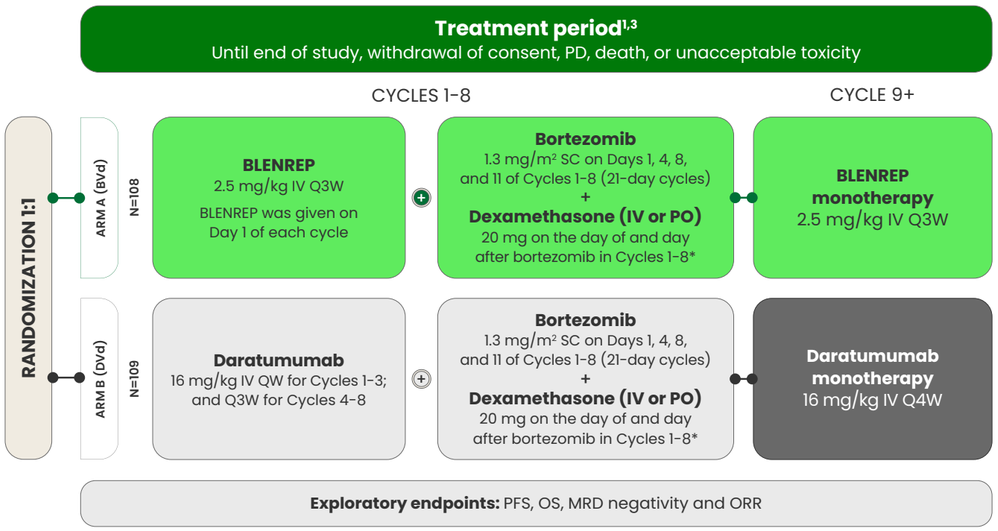
DREAMM-7 was a pivotal Phase 3 trial designed to study a triplet combination vs a daratumumab-based triplet[1,2]

- DREAMM-7 was an open-label, randomized (1:1), multicenter study in adult patients with multiple myeloma who received at least 1 prior line of therapy[1]
- FDA approval was based on a post hoc exploratory subgroup analysis of patients with at least 2 prior lines of therapy, including a proteasome inhibitor and immunomodulatory agent



- **Follow-up period:** PFS Q3W.† Disease assessment Q3W. Follow-up for OS Q12W[1-3‡]
- **Subgroup median follow-up:** 27.9 months (range: 0.1-40.0 months)
  - Efficacy data (except for OS) had a median follow-up of 27.9 months[1]
  - OS data had a median follow-up of 38.7 months[1]

Select eligibility criteria for efficacy population[3]

Inclusion criteria
- ✓ Adults with RRMM
- ✓ 2 prior lines of MM therapy, including a proteasome inhibitor and immunomodulatory agent
- ✓ Progressive disease during or after most recent therapy

Exclusion criteria
- Prior treatment with anti-BCMA therapy
- Refractory to or intolerant of daratumumab or bortezomib
- Current corneal epithelial disease§

Stratification
- Prior lines of treatment (1 vs 2 or 3 vs ≥4)
- R-ISS stage (I vs II/III)
- Prior bortezomib (yes vs no)

§Patients with current corneal disease, except for mild punctate keratopathy, were excluded.[1]

*The dose of dexamethasone in each arm was reduced by half in patients aged ≥75 years.[1]
†For patients who discontinue due to reasons other than PD.[3]
‡For patients who discontinue due to PD or other reasons.[3]

IMPORTANT SAFETY INFORMATION
WARNINGS AND PRECAUTIONS

Ocular Toxicity
BLENREP causes ocular toxicity, defined as changes in the corneal epithelium and changes in BCVA based on ophthalmic exam (including slit lamp exam), or other ocular adverse reactions as defined by the CTCAE.

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A subgroup analysis of DREAMM-7 studied patients who had a range of demographic backgrounds, clinical characteristics, and treatment histories[4]

In both arms:
- Almost **30%** of patients had high-risk cytogenetics*
- **95%** of patients had an ECOG status of ≤1
- **80%** of patients had prior exposure to lenalidomide, with **53%** refractory to lenalidomide

Prior treatment exposure	BVd (N=108)	DVd (N=109)
Median previous lines of therapy, n (%)*		
2	47 (44%)	50 (46%)
3	31 (29%)	34 (31%)
4+	30 (29%)	25 (23%)
Prior proteasome inhibitor (bortezomib, carfilzomib, ixazomib), n (%)	108 (100%)	109 (100%)
Prior bortezomib, n (%)	104 (96%)	105 (96%)
Previous immunomodulatory therapy (lenalidomide, thalidomide, pomalidomide), n (%)	108 (100%)	109 (100%)
Prior lenalidomide, n (%)	86 (80%)	83 (76%)
Refractory to lenalidomide, n (%)	57 (53%)	58 (53%)
Prior anti-CD38 therapy		
Prior daratumumab, n (%)	2 (2%)	2 (2%)
Prior autologous stem cell transplantation (ASCT)	77 (71%)	78 (72%)

Characteristics	BVd (N=108)	DVd (N=109)
Age (yr), median (range)	64.5 (42.0-86.0)	64.2 (39.0-85.0)
Age category, n (%)		
18 to <65 yr	54 (50%)	47 (43%)
65 to <75 yr	42 (39%)	51 (47%)
≥75 yr	12 (11%)	11 (10%)
Sex, n (%)		
Male	51 (47%)	65 (60%)
Female	57 (53%)	44 (40%)
Race, n (%)		
White	93 (86%)	94 (86%)
Black	2 (2%)	3 (3%)
Asian	13 (12%)	10 (9%)
R-ISS disease stage at screening, n (%)		
Stage I	40 (37%)	40 (37%)
Stage II	61 (56%)	60 (56%)
Stage III	6 (6%)	7 (6%)
Unknown	1 (<1%)	2 (2%)
Extramedullary disease, n (%)		
Yes	6 (6%)	17 (16%)
No	102 (94%)	92 (84%)
ECOG performance status, n (%)		
0	55 (51%)	47 (44%)
1	47 (44%)	58 (54%)
2	6 (6%)	2 (2%)
Patients with high-risk cytogenetics, n (%)†	34 (31%)	29 (27%)

*Due to rounding, totals may add up to more than 100%.[4]
†If the subject has at least 1 high-risk abnormality: T(4;14), T(14;16), or 17p13del.[4]

IMPORTANT SAFETY INFORMATION
WARNINGS AND PRECAUTIONS (CONT'D)

Ocular Toxicity (cont'd)
In DREAMM-7, ocular toxicity occurred in 92% of patients, including Grade 3 or 4 in 77% of patients. The most common ocular toxicities (>25%) were reduction in BCVA (89%) and corneal exam findings (86%) based on ophthalmic exam findings, blurred vision (66%), dry eye (51%), photophobia (47%), foreign body sensation in eyes (44%), eye irritation (43%), and eye pain (33%).

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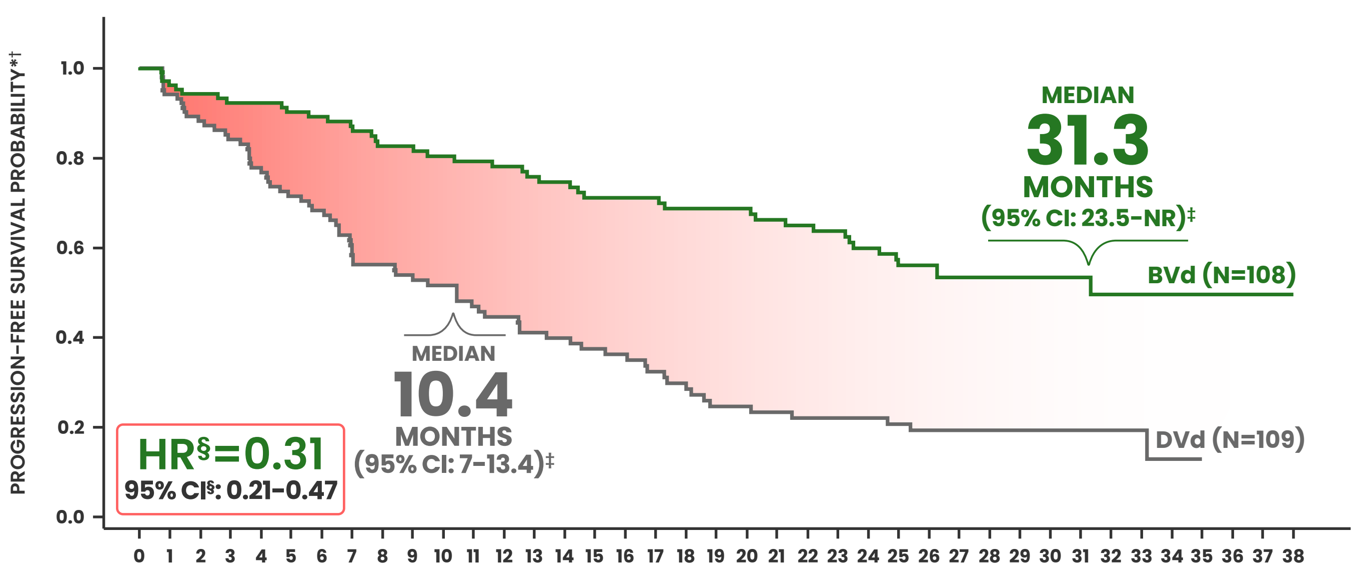
BLENREP triplet combination (BVd) delivered 3x mPFS vs a daratumumab-based triplet (DVd)[1]

The data presented are based on a post hoc analysis of a subgroup (N=217) that was exploratory and not adjusted for multiplicity nor powered to detect a statistical difference.

PFS: Median Follow-Up 27.9 Months[1]



NUMBERS AT RISK (NUMBER OF EVENTS)

BLENREP + bortezomib/dexamethasone	108 (0)	101 (4)	96 (6)	91 (8)	90 (8)	88 (10)	85 (11)	81 (13)	74 (17)	74 (17)	71 (19)	69 (20)	68 (21)	65 (23)	64 (24)	61 (27)	61 (27)	59 (27)	57 (29)	57 (29)
Daratumumab + bortezomib/dexamethasone	109 (0)	96 (6)	87 (12)	81 (16)	73 (23)	67 (28)	64 (31)	50 (42)	49 (42)	45 (45)	44 (46)	40 (50)	38 (52)	35 (55)	33 (56)	31 (58)	28 (59)	25 (62)	22 (65)	19 (68)

BLENREP + bortezomib/dexamethasone	56 (29)	53 (31)	52 (32)	50 (33)	47 (36)	45 (38)	42 (39)	38 (41)	31 (41)	29 (41)	26 (41)	18 (41)	13 (42)	10 (42)	7 (42)	5 (42)	3 (42)	3 (42)	0 (42)
Daratumumab + bortezomib/dexamethasone	19 (68)	18 (69)	17 (70)	17 (70)	16 (70)	15 (71)	14 (72)	12 (72)	8 (72)	7 (72)	6 (72)	5 (72)	3 (72)	3 (72)	1 (73)	0 (73)	0 (73)	0 (73)	0 (73)

Response was based on Independent Review Committee per International Myeloma Working Group criteria.[1]

BVd is the first and only triplet that improved mPFS vs a daratumumab-based triplet, with durable benefit observed[1]

*Based on all randomized patients who had received at least 2 prior lines of therapy including a proteasome inhibitor and immunomodulatory agent.[1]
†Median follow-up of 27.9 months.[1]
‡By Brookmeyer and Crowley method.[1]
§Based on stratified Cox regression model.[1]

IMPORTANT SAFETY INFORMATION
WARNINGS AND PRECAUTIONS (CONT'D)

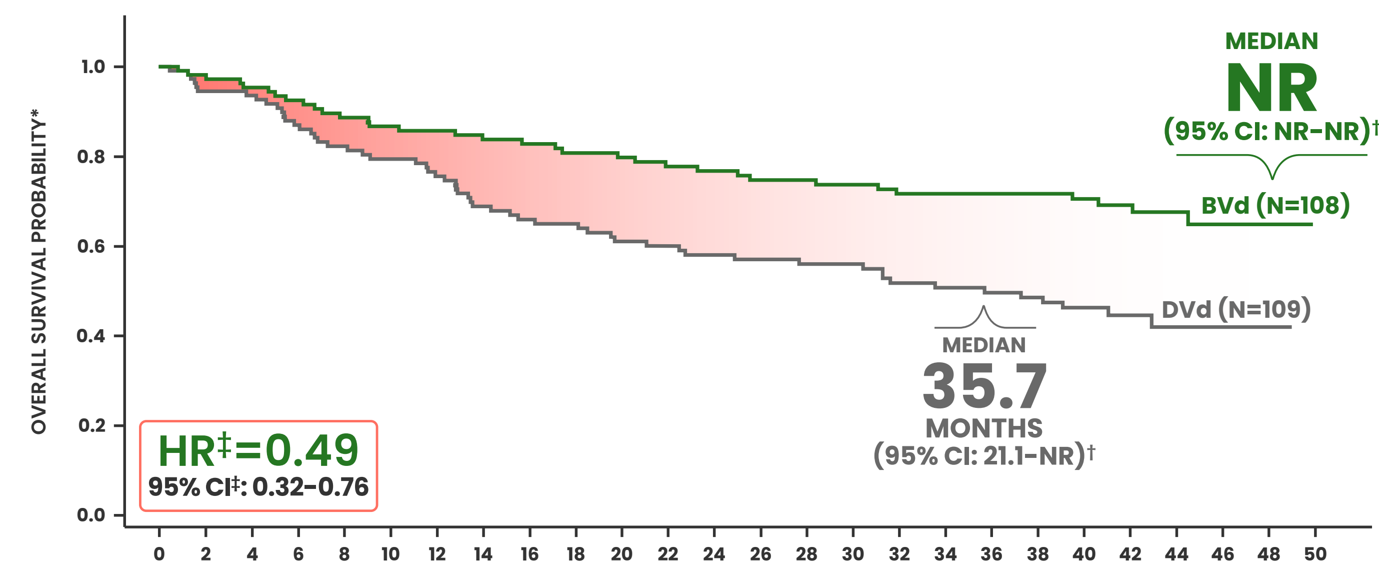
Ocular Toxicity (cont'd)
Ocular toxicity based on ophthalmic exam findings was reported as Grade 2 in 9% of patients, Grade 3 in 56% of patients, and Grade 4 in 21% of patients. The median time to onset of the first Grade 2 to 4 ophthalmic exam findings was 43 days (range: 15 to 611 days). The median duration of all Grade 2 to 4 ophthalmic exam findings was 85 days (range: 5 to 813 days). Patients experienced a median of 3 episodes (range: 1 to 11 episodes) of ocular toxicity based on ophthalmic exam findings. Of the patients with Grade 2 to 4 ophthalmic exam findings, 42% had improvement of the last event to Grade 1 or better; 22% had resolution of the last event based on return to baseline or normal ophthalmic exam findings.

Please see Important Safety Information continued throughout and click to see full <u>Prescribing Information</u>, including Boxed Warning for BLENREP.

BLENREP triplet combination (BVd) improved overall survival benefit vs DVd[1]

The data presented are based on a post hoc analysis of a subgroup (N=217) that was exploratory and not adjusted for multiplicity nor powered to detect a statistical difference.

OS: Median Follow-Up 38.7 Months[1]



NUMBERS AT RISK (NUMBER OF EVENTS)

BLENREP + bortezomib/dexamethasone	108 (0)	107 (1)	106 (2)	103 (3)	101 (5)	98 (7)	97 (8)	95 (10)	91 (12)	91 (12)	89 (14)	88 (15)	88 (15)	87 (16)	85 (17)	85 (17)	84 (18)
Daratumumab + bortezomib/dexamethasone	109 (0)	108 (1)	103 (6)	103 (6)	101 (7)	97 (9)	92 (14)	88 (18)	87 (19)	84 (21)	83 (22)	83 (22)	79 (26)	75 (30)	71 (33)	70 (34)	68 (36)

BLENREP + bortezomib/dexamethasone	82 (18)	80 (20)	80 (20)	79 (21)	78 (22)	77 (23)	77 (23)	76 (24)	76 (24)	74 (26)	74 (26)	74 (26)	73 (27)	72 (27)	72 (27)	70 (29)	70 (29)
Daratumumab + bortezomib/dexamethasone	67 (37)	66 (37)	64 (39)	62 (41)	61 (41)	60 (42)	58 (44)	58 (44)	57 (45)	56 (45)	55 (45)	54 (46)	54 (46)	53 (46)	52 (47)	49 (50)	49 (50)

BLENREP + bortezomib/dexamethasone	70 (29)	70 (29)	69 (29)	69 (29)	67 (29)	67 (29)	55 (30)	48 (31)	44 (31)	35 (32)	27 (32)	22 (33)	16 (33)	13 (33)	9 (33)	4 (33)	0 (33)
Daratumumab + bortezomib/dexamethasone	48 (51)	48 (51)	46 (52)	46 (52)	44 (53)	41 (54)	36 (55)	27 (55)	20 (56)	16 (57)	14 (57)	12 (57)	9 (57)	9 (57)	5 (57)	1 (57)	0 (57)

- mOS for BVd was not reached. At the time of the interim analysis data cutoff, fewer patients on BVd (33; 31%) had an event vs DVd (57; 52%)[1]
- OS data had a median follow-up of 38.7 months[1]

51% reduction in risk of death with BVd vs a daratumumab-based triplet[1]

*Based on all randomized patients who had received at least 2 prior lines of therapy including a proteasome inhibitor and immunomodulatory agent.[1]
†By Brookmeyer and Crowley method.[1]
‡Based on stratified Cox regression model.[1]

IMPORTANT SAFETY INFORMATION
WARNINGS AND PRECAUTIONS (CONT'D)

Ocular Toxicity (cont'd)
The most commonly reported corneal exam findings included superficial punctate keratopathy, microcyst-like deposits, epithelial changes, and haze. Cases of corneal ulcer, including cases with infection, have been reported and should be managed promptly by an eye care professional.

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Safety profile characterized in DREAMM-7[1]

In DREAMM-7, the safety of BLENREP with bortezomib and dexamethasone (n=242) compared to daratumumab with bortezomib and dexamethasone (n=246) was assessed in patients who received at least 1 prior line of therapy. Safety of BLENREP in combination with bortezomib and dexamethasone in patients who have received only 1 prior line of therapy (n=125) has not been established.

Adverse reactions (≥10%) in patients with relapsed or refractory multiple myeloma who received BLENREP in DREAMM-7[1]

	BLENREP + Bortezomib and Dexamethasone N=242		Daratumumab + Bortezomib and Dexamethasone N=246	
Adverse Reaction*	**All Grades (%)**	**Grades 3+4 (%)**	**All Grades (%)**	**Grades 3+4 (%)**
Eye disorders				
Reduction in BCVA†	89	57	44	9
Corneal exam findings†	86	72	19	3
Blurred vision	66	22	11	0.8
Dry eye‡	51	7	7	0
Photophobia	47	2	2	0
Foreign body sensation in eyes‡	44	3	4	0
Eye irritation	43	5	5	0
Eye pain‡	33	0.8	4	0.4
Cataract‡	24	8	14	3
Visual impairment	11	5	2	0.4
Gastrointestinal disorders				
Diarrhea	32	4	31	4
Nausea	16	0.8	12	0
Infections				
Upper respiratory tract infection‡§	38	2	36	2
Pneumonia‡§	26	16	17	5
COVID-19§	24	5	20	2
Hepatobiliary disorders				
Hepatotoxicity‡	33	14	16	2
General disorders and administration site conditions				
Fatigue‡	26	6	27	4
Pyrexia‡§	19	0.4	11	2

BCVA=Best-Corrected Visual Acuity.

Please see Important Safety Information continued throughout and click to see full Prescribing Information, including Boxed Warning for BLENREP.

Select laboratory abnormalities (>10%) that worsened from baseline in patients with relapsed or refractory multiple myeloma who received BLENREP in DREAMM-7[1]

	BLENREP + Bortezomib and Dexamethasone‖		Daratumumab + Bortezomib and Dexamethasone‖	
Laboratory Abnormality	**All Grades (%)**	**Grades 3+4 (%)**	**All Grades (%)**	**Grades 3+4 (%)**
Hematology				
Platelets decreased	100	74	88	48
Lymphocytes decreased	90	53	92	56
Leukocytes decreased	59	11	67	17
Neutrophils decreased	52	17	53	13
Hemoglobin decreased	51	10	60	12
Chemistry				
Aspartate aminotransferase increased	88	5	40	0
Gamma glutamyltransferase increased	73	15	44	3
Alanine aminotransferase increased	71	5	54	1
Creatinine increased	51	2	53	<1
Creatine phosphokinase increased	48	3	31	3

- **Serious adverse reactions** occurred in 50% of patients who received BVd. Serious adverse reactions in ≥2% of patients included pneumonia (18%), pyrexia (5%), thrombocytopenia (5%), COVID-19 (5%), upper respiratory tract infection (4%), sepsis (4%), second primary malignancy (3%), and anemia (2%)[1]
- **Fatal adverse reactions** occurred in 10% of patients who received BVd. Fatal adverse reactions which occurred in >1 patient included pneumonia (4%), sepsis (2%), COVID-19 (1%), respiratory failure (<1%), and intracranial hemorrhage (<1%)[1]
- **Dosage reductions** of BLENREP due to an adverse reaction occurred in 36% of patients. Adverse reactions which required dosage reductions for BLENREP in ≥3% of patients included ocular toxicity based on ophthalmic exam findings (30%), thrombocytopenia (14%), and blurred vision (10%)[1]
- **Dosage interruptions** of BLENREP due to an adverse reaction occurred in 78% of patients. Adverse reactions which required dosage interruption of BLENREP in ≥3% of patients included ocular toxicity based on ophthalmic exam findings (74%), blurred vision (32%), upper respiratory tract infection (20%), dry eye (14%), photophobia (14%), pneumonia (14%), eye irritation (13%), COVID-19 (12%), foreign body sensation in eyes (12%), eye pain (10%), thrombocytopenia (9%), visual impairment (7%), cataract (5%), diarrhea (4%), and neutropenia (4%)[1]
- **Permanent discontinuation** of BLENREP due to an adverse reaction occurred in 17% of patients. Adverse reactions which resulted in permanent discontinuation of BLENREP in ≥3% of patients included ocular toxicity (9%) and pneumonia (4%)[1]

*Adverse reactions, except ophthalmic exam findings, were graded according to CTCAE v5.0.[1]
†Based on ophthalmic exam findings.[1]
‡Grouped term includes other related terms.[1]
§Includes the following fatal adverse reactions: BVd: pneumonia (n=10), COVID-19 (n=3), upper respiratory tract infection (n=1); DVd: pneumonia (n=7), COVID-19 (n=5), pyrexia (n=1).[1]
‖The denominator used to calculate the rate varied from 238 to 241 (BVd) and 243 to 246 (DVd) based on the number of patients with a baseline value and at least 1 post-treatment value.[1]

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Ocular toxicity occurred in 92% of patients in DREAMM-7[1]

In DREAMM-7, Grade 3 or 4 ocular toxicity occurred in 77% of patients.

Ocular toxicity is defined as changes in the corneal epithelium and changes in Best-Corrected Visual Acuity (BCVA) based on ophthalmic exam findings or ocular adverse reactions per CTCAE v5.0.

Ophthalmic Exam Findings	
Definition	**Requires 2 exams conducted by an eye care professional (ophthalmologist or optometrist)[3,5]:** • Change in BCVA, which is a score reported as a fraction, such as 20/20, using a Snellen eye chart • Corneal exam findings, which are observed by a slit lamp
Incidence & Severity	• **Ocular toxicity based on ophthalmic exam findings** was reported as Grade 2 in 9% of patients, Grade 3 in 56% of patients, and Grade 4 in 21% of patients. The median time to onset of the first Grade 2 to 4 ophthalmic exam findings was 43 days (range: 15 to 611 days). The median duration of all Grade 2 to 4 ophthalmic exam findings was 85 days (range: 5 to 813 days). Patients experienced a median of 3 (range: 1 to 11) episodes of ocular toxicity based on ophthalmic exam findings. Of the patients with Grade 2 to 4 ophthalmic exam findings, 42% had improvement of the last event to Grade 1 or better; 22% had resolution of the last event based on return to baseline or normal ophthalmic exam findings[1] • **The most commonly reported corneal exam findings** included superficial punctate keratopathy, microcyst-like deposits, epithelial changes, and haze. Cases of corneal ulcer, including cases with infection, have been reported and should be managed promptly by an eye care professional[1] • **A reduction in BCVA** to 20/50 or worse in at least 1 eye occurred in 69% of patients, including 29% who experienced a change in BCVA to 20/100 or worse, and 12% who experienced a change in BCVA to 20/200 or worse[1]

Resolution of Best-Corrected Visual Acuity (BCVA)[4]

Event	BLENREP + bortezomib and dexamethasone[4] N=242		
	Of the patients with reduction in BCVA in at least one eye of:		
	20/50 or worse	20/100 or worse	20/200 or worse
Patients with at least one event, n/N (%)	166/242 (69%)	69/242 (29%)	29/242 (12%)
Resolution of patients with last event to baseline or better, n/N (%)*	101/166 (61%)	39/69 (57%)	14/29 (48%)
Ongoing event as of last follow-up, n/N (%)			
On treatment	24/166 (14%)	9/69 (13%)	4/29 (14%)
Discontinued treatment, follow-up ongoing	17/166 (10%)	9/69 (13%)	5/29 (17%)
Discontinued treatment, follow-up ended	24/166 (14%)	12/69 (17%)	6/29 (21%)

*The last event is "Resolved" only if it's resolved in both eyes; if either eye is ongoing, the event is "Ongoing."

IMPORTANT SAFETY INFORMATION
WARNINGS AND PRECAUTIONS (CONT'D)

Ocular Toxicity (cont'd)
A reduction in BCVA to 20/50 or worse in at least one eye occurred in 69% of patients, including 29% who experienced a change in BCVA to 20/100 or worse, and 12% who experienced a change in BCVA to 20/200 or worse. Of the patients with reduced BCVA to 20/50 or worse in at least one eye, 61% had resolution of the last event to baseline or better. Of the patients with reduced BCVA to 20/100 or worse, 57% had resolution of the last event. Of the patients with reduced BCVA to 20/200 or worse, 48% had resolution of the last event.

Please see Important Safety Information continued throughout and click to see full Prescribing Information, including Boxed Warning for BLENREP.

Considerations for ocular toxicity before and during treatment

During treatment, counsel patients[1]:

To read the **FDA-approved Medication Guide**

Ocular toxicity may occur during treatment with BLENREP

To **promptly tell their healthcare provider** if they notice any new or worsening eye symptoms

They will be sent to an eye care professional to obtain ophthalmic exams before starting BLENREP, before each dose, promptly for any new or worsening eye symptoms, and as clinically indicated

To **administer preservative-free artificial tears** at least 4 times per day starting with the first infusion and continuing until end of treatment and to avoid wearing contact lenses for the duration of therapy
- The BLENREP eye drop supportive care program provides eligible patients with eye drops throughout their treatment. Visit BLENREPhcp.com for more information.

To **use caution** when driving or operating machinery as BLENREP may adversely affect their vision

See the full Prescribing Information, including guidance on dosage and dosage modifications

BLENREP is available only through a restricted program called the BLENREP REMS because of the risk of ocular toxicity[1]

Notable requirements of the BLENREP REMS include the following:

- Prescribers must be certified in the BLENREP REMS by enrolling and completing training
- Prescribers must counsel patients receiving BLENREP on the risk of ocular toxicity, the need for monitoring via ophthalmic exams prior to each dose and provide patients with the BLENREP REMS Patient Guide
- Patients must be enrolled in the BLENREP REMS and adhere to monitoring
- Healthcare settings that dispense BLENREP must be certified in the BLENREP REMS by enrolling and must obtain authorization prior to dispensing
- Wholesalers and distributors must distribute BLENREP only to certified healthcare settings

Further information is available at www.BLENREPREMS.com and 1-855-690-9572

IMPORTANT SAFETY INFORMATION
WARNINGS AND PRECAUTIONS (CONT'D)

Ocular Toxicity (cont'd)
Ophthalmic exams (including slit lamp exam and BCVA assessment) should be conducted by an eye care professional, such as an ophthalmologist or optometrist, at baseline, before each dose of BLENREP, promptly for new or worsening symptoms, and as clinically indicated. Perform baseline exam within 4 weeks prior to the first dose. Perform each follow-up exam within 10 days prior to the next planned dose. All effort should be made to schedule the exam as close to BLENREP dosing as possible. Withhold BLENREP until improvement in both corneal exam findings and change in BCVA to Grade 1 or less and resume at same or reduced dose or permanently discontinue based on severity.

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INDICATION

BLENREP is indicated in combination with bortezomib and dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least two prior lines of therapy, including a proteasome inhibitor and an immunomodulatory agent.

IMPORTANT SAFETY INFORMATION

WARNING: OCULAR TOXICITY

- **BLENREP causes changes in the corneal epithelium resulting in changes in vision, including severe visual impairment, and symptoms such as blurred vision and dry eyes. In the clinical study, corneal ulcers, including cases with infection, also occurred.**
- **Conduct ophthalmic exams at baseline, before each dose, promptly for new or worsening symptoms, and as clinically indicated. In the clinical study, 83% of patients required a dosage modification due to ocular toxicity. Withhold BLENREP until improvement and resume or permanently discontinue, based on severity.**
- **Because of the risk of ocular toxicity, BLENREP is available only through a restricted program called the BLENREP Risk Evaluation and Mitigation Strategy (REMS).**

WARNINGS AND PRECAUTIONS

Ocular Toxicity
BLENREP causes ocular toxicity, defined as changes in the corneal epithelium and changes in BCVA based on ophthalmic exam (including slit lamp exam), or other ocular adverse reactions as defined by the CTCAE.

In DREAMM-7, ocular toxicity occurred in 92% of patients, including Grade 3 or 4 in 77% of patients. The most common ocular toxicities (>25%) were reduction in BCVA (89%) and corneal exam findings (86%) based on ophthalmic exam findings, blurred vision (66%), dry eye (51%), photophobia (47%), foreign body sensation in eyes (44%), eye irritation (43%), and eye pain (33%).

Ocular toxicity based on ophthalmic exam findings was reported as Grade 2 in 9% of patients, Grade 3 in 56% of patients, and Grade 4 in 21% of patients. The median time to onset of the first Grade 2 to 4 ophthalmic exam findings was 43 days (range: 15 to 611 days). The median duration of all Grade 2 to 4 ophthalmic exam findings was 85 days (range: 5 to 813 days). Patients experienced a median of 3 episodes (range: 1 to 11 episodes) of ocular toxicity based on ophthalmic exam findings. Of the patients with Grade 2 to 4 ophthalmic exam findings, 42% had improvement of the last event to Grade 1 or better; 22% had resolution of the last event based on return to baseline or normal ophthalmic exam findings.

The most commonly reported corneal exam findings included superficial punctate keratopathy, microcyst-like deposits, epithelial changes, and haze. Cases of corneal ulcer, including cases with infection, have been reported and should be managed promptly by an eye care professional.

A reduction in BCVA to 20/50 or worse in at least one eye occurred in 69% of patients, including 29% who experienced a change in BCVA to 20/100 or worse, and 12% who experienced a change in BCVA to 20/200 or worse. Of the patients with reduced BCVA to 20/50 or worse in at least one eye, 61% had resolution of the last event to baseline or better. Of the patients with reduced BCVA to 20/100 or worse, 57% had resolution of the last event. Of the patients with reduced BCVA to 20/200 or worse, 48% had resolution of the last event.

Ophthalmic exams (including slit lamp exam and BCVA assessment) should be conducted by an eye care professional, such as an ophthalmologist or optometrist, at baseline, before each dose of BLENREP, promptly for new or worsening symptoms, and as clinically indicated. Perform baseline exam within 4 weeks prior to the first dose. Perform each follow-up exam within 10 days prior to the next planned dose. All effort should be made to schedule the exam as close to BLENREP dosing as possible. Withhold BLENREP until improvement in both corneal exam findings and change in BCVA to Grade 1 or less and resume at same or reduced dose or permanently discontinue based on severity.

Counsel patients to promptly inform their healthcare provider of any ocular symptoms. Counsel patients to use preservative-free artificial tears at least 4 times a day starting with the first infusion and continuing until the end of treatment, and to avoid wearing contact lenses for the duration of therapy. Bandage contact lenses may be used under the direction of an eye care professional.

Changes in visual acuity may be associated with difficulty for driving and reading. Counsel patients to use caution when driving or operating machinery.

BLENREP Risk Evaluation and Mitigation Strategy (REMS)
BLENREP is available only through a restricted program called the BLENREP REMS because of the risk of ocular toxicity.

Further information is available at www.BLENREPREMS.com and 1-855-690-9572.

Thrombocytopenia
Thrombocytopenia of any grade occurred in 100% of patients in DREAMM-7.

Grade 2 thrombocytopenia occurred in 10% of patients, Grade 3 in 29% of patients, and Grade 4 in 45% of patients. Clinically significant bleeding (Grade ≥2) occurred in 7% of patients with concomitant low platelet levels (Grade 3 or 4).

Monitor complete blood cell counts at baseline and periodically during treatment as clinically indicated. Withhold or reduce the dose of BLENREP based on severity.

Embryo-fetal Toxicity
Based on its mechanism of action, BLENREP can cause fetal harm when administered to a pregnant woman because it contains a genotoxic compound (the microtubule inhibitor, monomethyl auristatin F [MMAF]) and it targets actively dividing cells.

Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with BLENREP and for 4 months after the last dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with BLENREP and for 6 months after the last dose.

ADVERSE REACTIONS

The most common adverse reactions (≥20%) with BLENREP in combination with bortezomib and dexamethasone are reduction in BCVA, corneal exam findings, blurred vision, dry eye, photophobia, foreign body sensation in eyes, eye irritation, upper respiratory tract infection, hepatotoxicity, eye pain, diarrhea, fatigue, pneumonia, cataract and COVID-19.

The most common Grade 3 or 4 (≥10%) laboratory abnormalities are decreased platelets, decreased lymphocytes, decreased neutrophils, increased gamma-glutamyl transferase, decreased white blood cells, and decreased hemoglobin.

Definitions

2L=second-line; BCMA=B-cell maturation antigen; BCVA=Best-Corrected Visual Acuity; BVd=BLENREP (B) + bortezomib (V) + dexamethasone (d); CI=confidence interval; CTCAE=Common Terminology Criteria for Adverse Events; DVd=daratumumab (D) + bortezomib (V) + dexamethasone (d); ECOG=Eastern Cooperative Oncology Group; HR=hazard ratio; IMiD=immunomodulatory agent; IV=intravenous; MM=multiple myeloma; mOS=median overall survival; mPFS=median progression-free survival; MRD negativity=minimal residual disease negativity; NR=not reached; ORR=overall response rate; OS=overall survival; PD=progressive disease; PFS=progression-free survival; PI=proteasome inhibitor; PO=by mouth; Q3W=every 3 weeks; Q4W=every 4 weeks; Q12W=every 12 weeks; QW=once weekly; REMS=Risk Evaluation and Mitigation Strategies; R-ISS=Revised International Staging System; RRMM=relapsed or refractory multiple myeloma; SC=subcutaneous.

References

1. BLENREP. Prescribing information. GSK; 2025. **2.** Hungria V, Robak P, Hus M, et al. Belantamab mafodotin, bortezomib, and dexamethasone for multiple myeloma. *N Engl J Med*. 2024;391(5):1-31. doi:10.1056/NEJMoa2405090 **3.** Hungria V, Robak P, Hus M, et al. Belantamab mafodotin, bortezomib, and dexamethasone for multiple myeloma. *N Engl J Med*. 2024;391(5)(suppl):1-31. doi:10.1056/NEJMoa2405090 **4.** Data on file, GSK. **5.** Liu G, Volpe N, Galetta S. The Neuro-Ophthalmic Examination. *Neuro-Ophthalmology*. *Diagnosis and Management*. Elsevier Inc; 2019:7-26. **6.** Fonseca R, Usmani SZ, Mehra M, et al. Frontline treatment patterns and attrition rates by subsequent lines of therapy in patients with newly diagnosed multiple myeloma. *BMC Cancer*. 2020;20(1087):1-11. doi:10.1186/s12885-020-07503-y **7.** Reilly J. What are the current treatment recommendations and unmet needs in early RRMM? Multiple Myeloma Hub. April 11, 2025. Accessed October 22, 2025. https://multiplemyelomahub.com/medical-information/what-are-the-current-treatment-recommendations-and-unmet-needs-in-early-rrmm

Please click to see full Prescribing Information including Boxed Warning for BLENREP.

BLENREP
belantamab mafodotin-blmf
for injection 70 mg

After 2L treatment, consider BLENREP for your appropriate patients with multiple myeloma[1]

Because of the risk of ocular toxicity, BLENREP has a Boxed Warning and is only available through a restricted program called the BLENREP Risk Evaluation and Mitigation Strategy (REMS)

After 2L treatment, **a need exists** for additional, accessible treatment options with a survival benefit[1,6,7]

BLENREP triplet combination (BVd) delivered 3x mPFS and improved overall survival benefit vs a daratumumab-based triplet[1]

- BVd (N=108) demonstrated mPFS*†‡ of 31.3 months (95% CI: 23.5-NR)§ and median overall survival (mOS) in months*‖ benefit (NR [95% CI: NR-NR])§ vs DVd (N=109)—10.4 months (95% CI: 7-13.4)§ and 35.7 months (95% CI: 21.1-NR)§, respectively
  - PFS: HR=0.31 (95% CI: 0.21-0.47)¶
  - OS: HR=0.49 (95% CI: 0.32-0.76)¶
- Based on a post hoc analysis of a subgroup that was exploratory and not adjusted for multiplicity nor powered to detect a statistical difference

BLENREP safety profile characterized in DREAMM-7[1]

- **The most common adverse reactions (≥20%)** with BLENREP in combination with bortezomib and dexamethasone were reduction in BCVA, corneal exam findings, blurred vision, dry eye, photophobia, foreign body sensation in eyes, eye irritation, upper respiratory tract infection, hepatotoxicity, eye pain, diarrhea, fatigue, pneumonia, cataract, and COVID-19

BLENREP is administered in any outpatient REMS-certified facility, **enabling broad accessibility of an anti-BCMA therapy[1,2]**

BLENREP **does not have a requirement for hospitalization to initiate treatment** and allows patients the potential to avoid traveling far for treatment[1,2]

*Based on all randomized patients who had received at least 2 prior lines of therapy including a proteasome inhibitor and immunomodulatory agent.[1]
†Median follow-up of 27.9 months.[1]
‡Response was based on Independent Review Committee per International Myeloma Working Group criteria.[1]
§By Brookmeyer and Crowley method.[1]
‖Median follow-up of 38.7 months.[1]
¶Based on stratified Cox regression model.[1]

INDICATION

BLENREP is indicated in combination with bortezomib and dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least two prior lines of therapy, including a proteasome inhibitor and an immunomodulatory agent.

IMPORTANT SAFETY INFORMATION

WARNING: OCULAR TOXICITY

- **BLENREP causes changes in the corneal epithelium resulting in changes in vision, including severe visual impairment, and symptoms such as blurred vision and dry eyes. In the clinical study, corneal ulcers, including cases with infection, also occurred.**
- **Conduct ophthalmic exams at baseline, before each dose, promptly for new or worsening symptoms, and as clinically indicated. In the clinical study, 83% of patients required a dosage modification due to ocular toxicity. Withhold BLENREP until improvement and resume or permanently discontinue, based on severity.**
- **Because of the risk of ocular toxicity, BLENREP is available only through a restricted program called the BLENREP Risk Evaluation and Mitigation Strategy (REMS).**

Please see Important Safety Information continued throughout and click to see full Prescribing Information, including Boxed Warning for BLENREP.

To report SUSPECTED ADVERSE REACTIONS, contact GSK at https://gsk.public.reportum.com or 1-888-825-5249 or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Intended for US healthcare professionals only.

US.GSK.COM

PMUS-BLMLBND250022 October 2025
Produced in USA.

File Name: Interactive Core Brochure.

BLENREP
belantamab mafodotin-blmf
for injection 70 mg