#TBD

Belantamab Mafodotin, Bortezomib, and Dexamethasone vs Daratumumab, Bortezomib, and Dexamethasone in Relapsed/Refractory Multiple Myeloma: Overall Survival Analysis and Updated Efficacy Outcomes of the Phase 3 DREAMM-7 Trial

Digital poster

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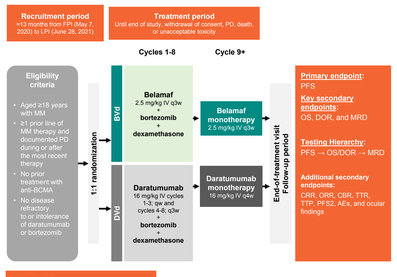
Introduction

- Patients with MM often have disease that becomes refractory to first-line triplet or quadruplet regimens and experience relapse; therefore, efficacious second-line combinations that incorporate new therapy classes are needed[1,2]
- The DREAMM-7 trial (NCT04246047) evaluated the anti-BCMA monoclonal antibody-drug conjugate belamaf in combination with bortezomib and dexamethasone vs DVd in patients with RRMM who had received ≥1 prior line of therapy[3]
- At the data cutoff of October 2, 2023, and a median follow-up of 28.2 months (range, 0.1-40.0 months), the primary endpoint was met, with a median PFS (95% CI) of 36.6 months (28.4 months-not reached) with BVd and 13.4 months (11.1-17.5 months) with DVd (HR, 0.41; 95% CI, 0.31-0.53; *P*<.001)[3,4]
- Although median OS was not reached in either arm in this primary analysis, a strong trend in favor of BVd vs DVd was observed, with an HR of 0.57 (95% CI, 0.40-0.80)[3,4]
- We report updated efficacy and safety from DREAMM-7, including a prespecified OS analysis, at a median follow-up of 39.4 months (data cutoff, October 7, 2024)

Methods

- DREAMM-7 is an ongoing, global, randomized, open-label phase 3 study[3] (**Figure 1**)
- Eligible patients with MM who experienced progression on or after ≥1 prior line of therapy were randomized 1:1 to BVd or DVd for 8 cycles, followed by belamaf or daratumumab monotherapy at cycle 9 and beyond
- The primary endpoint was IRC-assessed PFS with key secondary endpoints of OS, DOR, and MRD negativity in patients with ≥ CR, which was assessed by next-generation sequencing at a sensitivity of 10^{-5}; additional secondary endpoints included PFS2, response rates, and safety outcomes
  - AEs, including ocular adverse reactions, were graded in accordance with the NCI CTCAE (version 5.0)
- OS was compared between treatment groups with a stratified log-rank test, with HRs and corresponding 95% CIs estimated using a stratified Cox proportional-hazards model[3]
  - The Kaplan–Meier method was used to estimate the median OS; corresponding 95% CIs were calculated with the Brookmeyer–Crowley method

Figure 1: **DREAMM-7 study design and endpoints[3]**



AE, adverse event; BCMA, B-cell maturation antigen; belamaf, belantamab mafodotin; BVd, belantamab mafodotin, bortezomib, and dexamethasone; CBR, clinical benefit rate; CRR, complete response rate; DOR, duration of response; DVd, daratumumab, bortezomib, and dexamethasone; FPI, first patient in; IV, intravenous; LPI, last patient in; MM, multiple myeloma; MRD, minimal residual disease; ORR, overall response rate; OS, overall survival; PD, progressive disease; PFS, progression-free survival; PFS2, progression-free survival on second line of therapy; q3w, every 3 weeks; q4w, every 4 weeks; qw, once weekly; R-ISS, Revised International Staging System; TTP, time to progression; TTR, time to response.

Results

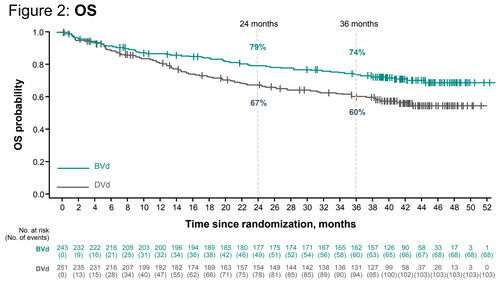
Patient Disposition and Baseline Characteristics

- From May 7, 2020, through June 28, 2021, 494 patients were randomized to receive BVd (N=243) or DVd (N=251) (**Figure S1**)
  - More patients remained on treatment with belamaf vs daratumumab, with progressive disease being the most common reason for discontinuation in both arms
- At data cutoff, the median follow-up was 39.4 months (range, 0.1-52.3 months), defined as the time from randomization to last contact or death
- As previously reported in the primary analysis,[3] baseline characteristics and prior treatments were well balanced across both arms (**Table S1**)
  - Approximately half of patients in each arm received 1 prior line of therapy; 52% of patients in each arm received prior lenalidomide and approximately one-third of patients had disease refractory to lenalidomide at baseline in both arms

Efficacy and Subsequent Therapies

- BVd resulted in an early, sustained, and statistically significant OS benefit vs DVd (HR, 0.58; 95% CI, 0.43-0.79; *P*=.00023) (**Figure 2**)
- Although median OS was not reached in either arm, simulation was used to calculate a predicted median OS, which is 84 months with BVd and 51 months with DVd (post hoc analysis using the observed data at the interim analysis, with 39.4-month median follow-up to extrapolate time to death in ongoing censored patients; subject to change as data mature)
- Due to earlier disease progression, more patients in the DVd arm received subsequent therapies than patients in the BVd arm (**Tables S2 and S3**)
  - While those in the DVd arm vs BVd arm proceeded to receive more immunomodulators, proteasome inhibitors, and steroids as subsequent therapy, more patients in the BVd arm vs DVd arm initiated monoclonal antibody therapy
  - In the BVd arm, the most common first subsequent therapies after study treatment were anti-CD38 monoclonal antibodies (daratumumab and isatuximab), pomalidomide, and lenalidomide; in the DVd arm, they were lenalidomide, carfilzomib, and pomalidomide
- PFS2 favored BVd vs DVd (HR, 0.59; 95% CI, 0.45-0.77), demonstrating a maintained treatment benefit with BVd following subsequent antimyeloma therapy (**Figure 3**)
- BVd maintained a greater depth of response vs DVd (**Figure 4**)
  - Due to the prespecified testing hierarchy and with the significant OS benefit at this data cutoff, MRD-negativity rates from the primary analysis could be formally compared and can now be considered statistically significant in favor of BVd vs DVd:[3]
    - With BVd vs DVd, rates of ≥ CR and MRD negativity were 24.7% vs 9.6% (*P*<.00001), respectively, and rates of ≥ VGPR and MRD negativity were 38.7% vs 17.1% (*P*<.00001)
- Median DOR with BVd was more than double that with DVd (40.8 months vs 17.8 months) (**Figure 5**)

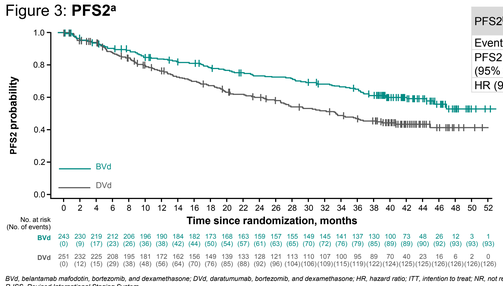
Figure 2: **OS**



OS[a]	BVd (N=243)	DVd (N=251)
Events, n (%)	68 (28)	103 (41)
OS, median (95% CI), months[b]	NR (NR, NR)	NR (41.0, NR)
HR (95% CI)[c]	0.58 (0.43-0.79)	
P value[d]	.00023	
24-Month survival (95% CI), %	79 (73-84)	67 (61-73)
36-Month survival (95% CI), %	74 (68-79)	60 (54-66)

BVd, belantamab mafodotin, bortezomib, and dexamethasone; DVd, daratumumab, bortezomib, and dexamethasone; HR, hazard ratio; ITT, intention to treat; NR, not reached; OS, overall survival; R-ISS, Revised International Staging System.
[a] Two patients in the ITT population were randomized, not treated, rescreened, and rerandomized. They are counted as 4 unique patients in this output. [b] CIs were estimated using the Brookmeyer–Crowley method. [c] HRs were estimated using a Cox proportional hazards model stratified by the number of lines of prior therapy (1 vs 2 or 3 vs ≥4), prior bortezomib (yes vs no), and R-ISS stage at screening (I vs II or III), with a covariate of treatment. [d] P value is from a 1-sided stratified log-rank test. At 111 actual events (48.2% OS information fraction), OS was declared significant if the P value was <.00112.

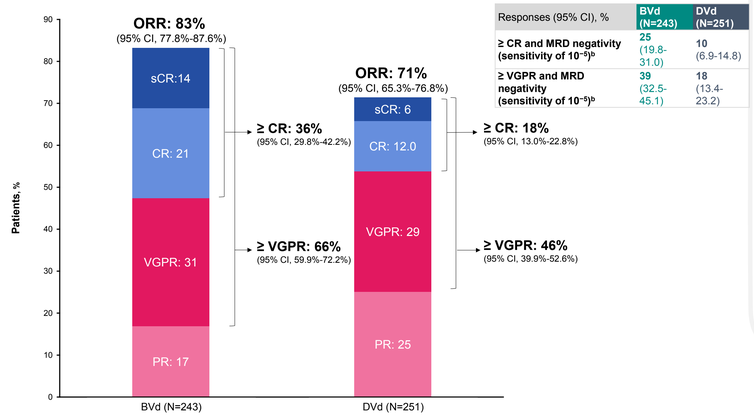
Figure 3: **PFS2[a]**



PFS2[b]	BVd (N=243)	DVd (N=251)
Events, n (%)	93 (38)	126 (50)
PFS2, median (95% CI), months[c]	NR (45.6, NR)	33.4 (26.7-44.9)
HR (95% CI)[d]	0.59 (0.45-0.77)	

BVd, belantamab mafodotin, bortezomib, and dexamethasone; DVd, daratumumab, bortezomib, and dexamethasone; HR, hazard ratio; ITT, intention to treat; NR, not reached; PFS2, progression-free survival on second line of therapy; R-ISS, Revised International Staging System.
[a] PFS2 was defined as time from randomization to disease progression after initiation of new antimyeloma therapy or death from any cause, whichever was earliest. [b] Two patients in the ITT population were randomized, not treated, rescreened, and rerandomized. They are counted as 4 unique patients in this output. [c] CIs were estimated using the Brookmeyer–Crowley method. [d] HRs were estimated using a Cox proportional hazards model stratified by the number of lines of prior therapy (1 vs 2 or 3 vs ≥4), prior bortezomib (yes vs no), and R-ISS stage at screening (I vs II or III), with a covariate of treatment.

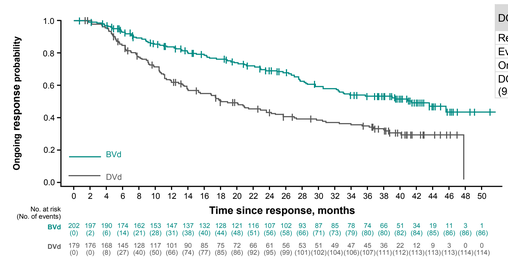
Figure 4: **Response rates and MRD negativity[a]**



Responses (95% CI), %	BVd (N=243)	DVd (N=251)
≥ CR and MRD negativity (sensitivity of 10^{-5})[b]	25 (19.8-31.0)	10 (6.9-14.8)
≥ VGPR and MRD negativity (sensitivity of 10^{-5})[b]	39 (32.5-45.1)	18 (13.4-23.2)

BVd, belantamab mafodotin, bortezomib, and dexamethasone; CR, complete response; DVd, daratumumab, bortezomib, and dexamethasone; ITT, intention to treat; MRD, minimal residual disease; NGS, next-generation sequencing; ORR, overall response rate; PR, partial response; sCR, stringent complete response; VGPR, very good partial response.
[a] CIs were based on the exact method. Two patients in the ITT population were randomized, not treated, rescreened, and rerandomized. They are counted as 4 unique patients in this output. [b] MRD-negativity rate is defined as the percentage of patients who were MRD-negative by NGS, based on a sensitivity of 10^{-5}.

Figure 5: **DOR**



DOR[a]	BVd (N=243)	DVd (N=251)
Responders, n	202	179
Events, n (%)	86 (43)	114 (64)
Ongoing response, n (%)	79 (39)	39 (22)
DOR, median (95% CI), months[b]	40.8 (30.5, NR)	17.8 (13.8-23.6)

BVd, belantamab mafodotin, bortezomib, and dexamethasone; DOR, duration of response; DVd, daratumumab, bortezomib, and dexamethasone; ITT, intention to treat; NR, not reached.
[a] Two patients in the ITT population were randomized, not treated, rescreened, and rerandomized. They are counted as 4 unique patients in this output. [b] CIs were estimated using the Brookmeyer–Crowley method.

Safety

- The safety population included patients who received ≥1 dose of study drug (BVd, N=242; DVd, N=246)
  - Median durations of exposure (total duration of exposure over all study treatments in an arm) with BVd and DVd were 15.9 months (range, 0.7-52.3 months) and 12.8 months (range, 0.2-48.8 months), respectively
- The overall safety profiles of the 2 regimens were consistent with results from the primary analysis[3] (**Table 1**)
  - While the BVd arm had numerically higher overall rates of grade 3/4 and SAEs than the DVd arm, these were generally comparable between arms when adjusting for total treatment exposure
  - More deaths due to myeloma were observed in the DVd arm vs BVd arm, while rates of fatal SAEs related to treatment were low across both arms
  - Commonly occurring AEs of clinical interest included blood and lymphatic system disorders, and infections; thrombocytopenia was more common in the BVd arm, including when adjusted for treatment exposure, and overall infection rates were similar between arms, which is consistent with the primary analysis[3]
- The BVd arm had an ocular safety profile that was consistent with the primary analysis[3]
  - Blurred vision was the most frequent ocular adverse reaction in the BVd arm, with 68% and 24% of patients experiencing all-grade and grade 3/4 events, respectively
  - Almost all patients with worsening of vision to 20/50 or worse had resolution to normal baseline or improvement of their first event (remaining patients had insufficient follow-up to assess for resolution); resolution or improvement was observed in all patients with worsening of vision to 20/200 or worse (**Table 2**)
  - In most patients, ocular events resolved with dose modification, with treatment discontinuation due to any ocular event occurring in 10%
- A post hoc analysis across the first 30 months of treatment was performed in patients in the BVd arm with 20/25 or better in ≥1 eye at baseline[4-6] (**Figure S2**)
  - With increasing duration of treatment, median time between doses increased; despite this, response rate (best confirmed response of ≥ PR in each interval) remained high throughout
  - Overall, 23% of patients experienced bilateral BCVA worsening to 20/50 or worse in the first 3 months of treatment; prevalence generally decreased thereafter
  - A low rate of treatment discontinuation due to ocular events was observed throughout

Conclusions

- BVd demonstrated a statistically significant and clinically meaningful improvement in OS compared with DVd in patients with RRMM after ≥1 prior line of therapy (HR, 0.58; 95% CI, 0.43-0.79; *P*=.00023)
  - OS benefit with BVd was early and sustained
  - Although median OS was not reached, predicted median OS using modeling is 84 months with BVd and 51 months with DVd
  - MRD-negativity rates in favor of BVd from the primary analysis can now be considered statistically significant[3]
- Treatment benefits with BVd were also maintained after subsequent antimyeloma therapy, with an HR (95% CI) for PFS2 of 0.59 (0.45-0.77)
- BVd maintained durable and deep responses and continued to result in greater than double the ≥ CR rates, MRD-negativity rates, and median DOR compared with DVd, with extended follow-up
- The safety profile of BVd was consistent with the primary analysis and known profiles of the individual agents[3]
  - Ocular events were generally resolved, were manageable with dose modifications, and led to low treatment discontinuation rates
- The results from this updated analysis of DREAMM-7 further support belamaf as a potential new standard-of-care for patients with RRMM

Table 1: **Safety summary**

	BVd (N=242)	DVd (N=246)
Any AE	242 (100)	246 (100)
Related to any study treatment[a]	242 (100)	234 (95)
Grade 3/4 AE[b]	230 (95)	191 (78)
Exposure-adjusted rate (per 100 person-years)[c]	57.17	55.71
Related to any study treatment[a]	222 (92)	166 (67)
AEs leading to permanent discontinuation of any study treatment	77 (32)	47 (19)
Exposure-adjusted rate (per 100 person-years)[c]	19.14	13.71
Related to any study treatment leading to permanent discontinuation of any study treatment[a]	67 (28)	36 (15)
AEs leading to dose reduction	181 (75)	146 (59)
Exposure-adjusted rate (per 100 person-years)[c]	44.99	42.58
AEs leading to dose delay	229 (95)	186 (76)
Exposure-adjusted rate (per 100 person-years)[c]	56.92	54.25
Any SAE	129 (53)	94 (38)
Exposure-adjusted rate (per 100 person-years)[c]	32.07	27.42
Related to any study treatment[a]	50 (21)	32 (13)
Fatal SAEs	26 (11)	20 (8)
Related to any study treatment[a]	7 (3)	2 (<1)
Deaths		
Deaths	69 (29)	101 (41)
Primary cause of death[d]		
Cancer	23 (10)	53 (22)
Equivocally due to myeloma	3 (1)	7 (3)
Unequivocally due to myeloma	19 (8)	44 (18)
Other cancer	1 (<1)	2 (<1)
Cardiovascular condition[e]	8 (3)	4 (2)
Sepsis	8 (3)	4 (2)
Stroke	0	1 (<1)
Trauma	0	1 (<1)
Other noncardiovascular condition	24 (10)	25 (10)
AEs of clinical interest[f]		
Blood and lymphatic system disorders	**All grades**	**Grade ≥3**	**All grades**	**Grade ≥3**
Thrombocytopenia[g]	169 (70)	135 (56)	122 (50)	87 (35)
Exposure-adjusted rate (per 100 person-years)[c]	42.01	33.56	35.58	25.37
Anemia[h]	48 (20)	21 (9)	65 (26)	25 (10)
Neutropenia[i]	45 (19)	34 (14)	44 (18)	24 (10)
Exposure-adjusted rate (per 100 person-years)[c]	11.19	8.45	12.83	7.00
Infections and infestations	176 (73)	80 (33)	167 (68)	49 (20)
Exposure-adjusted rate (per 100 person-years)[c]	43.75	19.89	48.71	14.29
Pneumonia	48 (20)	30 (12)	23 (9)	10 (4)
Exposure-adjusted rate (per 100 person-years)[c]	11.93	7.46	6.71	2.92

AE, adverse event; BVd, belantamab mafodotin, bortezomib, and dexamethasone; CTCAE, Common Terminology Criteria for Adverse Events; DVd, daratumumab, bortezomib, and dexamethasone; SAE, serious adverse event.
Data are n (%) unless otherwise noted. [a] "Related to any study treatment" includes responses of "yes" and missing responses to the following question: "Is there a reasonable possibility that the AE may have been caused by the study treatment?". [b] Includes patients who have had a separate Grade 5 event. [c] Exposure-adjusted rates were calculated as the total number of patients with an event divided by the total exposure time in person-years (per 100 person-years). Total person-years is the sum of all patient exposure calculated as (last dose − first dose + 1) / 365.25. [d] The primary cause of death was unknown for 6 patients in the BVd arm and 13 patients in the DVd arm. [e] Cardiovascular includes hemorrhage, heart failure, myocardial infarction, and other cardiovascular diagnosis. [f] Graded using CTCAE version 5.0. [g] If platelet count decrease is also reported, the percentages of thrombocytopenia events for all grades were 88% and 65% with BVd and DVd, respectively, and for grade 3/4 were 73% and 46%. [h] Red blood cells decreased was not reported. [i] Neutropenia includes preferred terms febrile neutropenia, neutropenia, and neutrophil count decreased.

Table 2: **BCVA in patients with normal baseline 20/25 or better**

BVd	Bilateral worsening of BCVA in patients with normal baseline 20/25 or better	
	20/50 or worse[a]	20/200 or worse[a]
Patients, n/N (%)	84/242 (35)	5/242 (2)
Time to onset of first event, median (range), days	79 (16-1320)	105 (47-304)
Time to resolution of first event to baseline, median (range), days[b]	64 (8-908)	87 (22-194)
Time to improvement of first event, median (range), days[c]	22 (6-257)	19 (8-26)
First event resolved, n/N (%)[b]	78/84 (93)	4/5 (80)
First event improved, n/N (%)[c]	81/84 (96)	5/5 (100)
Follow-up ended with event ongoing, n/N (%)	2/84 (2)	0

BCVA, best-corrected visual acuity; BVd, belantamab mafodotin, bortezomib, and dexamethasone.
[a] In patients with normal BCVA (20/25 or better in ≥1 eye) at baseline. [b] Resolution defined as a return to normal BCVA (20/25 or better in ≥1 eye). [c] Improvement was defined as BCVA of better than 20/50 (or 20/200) in ≥1 eye.

Abbreviations

AE, adverse event; BCMA, B-cell maturation agent; BCVA, best-corrected visual acuity; belamaf, belantamab mafodotin; BVd, belantamab mafodotin, bortezomib, and dexamethasone; CD, cluster of differentiation; CR, complete response; CTCAE, Common Terminology Criteria for Adverse Events; DOR, duration of response; DVd, daratumumab, bortezomib, and dexamethasone; HR, hazard ratio; IRC, independent review committee; MM, multiple myeloma; MRD, minimal residual disease; NCI, National Cancer Institute; OS, overall survival; PFS, progression-free survival; PFS2, progression-free survival on second line of therapy; PR, partial response; RRMM, relapsed/refractory multiple myeloma; SAE, serious adverse event; VGPR, very good partial response.

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Disclosures

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