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
SCAN ME

Vania Hungria, MD, PhD,[1] Pawel Robak, MD, PhD,[2] Marek Hus, MD, PhD, DsC,[3] Vera Zherebtsova, MD,[4] Christopher Ward, MD, PhD,[5] P Joy Ho, MBBS, DPhil,[6] Roman Hajek, MD, PhD,[7] Kihyun Kim, MD,[8] Sebastian Grosicki, MD, PhD,[9] Hanlon Sia, MBBS, FRACP, FRCPA,[10] Adam Bryant, MBBS (Hon), PhD, FRACP, FRCPA,[11] Marcelo Pitombeira de Lacerda, MD, PhD,[12] Gracia Aparecida Martinez, PhD,[13] Anna Maria Sureda Balarí, MD, PhD,[14] Irwindeep Sandhu, MD,[15] Claudio Cerchione, MD, PhD,[16] Peter Ganly, BMBCh, PhD,[17] Meletios Athanasios Dimopoulos, MD,[18] Chengcheng Fu, MD, PhD,[19] Mamta Garg, MD,[20] Al-Ola Abdallah, MD,[21] Moshe E. Gatt, MD,[22] Albert Oriol, MD,[23] Michele Cavo, MD,[24] Robert Rifkin, MD, FACP,[25] Tomoaki Fujisaki, MD, PhD,[26] Michał Mielnik, MD,[3] Nick Pirooz, MHA,[27] Joe Lee, PhD,[28] Astrid McKeown, PhD,[29] Rachel Rogers, MS,[27] Hena Baig, BS,[30] Lydia Eccersley, MBBS, PhD, MRCP, FRCPath,[28] Sumita Roy-Ghanta, MD,[27] Joanna Opalinska, MD, PhD,[27] María Victoria Mateos, MD, PhD[31]

[1]Clinica São Germano, São Paulo, Brazil; [2]Medical University of Lodz, Łódź, Poland; [3]Medical University of Lublin, Lublin, Poland; [4]Gorodskaya Klinicheskaya Bol'nitsa Im. S.p. Botkina, Moscow, Russia; [5]Royal North Shore Hospital, Sydney, NSW, Australia; [6]Royal Prince Alfred Hospital, Camperdown, NSW, Australia; [7]University Hospital Ostrava and University of Ostrava, Ostrava, Czech Republic; [8]Sungkyunkwan University, Samsung Medical Center, Seoul, Republic of Korea; [9]Medical University of Silesia, Katowice, Poland; [10]Pindara Private Hospital, Gold Coast, QLD, Australia; [11]Liverpool Hospital, Sydney, NSW, Australia; [12]Universidade da Região de Joinville and Centro de Hematologia e Oncologia, Joinville, Santa Catarina, Brazil; [13]Hospital das Clínicas and Instituto do Câncer do Estado de São Paulo, Universidade de São Paulo, São Paulo, Brazil; [14]Institut Català d'Oncologia-L'Hospitalet L.-Barcelona, Barcelona, Spain; [15]Cross Cancer Institute, University of Alberta, Edmonton, AB, Canada; [16]Hematology Unit, Istituto Romagnolo per lo Studio dei Tumori "Dino Amadori" - IRST IRCCS, Meldola, FC, Italy; [17]Christchurch Hospital, Christchurch, New Zealand; [18]National and Kapodistrian University of Athens, Athens, Greece; [19]The First Affiliated Hospital of Soochow University, Jiangsu, China; [20]University Hospitals of Leicester NHS Trust, Leicester, UK; [21]University of Kansas Cancer Center, Fairway, KS, USA; [22]Department of Haematology, Hadassah Medical Center, Faculty of Medicine, Hebrew University of Jerusalem, Jerusalem, Israel; [23]Institut Català d'Oncologia and Josep Carreras Research Institute, Hospital Germans Trias i Pujol, Badalona, Spain; [24]IRCCS Azienda Ospedaliero-Universitaria di Bologna, Istituto di Ematologia "Seràgnoli", Bologna, Italy; [25]Rocky Mountain Cancer Centers - Denver - Midtown, Denver, CO, USA; [26]Matsuyama Red Cross Hospital, Matsuyama, Japan; [27]GSK, Collegeville, PA, USA; [28]GSK, London, UK; [29]GSK, Stevenage, UK; [30]GSK, Mississauga, ON, Canada; [31]Hospital Universitario de Salamanca/IBSAL/CIC/Ciberonc, Salamanca, Spain

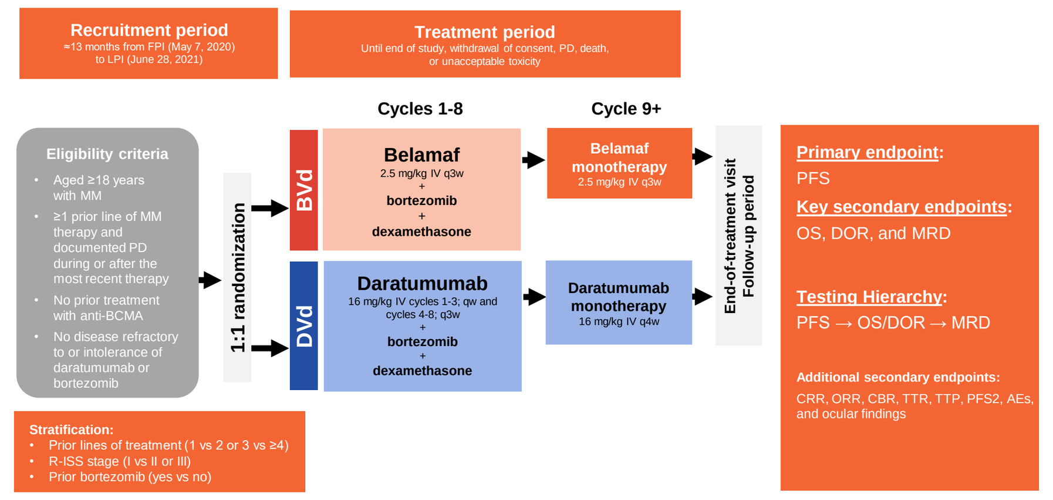
Introduction

- Patients with MM often have disease that becomes refractory to first-line triplet or quadruplet regimens and relapses; 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; CR, complete response; DOR, duration of response; DVd, daratumumab, bortezomib, and dexamethasone; 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; R-ISS, Revised International Staging System; TTP, time to progression; TTR, time to response.

Results

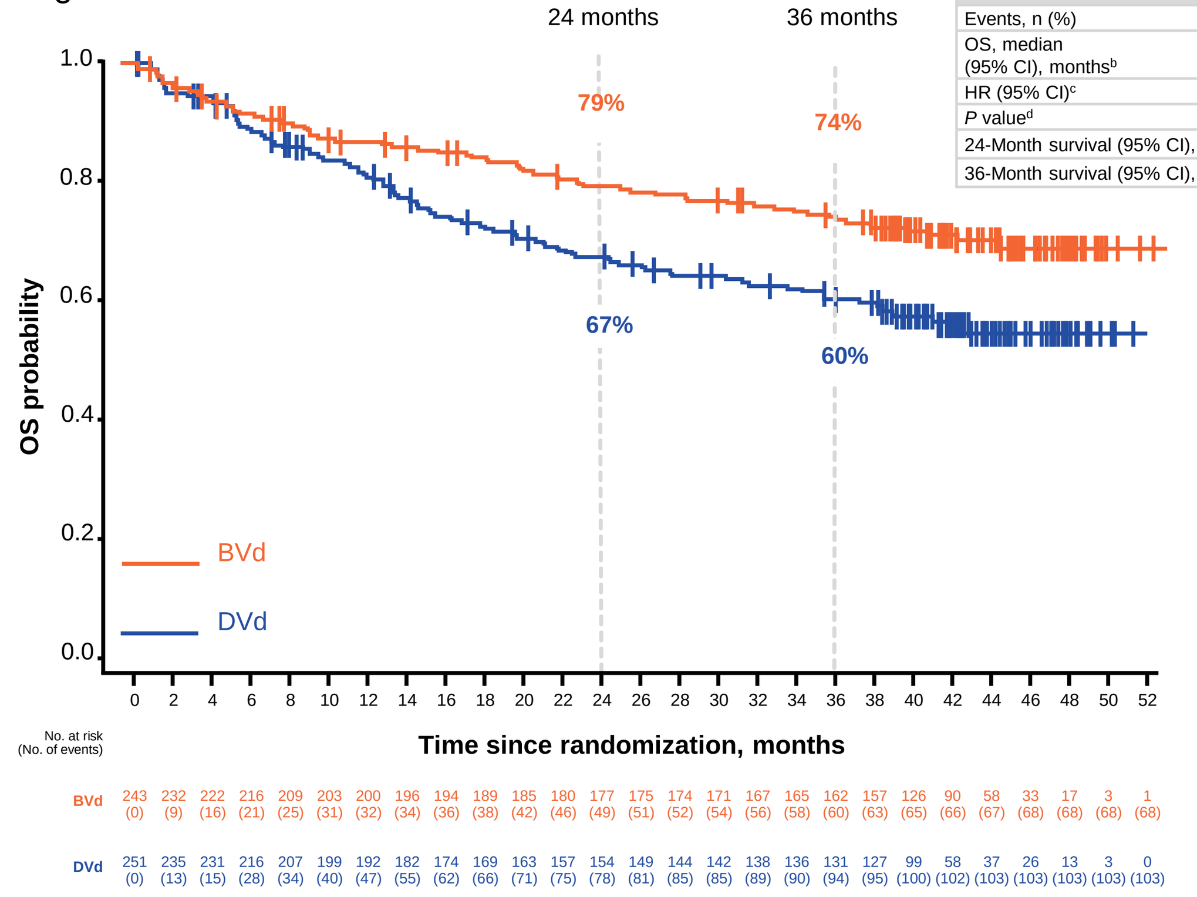
Patient Disposition and Baseline Characteristics

- From May 7, 2020, through June 28, 2021, 494 patients were randomized to receive BVd (N=243) or DVd (N=251)
  - More patients remained on treatment with belamaf (25%) vs daratumumab (15%), 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
  - 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 this 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 (52% vs 36%)
  - While those in the DVd arm vs BVd arm proceeded to receive more immunomodulators (37% vs 25%), proteasome inhibitors (32% vs 19%), and steroids (43% vs 32%) as subsequent therapy, more patients in the BVd arm vs DVd arm initiated monoclonal antibody therapy (26% vs 10%)
  - 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**)

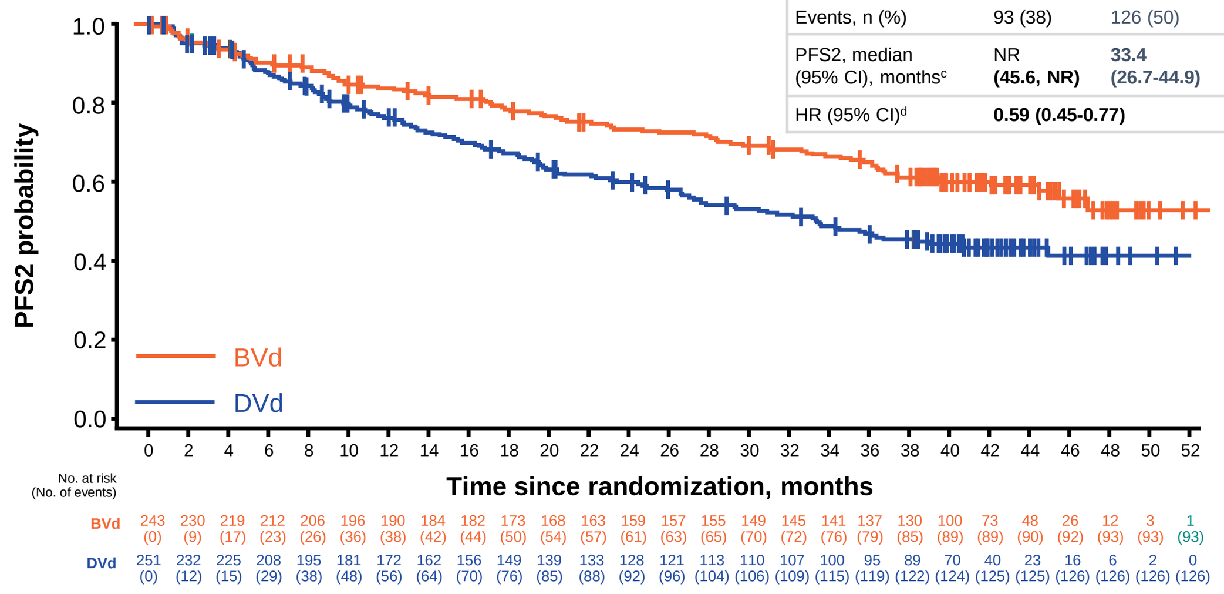
Figure 2: **OS**



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 171 actual events (48.2% OS information fraction), OS was declared significant if the P value was <.00112.

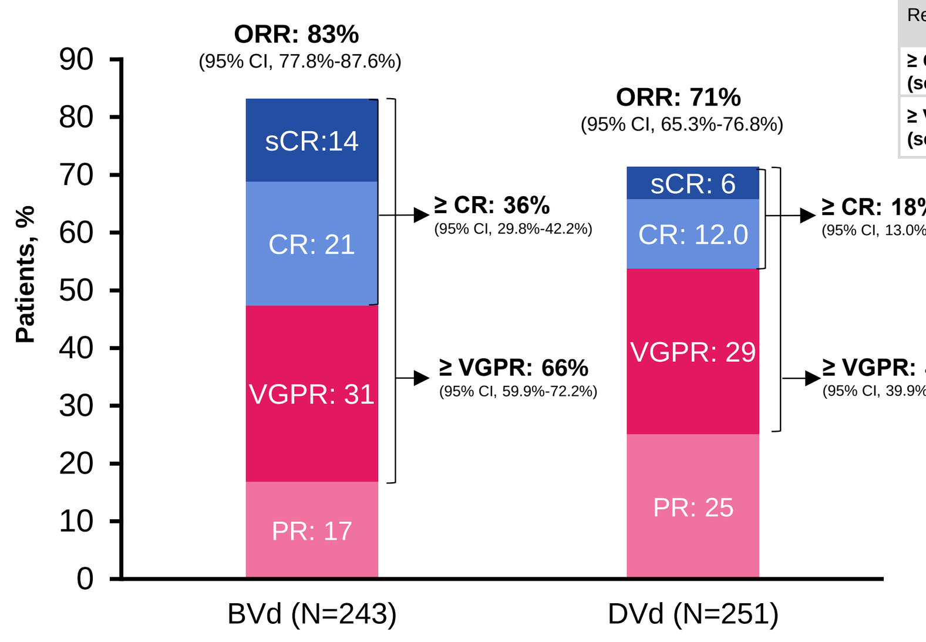
Figure 3: **PFS2[a]**



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.

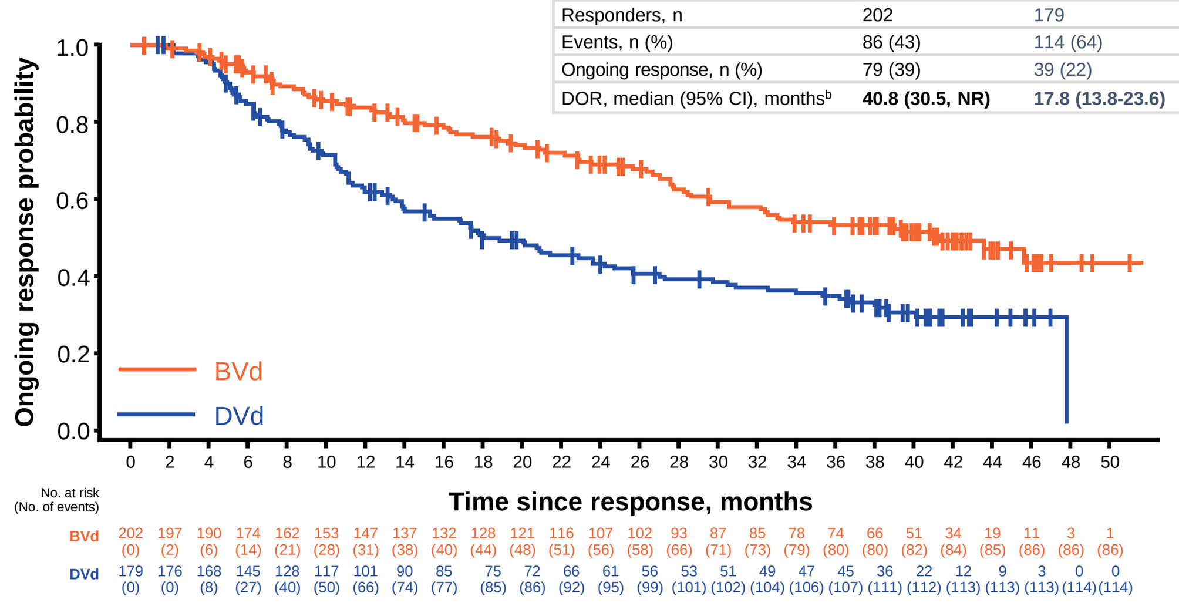
Figure 4: **Response rates and MRD negativity[a]**



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]
  - With increasing duration of treatment, median time between doses increased from 3 weeks to 12 weeks; despite this, response rate (best confirmed response of ≥ PR in each interval) remained high throughout (81%-97%)
  - Overall, 23% of patients experienced bilateral BCVA worsening to 20/50 or worse in the first 3 months of treatment; prevalence generally decreased thereafter to 4%
  - A low rate of treatment discontinuation due to ocular events was observed throughout (≤3.3%)

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)	
Unequivocally due to myeloma	19 (8)		44 (18)	
Equivocally due to myeloma	3 (1)		7 (3)	
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				
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 included, 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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Corresponding Author: Vania Hungria, MD, PhD, hungria@dialdata.com.br