Impact of dose modifications on efficacy outcomes with belantamab mafodotin in relapsed/refractory multiple myeloma: insights from the DREAMM-7 third-line or later proteasome inhibitor/immunomodulatory agent–exposed subgroup

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Consistent with the overall DREAMM-7 population, efficacy was maintained in the 3L+ subgroup following belamaf dose modifications that reduced relative dose intensity and extended dosing intervals

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Background

- Targeting BCMA has transformed the RRMM treatment landscape, with unprecedented improvement in OS outcomes vs SOC triplet regimens[1-4]
- Belamaf is a BCMA-targeting ADC with direct and indirect immunologic antitumor activity that avoids T-cell dysfunction and can be delivered in an outpatient setting[5,6]
- In DREAMM-7, BVd significantly improved PFS and OS in a head-to-head comparison vs DVd in patients with RRMM after ≥1 prior LOT[2,7]
- Ocular events were common but transient with belamaf and were addressed through protocol-defined dose modifications until improvement and co-management with an eye care professional[6,8]
- In patients treated with BVd and normal baseline vision,[a] dose modifications used to manage AEs, including ocular events, extended belamaf dosing intervals to a median of 8 weeks by 9 months[6]
- Here, we characterize the impact of extended belamaf dosing intervals on efficacy in a DREAMM-7 patient subgroup with ≥2 prior LOTs, including a proteasome inhibitor and immunomodulatory agent (3L+ subgroup)

[a] *Normal baseline vision in Mateos et al. was 20/25 or better in ≥1 eye.*

Conclusions

In the 3L+ subgroup, median PFS and OS favored BVd over DVd, with HRs (95%CIs) of 0.31 (0.21-0.47) and 0.49 (0.32-0.76), respectively

Dose modifications reduced belamaf RDI and extended dosing intervals, with a median RDI of 36% and a median dosing interval of 7.5 weeks at >12 to ≤24 months of belamaf treatment

Among patients in the 3L+ subgroup with extended belamaf dose intervals of >9 weeks, 90% had maintained or deepened responses during the first extended belamaf dosing interval

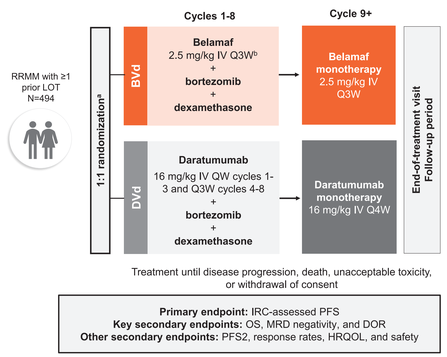
In patients in the 3L+ subgroup with ≥1 extended belamaf dosing interval of >9 weeks, median PFS was not reached, and 12- and 18-month PFS estimates were 94% and 83%, respectively

Consistent with the overall DREAMM-7 population, BVd demonstrated efficacy benefits in the 3L+ subgroup that were maintained following dose modifications resulting in extended belamaf dosing intervals

Methods

- DREAMM-7 (NCT04246047) is a phase 3, open-label, randomized trial evaluating the efficacy and safety of belamaf vs daratumumab with a Vd backbone (BVd vs DVd) in patients with RRMM and ≥1 prior LOT[2,7]

DREAMM-7 study design[2,7]



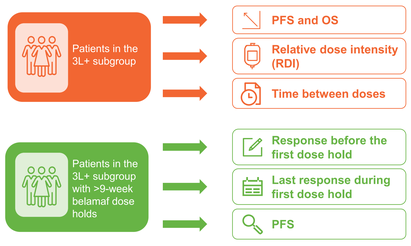
Treatment until disease progression, death, unacceptable toxicity, or withdrawal of consent

Primary endpoint: IRC-assessed PFS
Key secondary endpoints: OS, MRD negativity, and DOR
Other secondary endpoints: PFS2, response rates, HRQOL, and safety

[a] *Two patients in the ITT population underwent randomization but were not treated and underwent repeat screening and randomization; they are counted as 4 unique patients.* [b] *Dose modifications (delays or reductions) were permitted based on safety findings to manage AEs.*

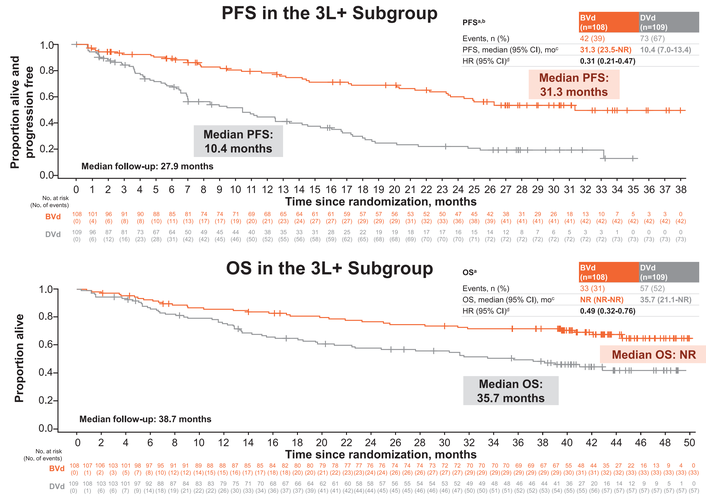
- This descriptive post hoc analysis assessed outcomes in a subset of patients with ≥2 prior LOTs, including treatment with both a proteasome inhibitor and immunomodulatory agent (3L+ subgroup; BVd, n=108; DVd, n=109)
- The data cutoff for this analysis was October 2, 2023, for PFS and response rate outcomes in the 3L+ subgroup and patients with extended dosing intervals, and October 7, 2024, for OS outcomes

Assessments conducted in the 3L+ subgroup



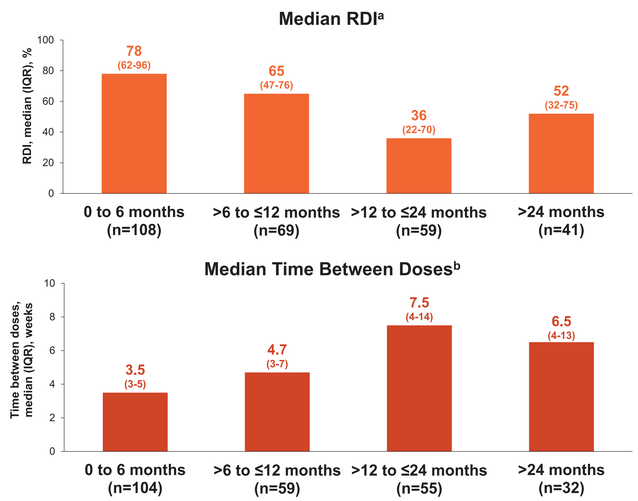
Results

Median PFS and OS favored BVd vs DVd in the 3L+ subgroup



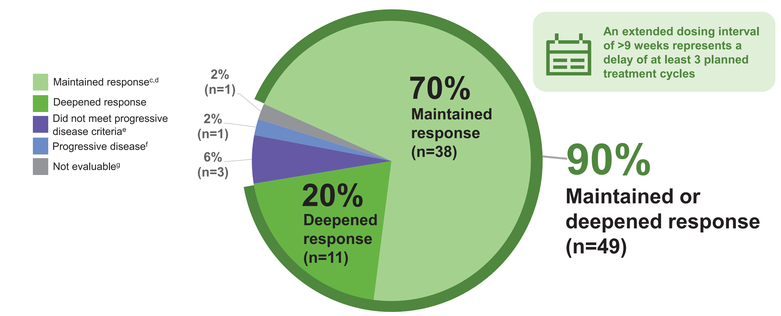
[a] *Based on all randomized patients who had received ≥2 prior LOTs, including a proteasome inhibitor and immunomodulatory agent.* [b] *Response was based on IRC assessment per International Myeloma Working Group criteria.* [c] *CIs were estimated using the Brookmeyer-Crowley method.* [d] *Based on the stratified Cox regression model.*

Dose modifications reduced belamaf RDI and extended the belamaf dosing interval in the 3L+ subgroup



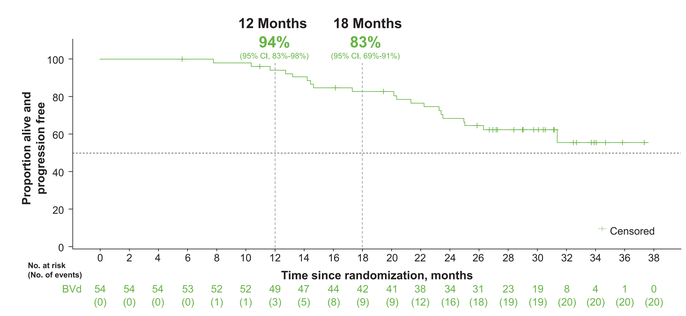
[a] *RDI was calculated as DI divided by 2.5, where DI was defined as cumulative dose divided by the number of 21-day cycles (DOE/21), and DOE was calculated as (last dose date + 20 days) minus first dose date + 1.* [b] *The time between doses only considered patients who had >1 visit during their treatment period.*

Responses were maintained or deepened in 90% of patients in the 3L+ subgroup during the first extended belamaf dose interval



[a] *In this post hoc analysis, response was based on the first assessment after a dose delay and may have excluded patients with delayed progression. In addition, the analysis excluded patients with ≤9-week dose delays who had disease progression or discontinued treatment.* [b] *Percentages were rounded, so the total adds up to 100%.* [c] *Maintained a last response of ≥ PR during the first extended dose delay.* [d] *Includes patients in a CR/sCR response category who maintained a response of ≥ VGPR.* [e] *Defined as patients who moved from a higher response category to a PR.* [f] *Developed progressive disease.* [g] *Not evaluable as the response assessment was not available or was incomplete.*

Median PFS was not reached in patients in the 3L+ subgroup with an extended belamaf dose interval of >9 weeks



[a] *CI for time variables estimated using the Brookmeyer-Crowley method.*

Abbreviations

3L+, third line or later; ADC, antibody-drug conjugate; AE, adverse event; BCMA, B-cell maturation antigen; belamaf, belantamab mafodotin; BVd, belantamab mafodotin, bortezomib, and dexamethasone; CR, complete response; DI, dose intensity; DOE, duration of exposure; DOR, duration of response; DVd, daratumumab, bortezomib, and dexamethasone; HR, hazard ratio; HRQOL, health-related quality of life; IRC, independent review committee; ITT, intention to treat; IV, intravenous; LOT, line of therapy; MRD, minimal residual disease; NR, not reached; OS, overall survival; PFS, progression-free survival; PFS2, progression-free survival on subsequent line of therapy; PR, partial response; Q3W, every 3 weeks; Q4W, every 4 weeks, QW, once weekly; RDI, relative dose intensity; RRMM, relapsed/refractory multiple myeloma; SOC, standard of care; Vd, bortezomib and dexamethasone; VGPR, very good partial response.

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Acknowledgments

The DREAMM-7 trial (NCT04246047) was sponsored by GSK (study ID: 207503).
We thank the patients who volunteered to participate in the trial, along with their families and caregivers, and the physicians and nurses who cared for the patients and supported this clinical trial.
Drug-linker technology was licensed from Seagen Inc; monoclonal antibody was produced using POTELLIGENT Technology, licensed from BioWa.
Medical writing and editorial assistance was provided by Nucleus Global, an Inizio company, and funded by GSK.

Disclosures

A-OA, **PR**, **MH**, **VZ**, **SG**, **HS**, and **MPdL** report no disclosures. **AC** reports a leadership or fiduciary role as a board member of The Arizona Clinical Oncology Society; current stock or stock options in KPTI; and prior stock or stock options in Pfizer. **M-VM** reports payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing, or educational events from Janssen, BMS, Amgen, GSK, Sanofi, AbbVie, Kite, Stemline, and Pfizer and participation on data safety monitoring or advisory boards with Janssen, BMS, Amgen, Sanofi, GSK, Roche, Pfizer, AbbVie, Kite, and Stemline. **CW** reports speaker fees and support for meeting attendance and/or travel from GSK. **PJH** reports participation on data safety monitoring or advisory boards for Australasian Leukemia & Lymphoma Group trials; unpaid advisory board roles with Antengene, Gilead, iTeos Therapeutics, Janssen, and Pfizer; and receipt of research support from Novartis, with medical writing for the unit paid to a medical writer. **RH** reports institutional grants or contracts from Janssen, Amgen, Celgene, BMS, Novartis, and Takeda; consulting fees from Janssen, Amgen, Celgene, AbbVie, BMS, Novartis, PharmaMar, and Takeda; payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing, or educational events from Janssen, Amgen, Celgene, BMS, PharmaMar, and Takeda; support for meeting attendance and/or travel from Amgen, Celgene, Takeda, and Janssen; and participation on data safety monitoring or advisory boards with BMS, Takeda, Amgen, Oncopeptides, Sanofi, Janssen, and GSK. **HB** reports employment, stock or stock options from GSK. **BK**, **TJ**, and **SW** reports employment, stock or stock options, and support for attending meetings and/or travel from GSK. **VH** reports payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing, or educational events from AbbVie, Amgen, BMS, GSK, Janssen, Sanofi, Takeda, and Pfizer and participation on data safety monitoring or advisory boards with BMS, GSK, Janssen, Kite, Regeneron, and Sanofi.

Society of Hematologic Oncology (SOHO) 2026 Annual Meeting | September 9-12, 2026 | Houston, TX, USA

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