

Patient-Reported Outcomes from DREAMM-7 and DREAMM-8 Using the EQ-5D-3L, Patient Global Impression of Severity and Patient Global Impression of Change

Suzanne Trudel,¹ Vania Hungria,² Maria-Victoria Mateos,³ **Jessica Best**,⁴ Chee Paul Lin,⁵ Julie Byrne,⁵ James Parker,⁴ Molly Purser,⁵ Sandhya Sapra,⁵ Farrah Pompilus,⁶ Sumita Roy-Ghanta,⁵ Giulia Fulci,⁷ Joanna Opalinska,⁵ Neal Sule,⁵ Brandon Kremer,⁵ Meletios A. Dimopoulos^{8,9}

¹Department of Medical Oncology and Hematology, Princess Margaret Cancer, Toronto, ON, Canada; ²Clinica São Germaino, São Paulo, Brazil; ³Hematology Department, University Hospital of Salamanca/IBSAL/Cancer Research Center-IBMCC (USAL-CSIC), Salamanca, Spain; ⁴GSK, London, UK; ⁵GSK, Collegeville, PA, USA; ⁶GSK, Boston, MA, USA; ⁷GSK, Waltham, MA, USA; ⁸Department of Clinical Therapeutics, School of Medicine, National and Kapodistrian University of Athens, Athens, Greece; ⁹Department of Medicine, Korea University, Seoul, Republic of Korea

Background

- The phase 3 **DREAMM-7** (NCT04246047) and **DREAMM-8** (NCT04484623) trials evaluated BVd vs DVd in patients with RRMM¹ and BPd vs PVd in patients with RRMM previously treated with lenalidomide,² respectively
 - In both studies, BVd and BPd conferred a significant benefit in progression-free survival
- In the **DREAMM-7**¹ and **DREAMM-8**² trials, PROs on The European Organisation for Research and Treatment of Cancer QLQ-C30 global health status/QOL were maintained throughout treatment and remained comparable between treatment arms over time
- To further characterise QOL, this analysis reports additional PROs using the EQ-5D-3L visual analog scale, Patient Global Impression of Severity and Patient Global Impression of Change, all of which are single-item, global scales that capture patients' direct assessment of their health and further inform the overall benefit-risk profile of belantamab mafodotin–based regimens
 - PGIS and PGIC reflect the patient's holistic impression of their disease state at a given time, which complements other QOL assessments

Conclusions

No difference in overall QOL (EQ-5D-3L VAS) was observed between belantamab mafodotin–based regimens and triple comparators in **DREAMM-7** and **DREAMM-8**

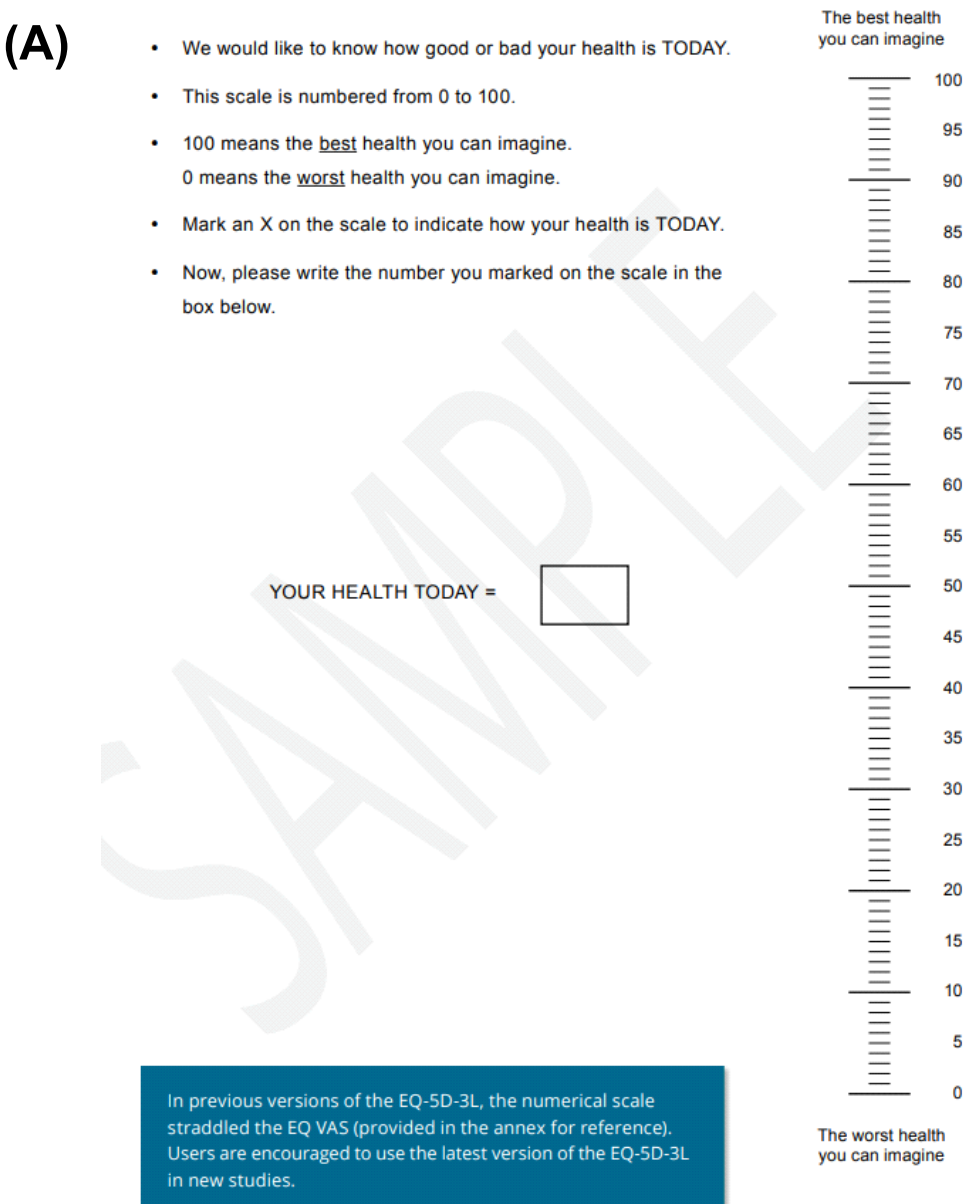
Patient-reported symptoms (PGIS) were consistently **less severe with BVd and BPd vs DVd and PVd**, respectively; PGIC scores were comparable across arms in both trials

Combined with the proven efficacy and manageable safety profiles of BVd and BPd, **these PRO data support the overall benefit of belantamab mafodotin–based regimens for patients with MM as early as first relapse**

Methods

- PROs were assessed using 3 instruments:
 - EQ-5D-3L VAS** is a standardised, patient-completed or interview-administered tool on which patients rate their overall health on a scale from 0 ('worst imaginable') to 100 ('best imaginable') to reflect their status on the day of assessment
 - PGIS** was used to evaluate overall symptom severity at baseline and subsequent timepoints, with patients rating their symptom status over the past week as 'none,' 'mild,' 'moderate,' 'severe,' or 'very severe'
 - PGIC** was used to assess change in overall symptom status since the start of treatment using a 5-point scale ranging from 'much better' to 'much worse'
- All PRO measures were assessed at baseline (day 1 cycle 1; except DREAMM-8 PGIC), throughout treatment (Q6W in DREAMM-7; Q8W for EQ-5D-3L and Q4W for PGIS and PGIC in DREAMM-8), at the end-of-treatment visit and during follow-up (PGIC and PGIS were not collected in DREAMM-8 OS follow-up)
- Descriptive statistics and line plots were used to summarise PROs
- The Kaplan-Meier method was used to estimate median times, with Brookmeyer-Crowley 95% CIs
- HRs for time-to-event endpoints were estimated using the Cox proportional hazards model, with Wald CIs

PRO Assessments (A) EQ-5D-3L VAS; (B) PGIS; (C) PGIC



(B) Patient Global Impression of Severity (PGIS)

Please choose the response below that best describes the severity of your overall status over the past week.

- ☐ None
- ☐ Mild
- ☐ Moderate
- ☐ Severe
- ☐ Very severe

(C) Patient Global Impression of Change (PGIC)

Since the start of the study, my overall status is:

Check 1 box only:

☐ Much better

☐ A little bit better

☐ No change

☐ A little worse

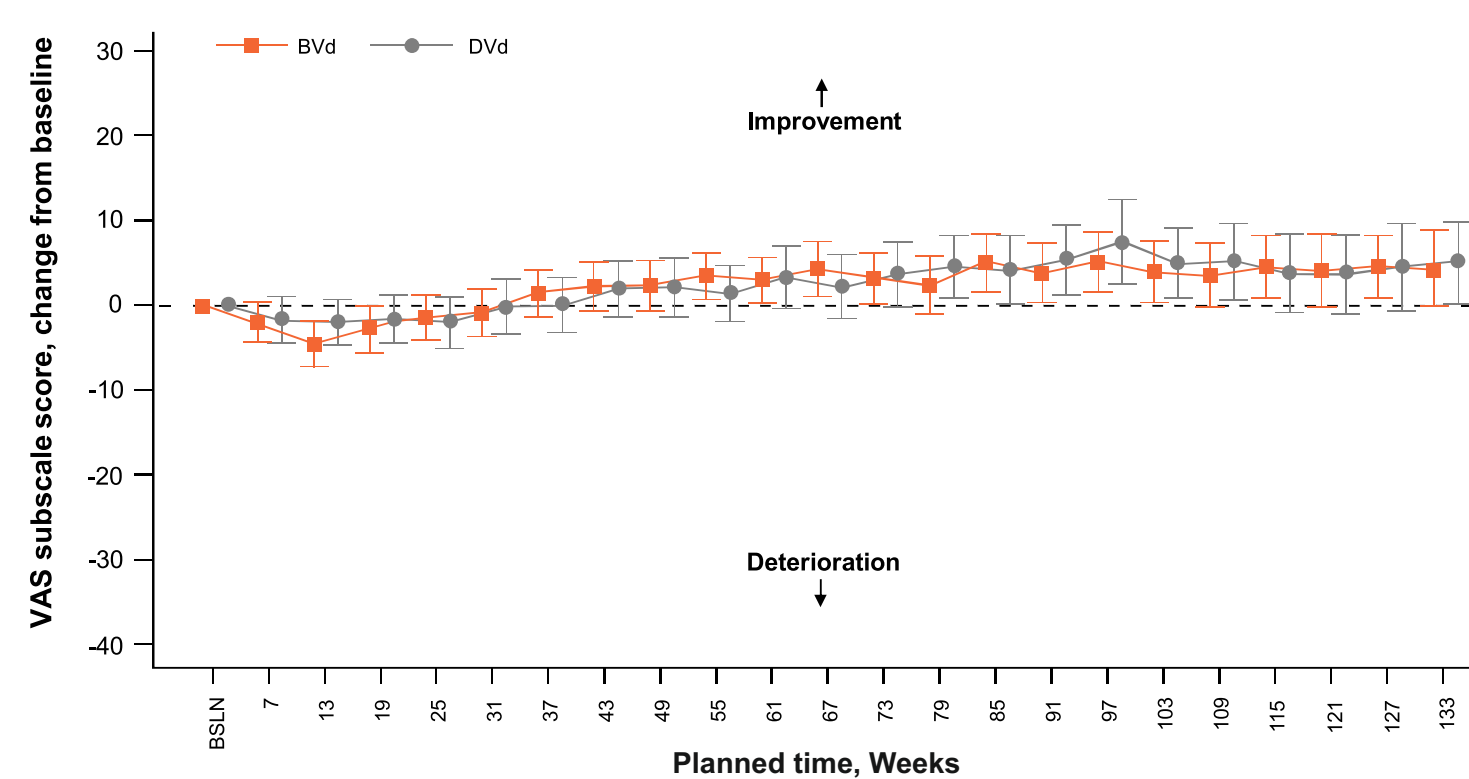
☐ Much worse

Results

EQ-5D-3L VAS

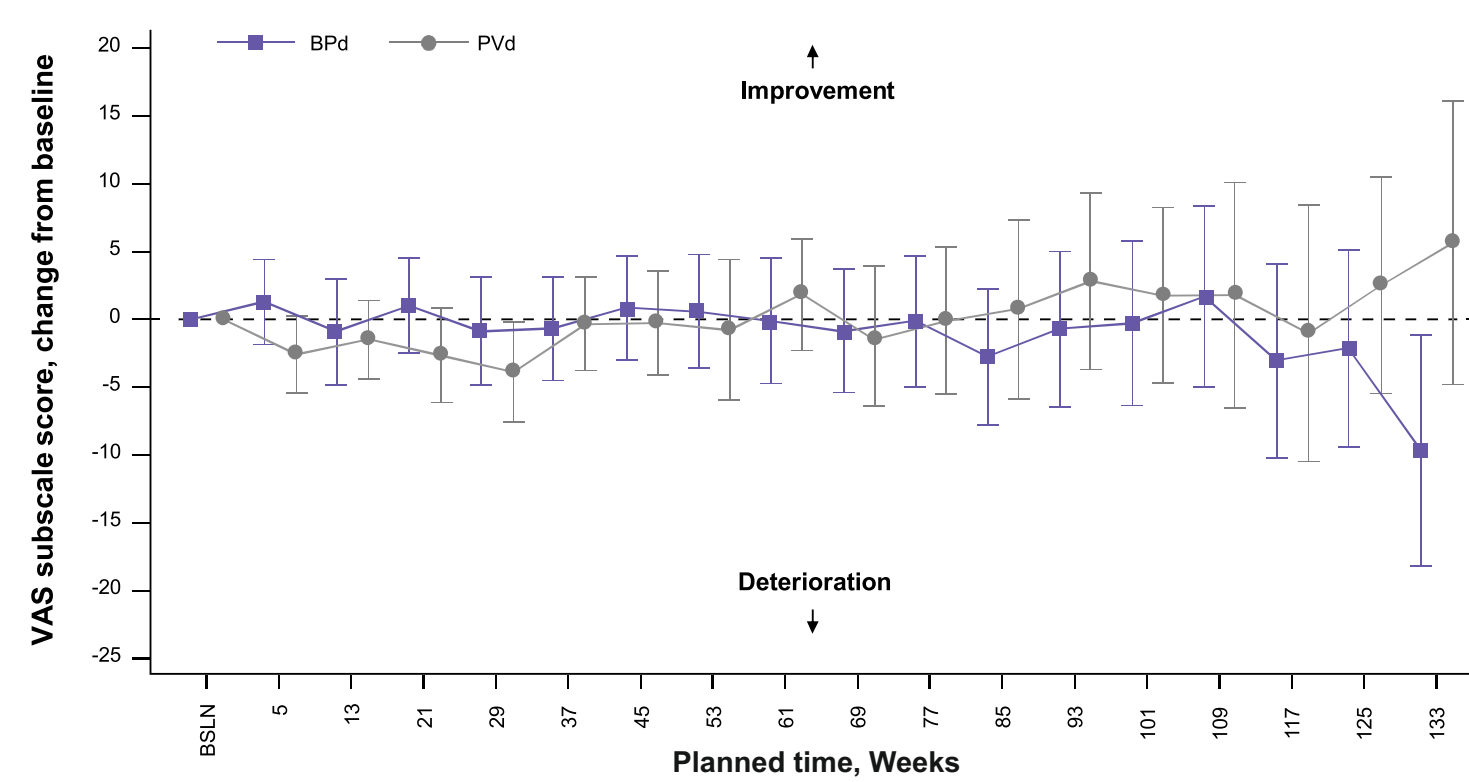
Overall QOL by EQ-5D-3L VAS did not differ between treatment arms in both DREAMM-7 and DREAMM-8

(A) DREAMM-7^{a,b}



DREAMM-7	BVd	DVd
Time to first improvement, median (95% CI), months	46.5 (24.8–NR)	38.7 (21.9–NR)
Inverse HR (95% CI)	1.09 (0.79–1.50)	
Time to first deterioration, median (95% CI), months	9.5 (5.6–32.5)	13.7 (6.9–NR)
HR (95% CI)	1.08 (0.84–1.41)	

(B) DREAMM-8^{a,c,d}



DREAMM-8	BPd	PVd
Time to first improvement, median (95% CI), months	NR (21.0–NR)	21.8 (17.5–NR)
Inverse HR (95% CI)	1.09 (0.74–1.62)	
Time to first deterioration, median (95% CI), months	17.7 (8.1–NR)	9.3 (6.5–16.4)
HR (95% CI)	0.84 (0.60–1.17)	

BPd, belantamab mafodotin, pomalidomide and dexamethasone; BSLN, baseline; BVd, belantamab mafodotin, bortezomib and dexamethasone; CI, confidence interval; DVd, daratumumab, bortezomib and dexamethasone; EOT, end-of-treatment; HR, hazard ratio; ITT, intention-to-treat; NR, not reached; PVd, pomalidomide, bortezomib and dexamethasone; VAS, visual analog scale.

Figures present data up to 133 Weeks due to low patient numbers at subsequent timepoints.

^a Intervals presented represent 95% confidence limits around the mean of each planned timepoint. ^b Two patients in the ITT analysis population were randomised, rescreened and randomised again, reflecting 4 unique patient IDs. ^c Confidence limits were populated if n=3. ^d Data collected at the EOT visit are summarised under both EOT visit and the nearest scheduled Week X visit.

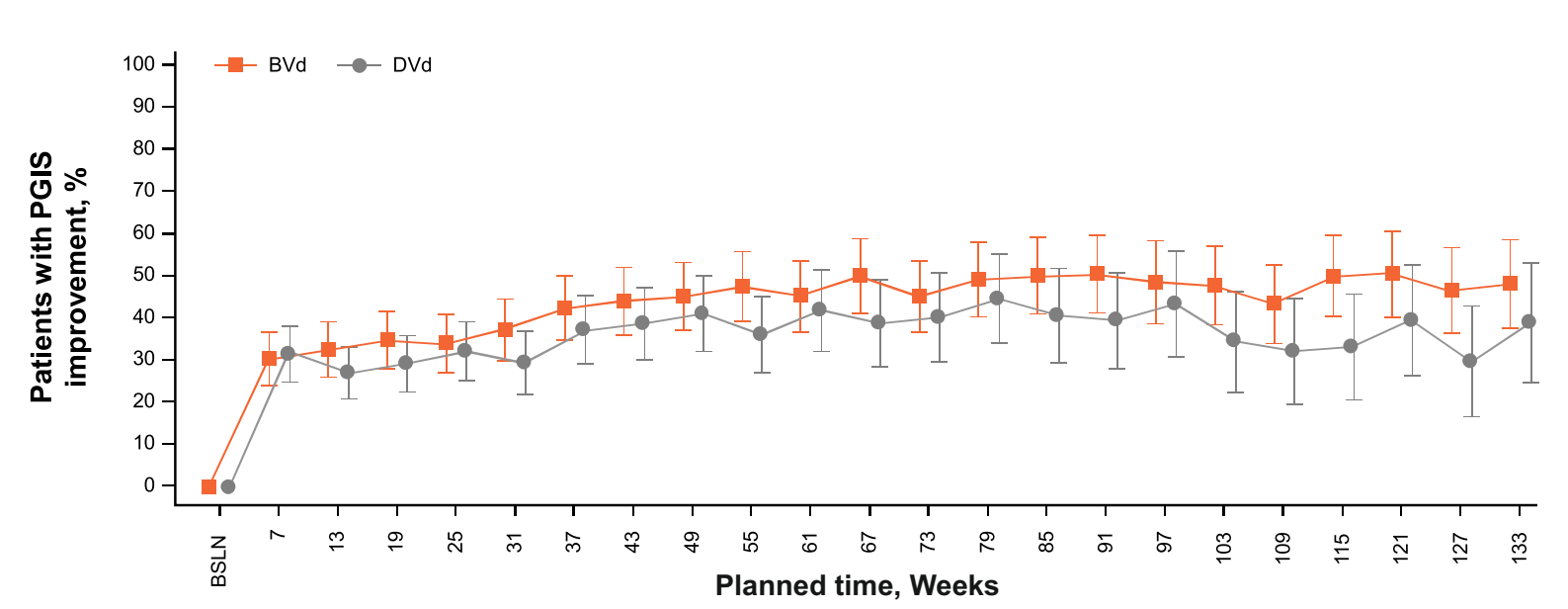


PROs (EQ-5D-3L, PGIS, and PGIC) demonstrated maintenance of overall QOL and reduced symptom burden with belantamab mafodotin–based regimens vs standard therapies in MM at first relapse

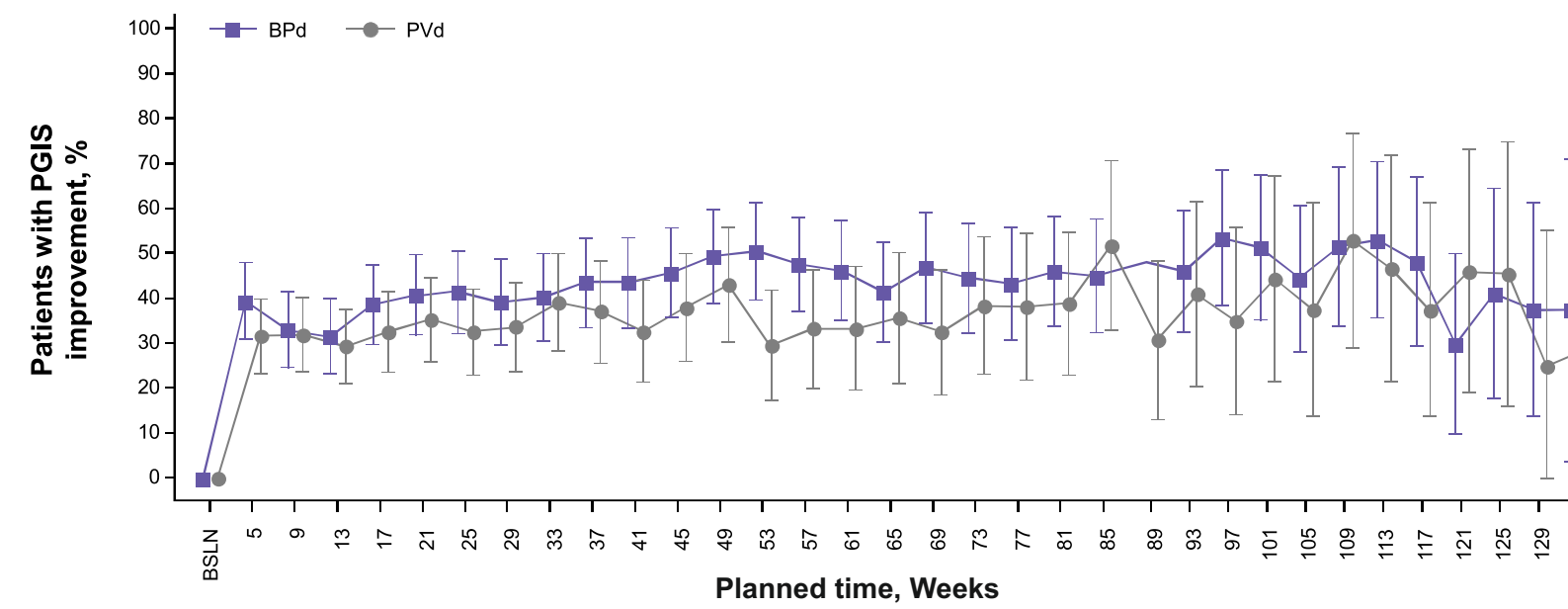
PGIS

A greater proportion of patients in the BVd and BPd arms reported ≥1-point improvements in PGIS symptom severity scores at nearly every assessment during treatment compared with DVd and PVd, respectively

(A) DREAMM-7 Percentage of Patients with Improvement by Visit^{a,c}



(B) DREAMM-8 Percentage of Patients with Improvement by Visit^{a,b}



BPd, belantamab mafodotin, pomalidomide and dexamethasone; BSLN, baseline; BVd, belantamab mafodotin, bortezomib and dexamethasone; CI, confidence interval; DVd, daratumumab, bortezomib and dexamethasone; HR, hazard ratio; ITT, intention-to-treat; Mo, months; NR, not reached; PGIS, Patient Global Impression of Severity; PVd, pomalidomide, bortezomib and dexamethasone.

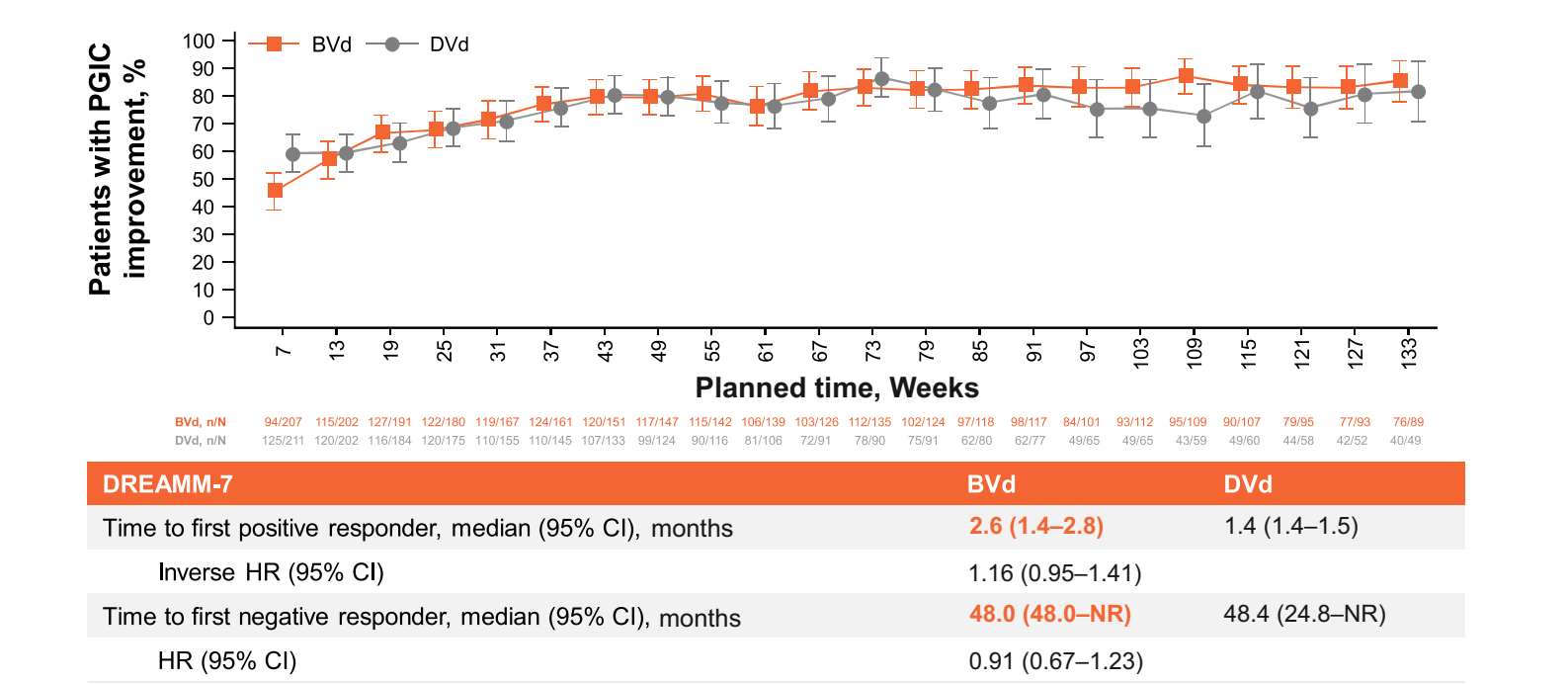
Data in (A) and (B) are presented up to 133 Weeks due to low patient numbers at subsequent timepoints.

^a PGIS improvement was defined as a decrease in PGIS score of ≥1 from baseline. ^b n is the number of patients with PGIS improvement at a particular visit, and N is the total number of patients at a particular visit. ^c Two patients in the ITT analysis population were randomised, rescreened and randomised again, reflecting 4 unique patient IDs.

PGIC

PGIC scores were similar between treatment arms across timepoints in DREAMM-7 and DREAMM-8

(A) DREAMM-7^{a,c}



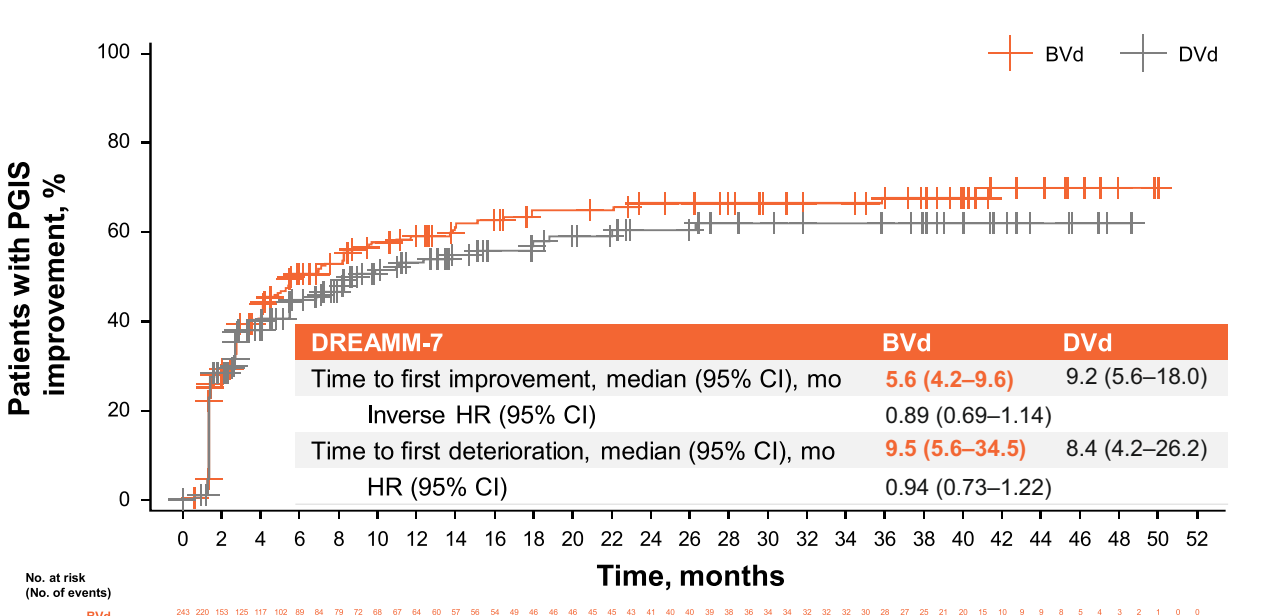
DREAMM-7	BVd	DVd
Time to first positive responder, median (95% CI), months	2.6 (1.4–2.8)	1.4 (1.4–1.5)
Inverse HR (95% CI)	1.16 (0.95–1.41)	
Time to first negative responder, median (95% CI), months	48.0 (48.0–NR)	48.4 (24.8–NR)
HR (95% CI)	0.91 (0.67–1.23)	

BPd, belantamab mafodotin, pomalidomide and dexamethasone; BVd, belantamab mafodotin, bortezomib and dexamethasone; CI, confidence interval; DVd, daratumumab, bortezomib and dexamethasone; HR, hazard ratio; ITT, intention-to-treat; NR, not reached; PGIC, Patient Global Impression of Change; PVd, pomalidomide, bortezomib and dexamethasone.

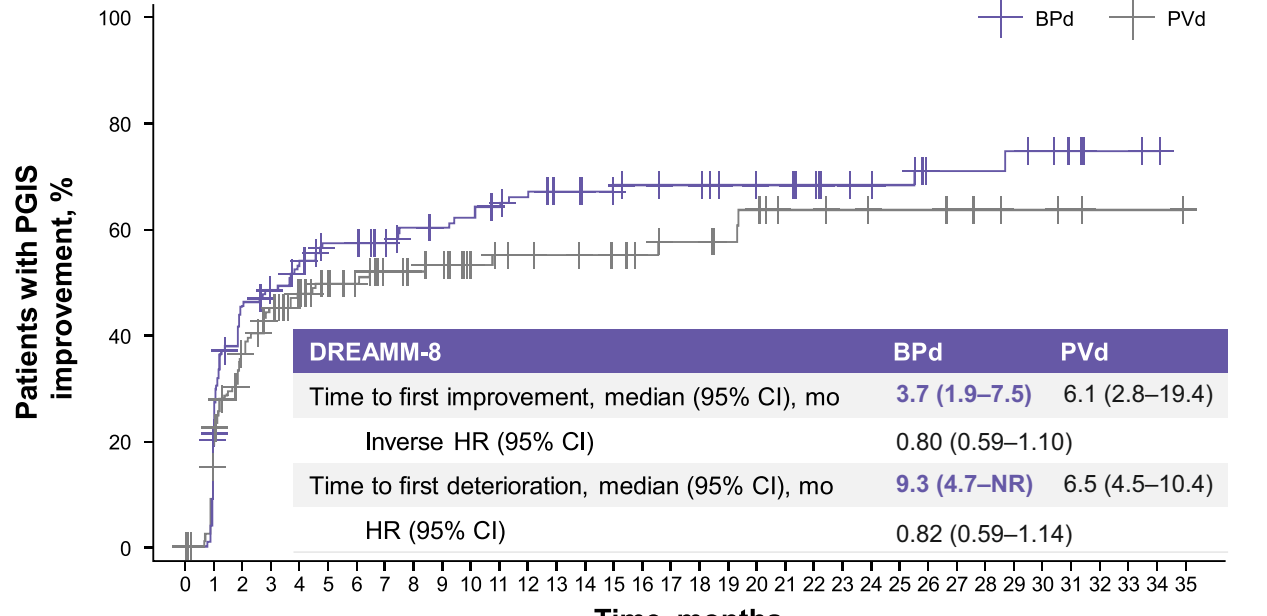
Data are presented up to 133 Weeks due to low patient numbers at subsequent timepoints.

^a PGIC improvement was defined as a PGIC value of 0 (much better) or 1 (a little better). ^b n is the number of patients with PGIC improvement at a particular visit, and N is the total number of patients at a particular visit. ^c Two patients in the ITT analysis population were randomised, rescreened and randomised again, reflecting 4 unique patient IDs.

(C) DREAMM-7 Time to First Improvement^a



(D) DREAMM-8 Time to First Improvement

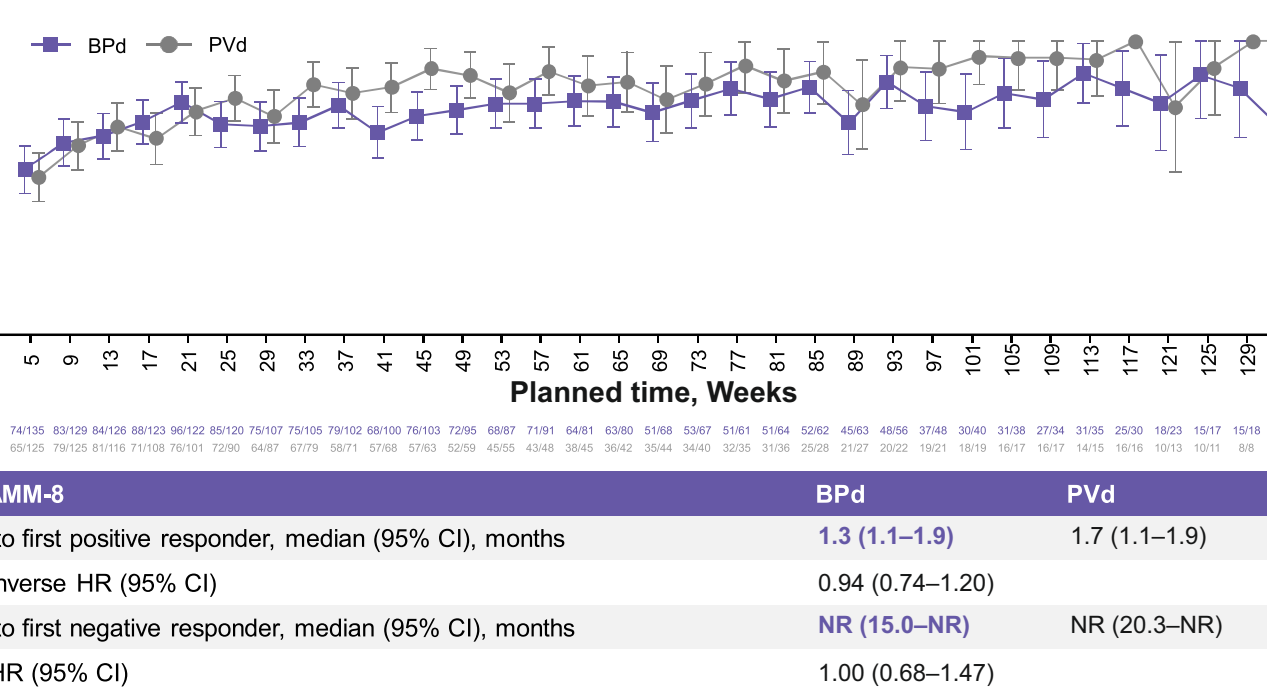


BPd, belantamab mafodotin, pomalidomide and dexamethasone; BSLN, baseline; BVd, belantamab mafodotin, bortezomib and dexamethasone; CI, confidence interval; DVd, daratumumab, bortezomib and dexamethasone; HR, hazard ratio; ITT, intention-to-treat; NR, not reached; PGIC, Patient Global Impression of Severity; PVd, pomalidomide, bortezomib and dexamethasone.

Data in (A) and (B) are presented up to 133 Weeks due to low patient numbers at subsequent timepoints.

^a PGIS improvement was defined as a PGIC value of 0 (much better) or 1 (a little better). ^b n is the number of patients with PGIC improvement at a particular visit, and N is the total number of patients at a particular visit. ^c Two patients in the ITT analysis population were randomised, rescreened and randomised again, reflecting 4 unique patient IDs.

(B) DREAMM-8^{a,b}



DREAMM-8	BPd	PVd
Time to first positive responder, median (95% CI), months	1.3 (1.1–1.9)	1.7 (1.1–1.9)
Inverse HR (95% CI)	0.94 (0.74–1.20)	
Time to first negative responder, median (95% CI), months	NR (15.0–NR)	NR (20.3–NR)
HR (95% CI)	1.00 (0.68–1.47)	

References

- Hungria V, et al. *N Engl Med*. 2024;391:393-407.
- Dimopoulos MA, et al. *N Engl Med*. 2024;391:408-421.

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Disclosures

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Jessica Best will be presenting this encore poster on behalf of the original authors and with their permission.

Presenter: Jessica Best, jessica.8.best@gsk.com