Durable clinical benefit with BCMA-directed therapy, belantamab mafodotin plus pomalidomide and dexamethasone in relapsed/refractory multiple myeloma: DREAMM-8 long-term responder analysis

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Almost 40% of patients treated with BPd had prolonged remission as long-term responders (PFS ≥30 months), and >80% of these patients maintained PFS at 4 years

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Background

- Targeting BCMA has transformed the RRMM treatment landscape, delivering unprecedented survival benefits over standard-of-care triplets[1,2]
- Belamaf is an antibody-drug conjugate representing a unique BCMA-targeting modality that is accessible across all sites of care
- Belamaf, in combination with Pd, significantly improved PFS vs PVd in the DREAMM-8 phase 3 trial (HR, 0.52; 95% CI, 0.37-0.73; *P*<0.001)[3]
- This post hoc analysis was conducted to investigate the characteristics of and outcomes in patients who achieved sustained clinical benefit with BPd and are considered LTRs

Conclusions

Almost 40% of patients treated with BPd achieved LTR status, representing a 2.5-fold higher rate than with PVd

Higher LTR rates were also seen with BPd in patients with high-risk cytogenetics

BPd-treated LTRs had deeper responses compared with PVd-treated LTRs

BPd-treated LTRs demonstrated a trend toward prolonged PFS and PFS2

The safety profile in LTRs (PFS ≥30 months) was generally consistent with previous reports in the overall safety population[3]

Methods

- DREAMM-8 is a phase 3 trial of BPd vs PVd in patients with RRMM after ≥1 prior LOT including lenalidomide[3]

DREAMM-8 study design[3]

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

Primary endpoint: PFS (IRC assessed per IMWG)

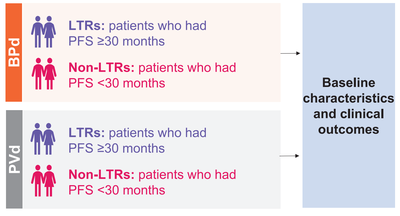
Key secondary endpoints: OS, MRD negativity, DOR

Other secondary endpoints: ORR, CRR, ≥ VGPR, TTBR, TTR, TTP, PFS2,[b] AEs, ocular findings, HRQOL, PROs

[a] Patients aged >75 years with comorbidities or intolerance of the 40-mg dose in arm A or 20-mg dose in arm B could have dose level reduced to half per investigator discretion. [b] PFS2 was defined as time from randomization to disease progression after initiation of new antimyeloma therapy or death from any cause, whichever was earliest.

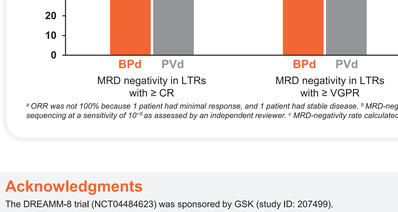
- This post hoc analysis evaluated baseline characteristics and clinical outcomes in LTRs, defined as patients who had PFS ≥30 months
- All patients who have remained on study have been on study for >30 months
  - Data cutoff: July 7, 2025; median follow-up, 36 months in both arms

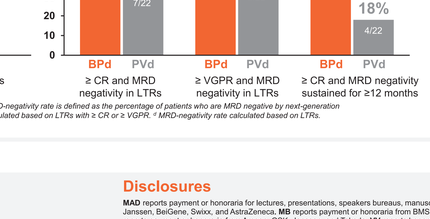
Post hoc analysis in LTRs and non-LTRs



Results

The proportion of LTRs was higher with BPd, including patients with high-risk cytogenetics





[a] High-risk cytogenetics was defined as the presence of ≥1 of the following: t(4;14), t(14;16), or del(17p13). Standard-risk cytogenetics was defined as negative results for all high-risk abnormalities: t(4;14), t(14;16), and del(17p13). Cytogenetic data were missing or nonevaluable in 12 BPd- and 3 PVd-treated LTRs and 19 BPd- and 22 PVd-treated non-LTRs.

- Of the 302 patients in DREAMM-8, 81 were LTRs

BPd-treated LTRs had deeper responses vs PVd-treated LTRs

[a] ORR was not 100% because 1 patient had minimal response, and 1 patient had stable disease. [b] MRD-negativity rate is defined as the percentage of patients who are MRD negative by next-generation sequencing at a sensitivity of 10^{-5} as assessed by an independent reviewer. [c] MRD-negativity rate calculated based on LTRs with ≥ CR or ≥ VGPR. [d] MRD-negativity rate calculated based on LTRs.

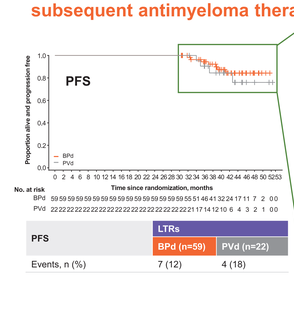
Treatment arms were generally balanced at baseline with a higher proportion of LTRs in earlier therapy lines

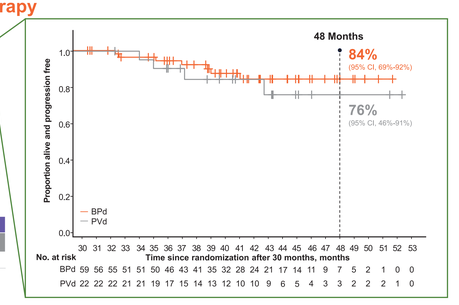
	LTRs	
Baseline characteristics	**BPd (n=59)**	**PVd (n=22)**
Female/male sex, n (%)	25 (42) / 34 (58)	12 (55) / 10 (45)
Age, median (range), years	65.0 (44-79)	69.5 (42-79)
ISS at screening, n (%)		
I	39 (66)	15 (68)
II	15 (25)	6 (27)
III	5 (8)	1 (5)
Line of therapy completed at screening, n (%)		
1	39 (66)	15 (68)
2	14 (24)	4 (18)
≥3	6 (10)	3 (14)

- The safety profile in LTRs was generally consistent with previous reports in the overall DREAMM-8 safety population[3]
- In BPd vs PVd LTRs, exposure-adjusted rates per 100 patient-years of neutropenia[a] (23.4 vs 21.1), infections[b] (27.4 vs 27.6), and pneumonia (9.6 vs 9.2) were similar, as were exposure-adjusted rates of grade 3/4 events (30 vs 25)
- Grade ≥3 exposure-adjusted rates per 100-patient years of infections[b] (17.8 vs 6.6) and pneumonia (8.1 vs 3.9) were higher for BPd vs PVd LTRs

[a] Neutropenia includes preferred terms febrile neutropenia, neutropenia, and neutrophil count decreased. [b] System organ class event.

BPd-treated LTRs demonstrated prolonged PFS that continued following first subsequent antimyeloma therapy





	LTRs	
PFS	**BPd (n=59)**	**PVd (n=22)**
Events, n (%)	7 (12)	4 (18)

	LTRs	
PFS2	**BVd (n=59)**	**PVd (n=22)**
Events, n (%)	4 (7)	3 (14)

- PFS and PFS2 follow-up in the DREAMM-8 study is ongoing

Abbreviations

ADC, antibody-drug conjugate; AE, adverse event; BCMA, B-cell maturation antigen; belamaf, belantamab mafodotin; BPd, belamaf, pomalidomide, and dexamethasone; CR, complete response; CRR, complete response rate; DOR, duration of response; HR, hazard ratio; HRQOL, health-related quality of life; IMWG, International Myeloma Working Group; IRC, independent review committee; ISS, International Staging System; IV, intravenous; LOT, line of therapy; LTR, long-term responder; MRD, minimal residual disease; ORR, overall response rate; OS, overall survival; Pd, pomalidomide and dexamethasone; PFS, progression-free survival; PFS2, progression-free survival on subsequent line of therapy; PR, partial response; PRO, patient-reported outcome; PVd, pomalidomide, bortezomib, and dexamethasone; Q4W, every 4 weeks; RRMM, relapsed/refractory multiple myeloma; SC, subcutaneous; sCR, stringent complete response; TTBR, time to best response; TTP, time to progression; TTR, time to response; VGPR, very good partial response.

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