

Deep responses and durable outcomes in patients treated with belantamab mafodotin plus pomalidomide and dexamethasone from long-term follow-up of the phase 3 DREAMM-8 study

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Background

- In the phase 3, open-label, randomized DREAMM-8 trial (NCT04484623) in patients with RRMM after ≥1 prior line of therapy including lenalidomide, BPd significantly improved PFS vs Pvd (data cutoff: January 29, 2024; median follow-up, 21.8 months; HR, 0.52; 95% CI, 0.37-0.73; $P < 0.001$)¹
- To better characterize the durability of BPd treatment benefit in RRMM, we report long-term follow-up from the DREAMM-8 trial (data cutoff: July 7, 2025; median follow-up, 35.8 months), including updated efficacy (PFS, MRD negativity, DOR, and PFS2) and safety

Conclusions

BPd led to a 5-fold increase in MRD negativity and sustained MRD negativity vs Pvd in patients with RRMM, most of whom had lenalidomide-refractory disease and a quarter of whom had disease refractory to anti-CD38 monoclonal antibodies

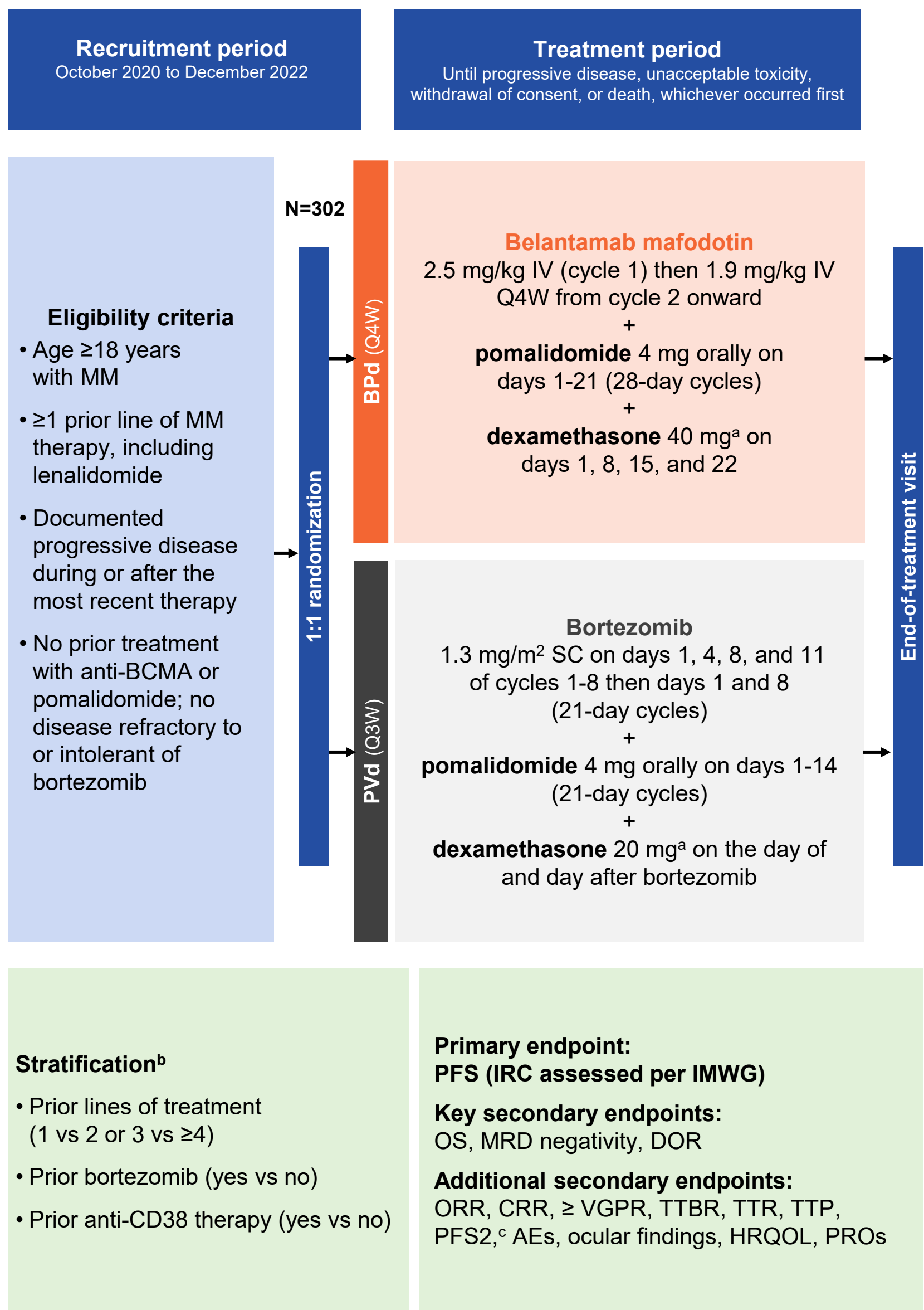
BPd was associated with an approximately 3-fold greater median PFS vs Pvd (increase of >20 months), with greater than double the benefit following subsequent antineoplastic therapy (median PFS2); follow-up for OS is ongoing

Long-term follow-up from the DREAMM-8 trial demonstrated that BPd maintained superiority over Pvd across all efficacy endpoints, including PFS, MRD negativity, sustained MRD negativity, and DOR. Importantly, benefit was maintained following subsequent antineoplastic therapy

Collectively, findings support BPd as a new outpatient and off-the-shelf BCMA treatment as standard of care in MM at first relapse

Methods

DREAMM-8 is a phase 3 trial of BPd vs Pvd in patients with RRMM after ≥1 prior line of therapy, including lenalidomide¹



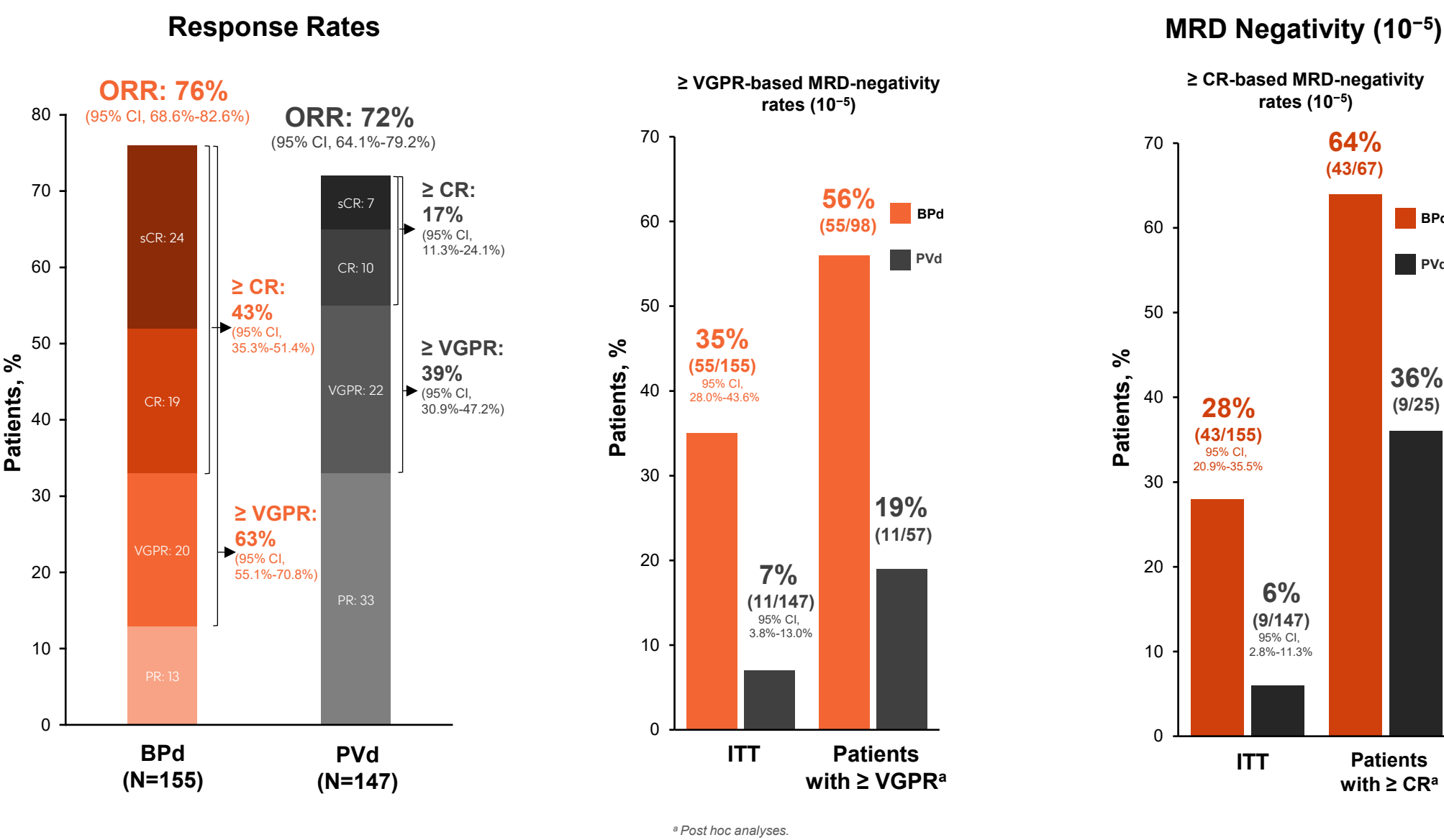
^aPatients aged >75 years with comorbidity or intolerance of the 40-mg dose in arm A or 20-mg dose in arm B could have dose level reduced to half per investigator discretion. ^bSome patients were ineligible for OS stage 1 or 2. ^cAEs were assessed on April 22, 2021. ^dPatients who discontinued therapy with prior anti-CD38 treatment (yes vs no). ^ePFS2 was defined as time from randomization to disease progression after initiation of new antineoplastic therapy or death from any cause, whichever is earlier.

Results

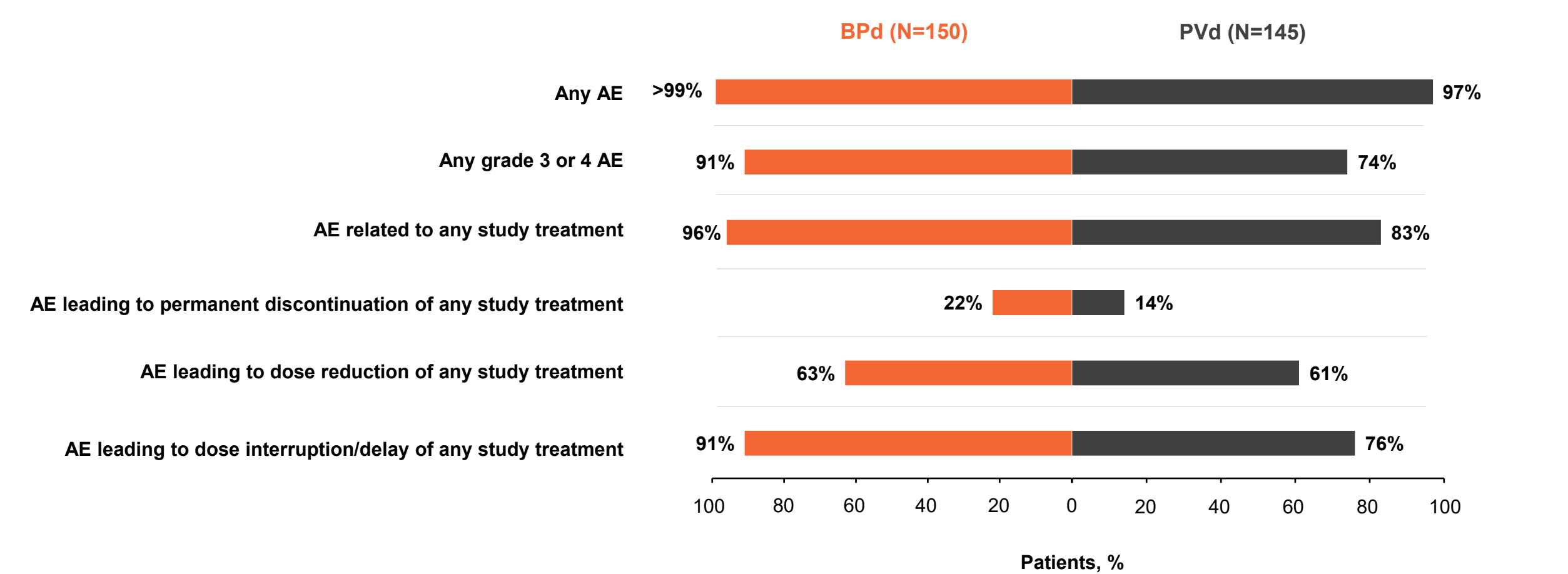
Most patients had lenalidomide-refractory disease, and a quarter had disease refractory to anti-CD38 monoclonal antibodies¹

- Overall, 159 patients (53%) had received 1 prior line of therapy, 102 (34%) had received 2 or 3, and 41 (14%) had received ≥4
- All patients had previously received lenalidomide; 25% (38/155) in the BPd arm had previously received anti-CD38 antibodies vs 29% (42/147) in the Pvd arm
- Approximately one-quarter of patients in each arm were triple-class exposed: 22% (34/155) in the BPd arm and 27% (39/147) in the Pvd arm

Treatment with BPd led to higher rates of deep and durable responses compared with Pvd

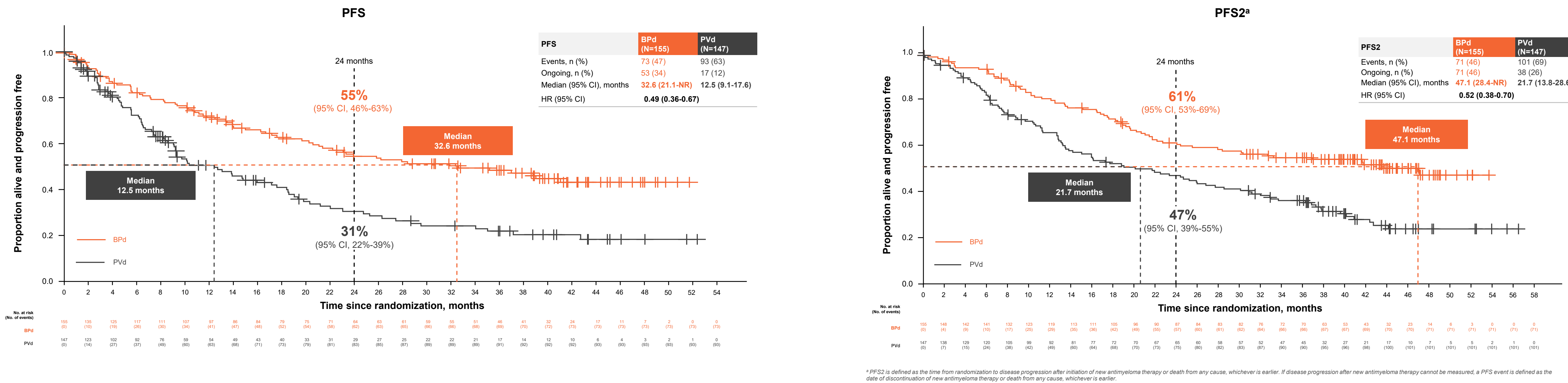


The updated safety profile of BPd was broadly consistent with the primary analysis



- In patients who were ≥ CR-based MRD negative,^a 56% (24/43) in the BPd arm and 44% (4/9) in the Pvd arm had sustained MRD negativity for ≥12 months

Deep and durable responses with BPd were associated with substantial PFS benefit that was maintained following subsequent antineoplastic therapy



Abbreviations

AE, adverse event; BCMA, B-cell maturation antigen; BPd, belantamab mafodotin; pomalidomide, and dexamethasone; CD, cluster of differentiation; 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; ITT, intention to treat; IV, intravenous; MM, multiple myeloma; MRD, minimal residual disease; NGS, next-generation sequencing; NR, not reached; ORR, overall response rate; OS, overall survival; PFS, progression-free survival; PR, partial response; PRO, patient-reported outcome; Pvd, pomalidomide, bortezomib, and dexamethasone; Q4W, every 4 weeks; QW, every 1 week; RRMM, relapsed and refractory multiple myeloma; SC, subcutaneous; sCR, stringent complete response; TTR, time to best response; TTP, time to progression; TTR, time to response; VGPR, very good partial response.

Reference

- Dimopoulos MA, et al. *N Engl J Med*. 2024;391(15):408-421.

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