LBA105 Clinical Science Symposium

Results from the randomized phase 3 DREAMM-8 study of belantamab mafodotin plus pomalidomide and dexamethasone (BPd) vs pomalidomide plus bortezomib and dexamethasone (PVd) in relapsed/refractory multiple myeloma (RRMM).

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Background: Use of triplet/quadruplet therapies for 1L MM raises the need for novel combinations at first relapse, which belantamab mafodotin (belamaf) combos may address. In DREAMM-7, BVd led to a significant improvement in progression-free survival (PFS) and a strong trend in improved overall survival (OS) vs daratumumab-Vd in patients (pts) with ≥1 prior therapy. We report results from DREAMM-8 (NCT04484623), which tested a different belamaf combo (BPd) and met its primary endpoint of independent review committee–assessed PFS at a prespecified interim analysis. **Methods:** DREAMM-8 is a phase 3, open-label, randomized, multicenter trial evaluating the efficacy and safety of BPd vs PVd in RRMM pts who received ≥1 prior line of therapy (LoT), including lenalidomide. Pts were randomly assigned 1:1 to BPd (28-d cycles): belamaf 2.5 mg/kg IV (D1, C1), 1.9 mg/kg (D1, C2+) + pom 4 mg (D1-21, all C) + dex 40 mg (D1, QW, all C), or PVd (21-d cycles): pom 4 mg (D1-14, all C) + bortezomib 1.3 mg/m^2 SC (D1, 4, 8, 11 [C1-8]; and D1, 8 [C9+]) + dex 20 mg (day of and 1 day after bortezomib dose). **Results:** 155 pts were randomly assigned to BPd and 147 to PVd. With a median (range) follow-up of 21.78 mo (0.03-39.23), median PFS (95% CI) was not reached (NR; 20.6-NR) with BPd vs 12.7 mo (9.1-18.5) with PVd (HR, 0.52; 95% CI, 0.37-0.73; $P<0.001$). 12-month PFS rate (95% CI) was 71% (63-78%) with BPd vs 51% (42-60%) with PVd. ORR (95% CI) was 77% (70.0-83.7%) with BPd vs 72% (64.1-79.2%) with PVd; rate of complete response or better (95% CI) was 40% (32.2-48.2%) with BPd vs 16% (10.7-23.3%) with PVd. Median duration of response (95% CI) was NR (24.9-NR) with BPd vs 17.5 mo (12.1-26.4) with PVd. A positive trend favoring BPd was seen for OS (HR, 0.77; 95% CI, 0.53-1.14); follow up for OS is ongoing. Adverse events (AEs) were reported in >99% and 96% of pts in the BPd and PVd arms, respectively. Of pts treated with BPd, 89% had ocular AEs (CTCAE grade 3/4, 43%) vs 30% (grade 3/4, 2%) in the PVd arm. AEs were generally manageable, and broadly consistent with known safety profile of individual agents. **Conclusions:** The DREAMM-8 study demonstrated a statistically significant and clinically meaningful PFS benefit with BPd vs PVd in RRMM with >1 prior LoT. BPd also led to deeper and more durable responses, showed a favorable OS trend, and had a manageable safety profile. Clinical trial information: NCT04484623. Research Sponsor: GSK plc.

Additional baseline and safety data.

Baseline Characteristics	BPd (n=155)	PVd (n=147)
Prior LoT, median (range)	1 (1-6)	1 (1-9)
Prior antimyeloma therapy, n (%)		
Immunomodulator	155 (100)	147 (100)
Proteasome inhibitor	140 (90)	136 (93)
Anti-CD38 antibody	38 (25)	42 (29)
Safety	**(n=150)[a]**	**(n=145)[a]**
Grade 3/4 AEs, n (%)	136 (91)	106 (73)
Any SAEs; fatal SAEs, n (%)	95 (63); 17 (11)	65 (45); 16 (11)
AEs leading to discontinuation of any study treatment, n (%)	22 (15)	18 (12)

[a]Safety data were evaluated in the safety analysis set.