

Endpoints: **Primary** - PFS (IRC-assessed, per IMWG).
Secondary - OS, MRD negativity, DoR.

Eligibility: ≥1 prior line of MM therapy including lenalidomide; no prior treatment with anti-BCMA or pomalidomide; not refractory/intolerant to bortezomib; progressive disease during or after the most recent therapy.

STUDY DESIGN (NCT04484623)

1:1 randomization

Treatment continues until PD, death, unacceptable toxicity, end of study, or withdrawal of consent.

BPd arm (Q4W)

Belantamab mafodotin

2.5 mg/kg (Cycle 1)
1.9 mg/kg Q4W (Cycle 2 onwards)

Pomalidomide | 4 mg

Days 1–21 (28-day cycles)

Dexamethasone | 40 mg*

Days 1, 8, 15, and 22

PVd arm (Q3W)

Bortezomib | 1.3 mg/m²

Days 1, 4, 8, and 11 (Cycles 1–8)
Days 1 and 8, Cycle 9 onwards (21-day cycles)

Pomalidomide | 4 mg

Days 1–14 (21-day cycles)

Dexamethasone | 20 mg*

Day of and day after bortezomib

*Patients aged >75 years, with comorbidities, or intolerant to 40 mg dose in Arm A or 20 mg dose in Arm B could have dose level reduced to half, per investigator discretion.

EFFICACY

BPd arm

ORR 77%

PR 14%

VGPR 24%

CR 31%

sCR 9%

MRD negativity in ≥CR: 24% (of 40%)

PVd arm

ORR 72%

PR 34%

VGPR 22%

CR 14%

sCR 3%

MRD negativity in ≥CR: 5% (of 17%)

Median PFS (p < 0.001)

NR

12.7

Disease progression/death HR: 0.52 (0.37–0.73)

Median DoR

NR

17.5

Median OS

NR

NR

1-year outcomes (BPd, n = 155; PVd, n = 147)

PFS

71%

51%

DoR

79%

61%

OS

83%

76%

SAFETY

BPd arm | PVd arm

Grade ≥3 AEs

94%

76%

SAEs

63%

45%

Bilateral worsening in BCVA BPd arm

20/50 or worse

34%

First event resolved: 84%

First event improved: 92%

20/200 or worse

1%

First event resolved: 50%

First event improved: 100%

Most common ocular AESIs with BPd

Any grade

89%

Any event

43%

79%

Vision blurred

17%

61%

Dry eye

8%

61%

Foreign body sensation in eye

6%

50%

Eye irritation

4%

44%

Photophobia

3%

33%

Eye pain

2%

Dose modifications on safety and efficacy

Bilateral worsening of BCVA 20/50 or worse

Discontinued (KVA or CTCAE ocular event)

Median time between doses

Patients (%)

Time since first belantamab mafodotin dose (months)

Median average time between doses (weeks)

Belantamab mafodotin demonstrated a significant reduction in the risk of progression or death vs PVd, along with promising efficacy. Ocular toxicities were managed through dose modifications. These data support the use of belantamab mafodotin in the relapsed setting, particularly for patients without access to CAR T-cell or bispecific antibody therapies.

Abbreviations: AE, adverse event; AESI, adverse event of special interest; BCMA, B-cell maturation antigen; BCVA, best corrected visual acuity; BPd, belantamab mafodotin-pomalidomide-dexamethasone; CTCAE, common terminology criteria for adverse events; DoR, duration of response; IMWG, International Myeloma Working Group; IRC, independent review committee; KVA, keratopathy and visual acuity; MM, multiple myeloma; MRD, measurable residual disease; NR, not reached; ORR, overall response rate; OS, overall survival; PD, progression of disease; PFS, progression-free survival; PR, partial response; PVd, pomalidomide-bortezomib-dexamethasone; RR, relapsed/refractory; SAE, serious adverse event; sCR, stringent complete response; VGPR, very good partial response; Q3W, every 3 weeks; Q4W, every 4 weeks.

Dimopoulos M. Oral abstract #5682. EHA 2024 Hybrid Congress; Jun 13–16, 2024; Madrid, ES.
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