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BOSTON trial subgroup analysis[1]

Impact of prior treatment with lenalidomide on SVd outcomes in relapsed/refractory multiple myeloma

Overall population

BOSTON study design[2]

BOSTON patients (N=402) were **randomized 1:1** to selinexor, bortezomib, and dexamethasone (**SVd**; n=195) **OR** bortezomib and dexamethasone (**Vd**; n=207) treatment (NCT03110562).*

Inclusion criteria: Patients ≥18 years with measurable myeloma (IMWG criteria); evidence of PD on/after previous treatment; 1–3 previous treatments for MM†

BOSTON study results[2]

BL characteristics:

- 2 groups were balanced
- Median age: **67 years** (IQR, 59–73)
- High-risk cytogenetic abnormalities: **192 (42%)**
- Median time since initial diagnosis: **3.7** years (2.3–5.5)
- **19%** received 3 previous regimens

Follow-up duration: SVd: **13.2 months**; Vd: **16.5 months**

Efficacy results

- **Primary endpoint – median PFS (95% CI)**: SVd: **13.93 months (11.73–NE)**; Vd: **9.46 months (8.11–10.78)** (HR, 0.70 [95% CI, 0.53–0.93], **P=0.0075**‡)
- **Median OS**: Not reached in SVd; **25 months** in Vd; median follow-up, 17.3 and 17.5 months, respectively (HR, 0.84 [95% CI, 0.57–1.23], P=0.1852‡)
- ORR (95% CI): SVd group (**76.4%** [69.8–82.2]) higher than Vd group (**62.3%** [55.3–68.9]); **P=0.0012**§

Safety results

- Most frequent grade 3–4 AEs with SVd: Thrombocytopenia (39%), anemia (16%), fatigue (13%), and pneumonia (12%)
- Peripheral neuropathy (≥grade 2) occurred less frequently with SVd versus Vd (21% vs 34%)
- Overall safety profile was manageable, with similar mortality rates with SVd versus Vd (24% vs 30%)

Lenalidomide-refractory population

Post hoc analysis[1]

Post hoc analysis of **PFS**, **OS**, and **safety** from the BOSTON trial (N=402)[2] for **lenalidomide-refractory**‖ patient subgroup (n=106) (NCT03110562)[6]

BL characteristics[1]

106 lenalidomide-refractory patients: SVd **(n=53)** and Vd **(n=53)**

Follow-up duration: SVd: **28.2 months**; Vd: **27.1 months**

Consistent with overall study population

	SVd	Vd
Median age	65 years	66 years
Received 3 previous regimens	30%	36%
Time since diagnosis	3.7 years	3.5 years
High-risk cytogenetic abnormalities	55%	43%

Results[1]

Efficacy: PFS[1]

In the lenalidomide-refractory subgroup, clinically meaningful improvements in PFS were observed with SVd versus Vd

Lenalidomide-refractory PFS (months)‡

P=0.006

SVd **10.2** | Vd **7.1**

HR (95% CI), 0.52 (0.31–0.99)

Supports another treatment option for RRMM populations with lenalidomide-refractory disease[1]

Efficacy: OS[1]

The median OS in the lenalidomide-refractory subgroup was **8 months** longer with SVd versus Vd

Lenalidomide-refractory OS (months)‡

P=0.015

SVd **26.7** | Vd **18.6**

HR (95% CI), 0.53 (0.30–0.95)

Safety[1]

- Lenalidomide-refractory group median time to discontinuation: 6.1 months for SVd; 4.7 months for Vd
- Consistent with BOSTON primary analysis

TRAE, n (%)	Lenalidomide-refractory	
	SVd (n=53)	Vd (n=52)
Hematologic		
Thrombocytopenia	24 (45)	16 (31)
Anemia	4 (8)	2 (4)
Neutropenia	2 (4)	1 (2)
Non-hematologic		
Fatigue	5 (9)	0
Nausea	5 (9)	0
Diarrhea	6 (11)	0
Neuropathy peripheral	2 (4)	4 (8)
Asthenia	1 (2)	1 (2)
Cataract	7 (13)	1 (2)
Vomiting	4 (8)	0

Table 1. Grade 3–4 TRAEs occurring in >5% of patients in the lenalidomide-refractory subgroup

Secondary endpoints in the lenalidomide-refractory subgroup[1]

In the SVd group versus Vd group:

- ORR was **higher** (P=0.009) (**67.9%** versus **47.2%**; OR, 2.59 [95% CI, 1.17–5.77])§
- VGPR was **higher** (P=0.109) (**35.8%** versus **24.5%**; OR, 1.74 [95% CI, 0.72–4.21])
- Median TTNT was **longer** (P=0.006): **13.0 months** versus **7.6 months**

Conclusion[1]

BOSTON post hoc analysis shows **clinically meaningful outcomes and a manageable safety profile** in the SVd treatment arm over Vd arm for RRMM patients with lenalidomide-refractory disease, supporting an additional viable treatment option.

*SVd arm: 5-week cycles including oral selinexor 100 mg (days 1, 8, 15, 22, 29), bortezomib 1.3 mg/m^2 SC once per week (days 1, 8, 15, 22), oral dexamethasone 20 mg (days 1, 2, 8, 9, 15, 16, 22, 23, 29, 30). Vd arm: bortezomib 1.3 mg/m^2 SC (days 1, 4, 8, 11) and oral dexamethasone 20 mg (days 1, 2, 4, 5, 8, 9, 11, 12) during eight 3-week cycles; starting at cycle 9, each cycle lasted 5 weeks with bortezomib given on days 1, 8, 15, and 22 and dexamethasone on days 1, 2, 8, 9, 15, 16, 22, 23, 29, and 30. Dose modifications were allowed to help manage tolerability. †Patients with systemic light-chain amyloidosis, central nervous system involvement, or grade 2 painful or grade ≥2 peripheral neuropathy were excluded from the study. ‡Compared using stratified log-rank test. HRs and CIs estimated with a stratified Cox proportional-hazards model with treatment as the single variate. §OR for ORR calculated with Cochran–Mantel–Haenszel χ^2 test. ‖Lenalidomide-refractory status was defined as PD within 60 days of lenalidomide treatment or best response of stable disease or PD. ¶Post hoc analysis also included PI-naive (n=95), bortezomib-naive (n=123), and 1LOT (n=198) subgroups. 1LOT, one prior line of therapy; AE, adverse event; BL, baseline; CI, confidence interval; HR, hazard ratio; IMWG; International Myeloma Working Group; IQR, interquartile range; MM, multiple myeloma; NE, not evaluable; OR, odds ratio; ORR, overall response rate; OS, overall survival; PD, progressive disease; PFS, progression-free survival; PI, proteasome inhibitor; RRMM, relapsed/refractory MM; SC, subcutaneously; SVd, selinexor + bortezomib + dexamethasone; TRAE, treatment-related adverse event; TTNT, time to next treatment; Vd, bortezomib + dexamethasone; VGPR, very good partial response.

1. Mateos M, et al. *Eur J Haematol*. 2024;113(2):242–252. **2.** Grosicki S, et al. *Lancet*. 2020;396(10262):1563–1573.

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