Weekly Selinexor, Bortezomib and Dexamethasone (SVd) Versus Twice Weekly Bortezomib and Dexamethasone (Vd) in Patients with Multiple Myeloma (MM) After 1–3 Prior Therapies: Initial Results of the Phase 3 BOSTON Study

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Selinexor: First-in-Class, Oral Selective Inhibitor of Nuclear Export (SINE)¹-⁴

Demonstrates synergistic activity in combination with bortezomib in vitro and in vivo

- Exportin 1 (XPO1) is the major nuclear export protein for:
  - Tumor suppressor proteins (TSPs, e.g., p53, IκB and FOXO)
  - eIF4E-bound oncoprotein mRNAs (e.g., c-Myc, Bcl-xL, cyclins)
  - Glucocorticoid receptor (GR)

- XPO1 is overexpressed in multiple myeloma (MM):
  - High XPO1 levels enable cancer cells to escape TSP-mediated cell cycle arrest and apoptosis
  - XPO1 levels correlate with poor prognosis and drug resistance

- Selinexor is an oral selective XPO1 inhibitor that:
  - Reactivates multiple TSPs by preventing nuclear export
  - Inhibits oncoprotein translation
  - Reactivates GR signaling in presence of dexamethasone

- Selinexor + dexamethasone is approved in the US for MM refractory to ≥4 therapies including ≥2 PIs, ≥2 IMiDs and an anti-CD38 mAb

Selinexor + Bortezomib + Dexamethasone (SVd): ORR 84%, mPFS 17.8 months

STOMP*: A Phase 1b/2 Study in Patients With MM >1 Prior Therapy

The STOMP study does not have a control/comparative arm. The Vd Benchmark data are provided to contextualize the design of the BOSTON phase 3 trial.

The STORM trial established single agent (ORR 26%) in triple class refractory MM

RP2D: Once Weekly SVd (MTD not reached)

- Selinexor: orally 100 mg once weekly
- Bortezomib: subcutaneous 1.3 mg/m^2 once weekly
- Dexamethasone: orally 40 mg per week

Safety

- Most common Grade 1/2 AEs were constitutional symptoms (e.g., nausea, fatigue, anorexia)
- Most common Grade 3/4 AEs were cytopenias (e.g., thrombocytopenia, neutropenia, anemia)
- SVd reported peripheral neuropathy across all patients was Grade 1/2 only and limited to four patients (10%)
BOSTON Trial: Phase 3, Global, Randomized, Open Label, Controlled Study in Patients With MM who Had Received 1–3 Prior Therapies

**SVd Weekly**
- 35-day cycles
- Selinexor (oral) 100 mg Days 1, 8, 15, 22, 29
- Bortezomib (SC) 1.3 mg/m² Days 1, 8, 15, 22
- Dexamethasone (oral) 20 mg Days 1, 2, 8, 9, 15, 16, 22, 23, 29, 30

**Vd Twice Weekly**
- 21-day cycles
- Cycles 1-8
- Bortezomib (SC) 1.3 mg/m² Days 1, 4, 8, 11
- Dexamethasone (oral) 20 mg Days 1, 2, 4, 5, 8, 9, 11, 12

If IRC confirmed PD: crossover to SVd or Sd permitted

**Vd Weekly**
- 35-Day cycles
- Cycles ≥9

**Planned** 40% lower bortezomib and 25% lower dexamethasone dose at 24 weeks (8 cycles) in SVd arm vs. Vd arm

**Stratification:**
- Prior PI therapies (Yes vs No)
- Number of prior anti-MM regimens (1 vs >1)
- R-ISS stage at study entry (Stage III vs Stage I/II)

5HT-3 prophylactic recommended in SVd arm

**Primary endpoint:** PFS

**Key secondary endpoints:**
- ORR
- ≥VGPR
- Grade ≥2 PN

**Secondary endpoints:**
- OS
- DoR
- TTNT
- Safety

**Efficacy Assessed by IRC**

CR= complete response, DoR = duration of response, IMWG = International Myeloma Working Group, IRC = Independent Review Committee, OS = overall survival, PD = progressive disease, PFS = progression free survival, PR = partial response, PN = peripheral neuropathy, sCR = stringent complete response, TTNT = time to next therapy, VGPR = very good partial response. PFS defined as: Time from date of randomization until the first date of progressive disease, per IMWG response criteria, or death due to any cause, whichever occurred first, as assessed by IRC. ORR: Any response ≥PR (ie, PR, VGPR, CR, or sCR) based on the IRC’s response outcome assessments, according to IMWG response criteria (Kumar et al. Lancet oncology 2016). All changes in MM disease assessments were based on baseline MM disease assessments.

*Vd weekly dosing and schedule for cycles 9 as per SVd arm description.
BOSTON Trial: Inclusion/Exclusion Criteria

Key Inclusion Criteria

• Progressive measurable MM per IMWG criteria¹
• 1–3 prior anti-MM regimens (at least a PR to a prior PI, if received)
• Patients with moderate or severe renal impairment (CrCl ≥ 20mL/min) allowed, patients requiring dialysis excluded
• ECOG status score 0–2
• Adequate hepatic and hematopoietic function
  • ANC > 1,000/μL
  • Platelets > 75,000/μL

Key Exclusion Criteria

• > Grade 2 neuropathy or ≥ Grade 2 neuropathy with pain at baseline
• Prior exposure to a SINE, including selinexor
• Prior malignancy that required treatment/had evidence of recurrence
• Concurrent medical condition/disease/active infection
• Active plasma cell leukemia
• MM involving the CNS


ANC = absolute neutrophil count, CNS = central nervous system, CrCl = creatinine clearance, ECOG = Eastern Cooperative Oncology Group.
### BOSTON Trial: Patient Disposition

**402 patients enrolled**

- **SVd**
  - N=195
  - Received study drug (any dose) n=195
  - 37 on treatment
  - Survival follow up (n=65) 35 deaths during follow up 9 discontinuations
  - 102 on study

- **Vd**
  - N=207
  - Received study drug (any dose) n=204
  - 36 on treatment
  - Survival follow up (n=51) 41 deaths during follow up 13 discontinuations
  - 101 on study

### Patient Disposition

<table>
<thead>
<tr>
<th></th>
<th>SVd arm N=195</th>
<th>Vd arm N=204</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discontinued Treatment*</td>
<td>158 (81%)</td>
<td>168 (82%)</td>
</tr>
<tr>
<td>Disease progression</td>
<td>67 (34%)</td>
<td>107 (52%)</td>
</tr>
<tr>
<td>AEs/toxicity</td>
<td>33 (17%)</td>
<td>23 (11%)</td>
</tr>
<tr>
<td>Deaths</td>
<td>12 (6%)</td>
<td>12 (6%)</td>
</tr>
<tr>
<td>Patient withdrawal</td>
<td>37 (19%)</td>
<td>18 (9%)</td>
</tr>
<tr>
<td>No information reported</td>
<td>11 (6%)</td>
<td>5 (2%)</td>
</tr>
<tr>
<td>Related to AE</td>
<td>9 (5%)</td>
<td>6 (3%)</td>
</tr>
<tr>
<td>Other†</td>
<td>17 (9%)</td>
<td>7 (3%)</td>
</tr>
<tr>
<td>Discontinued Study</td>
<td>93 (48%)</td>
<td>103 (50%)</td>
</tr>
<tr>
<td>Patient withdrawal</td>
<td>37 (19%)</td>
<td>35 (17%)</td>
</tr>
<tr>
<td>Deaths</td>
<td>47 (24%)</td>
<td>61 (30%)</td>
</tr>
<tr>
<td>Lost to follow-up/Other</td>
<td>9 (5%)</td>
<td>7 (3%)</td>
</tr>
</tbody>
</table>

*In the SVd arm, 7 and 2 patients discontinued treatment due to physician decision and lost to follow up, respectively. In the Vd arm, 5, 2, and 1 patients discontinued treatment due to physician decision, lost to follow up and noncompliance, respectively.

†Other: Logistic reasons (such as patient could not travel to site, patient relocated), hospice (poor health), assessment burden, IRC-approved PD. Data cut-off February 18, 2020.
BOSTON Trial: Baseline Characteristics
Patient and Disease Characteristics Well Balanced Between Treatment Arms

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>SVd arm (n=195)</th>
<th>Vd arm (n=207)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Media Age, years (range)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥75 years, n (%)</td>
<td>66 (40, 87)</td>
<td>67 (38, 90)</td>
</tr>
<tr>
<td></td>
<td>34 (17)</td>
<td>47 (23)</td>
</tr>
<tr>
<td><strong>Male, n (%)</strong></td>
<td>115 (59)</td>
<td>115 (56)</td>
</tr>
<tr>
<td><strong>Creatinine Clearance, mL/min, n (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;30</td>
<td>3 (2)</td>
<td>10 (5)</td>
</tr>
<tr>
<td>30-60</td>
<td>53 (27)</td>
<td>60 (29)</td>
</tr>
<tr>
<td><strong>Time since initial diagnosis, years, (range)</strong></td>
<td>3.8 (0.4, 23.0)</td>
<td>3.6 (0.4, 22.0)</td>
</tr>
<tr>
<td><strong>High Risk Cytogenetic, [del (17p) or t (14;16) or t (4;14) or amp 1q21] n (%)</strong></td>
<td>97 (50)</td>
<td>95 (46)</td>
</tr>
<tr>
<td><strong>R-ISS disease stage at screening, n (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I or II</td>
<td>173 (89)</td>
<td>177 (86)</td>
</tr>
<tr>
<td>III</td>
<td>12 (6)</td>
<td>16 (8)</td>
</tr>
<tr>
<td>Unknown</td>
<td>10 (5)</td>
<td>14 (7)</td>
</tr>
<tr>
<td><strong>Number of prior lines of therapy, n (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>99 (51)</td>
<td>99 (48)</td>
</tr>
<tr>
<td>2</td>
<td>65 (33)</td>
<td>64 (31)</td>
</tr>
<tr>
<td>3</td>
<td>31 (16)</td>
<td>44 (21)</td>
</tr>
<tr>
<td><strong>Prior Therapies, n (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bortezomib</td>
<td>134 (68.7)</td>
<td>145 (70.0)</td>
</tr>
<tr>
<td>Carfilzomib</td>
<td>20 (10.3)</td>
<td>21 (10.1)</td>
</tr>
<tr>
<td>Daratumumab</td>
<td>11 (5.6)</td>
<td>6 (2.9)</td>
</tr>
<tr>
<td>Lenalidomide</td>
<td>77 (39.5)</td>
<td>77 (37.2)</td>
</tr>
</tbody>
</table>

*Fluorescence in-situ hybridization was performed at a central laboratory and used to assess cytogenetic risk status. 1q21 required at least 3 copies.
BOSTON Trial: PFS Significantly Longer With SVd Compared to Vd
Early and Sustained PFS Benefit (Assessed by IRC)

Median PFS (months)  
SVd  13.93  
Vd  9.46

Hazard Ratio: * 0.70, P=0.0075  
30% reduced risk of progression/death with SVd

Median follow-up: 13.2 and 16.5 months in SVd and Vd arms, respectively.

*Hazard Ratio 95% CI=0.53–0.93 one-sided P value.
### BOSTON Trial: Consistent PFS Benefit for SVd Across Subgroups

<table>
<thead>
<tr>
<th>Subgroups</th>
<th># Patients</th>
<th>HR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;65 years</td>
<td>161</td>
<td>0.74 (0.49–1.11)</td>
</tr>
<tr>
<td>≥65 years</td>
<td>241</td>
<td>0.55 (0.37–0.83)</td>
</tr>
<tr>
<td><strong>High-risk Cytogenetics</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes Del[17p] or t[4;14] or t[14;16] or 1q21</td>
<td>192</td>
<td>0.67 (0.45–0.98)</td>
</tr>
<tr>
<td>No</td>
<td>210</td>
<td>0.62 (0.42–0.95)</td>
</tr>
<tr>
<td>Del[17p]</td>
<td>37</td>
<td>0.38 (0.16–0.86)</td>
</tr>
<tr>
<td><strong>Frailty</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Frail</td>
<td>130</td>
<td>0.69 (0.40–1.17)</td>
</tr>
<tr>
<td>Fit</td>
<td>272</td>
<td>0.66 (0.47–0.93)</td>
</tr>
<tr>
<td><strong>Previous PI Therapies</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>307</td>
<td>0.78 (0.58–1.06)</td>
</tr>
<tr>
<td>No</td>
<td>95</td>
<td>0.26 (0.11–0.60)</td>
</tr>
<tr>
<td><strong>Previous lenalidomide Therapy</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>154</td>
<td>0.63 (0.41–0.97)</td>
</tr>
<tr>
<td>No</td>
<td>248</td>
<td>0.66 (0.45–0.96)</td>
</tr>
<tr>
<td><strong>No. of Prior Lines of Therapy</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>198</td>
<td>0.63 (0.41–0.95)</td>
</tr>
<tr>
<td>2–3</td>
<td>204</td>
<td>0.69 (0.48–1.01)</td>
</tr>
</tbody>
</table>

SVd Was Associated With a Significantly Higher ORR Overall and Across Subgroups

Overall response, based on Independent Review Committee’s response outcome assessments, according to IMWG response criteria (Kumar et al. Lancet Oncology 2016). All changes in MM disease assessments were based on baseline MM disease assessments.
SVd: Significantly Higher Rate of Deep Responses
(≥VGPR, \(P=0.0082\))

- Significantly higher rate of deep responses with SVd (≥VGPR, \(P=0.0082\))

- Median Time to Response (months)
  - SVd arm: 1.1 months
  - Vd arm: 1.4 months

- Median Duration of Response (months)
  - SVd arm: 20.3 months
  - Vd arm: 12.9 months

- Fewer patients with progressive disease: SVd (n=1, 0.5%) vs Vd (n=10, 4.8%)

CR= complete response, MR = minimal response, PD = progressive disease, PR = partial response, sCR = stringent complete response, SD = stable disease, VGPR = very good partial response. All Responses assessed by an Independent Review Committee (IRC), according to the IMWG criteria (Kumar et all. Lancet Oncology 2016) †Unadjusted Time from date of randomization until first response per IMWG response criteria. *Duration of the time interval between the first IRC-confirmed PR or better response and the first IRC-confirmed PD or death due to any cause, whichever occurred first. Data cut-off February 18, 2020.
BOSTON Trial: Time to Next Therapy Analysis and Overall Survival Interim Analysis (109 Deaths [27%])

**SVd** | **Vd**
---|---
Median TTNT (mos) | 16.1 | 10.8
HR 0.66 (95% CI: 0.50, 0.86) *P*=0.0012

# Death Events (n) | **SVd** | **Vd**
---|---|---
Median OS (mos) | 47 | 62
Not Reached | 25
HR 0.84 (95% CI: 0.57, 1.23) *P*=0.19

Peripheral Neuropathy Rates Were Significantly Lower With SVd Than With Vd (Both Subcutaneous Bortezomib)

Peripheral neuropathy was the most common AE leading to treatment discontinuation: 4.6% on SVd, 7.4% on Vd

Adverse events were graded according to the National Cancer Institute Common Terminology Criteria for Adverse Events, version 4.03. Data cut-off February 18, 2020.
### BOSTON Trial: Safety – Selected Hematological TEAEs*

<table>
<thead>
<tr>
<th>Hematological (%)</th>
<th>SVd (n=195)</th>
<th>Vd (n=204)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Any Grade</td>
<td>Grade 3/4</td>
</tr>
<tr>
<td>Thrombocytopenia</td>
<td>60.0†</td>
<td>39.5</td>
</tr>
<tr>
<td>Grade ≥3 bleeding</td>
<td>2.1</td>
<td></td>
</tr>
<tr>
<td>Anemia</td>
<td>36.4</td>
<td>15.9</td>
</tr>
<tr>
<td>Neutropenia</td>
<td>14.9</td>
<td>8.7</td>
</tr>
<tr>
<td>Febrile neutropenia</td>
<td>0.5</td>
<td>0.5</td>
</tr>
</tbody>
</table>

*Shown are events that occurred in at least 10% of patients and had a >5% difference between treatment arms. Adverse events were graded according to the National Cancer Institute Common Terminology Criteria for Adverse Events, version 4.03. For patients who crossed over, adverse events that occurred after the crossover are not included. †Includes 3 fatal events. Data cut-off February 18, 2020.

- Thrombopoietin receptor agonists were used to mitigate thrombocytopenia in 35 patients on SVd and 2 patients on Vd, and reduced dose interruptions and reductions
- Twelve patients on SVd and 13 patients on Vd received platelet transfusions to manage thrombocytopenia
BOSTON Trial: Safety – Selected Non-Hematological TEAEs*

<table>
<thead>
<tr>
<th></th>
<th>SVd (n=195)</th>
<th>Vd (n=204)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Any Grade</td>
<td>Grade 3/4</td>
</tr>
<tr>
<td><strong>Non-hematological (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nausea</td>
<td>50.3</td>
<td>7.7</td>
</tr>
<tr>
<td>Fatigue</td>
<td>42.1</td>
<td>13.3</td>
</tr>
<tr>
<td>Decreased Appetite</td>
<td>35.4</td>
<td>3.6</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>32.3</td>
<td>6.2</td>
</tr>
<tr>
<td>Peripheral Neuropathy†</td>
<td>32.3</td>
<td>4.6</td>
</tr>
<tr>
<td>Upper Respiratory Tract Infection‡</td>
<td>29.2</td>
<td>3.6</td>
</tr>
<tr>
<td>Weight decreased</td>
<td>26.2</td>
<td>2.1</td>
</tr>
<tr>
<td>Asthenia</td>
<td>24.6</td>
<td>8.2</td>
</tr>
<tr>
<td>Cataract§</td>
<td>21.5</td>
<td>8.7</td>
</tr>
<tr>
<td>Vomiting</td>
<td>20.5</td>
<td>4.1</td>
</tr>
</tbody>
</table>

*Shown are events that occurred in at least 15% of patients and had a >5% difference between treatment arms. Adverse events were graded according to the National Cancer Institute Common Terminology Criteria for Adverse Events, version 4.03. For patients who crossed over, adverse events that occurred after the crossover are not included. †Includes high-level term Peripheral Neuropathies NEC. ‡Includes upper respiratory infection, nasopharyngitis, pharyngitis, respiratory syncytial virus infection, respiratory tract infection, rhinitis and viral upper respiratory tract infection. §Per Ophthalmology exam during 24% patients on the SVd arm versus 8.5% patients on the Vd arm had new-onset cataracts and worsening of cataracts on study was noted in 20.5% patients on the SVd arm versus 7.9% on the Vd arm. Data cut-off February 18, 2020.
BOSTON Trial Conclusions

• BOSTON is the first trial to assess a once-weekly triplet of the novel oral agent selinexor + subcutaneous bortezomib in MM (1–3 prior therapies) with a treat to progression plan

• Once-weekly SVd significantly prolongs PFS (mPFS improvement of 47%, HR 0.70, \( P=0.0075 \)) vs Vd
  
  • SVd was superior to Vd across all efficacy endpoints (PFS, ORR, ≥VGPR, TTNT, DoR) including in patients with prior lenalidomide and with del(17p)
  
  • Median OS not reached with SVd versus 25 months with Vd

• Once-weekly dosing used in the SVd arm was associated with significantly lower rates and severity of bortezomib induced peripheral neuropathy compared with twice-weekly Vd

• Adverse events associated with SVd manageable and reversible
  
  • Most common hematological and non-hematological AEs: cytopenia, infections, GI, weight decreased, fatigue, cataract
  
  • Discontinuation rate due to adverse events was 17% (SVd) and 11% (Vd)

In patients with MM who have received 1–3 prior therapies, including prior lenalidomide or PI once-weekly oral selinexor + SC Vd offers patients an effective, convenient, IMiD free, novel triplet therapy requiring ~40% less clinic visits and reduced rate of peripheral neuropathy
Acknowledgements BOSTON Trial

• Our Patients, their Families and Caregivers
• Investigators, Co-investigators and Study Teams at each participating center

AUSTRALIA
Jason Paul Butler
Naadir Gutta
Noemi Horvath
Wojciech Janowski
Hang Quach
Andrew Spencer
Craig Wallington-Beddoe

EUROPE
Predrag Djurdjevic
Miklós Egyed
Monika Engelhardt
Thierry Facon
Roberto Foà
Laurent Frenzel
Mamtà Krishnan Garg
Klaus Geissler
Krzysztof Giannopoulos
Mercedes Gironeña Mesa
Lana Golubovic Macukanovic
Vesseline Stefanova Goranova-Marinova
Sebastian Grosicki
Eberhard Gunsilius
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Jeevan Kumar
Pankaj Malhotra
Davinder Paul
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Anita Ramesh
Krishna Kumar Rathnam
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This study was sponsored by Karyopharm Therapeutics Inc.