Welcome and Introductions

Joan Levy, PhD
Multiple Myeloma Research Foundation
Norwalk, CT
FDA Approvals and Overall Trends

Angela Dispenzieri, MD
Mayo Clinic
Rochester, MN
### Recent FDA Approvals

<table>
<thead>
<tr>
<th>Drug</th>
<th>FDA Approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Panobinostat (Farydak®)</td>
<td>February 23</td>
</tr>
<tr>
<td>Carfilzomib (Kyprolis®)¹</td>
<td>July 24</td>
</tr>
<tr>
<td>Daratumumab (Darzalex™)</td>
<td>November 16</td>
</tr>
<tr>
<td>Ixazomib (Ninlaro®)</td>
<td>November 20</td>
</tr>
<tr>
<td>Elotuzumab (Empliciti™)</td>
<td>November 30</td>
</tr>
</tbody>
</table>

¹ Carfilzomib was approved on this date for a new indication: for use with lenalidomide and dexamethasone to treat relapsed multiple myeloma with 1–3 prior lines of therapy.

### Overall Trends in 2016

- Heavy emphasis on new treatments for relapsed/refractory multiple myeloma (RRMM) this year
- Lots of research on novel immunotherapies, mostly combined with chemotherapy, for RRMM
  - Daratumumab (Darzalex), isatuximab, pembrolizumab (Keytruda), elotuzumab (Empliciti)
- Several studies of other novel therapies for RRMM
  - Venetoclax (Venclexta), carfilzomib (Kyprolis), ixazomib (Ninlaro), panobinostat (Farydak)
- Confirmation of the roles of autologous stem cell transplant (ASCT) and post-ASCT maintenance therapy
Immunotherapy

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Georgetown University
Washington, DC
John Theurer Cancer Center
Hackensack, NJ

Daratumumab

- Daratumumab (Darzalex) is a monoclonal antibody that binds to the CD38 molecule
  - CD38 is highly expressed by myeloma cells
- Approved by the FDA for RRMM
  - Patients must have tried at least 3 other therapies, including a proteasome inhibitor (PI) and an immunomodulatory drug (IMiD), or be double-refractory to a PI and an IMiD

RRMM, relapsed/refractory multiple myeloma
Daratumumab

**Direct ON-TUMOR Actions**
- CDC: Complement-dependent cytotoxicity
- ADCC: Antibody-dependent cell-mediated cytotoxicity
- ADCP: Antibody-dependent cellular phagocytosis
- Apoptosis

**IMMUNOMODULATORY Actions**
- Modulation of tumor microenvironment
- Depletion of immuno-suppressive cells
- Increase in cytotoxic & helper T cells
- MYELOMA CELL DEATH


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**CASTOR trial: Daratumumab for RRMM**

- CASTOR is a multicenter, phase 3, randomized, open-label controlled trial
- All patients had RRMM with at least one previous line of therapy
  - Patients had a median of 2 prior lines of therapy
- Compared daratumumab + bortezomib + dexamethasome (DVd) to bortezomib + dexamethasome alone (Vd)

IMiD, immunomodulatory drug; PI, proteasome inhibitor; RRMM, relapsed/refractory multiple myeloma

CASTOR Design and Results

- Relapsed/refractory
- 1+ prior therapy
- Not refractory to VEL

Daratumumab + VEL + DEX (DVd, N = 251)
VEL + DEX (Vd, N = 247)

Endpoints:
- PFS
- OS, ORR, CR, VGPR
- MRD
- Time to progression
- Time to response
- Duration of response

<table>
<thead>
<tr>
<th>Response</th>
<th>DVd</th>
<th>Vd</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median PFS, months</td>
<td>not reached</td>
<td>7.2</td>
</tr>
<tr>
<td>ORR, %</td>
<td>83</td>
<td>63</td>
</tr>
<tr>
<td>≥ CR, %</td>
<td>19</td>
<td>9</td>
</tr>
<tr>
<td>≥ VGPR, %</td>
<td>59</td>
<td>29</td>
</tr>
</tbody>
</table>

- 61% reduction in risk of disease progression or death for DVd vs. Vd

CR: complete response; DEX: dexamethasone; MRD: minimal residual disease; PFS: progression-free survival; ORR: overall response rate; OS: overall survival; VEL: bortezomib (Velcade); VGPR: very good partial response


PI-based Studies

<table>
<thead>
<tr>
<th></th>
<th>Daratumumab DVd vs Vd</th>
<th>Carfilzomib Kd vs Vd</th>
<th>Panobinostat PVd vs Vd</th>
<th>Elotuzumab EVd vs Vd</th>
</tr>
</thead>
<tbody>
<tr>
<td>PFS HR (95% CI)</td>
<td>0.39 (0.28-0.53)</td>
<td>0.53 (0.44-0.65)</td>
<td>0.63 (0.52-0.76)</td>
<td>0.72 (0.59-0.88)</td>
</tr>
<tr>
<td>PFS Median mo</td>
<td>NE</td>
<td>18.7</td>
<td>12.0</td>
<td>9.7</td>
</tr>
<tr>
<td>&gt;VGPR</td>
<td>59%</td>
<td>54%</td>
<td>28%</td>
<td>36%</td>
</tr>
<tr>
<td>&gt;CR</td>
<td>19%</td>
<td>13%</td>
<td>11%</td>
<td>4%</td>
</tr>
<tr>
<td>Duration of response, mo</td>
<td>NE</td>
<td>21.3</td>
<td>13.1</td>
<td>11.4</td>
</tr>
<tr>
<td>OS HR (95% CI)</td>
<td>0.77 (0.47, 1.26)</td>
<td>0.79 (0.58-1.08)</td>
<td>0.94 (0.78-1.14)</td>
<td>0.61 (0.32-1.15)</td>
</tr>
</tbody>
</table>

• The “twin” study to CASTOR
• Same study design as CASTOR, except instead of adding bortezomib and dexamethasone to the daratumumab, investigators added lenalidomide (Revlimid) and dexamethasone
• Study design was notated as DRd (n = 286) versus Rd (n = 283)
• All eligibility criteria and endpoints were the same, except for exclusion of patients refractory to lenalidomide (instead of to bortezomib as in CASTOR)


<table>
<thead>
<tr>
<th>Response</th>
<th>DRd</th>
<th>Rd</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median PFS, months</td>
<td>not reached</td>
<td>18.4</td>
</tr>
<tr>
<td>ORR, %</td>
<td>93</td>
<td>76</td>
</tr>
<tr>
<td>≥ CR, %</td>
<td>43</td>
<td>19</td>
</tr>
<tr>
<td>≥ VGPR, %</td>
<td>76</td>
<td>44</td>
</tr>
</tbody>
</table>

• 63% reduction in risk of disease progression or death for DRd vs. Rd
• Treatment effects were consistent across all subgroups and regardless of prior lenalidomide exposure
• DRd doubled the complete response rates and quadrupled the rate of negativity for minimal residual disease

CR, complete response; DRd, daratumumab, lenalidomide, and dexamethasone; PFS, progression-free survival; ORR, overall response rate; VGPR, very good partial response

# Lenalidomide-based Studies

<table>
<thead>
<tr>
<th></th>
<th>POLLUX DRd vs Rd</th>
<th>ASPIRE KRd vs Rd&lt;sup&gt;1&lt;/sup&gt;</th>
<th>ELOQUENT-2 ERd vs Rd&lt;sup&gt;2,3&lt;/sup&gt;</th>
<th>TOURMALINE-MM1 NRd vs Rd&lt;sup&gt;4&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>PFS HR (95% CI)</td>
<td>0.37 (0.27-0.52)</td>
<td>0.69 (0.57-0.83)</td>
<td>0.73 (0.60-0.89)</td>
<td>0.74 (0.59-0.94)</td>
</tr>
<tr>
<td>ORR</td>
<td>93%</td>
<td>87%</td>
<td>79%</td>
<td>78%</td>
</tr>
<tr>
<td>≥VGPR</td>
<td>76%</td>
<td>70%</td>
<td>33%</td>
<td>48%</td>
</tr>
<tr>
<td>≥CR</td>
<td>43%</td>
<td>32%</td>
<td>4%</td>
<td>14%</td>
</tr>
<tr>
<td>Duration of response, mo</td>
<td>NE</td>
<td>28.6</td>
<td>20.7</td>
<td>20.5</td>
</tr>
<tr>
<td>OS HR (95% CI)</td>
<td>0.64 (0.40-1.01)</td>
<td>0.79 (0.63-0.99)</td>
<td>0.77 (0.61-0.97)</td>
<td>NE</td>
</tr>
</tbody>
</table>

K, carfilzomib; E, elotuzumab; N, ixazomib.


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# Isatuximab

- Isatuximab (ISA) is a novel monoclonal antibody that is effective and well tolerated as a monotherapy
- Like daratumumab, it targets CD38 molecules

ISA + REV + DEX

- Phase 1 study of isatuximab (ISA) plus lenalidomide (REV) and dexamethasone (DEX)
- As a phase 1 study, the goal was to identify the maximum tolerated dose (MTD) and the optimal dose schedule, to determine how to prescribe it in future studies and eventually in practice
- Subjects had RRMM with at least 2 prior therapies (median 4–6 prior lines of therapy)

DEX, dexamethasone; ISA, isatuximab; REV, lenalidomide (Revlimid); RRMM, relapsed/refractory multiple myeloma


ISA/REV/DEX Results

- The combination had an acceptable safety profile, with adverse events similar to those of the individual drugs
- No drug-drug interactions were seen between ISA and REV
- Overall response rate was 57%, and median duration of response was 7.6 months

Conclusion: a phase 3 trial of ISA/REV/DEX at 10 mg/kg once weekly/once every 2 weeks will begin soon

DEX, dexamethasone; ISA, isatuximab; REV, lenalidomide (Revlimid)

**Infusion-related Reactions**

- One common toxicity seen with anti-CD38 monoclonal antibodies like DARA and ISA is infusion-related reactions (IRRs)
- Most reactions are mild to moderate, and the great majority (≥ 90%) occur during the very first infusion
- Very few patients needed to discontinue DARA or ISA due to IRRs (<1% in CASTOR and POLLUX)

DARA, daratumumab; ISA, isatuximab


**Immune Checkpoint Antibodies**

How the Anti-PD-1 Antibody Works

Without the antibody

Cancer cell -PD-L1 -PD-1 -Immune cell

T cell is blocked

When PD-L1 binds with PD-1, the cancer puts the brakes on immune cells (T cells) and blocks attacks on cancer cells.

With the antibody

Cancer cell -Nivolumab -Immune cell -T cell is reactivated and attacks cancer cell

Nivolumab removes the brakes on T cells by preventing PD-L1 from binding with PD-1, thereby reactivating T cells and allowing them to attack cancer cells.
**Pembrolizumab and the PD-1 Pathway**

- Pembrolizumab (Keytruda) is a highly selective humanized monoclonal antibody directed against the cell surface receptor programmed cell death-1 (PD-1), allowing the immune system to attack tumor cells.
- PD-1 inhibitors do not work alone, but they work synergistically (together) with IMiDs like REV to fight myeloma.
- Keynote presentation at ASCO described using a combination of pembrolizumab plus REV/DEX in patients who previously did not respond to a PI and an IMiD.

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**Pembrolizumab + REV/DEX**

- Patients had heavily pretreated RRMM (median 4 prior therapies), 86% had received a stem cell transplant, and 75% were refractory to lenalidomide.
  - 49% were unresponsive to two, three, or four medications.
- Acceptable safety profile, with adverse events similar to those seen using pembrolizumab in solid tumors.
- ORR was 50%, and disease control rate (CR, PR or SD) was 98%.

**Conclusion:** Results are promising; phase 3 studies of pembrolizumab are now underway.

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CR, complete response; PR, partial response; RRMM, relapsed/refractory multiple myeloma; SD, stable disease.
CAR-BCMA T Cells in MM: Background

- **BCMA**: protein in TNF superfamily expressed by normal and malignant plasma cells and B cells
- Autologous T cells can be genetically modified to express CARs targeted to malignancy-associated antigens
  - BCMA a potential target for myeloma CAR T-cell therapy
  - BCMA expressed uniformly on malignant plasma cells from 60% to 70% of pts with MM
- Current study evaluated CAR-BCMA T-cell infusion for treatment of advanced MM
  - Autologous T cells were stimulated, transduced with CAR-BCMA retroviruses, and cultured for 9 days before infusion

CAR-BCMA T Cells in MM: Study Design

- First-in-human phase I trial
  
  Pts with advanced R/R MM; ≥ 3 prior lines of therapy; normal organ function; clear, uniform BCMA expression on MM cells (N = 12)

  Cyclophosphamide 300 mg/m²  
  Fludarabine 30 mg/m²  
  QD for 3 days  

  CAR-BCMA T cells*  
  Single infusion  

  *Dose escalation of CAR+ T cells/kg  
  0.3 x 10⁶  
  1.0 x 10⁶  
  3.0 x 10⁶  
  9.0 x 10⁶

- CAR-BCMA expression determined by flow cytometry


CAR-BCMA T Cells in MM: Conclusions

- First demonstration that CAR T cells have activity in MM
- CAR-BCMA T cells eliminated plasma cells without causing direct organ damage
- Responses included ongoing sCR in pt with a high disease burden that was chemotherapy-resistant
- Substantial but reversible toxicity comparable to that observed in previous CAR T-cell studies
  - Highest dose level of CAR-BCMA T cells to be reserved for pts with ≥ 50% bone marrow plasma cells
- Authors conclude that CAR-BCMA T cells represent a promising novel therapy for MM

Ali SA, et al. ASH.
Stem Cell Transplants v. Chemotherapy in Newly Diagnosed Myeloma

- High-dose chemotherapy (HDM) with ASCT has traditionally been the standard of care for younger, fit patients with NDMM
- In recent years, novel agents have dramatically increased response rates and extended survival in previously untreated MM patients, questioning the role of upfront ASCT in NDMM
- Are stem cell transplants still the best option for NDMM?

ASCT, autologous stem cell transplant; HDM, high-dose melphalan; NDMM, newly diagnosed multiple myeloma

EMN02/HO95 MM Trial: Study Design

**VCD** x three-four 21-d cycles
Bort 1.3 mg/sm twice weekly; CTX 500 mg/sm d1-8; Dex 40 mg on day of and after bort

CTX (2-4 g/sm) + G-CSF + PBSC collection

**R1**

VMP x 4 cycles (n=497)

**R2**

VRD x two 28-d cycles
Bort 1.3 mg/sm, twice weekly;
len 25 mg d1-21;
dex 20 d1-2-4-5-8-9-11-12

No consolidation therapy

Lenalidomide 10 mg/day, d1-21/28


Transplant(s) v. Chemotherapy

- Progression-free survival at 3 years:

<table>
<thead>
<tr>
<th>2 ASCTs</th>
<th>1 ASCT</th>
<th>VMP</th>
</tr>
</thead>
<tbody>
<tr>
<td>73.1%</td>
<td>63.0%</td>
<td>57.5%</td>
</tr>
</tbody>
</table>

- No information yet on whether there is a survival benefit
- No information on whether the 2 cycles of consolidation therapy before starting lenalidomide maintenance provides benefit

ASCT, autologous stem cell transplant; VMP, bortezomib (Velcade), high-dose melphalan, and prednisone
Maintenance after Transplantation

• Upfront ASCT is the standard of care, but many patients relapse, even with complete response to ASCT
• Lenalidomide maintenance after ASCT reduces the risk of progression by 50%

Maintenance After Transplantation

• **Objective**: to assess the effect of post-ASCT lenalidomide maintenance on OS using data from previous studies
  • 3 studies fulfilled all criteria
  • Mean follow-up time of 80 months
  • 7-year OS = 62% in lenalidomide arm vs. 50% in control arm (2.5-year increase in median survival)

**Conclusion**: post-ASCT lenalidomide maintenance can be considered the standard of care
**Overall Survival**

- There is a 26% reduction in risk of death, representing an estimated 2.5-year increase in median survival.<sup>a</sup>
- Median for lenalidomide treatment arm was extrapolated to be 116 months based on median of the control arm and HR (median, 86 months; HR = 0.74).

**Venetoclax**

- **Background**: BCL-2 and MCL-1 promote myeloma survival.
- Bortezomib (B; Velcade) inhibits MCL-1, and venetoclax (VEN; Venclexta) is a BCL-2 inhibitor that enhances the efficacy of B.
- This phase 1b/2 study combined VEN with B and dexamethasone (D) for 11 cycles, with VEN alone after that, in patients with RRMM, to determine dosing and to evaluate safety and efficacy.
- The 45 enrolled patients had a median of 4 previous therapies, and 32 had had ASCT. Most had received prior B (N = 38) and lenalidomide (Revlimid; N = 36) therapy.

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<sup>a</sup> Median for lenalidomide treatment arm was extrapolated to be 116 months based on median of the control arm and HR (median, 86 months; HR = 0.74). HR, hazard ratio; NE, not estimable; OS, overall survival.

Venetoclax + Bortezomib Results

- Overall response rate (ORR) was 51%

<table>
<thead>
<tr>
<th>Lines of therapy</th>
<th>1-3 prior</th>
<th>4-6 prior</th>
<th>≥ 7 prior</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall response rate</td>
<td>83%</td>
<td>38%</td>
<td>10%</td>
</tr>
</tbody>
</table>

- Response rates were also higher in those with no prior B treatment and in those who were not refractory to B
- Best responses were seen in patients with a t(11;14)

Conclusion: VEN + B + D has an acceptable safety profile and evidence of anti-tumor activity in RRMM

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- Best responses were seen in patients with a t(11;14)

Conclusion: VEN + B + D has an acceptable safety profile and evidence of anti-tumor activity in RRMM

Carfilzomib + Pomalidomide + Dexamethasone (KPd)

- Multicenter, single-arm study
- This study combined 28-day cycles of carfilzomib, pomalidomide, and dexamethasone (KPd)
- Patients were refractory to lenalidomide but naïve to (or sensitive to) PIs such as carfilzomib
- Goals: determine MTD (phase 1b) and efficacy (phase 2)

Carfilzomib + Pomalidomide + Dexamethasone (KPd)

- Multicenter, single-arm study
- This study combined 28-day cycles of carfilzomib, pomalidomide, and dexamethasone (KPd)
- Patients were refractory to lenalidomide but naïve to (or sensitive to) PIs such as carfilzomib
- Goals: determine MTD (phase 1b) and efficacy (phase 2)
Carfilzomib + Pomalidomide + Dexamethasone (KPd) Results

- 84% of 55 treated patients achieved a partial response or better; 72% achieved this after only 4 cycles of KPd

<table>
<thead>
<tr>
<th>Outcome</th>
<th>PFS</th>
<th>OS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median duration, months</td>
<td>12.9</td>
<td>NR</td>
</tr>
<tr>
<td>1-year rate</td>
<td>53%</td>
<td>91%</td>
</tr>
<tr>
<td>2-year rate</td>
<td>22%</td>
<td>78%</td>
</tr>
</tbody>
</table>

Conclusion: Results warrant further investigation of KPd in randomized trials

d, dexamethasone; K, carfilzomib (Kyprolis); NR, not reached; OS, overall survival; P, pomalidomide; PFS, progression-free survival


Ixazomib + Pomalidomide + Dexamethasone (IPd)

- Triplet combinations to attack different pathways to eradicate MM cells are commonly used upfront and in RRMM
- Ixazomib (Ninlaro) was approved by the FDA in November 2015 in combination with lenalidomide (Revlimid; LEN) and dexamethasone for RRMM with at least 1 prior therapy
- An all-oral regimen of Ix + POM + DEX (IPd) could be useful in LEN-refractory RRMM

IMiD, immunomodulatory drug; MM, multiple myeloma; PI, proteasome inhibitor; RRMM, relapsed/refractory multiple myeloma

Ixazomib + Pomalidomide + Dexamethasone (IPd) Results

- Preliminary results of the phase 1/2 trial of IPd in 32 patients
- Eligibility: RRMM, 1–5 previous therapies, including a PI and LEN, and refractory to LEN
- ORR = 44% (including 28% partial response and 16% very good partial response)
- IPd was well tolerated

Conclusion: IPd is an active regimen

Ongoing Trials to Watch

<table>
<thead>
<tr>
<th>Trial</th>
<th>Topic</th>
</tr>
</thead>
<tbody>
<tr>
<td>TOURMALINE</td>
<td>Lenalidomide, and dexamethasone + Ixazomib (or placebo) in newly diagnosed MM (NDMM)</td>
</tr>
<tr>
<td>ELOQUENT-1</td>
<td>Lenalidomide and dexamethasone + Elotuzumab (or placebo) in NDMM</td>
</tr>
<tr>
<td>DRd v Rd</td>
<td>Lenalidomide and dexamethasone ± Daratumumab in non-transplant NDMM</td>
</tr>
<tr>
<td>E1A11</td>
<td>Carfilzomib, lenalidomide, dex versus Bortezomib, lenalidomide, dex in NDMM</td>
</tr>
<tr>
<td>DVMP vs VMP</td>
<td>4 drugs vs 3 drugs in-transplant NDMM</td>
</tr>
<tr>
<td>Ixazomib maintainance</td>
<td>Ixazomib maintenance vs placebo post-ASCT</td>
</tr>
</tbody>
</table>

IMiD, immunomodulatory drug; IPd, ixazomib, pomalidomide, dexamethasone; LEN, lenalidomide; ORR, overall response rate; PI, proteasome inhibitor; RRMM, relapsed/refractory multiple myeloma

Find more trial information at:
www.myelomatrials.org; www.clinicaltrials.gov
# Novel Therapies to Watch For (1)

<table>
<thead>
<tr>
<th>Antibody (Target)</th>
<th>Proteasome inhibitors</th>
</tr>
</thead>
<tbody>
<tr>
<td>B-B4, DL101 (CD138)</td>
<td>Marizomib*</td>
</tr>
<tr>
<td>Lucatumumab (CD40)</td>
<td>Oprozomib</td>
</tr>
<tr>
<td>IPH-2101 (KIR)</td>
<td></td>
</tr>
<tr>
<td>Atezolizumab (PD-L1)*</td>
<td>HDAC inhibitors</td>
</tr>
<tr>
<td>Nivolumab (PD-1)</td>
<td>Ricolinostat</td>
</tr>
<tr>
<td>Durvalumab (PD-L1)</td>
<td>ACY-241</td>
</tr>
<tr>
<td>Indatuximab (CD38)</td>
<td></td>
</tr>
</tbody>
</table>

* Drugs studied in the

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# Novel Therapies to Watch For (2)

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Agents</th>
</tr>
</thead>
<tbody>
<tr>
<td>KSP inhibitors</td>
<td>Filanesib (ARRY-520)*</td>
</tr>
<tr>
<td>BTK inhibitors</td>
<td>Ibrutinib*, AVL-292</td>
</tr>
<tr>
<td>CDK inhibitors</td>
<td>PD0332991*, SCH727965, AT7519*</td>
</tr>
<tr>
<td>BCL antagonist</td>
<td>Venetoclax*</td>
</tr>
<tr>
<td>HSP90 inhibitors</td>
<td>Ganetespib (STA-9090)*</td>
</tr>
<tr>
<td>SINE XPO1 antagonists</td>
<td>Selinexor (KPT-330)*</td>
</tr>
<tr>
<td>FGFR3 inhibitor/antibodies</td>
<td>TKI258*, MFGR1877S</td>
</tr>
<tr>
<td>Mutant B-Raf inhibitor</td>
<td>Vemurafenib</td>
</tr>
</tbody>
</table>

* Drugs studied in the

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Question & Answer

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John Theurer Cancer Center
Hackensack, NJ

Closing Remarks

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Norwalk, CT

To learn more about the MMRF, please visit:
www.multiplemyeloma.org
Resources for You!

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