Clinical Advances in Immunotherapy in Myeloma

Webinar 1, June 14, 2017
Monoclonal Antibodies

Speakers

Moderator:
Mary DeRome
Multiple Myeloma Research Foundation
Norwalk, Connecticut

Faculty:
Tom Martin, MD
University of California, San Francisco
San Francisco, California

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University of California, San Francisco
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Gary Rudman, CSP
Myeloma Patient Advocate
Topics for Discussion

- Current and future monoclonal antibodies (what they are, how they work)
- Management of side effects in the era of monoclonal antibodies
- Patient experience on phase 2 clinical trial of Empliciti (elotuzumab)

Tom Martin, MD
Current Overall Survival for Newly Diagnosed Myeloma

A good trend but we always need to improve!!

Myeloma Treatment: It’s an Art
New Agents in Myeloma Therapy

New IMiDs
- Lenalidomide
- Pomalidomide
- CC-122
- CC-220
- Bortezomib
- Carfilzomib
- Ixazomib
- Oprozomib
- Marizomib

Oral proteasomes
- Velcade
- NEMAIL
- Ixazomib
- Oprozomib
- MARZ

Kinase inhibitors
- Venetoclax
- Belinexor
- Filanesib
- Panobinostat
- Ricinostat
- Daratumumab
- Elotuzumab
- Isatuximab
- Idasanutlin

Novel MOA
- Vemurafenib
- Afuresertib
- Dinaciclib
- Ibrutinib
- Trametinib
- Dabrafenib
- JNJ-42756493
- Sotatercept
- CB-5083

HDAC inhibitors
- Panobinostat
- Ibrutinib
- Trametinib
- Dabrafenib
- JNJ-42756493
- Sotatercept
- CB-5083

Immuno-therapies
- Monoclonal antibodies
- Daratumumab
- Elotuzumab
- Isatuximab
- Idasanutlin
- Immune checkpoint inhibitors
- Pembrolizumab
- Durvalumab
- Immune cell therapy
- CAR-T
- BiTEs
- Vaccines

Harnessing the Immune System to Fight Myeloma

Types of Immunotherapy, Immuno-Oncology

Passive
- Monoclonal antibodies

Active
- Chimeric antigen receptor (CAR) T cells
- Vaccines (therapeutic not preventive)

MAC, membrane attack complex; CDC, complement dependent cytotoxicity; ADC, antibody directed cellular cytotoxicity
Types of Monoclonal Antibodies

- **Naked**
  - Nothing is attached

- **Drug conjugates**
  - A toxin or radioactive isotope is attached

- **Bispecific**
  - Targets in MM

  - BCMA
  - SLAMF7
  - CD38
  - CD3
  - PD-1
  - CD16

Monoclonal Antibodies Can Kill Myeloma Cells in Multiple Ways

**DIRECT EFFECT**
- Interferes with survival or delivers myeloma-killing substances

**INDIRECT EFFECTS**
- Labels myeloma cells for killing by complement
- Labels myeloma cells for killing by NK cells
- Activates T cells by "taking the brakes off"
Two Approved Monoclonal Antibodies: Elotuzumab and Daratumumab

Elotuzumab
- Received approval for patients with relapsed/refractory myeloma from a large randomized combination phase 3 trial 1

Daratumumab
- Received approval following a phase 2 single-agent trial 2 for patients with relapsed/refractory myeloma


Elotuzumab (Empliciti)

- Anti-SLAMF7 mAb
- SLAMF7 expressed on both MM cells and NK cells
- Tags MM cells for ADCC via NK cells and activates NK cells via EAT-2 for MM cell destruction independent of ADCC
- Activity in combination with lenalidomide led to ELOQUENT trial

NK, natural killer; ADCC, antibody-dependent cellular cytotoxicity
Phase 3 Trial of Elotuzumab ELOQUENT-2

Relapsed/refractory myeloma patients

- Compared to Revlimid and dexamethasone alone, the addition of elotuzumab significantly increased:
  - Progression-free survival
  - Overall response rates
- The triple combination resulted in a 30% reduction in the risk of disease progression or death
- Another phase 3 trial comparing the same combinations is underway in patients with newly diagnosed disease


Monoclonal Antibody: Empliciti (elotuzumab)

Current Indications
- In combination with Revlimid and dexamethasone for patients with relapsed/refractory myeloma (who have received one to three prior therapies [2015])

How is Empliciti administered?
- IV
- Once a week for the first 8 weeks then every 2 weeks
- Pre-medication in anticipation of infusion reactions

What are the possible side effects?
- Fatigue
- Diarrhea
- Fever
- Constipation
- Cough
- Peripheral neuropathy
- Infusion reactions
- Nasopharyngitis
- Upper respiratory tract infection
- Decreased appetite
- Pneumonia
- Small chance of second new cancer
**Daratumumab (Darzalex)**

- Naked monoclonal that binds to CD38 on myeloma cells
- Active as single agent and in combination with lenalidomide
- First mAb approved for treatment of myeloma patients who have received at least three prior lines of therapy (including a PI and an IMiD) or who are double refractory to a PI and an IMiD
- Infusion reactions main side effect
- Potential impact on both standard- and high-risk disease

**Phase 3 Trials of Daratumumab**

**CASTOR** 1  
Relapsed/refractory myeloma patients  
- Dara + Vel + dex  
- Vel + dex  
- 61% reduction in risk of disease progression or death for DVd vs Vd.

**POLLUX** 2  
Relapsed/refractory myeloma patients  
- Dara + Rev + dex  
- Rev + dex  
- 63% reduction in risk of disease progression or death for DRd vs Rd

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Monoclonal Antibody: Darzalex (daratumumab)

**Current indications**
- In combination with Revlimid and dexamethasone, or Velcade and dexamethasone, for patients who have received at least one prior therapy (2016)
- As monotherapy, for patients who have received at least three prior lines of therapy including a PI and an immunomodulatory agent or who are double refractory to a PI and an immunomodulatory agent (2015)

**How is Darzalex administered?**
- IV
- Once a week for the first 8 weeks, then every 2 weeks for 4 months, then monthly
- Pre- and post-medication for infusion reactions

**What are the possible side effects?**
- Infusion reactions
- Fatigue
- Nausea
- Back pain
- Fever
- Cough
- Upper respiratory tract infection

Immune Checkpoint Inhibitors in Multiple Myeloma

- Target PD-1, PDL-1
- Allow T cells to function
- Current agents under investigation in myeloma: nivolumab and pembrolizumab
- Activity only in combination with other myeloma agents

Patna B et al., Leukemia. 2015;29:2110.
Homet Moreno B, Ribas A. Br J Cancer. 2015;112:1421.
Clinical Advances in Immunotherapy in Myeloma
Webinar 1: Monoclonal Antibodies: A New Type of Myeloma Drug

Phase 1 Trial of Pembrolizumab: Keynote 023

- Patients had heavily pretreated RRMM (median four 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 in patients using pembrolizumab in solid tumors
- Overall response rate was 50% and disease control rate (CR, PR, or SD) was 98%

n = 51

Pembrolizumab + Rev + low-dose dex

Conclusion: results are promising; phase 3 studies of pembrolizumab are now under way.

Monoclonal Antibodies in Development: Phase 3 Trials

<table>
<thead>
<tr>
<th>Drug</th>
<th>Administration</th>
<th>Type</th>
<th>Trials</th>
<th>Side Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isatuximab†</td>
<td>IV</td>
<td>mAb</td>
<td>RR MM, Pomalyt* + dex ± Isatuximab†</td>
<td>Fatigue, nausea, cough, dyspnea, anemia, thrombocytopenia, neutropenia, infusion-associated reactions</td>
</tr>
<tr>
<td>Opdivo‡ (nivolumab)</td>
<td>IV</td>
<td>mAb</td>
<td>RR MM, Nivolumab*, Emplicit®, Pomalyt*, and dex</td>
<td>Fatigue, skin rash, muscle pain</td>
</tr>
<tr>
<td>Keytruda‡ (pembrolizumab)</td>
<td>IV</td>
<td>mAb</td>
<td>Newly diagnosed MM, Revlimid + dex ± Pembrolizumab‡, RR MM, Pembrolizumab‡</td>
<td>Myelosuppression, pneumonia, infection</td>
</tr>
<tr>
<td>Xgeva‡ (denosumab, AMG 162)</td>
<td>IV</td>
<td>Bone-targeted mAb</td>
<td>Newly diagnosed MM, Xgeva‡ vs Zometa</td>
<td>Hypocalcemia, nausea, anemia, dyspnea, fatigue, constipation</td>
</tr>
</tbody>
</table>

Monoclonal antibodies in phase 1 or 2 trials:
- ABBV-838, atezolizumab, DFRF4039A, durvalumab, indatuximab, lorvotuzumab mertansine, milatuzumab, MOR03087, tabalumab, ulocuplumab

IV, intravenous; mAb, monoclonal antibody; RRMM, relapsed/refractory multiple myeloma
*FDA-approved for RR disease; †Experimental therapy not yet FDA approved; ‡FDA approved for a non-MM indication

Trials found at www.clinicaltrials.gov

PI, proteasome inhibitor; IMiD, immunomodulatory drug
How will we cure myeloma?

Army

Navy

Marines

CD38

CS-1

All patients are appropriate for clinical trials.

Amy Marsala, MPH, MSN, NP
Daratumumab, Elotuzumab, Isatuximab

Monoclonal antibodies are generally well tolerated: adverse events dependent
- On- and off-target effects: based on target antigen expression
- Infusion associated reactions (IAR) most common
- Elotuzumab: targets SLAMF7
  - In combination with Revlimid: consider Rev side effect profile
  - Low toxicity profile
  - IAR seen in ~10% with pre-medications → infusion reaction (Grades 1 & 2), chills, fevers, hypertension > hypotension, bradycardia
- Phase I/II Elo-Rev-Dex vs Rd →
  - Lymphopenia (77% vs 49%)
  - Varicella zoster virus re-activation (13.5% vs 6%) and fungal infection (9.7% vs 5.4%)
  - Fatigue, diarrhea, fever, constipation, peripheral neuropathy, decreased appetite, risk of second malignancy

Toxicity: Antibody Therapy in Myeloma
Toxicity: Anti-CD38 Antibody Therapy in Myeloma

- Daratumumab toxicity
  - IAR: ~50% with mandatory pre-medications
    - >90% occur within the first infusion (few Grade 3–4); <2% discontinued therapy
      - Most common presentation: nasal congestion, throat irritation, cough, shortness of breath, chills, nausea, vomiting
  - Phase I/II monotherapy
    - Hematologic toxicity: anemia (45%), thrombocytopenia (48%), neutropenia (23%)
    - Non-hematologic: fatigue (40%), nausea (29%)
  - Phase III: Dara/Len/Dex → neutropenia (59.4% vs 43.1%) and diarrhea (42.8% vs 24.6%)
  - Phase III: Dara/Bor/Dex: → thrombocytopenia (58.8% vs 43.9%) and cough (23.9% vs 12.7%)

Isatuximab Toxicity

- IAR: ~50%: mandatory pre-medications (increased reaction at increased infusion rate)
- Phase I/II
  - Non-hematologic: fatigue, nausea, cough
  - Hematologic: anemia, thrombocytopenia + neutropenia
Clinical Advances in Immunotherapy in Myeloma

Webinar 1: Monoclonal Antibodies: A New Type of Myeloma Drug

Administration of Monoclonal Antibodies: Infusion Data

<table>
<thead>
<tr>
<th>Elotuzumab&lt;sup&gt;1&lt;/sup&gt;</th>
<th>Daratumumab&lt;sup&gt;2&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dose</strong></td>
<td><strong>Dose</strong></td>
</tr>
<tr>
<td>10 mg/kg every week for 8 weeks, then every 2 weeks</td>
<td>16 mg/kg every week for 8 weeks, then every 2 weeks for 16 weeks, then every 4 weeks</td>
</tr>
<tr>
<td><strong>Premedication</strong></td>
<td><strong>Premedication</strong></td>
</tr>
<tr>
<td>• Dex 8 mg IV (28 mg orally)</td>
<td>• Methylprednisolone 100 mg</td>
</tr>
<tr>
<td>• Acetaminophen 650–1,000 mg</td>
<td>• Acetaminophen 1,000 mg</td>
</tr>
<tr>
<td>• Diphenhydramine 25–50 mg</td>
<td>• Cetirizine 10 mg or equivalent</td>
</tr>
<tr>
<td>Ranitidine 50 mg IV</td>
<td>• Dex 4 mg on Days 2 + 3</td>
</tr>
<tr>
<td><strong>Infusion-Associated Reactions</strong></td>
<td><strong>Infusion-Associated Reactions</strong></td>
</tr>
<tr>
<td>~10%</td>
<td>~49%–71%</td>
</tr>
<tr>
<td>• G1–2</td>
<td>• G1–2</td>
</tr>
<tr>
<td>• 1st infusion</td>
<td>• 1st–2nd infusion (8%)</td>
</tr>
<tr>
<td>~&lt;1% DC</td>
<td>~&lt;1% DC</td>
</tr>
<tr>
<td><strong>Infusion Rate/Time</strong></td>
<td><strong>Infusion Rate/Time</strong></td>
</tr>
<tr>
<td>Start 0.5 mL/min, increase to 2 mL/min (~2–3 hours)</td>
<td>1,000 mL - @50 mL/hr inc. to 200 mL/hr 1st: 7h 2nd: 3.25–4 h</td>
</tr>
<tr>
<td><strong>Rapid Infusion</strong></td>
<td><strong>Rapid Infusion</strong></td>
</tr>
<tr>
<td>(≤90 min) Yes</td>
<td>TBD</td>
</tr>
</tbody>
</table>


UCSF Premedications and Rescue Medications

**Pre-medications (daratumumab)**
- Administered 1 hour before infusion
  - Tylenol 650 mg orally × 1
  - Cetirizine 10 mg orally × 1
  - Montelukast 10 mg tablet × 1
  - (daratumumab/isatuximab only)
  - Pepcid 20 mg IV × 1
  - Solu-Medrol 100 mg IV × 1
  - Dexamethasone 8 mg IV × 1 (elotuzumab only)

**Rescue medications**
- Oxygen per nasal cannula
- Diphenhydramine (Benadryl) 50 mg injection × 1
- Solu-Cortef 100 mg IV × 1
- Albuterol 90 mcg/actuation inhaler two puffs
- Epinephrine 0.3 mg injection
Sample Patient Infusion Reaction

- Patient first treated with daratumumab at 50 mL/hr. After 1 hour, rate was increased to 100 mL/hr, but 32 minutes into this rate the patient experienced chills and mild rigors.
- 12:02 PM, dara stopped
  - Caught very early, drug stopped and already started to resolve within 5 minutes. Tamp up to 37.7. Rescue medications given IV hydrocortisone and IV Benadryl, did not feel Demerol IV was necessary.
  - Pt is aware he will become sleepy and placed in bed. Will keep the drug off for awhile and monitor patient for 45 minutes before restarting.
- 12:50 PM chills were 80% resolved. Will continue to monitor.
- 13:15 PM resumed dara at 50ml/hr × 60 minutes
  - Pt continues to improve, not 100% resolved, drug has been off 75 min will give a trial and restart.
  - Max rate of 200ml/hr was achieved.
- 19:18 PM infusion finished
- Dara to be mixed in 1000mls for next dose
- Pt aware to monitor for 4 hours tonight for any re-development of hypersensitivity reaction (SOB, chest tightness, throat constriction, acute onset nasal drainage) he must go to the ER.

Clinical Issues: Monoclonal Antibody Therapy in Myeloma

- Daratumumab binds to CD38 on reagent cells interfering with the indirect anti-globulin test
- Daratumumab bound to RBCs masks detection of antibodies to minor antigens in the patient’s serum. The determination of a patient’s blood type are not impacted
- Patients should have baseline antibody screening PRIOR to first infusion
- Advise patients to inform health care providers (including blood transfusion personnel) that they are taking Darzalex, in the event of a planned transfusion
- Effects can last up to 6 months after last dose (notify blood bank if CD38 antibody given)
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Webinar 1: Monoclonal Antibodies: A New Type of Myeloma Drug

Treatment: Patient Considerations

- Location and transportation
- Financial resources
- Family support
- Caregivers
- Time
- Nursing care
- Dosing frequency
- Side effect profiles
- Aesthetics, hair loss, muscle atrophy

Case Study

First and still going

- 74-year-old woman diagnosed in 2011 with IgGκ myeloma
  - Presented with severe anemia
  - IgG 8,875
  - κ 255
  - 80% plasma cells in bone marrow
- Treatment
  - 2 cycles of RVD (2012)
  - 6 cycles of VDC → partial response → IgG 4,300
  - 6 cycles of BiRD → stable disease IgG 3,000
  - Not a candidate for carfilzomib or transplant due to cardiac toxicity

Darzalex initiation

- Treatment changed to inpatient high dose chemotherapy
- 6 rounds of high-dose cytoxan + dex (January 2015–November 2015)
  - Achieved a VGPR
- IgG 1,200
- By January 2016 IgG rose to 6,788
- January 11, 2016: Started DARZALEX monotherapy

Cycle 18

- Infusion started at 50 mL/hr and increased per protocol
- Patient given premedications according to SOP
- Tolerated without infusion reaction
- Advanced to 100 → 150 and 200 mL/hr
- Given dex 4 mg on days 2 and 3
  - No post-infusion reaction
- IgG: 5,420 → 4,935 → 2,450 → 1,470 → 1,040 → 866 → 648
- 18 cycles later (17 months), patient remains on monotherapy

Observed toxicities

- On initiation of treatment, patient was getting G-CSF weekly for ANC <1.0
  - Resolved after month 6 on treatment.
- Anemia → mild 10.0–11.0 g/dL
- Two cases of URI, one developed into PNE
  - No treatment interruption
- No GI toxicity; appetite normal
- Joint pain and general aches...daratumumab?
What are people really saying?

- Observationally, daratumumab and elotuzumab are well tolerated as compared with chemotherapy combination drug regimens
- Patients primary complaints include
  - Initial infusion reactions
  - Time spent receiving therapy
  - Worsening of fatigue on the days following the infusions
- Patients report less overall nausea, vomiting, GI upset, bone pain
- Patients are eager for additional immunotherapies and combination regimens

Closing the Gap on Cure....
Empliciti Patient Experience Phase 2 Clinical Trial

Mr. Gary S. Rudman
Multiple Myeloma Patient

Snapshot

• Diagnosed April 2015
• Stem cell transplant August 4, 2015
  – MD Anderson Cancer Center, Houston
• Clinical trials
  – Pre-SCT: busulfan-melphalan
  – Post-SCT: Empliciti, Revlimid, dexamethasone
  – Post-SCT: minocycline vs placebo
• Complete remission
Finding a Clinical Trial

1. Ask your oncologist about available trials
2. Check with any academic medical centers
4. Multiple Myeloma Research Foundation (www.themmrf.org)

Phase 2 Clinical Trial

- Empliciti
- Revlimid
- Dexamethasone

- Revlimid
- Dexamethasone
My Empliciti Experience

<table>
<thead>
<tr>
<th>Research protocol</th>
<th>Infusion preparation</th>
<th>Infusion</th>
<th>Infusion reaction</th>
<th>Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>• First 9 weeks</td>
<td>• Lab work 2 hours prior to oncologist</td>
<td>• Premedication Minimizes expected side effects</td>
<td>• Possible during or within 24 hours of infusion</td>
<td>• Remain in hospital local area overnight</td>
</tr>
<tr>
<td>– Meet with oncologist first week of month</td>
<td>• Meet with oncologist Review history and labs</td>
<td>– Dexamethasone (4 mg)</td>
<td>• Cancer center better prepared to handle issues</td>
<td></td>
</tr>
<tr>
<td>– Empliciti infusion every week</td>
<td>– Ensure no limiting factors</td>
<td>– Pepcid AC</td>
<td>– Experience with trial medications</td>
<td></td>
</tr>
<tr>
<td>– High cumulative fatigue</td>
<td>– Discuss new issues</td>
<td>– Benadryl</td>
<td>– Doctors know what to expect</td>
<td></td>
</tr>
<tr>
<td>• Next 2 months</td>
<td>– Receive thumbs up</td>
<td>– Tylenol</td>
<td>– Depart for home if no reactions</td>
<td></td>
</tr>
<tr>
<td>– Empliciti infusion every other week</td>
<td>• Proceed to infusion treatment center</td>
<td>• Empliciti Infusion from 4 to 1.5 hours</td>
<td>• Preventative measures</td>
<td></td>
</tr>
<tr>
<td>– Slightly reduced fatigue</td>
<td>• Be ready to wait—patience is critical</td>
<td>• Slower rate at first due to unknown side effects</td>
<td>– Compazine</td>
<td></td>
</tr>
<tr>
<td>• Month ≥5</td>
<td>• Have something to do</td>
<td>• Increased rate without side effects</td>
<td>– Return to ER if temperature &gt;101.0°</td>
<td></td>
</tr>
<tr>
<td>– Empliciti infusion once per month</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

Empliciti Side Effects

- Fatigue
- Diarrhea
- Fever
- Constipation
- Cough
- Numbness, weakness, or tingling or burning pain in your arms and legs
- Sore throat or runny nose
- Upper respiratory infection
- Decreased appetite
- Pneumonia
Reactions

- Empliciti: none
- Returning from Houston to Columbia
  - Loss of appetite, dehydration, temp >101.0°
    - Most likely travel related
    - Two nights in hospital
    - Not infusion related

Progress

- Clinical trial started January 2016
- Completed 25 Empliciti infusions
- Post-infusion
  - Walk to hotel from hospital
  - Elliptical, treadmill to unwind
  - Enjoy a nice dinner
Gary’s Empliciti Results

- Maintaining complete remission
- Minimal residual disease (MRD) negative

Empliciti in combination with Revlimid, dexamethasone, and my immune system are working together to keep me myeloma free.
Questions & Answers

Closing
Have questions about the trials or information you heard today? Call our MMRF nurse specialists.

An MMRF nurse specialist can guide you through your multiple myeloma journey every step of the way. Call Monday–Friday, 9–7 ET

Call now 1-866-603-MMCT(6628)
### Upcoming MMRF Webinars
#### Summer 2017

<table>
<thead>
<tr>
<th>Series</th>
<th>Topic</th>
<th>Date</th>
<th>Time</th>
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<tbody>
<tr>
<td>Immunotherapy</td>
<td>Vaccines for Myeloma (and Other Advances in Immunotherapy)</td>
<td>July 26, 2017</td>
<td>1:00 PM ET</td>
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<td>Engineered Immune Cells</td>
<td>August 9, 2017</td>
<td>1:00 PM ET</td>
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<td>Meeting Highlights</td>
<td>American Society of Clinical Oncology and the European Hematology Association</td>
<td>July 19, 2017</td>
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For more information or to register, visit: theMMRF.org

### MMRF Multiple Myeloma Summits
#### Fall 2017

<table>
<thead>
<tr>
<th>Location</th>
<th>Date</th>
<th>Chair</th>
<th>Institute(s)</th>
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<tbody>
<tr>
<td>Chicago, Illinois</td>
<td>Saturday, September 16, 2017</td>
<td>Andrzej Jakubowiak, MD–Chair</td>
<td>University of Chicago Medical Center</td>
</tr>
<tr>
<td>Charlotte, North Carolina</td>
<td>Saturday, October 14, 2017</td>
<td>Saad Z. Usmani, MD–Chair</td>
<td>Institute for Myeloma and Bone Cancer Research</td>
</tr>
<tr>
<td>New York City, New York</td>
<td>Friday, November 3, 2017</td>
<td>Sundar Jagannath, MD–Chair</td>
<td>Mount Sinai Medical Center Tisch Cancer Institute Mount Sinai School of Medicine Levine Cancer Institute</td>
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<tr>
<td>Los Angeles, California</td>
<td>Saturday, November 18, 2017</td>
<td>James Berenson, MD–Co-Chair</td>
<td>Institute for Myeloma and Bone Cancer Research Judy and Bernard Briskin Center for Multiple Myeloma Research</td>
</tr>
<tr>
<td>Los Angeles, California</td>
<td>Saturday, November 18, 2017</td>
<td>Amrita Y. Krishnan, MD–Co-Chair</td>
<td>Judy and Bernard Briskin Center for Multiple Myeloma Research</td>
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</tbody>
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To register, please visit: theMMRF.org/Patient