Bortezomib, Lenalidomide and Dexamethasone vs. Lenalidomide and Dexamethasone in Patients (Pts) with Previously Untreated Multiple Myeloma Without an Intent for Immediate Autologous Stem Cell Transplant (ASCT): Results of the Randomized Phase III Trial SWOG S0777

Brian G.M. Durie, MD, Antje Hoering, PhD, S. Vincent Rajkumar, MD, Muneer H. Abidi, MD, Joshua Epstein, DSc, Stephen P. Kahanic, MD, Mohan Thakuri, MD, Frederic Reu, MD, Christopher M. Reynolds, MD, Rachael Sexton, MS, Robert Z. Orlowski, MD, PhD, Bart Barlogie, MD, PhD, Angela Dispenzieri, MD

ASH, December 2015
SWOG S0777 Study Design

Eight 21-day Cycles of VRd

- **Bortezomib 1.3/mg² IV**
  - Days 1, 4, 8, and 11
- **Lenalidomide 25 mg/day PO**
  - Days 1-14
- **Dexamethasone 20 mg/day PO**
  - Days 1, 2, 4, 5, 8, 9, 11, 12

Six 28-day Cycles of Rd

- **Lenalidomide 25 mg/day PO**
  - Days 1-21
- **Dexamethasone 40 mg/day PO**
  - Days 1, 8, 15, 22

Randomization

- N = 525

Stratification:

- ISS (I, II, III)
- Intent to transplant @ progression (yes/no)
Progression-Free Survival By Assigned Treatment Arm

Log-rank P value = 0.0018 (one sided)*

HR = 0.712 (0.560, 0.906)*
Log-rank P value = 0.0018 (one sided)*

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Events</th>
<th>N</th>
<th>Median in Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>VRd</td>
<td>137</td>
<td>242</td>
<td>43 (39, 52)</td>
</tr>
<tr>
<td>Rd</td>
<td>166</td>
<td>229</td>
<td>30 (25, 39)</td>
</tr>
</tbody>
</table>
S0777 Timeline

Cathy Rankin, Oishi Symposium, Spring 2017
SWOG SDMC Personnel

- **Original Study Team**
  - Statisticians
    - Rachael Sexton
    - Antje Hoering
  - DCs
    - Jeri Jardine

- **Additional Staff for Celgene Collaboration – Core Team**
  - PM
    - Sarah Basse
  - Statistician:
    - Cathy Rankin
  - DM – senior professional
    - Evonne Lackey
  - DCs
    - Jeri Jardine
    - Laura Kingsbury
  - Project Assistant
    - Sam Dzingle
What happened since then?
- In Numbers

- **Since April 2017**
  - Queries posted: **2660**
  - Number of patients re-consented: **220**
  - Number of monitoring visits: **81**
  - Number of monitoring days: **238**

- **Since April 2016**
  - New CRFs submitted: **3056**
  - Queries posted: **9364**
  - Number of monitoring visits: **242**
  - Number of monitoring days: **1032**
And now?

- We (YOU!) did it!
- Final data set and casebooks submitted to Celgene: September 2017
- FDA submission planned: January 2018
- Myeloma patients world-wide will hopefully have access to additional treatment choices.

THANK YOU!