A Pooled Analysis of the Impact of Age on Outcomes in Patients With Refractory or Relapsed and Refractory Multiple Myeloma Treated With Pomalidomide + Low-Dose Dexamethasone

Antonio Palumbo,1 Melanesia A. Dimopoulos,2 Paul G. Richardson,3 David S. Singel,4 Michelle Cavo,5 Paolo Corradini,6 Katja C. Weisel,7 Michel Delorge,8 Christine Chen,9 Hartmut Goldschmidt,10 Sundar Jagannath,11 Henk M. Lokhorst,12 Philippe Moreau,13 Torben Plesner,14 Lars Stroms15, Teresa Peluso,6 Kevin Hong,16 Jennifer Herrington,17 Xin Yu,16 Mohamed H. Zaki,18 Jesus San Miguel12

1University of Torino, Torino, Italy; 2National and Kapodistrian University of Athens, Athens, Greece; 3Jenner Institute Multiple Myeloma Center, Department of Medical Oncology, Daniele-Faber Cancer Institute, Hannover Medical School, Braunschweig, Germany; 4John Thorpe Cancer Center, Hackensack University Medical Center, Hackensack, NJ; 5San Raffaele Institute of Hematology, University of Milan, Milan, Italy; 6University of Southern Denmark, Department of Medicine, Odense University Hospital, Odense, Denmark; 7University of Southern Denmark, Department of Haematology, Odense University Hospital, Odense, Denmark; 8Genzyme Corporation, Summit, NJ; 9Genzyme International, Soller, Spain; 10University of Padua, Padua, Italy; 11University of Padua, Padua, Italy; 12University of Southern Denmark, Department of Medicine, Odense University Hospital, Odense, Denmark; 13University Hospital Hotel-Dieu, Nantes, France; 14University of Southern Denmark, Department of Hematology, Lerner Children’s Hospital of Cleveland, OH; 15Seràgnoli Institute of Hematology, Bologna University School of Medicine, Bologna, Italy; 16Celgene International Sàrl, Boudry, Switzerland; 17Clinica Universidad de Navarra, CIMA, IDISNA, Pamplona, Spain

METHODS

Study Design

Three Pom + LoDEX clinical trials were used for this pooled analysis: MM-002 (NCT00383383), MM-003 (NCT01311867), EudraCT number 2010-189520-30, and MM-010 (NCT01712788), EudraCT number 2010-018888-78. Key eligibility criteria in these trials included:

- Age ≥ 18 years with documented RRMM
- Progressive disease ≤ 60 days of the last prior therapy after having received ≥ 2 prior therapies, including ≥ 2 cycles of LEN and BORT (alone or in combination).
- Refractoriness to LEN and/or BORT (or intolerance of BORT) was allowed (MM-002 or MM-003 and MM-010)

- Pts received 28-day cycles of Pom 4 mg/day on days 1-21 + LoDEX 40 mg (20 mg if aged > 75 yrs) weekly until disease progression or unacceptable toxicity

RESULTS (cont)

Safety

The safety profile was similar for all age groups (Table 2).

- Neutropenia and anemia were the most common adverse events (AEs).
- Grade 3/4 deep vein thrombosis/pulmonary embolism and peripheral neuropathy were uncommon (≤ 2% in all age groups).
- Rates of dose reductions and dose interruptions due to AEs were similar across age groups.

RESULTS (cont)

Efficacy

- Outcomes were consistent across analyzed age groups.
- Median overall survival was slightly longer in pts aged ≤ 65 vs those aged >65 yrs (13.4 vs 11.9 months) and was maintained in pts aged ≤ 75 and those aged >75 yrs (Table 4)
- Duration of response was slightly longer in the older age subgroup (7.7 and 9.0 months for ≤ 65 and >75 yrs, respectively) compared with the younger age subgroup (7.0 and 7.1 months for ≤ 65 and >75 yrs, respectively; Figure 1)

Table 4. PFS and OS

<table>
<thead>
<tr>
<th>Median PFS (mos) (n)</th>
<th>Median OS (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 65 yrs (n = 542)</td>
<td>≥ 65 yrs (n = 555)</td>
</tr>
<tr>
<td>4.4 (3.4-8.4)</td>
<td>4.4 (3.4-8.4)</td>
</tr>
<tr>
<td>13.2 (10.7-16.8)</td>
<td>11.9 (10.6-16.8)</td>
</tr>
</tbody>
</table>

Table 3. Pom Dose Modifications Due to AEs and Dose Intensity

<table>
<thead>
<tr>
<th>Median P Dose xg modifications due to AEs and Dose Intensity</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 65 yrs (n = 551)</td>
</tr>
<tr>
<td>4.8 (0.4-7.6)</td>
</tr>
<tr>
<td>2 - Dose reduction≤ 75 yrs</td>
</tr>
<tr>
<td>2 - Dose reduction&gt; 75 yrs</td>
</tr>
<tr>
<td>2 - Dose reduction≤ 75 yrs</td>
</tr>
</tbody>
</table>

CONCLUSIONS

In this large pooled analysis of outcomes from more than 1000 heavily pretreated pts with RRMM, Pom + LoDEX showed similar safety and efficacy profiles across 4 age groups.

A full text of this poster can be found in Blood Cancer Journal. www.bloodcancerjournal.com

REFERENCES


ACKNOWLEDGEMENTS

We thank all the patients, nurses, study personnel, and investigators who participated in these studies.

The authors acknowledge the financial support for this analysis from Celgene Corporation. The authors also acknowledge editorial assistance from MediTech Media (Kerry Garza, PhD and Mihaela Marina, PhD) and a grant-in-aid from Celgene Corporation. The authors received editorial assistance from MediTech Media, sponsored by Celgene Corporation.

DISCLOSURES

A P.I. reports consulting and honoraria for Amgen, BMS, Centocor, Celgene, Celgene, Geisinger, Janssen, Millennium, Novartis, Onyx, and Takeda, and has research funding from Amgen, Celgene, Genmab, Janssen, Millennium, Novartis, Onyx, and Takeda. S.J. reports advisory board for Celgene, BMS, Millennium, Celgene, Janssen, and research funding from Celgene, Janssen, Millennium, Novartis, Onyx. H.L. reports advisory board for Amgen. M.P. reports honoraria from and consulting for Amgen, Celgene, and research funding from Amgen, Celgene, Takeda, for serving on advisory boards for Amgen and Celgene, and serving on the Data Safety Monitoring Board for Amgen for a clinical trial. D.S.S. reports stock in COTA, honoraria, consultancy, speakers bureau, and travel for Celgene, Takeda, Amgen, BMS, Novartis, Janssen, and M.P., D.S.S. reports consulting and honoraria from BMS, Celgene, Janssen, Millennium, P.C.; has nothing to report. A.C.H., C.R., is consulting honoraria, travel, and travel subsistence for Amgen, Celgene, and research funding from Amgen; M.P., is consulting honoraria and travel for Amgen, Celgene, Novartis, and Takeda; and has research funding from Amgen, Celgene, and Janssen. C.C. has received grants from Janssen, Takeda, Celgene, and Amgen, Takeda, research funding from Celgene, C.D., reports consulting honoraria, speaking fees, travel grants, and consultancy for Amgen, Celgene, Janssen, Millennium, Celgene; M.P., reports financial interest, travel, research funding, and speaking fees for Amgen, Celgene, Janssen, Takeda, speakers bureau, and travel for Celgene, Takeda, Amgen, BMS, Novartis, Janssen, and Genmab; and has research funding from Amgen, Celgene, Janssen, Millennium, P.C., and travel, speakers bureau, consulting honoraria, and research funding from Amgen; J.S., reports consulting honoraria and travel for Amgen, Celgene, Millennium, Janssen, and research funding from Amgen, Celgene, and service on an advisory board for Genentech; J.H., reports speaking honoraria from Celgene, Genmab, and Amgen, and consulting honoraria from Amgen, Celgene, and research funding from Amgen; B.M., reports consulting honoraria and travel for Amgen, Genentech, and honoraria and research funding from Amgen. H.M.L., J.R. reports consulting honoraria from and honoraria from Genentech, Janssen, and research funding from Celgene, Janssen, and Amgen. S.J. reports advisory board for Janssen, BMS, MDx, MSD, Celgene, Janssen, Millennium, and Novartis. A.P. reports consultancy and honoraria for Amgen, BMS, Novartis, Janssen, Celgene, Millennium, serait, Celgene, Genmab. C.C. reports consulting honoraria, travel grants, and speaking fees for Amgen, Celgene, Janssen, and research funding from Amgen, Celgene, and Takeda. A.P. reports consulting honoraria and travel grants for Amgen, Celgene, Janssen, and research funding from Amgen, Celgene, and Takeda. A.P. reports consulting honoraria and travel grants for Amgen, Celgene, Janssen, and research funding from Amgen, Celgene, and Takeda.

CORRESPONDENCE

Antonio Palumbo, MD - palumboa@yahoo.com

Presented at the 21st Annual European Hematology Association Congress, June 9-12, 2016, Copenhagen, Denmark.