MM-008: A Phase 1 Trial Evaluating Pharmacokinetics and Tolerability of Pomalidomide + Low-Dose Dexamethasone in Patients With Relapsed or Refractory Multiple Myeloma and Renal Impairment

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INTRODUCTION

- Pomalidomide (POM) is indicated for patients (pts) with relapsed/refractory multiple myeloma (RRMM) who received ≥ 2 prior therapies, including lenalidomide (LEN) and bortezomib, and has been shown to improve progression-free survival (PFS) and overall survival (OS).

METHODS (cont)

RESULTS (cont)

OBJECTIVE

- This study examines the PK and safety of POM + LoDEX in pts with severe renal impairment (RI) caused by renal disease, and with or without previous therapies, including LEN and thalidomide (THAL).

METHODS

- Trial Design (Figure 1)
  - Cohort A: Creative norm, renal normal or mild RI (CrCl ≥ 60 mL/min).
  - Cohort B: Severe RI (CrCl < 30 mL/min) not requiring hemodialysis.

RESULTS

- Table 1. Patient Characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>Cohort A (n=4)</th>
<th>Cohort B (n=2)</th>
<th>Overall (N=15)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yrs)</td>
<td>67.6 (67.1-68.7)</td>
<td>69.4 (67.7-72)</td>
<td>68 (67.1-68.7)</td>
</tr>
<tr>
<td>Median time from diagnosis</td>
<td>3.8 (3.0-12.5)</td>
<td>4.0 (2.0-12.5)</td>
<td>4.0 (2.0-12.5)</td>
</tr>
</tbody>
</table>

- Table 2. Most Frequent Grade 3-4 Adverse Events

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>Cohort A (n=4)</th>
<th>Cohort B (n=2)</th>
<th>Overall (N=6)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fatigue</td>
<td>2 (25)</td>
<td>0</td>
<td>2 (13.3)</td>
</tr>
</tbody>
</table>

- Table 3. POM Dose Modification, Discontinuations, and Dose Intensity

CONCLUSIONS

- MM-008 is an ongoing trial prospectively evaluating the PK and safety of POM + LoDEX in pts with severe RI (CrCl < 30 mL/min) and those with normal renal function or mild RI.

REFERENCES

- MM-008: A phase 1 trial evaluating pharmacokinetics and tolerability of pomalidomide + low-dose dexamethasone in patients with relapsed or refractory multiple myeloma and renal impairment.

DISCLOSURES

- JF serves on an advisory board for Celgene Corporation.
- DSS: serves on an advisory board for Celgene Corporation.
- SL: consults/advises for and received research funding from BMS, Celgene, Millennium, Novartis, Onyx, and Sanofi.
- RDH: received research funding from Celgene.
- OK, LS, LH: employment/equity ownership in Celgene LLC.
- JD, JR: consult/adviser for and received research funding from Celgene Corporation.

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