A Phase Ib Study of the Akt Inhibitor GDC-0068 with Docetaxel or mFOLFOX6 in Patients with Advanced Solid Tumors


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RESULTS

Table 1. Demographic and Baseline Characteristics. Data collected 1/15 to 3/15.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>All Subjects (n=24)</th>
<th>Arm A (GDC-0068 + Docetaxel)</th>
<th>Arm B (GDC-0068 + mFOLFOX6)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yr), median (range)</td>
<td>62 (26-80)</td>
<td>63 (33-80)</td>
<td>62 (25-80)</td>
</tr>
<tr>
<td>Sex, male</td>
<td>19 (80)</td>
<td>11 (78)</td>
<td>8 (33)</td>
</tr>
<tr>
<td>Race, white</td>
<td>20 (83)</td>
<td>11 (78)</td>
<td>9 (38)</td>
</tr>
<tr>
<td>Performance status, ECOG 0</td>
<td>20 (83)</td>
<td>11 (78)</td>
<td>9 (38)</td>
</tr>
</tbody>
</table>

Safety

- Safety data was available for 47 patients (24 patients in Arm A and 23 patients in Arm B).
- All GDC-0068-related AEs were Grade 1 or 2, except Grade 3 diarrhea (n=1), leukopenia (n=1), and hypophosphatemia (n=1) in Arm A, and Grade 3 hypophosphatemia (n=1) in Arm B.
- There were no Grade 4 drug-related AEs, and there were no DLTs.

Figure 1. Enhanced Activity Seen When GDC-0068 is Combined with Chemotherapeutic Agents

Figure 2. Pharmacodynamic Effects Achieved at Clinical GDC-0068 Doses ≤110 mg.

Figure 3. Disease Stabilization.

Figure 4. Time on Study: Arm A (GDC-0068 + Docetaxel) and Arm B (GDC-0068 + mFOLFOX6).

Figure 5. Examples of Patients Experiencing Partial Response. See Table 4 for Patient Information.

Figure 6. Pharmacokinetics

REFERENCES


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