Phase II open-label, multi-centre study of bemcentinib (BGB324), a first-in-class selective AXL inhibitor, in combination with pembrolizumab in patients with advanced NSCLC.

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Background & objective

Phase II open-label, multi-centre study of bemcentinib (BGB324), a first-in-class selective AXL inhibitor, in combination with pembrolizumab in patients with advanced NSCLC.

Key inclusion and exclusion criteria

1. Histologically or cytologically confirmed, metastatic non-small cell lung cancer (NSCLC)
2. ECOG performance status of 0 or 1
3. Adequate organ function
4. Pembrolizumab alone or in combination with another anti-PD-1/PD-L1/PD-L2 therapy not allowed
5. No prior anti-AXL therapy

Assessments - efficacy & safety

1. Efficacy: Best overall response (BOR) assessed centrally according to Response Evaluation Criteria in Solid Tumors (RECIST) v1.1
2. Safety: Adverse events (AEs)

Pharmacodynamics

Table 1: Baseline demographics

<table>
<thead>
<tr>
<th>Group</th>
<th>N</th>
<th>Age (median, range)</th>
<th>Sex</th>
<th>PD-L1 status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group A</td>
<td>10</td>
<td>65 (25-75)</td>
<td>Male</td>
<td>70%</td>
</tr>
<tr>
<td>Group B</td>
<td>10</td>
<td>62 (45-75)</td>
<td>Female</td>
<td>60%</td>
</tr>
</tbody>
</table>

Safety

Table 2: Treatment emergent adverse events related to other bemcentinib, pembrolizumab

<table>
<thead>
<tr>
<th>Event</th>
<th>Group A</th>
<th>Group B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diarrhea</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Fatigue</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Nausea</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Vomiting</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

Results

No grade 3 or 4 toxicities were observed in either group.

Conclusions

- The combination of bemcentinib and pembrolizumab shows promising activity
- Response to treatment was most marked in tumours that were PD-L1 negative and AXL positive
- Soluble AXL demonstrates potential as an enrichment strategy
- The incidence of grade ≥3 treatment-related adverse events was low

References

[List of references]

Contact

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