Avelumab (MSB0010718C; anti-PD-L1) as a first-line treatment for patients with advanced NSCLC from the JAVELIN Solid Tumor Phase 1b trial: safety, clinical activity, and PD-L1 expression


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Cancer: Lung Cancer

• Despite improvements in chemotherapy options and supportive care, 1-year survival rates with chemotherapy for advanced NSCLC remain low.

Background

• PD-1/PD-L1 pathway:

  • Binds PD-L1

  • Programmed death-1 receptor (PD-1) and its ligand (PD-L1) are key therapeutic targets in the reactivation of the immune response against multiple cancers

• Clinical activity associated with PD-L1 expression level

  • Clinical activity was assessed in evaluable patients (n=67) with ≥13 weeks follow-up, baseline tumor assessment, and ≥1 post-baseline assessment.

Methods

• Select patient eligibility criteria:

  • Higher tumor burden was not a requirement for enrollment

• Treatment and assessments:

  • Avelumab was administered IV Q2W at 10 mg/kg dose

• Safety:

  • Adverse events (AEs) and patient discontinuations (PDNs) were reported to the investigator as soon as possible

• PD-L1 expression

  • PD-L1 expression (positive or negative) in tumor samples was assessed using a proprietary immunohistochemistry assay.

• Results:

  • Early and durable responses were observed (ORR: 18.7% (95% CI: 10.6, 29.3), DCR: 51.8% (95% CI: 38.4, 64.8), stable disease: 45.3%)

Table 1. Patient and disease characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>n (%)</th>
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<tbody>
<tr>
<td>Age (years)</td>
<td>18-60 50 (35.0) 61-80 95 (66.2) ≥81 0</td>
</tr>
<tr>
<td>Gender</td>
<td>Male 87 (60.0) Female 58 (40.0)</td>
</tr>
<tr>
<td>Race</td>
<td>Caucasian 140 (96.4) Other 5 (3.6)</td>
</tr>
<tr>
<td>Performance status</td>
<td>ECOG PS 0-1 145 (100.0)</td>
</tr>
<tr>
<td>Histology</td>
<td>Adenocarcinoma 87 (60.0) Squamous 46 (32.0) Other 12 (8.0)</td>
</tr>
<tr>
<td>Tumor burden</td>
<td>T2 29 (18.2) T3-4 136 (89.8)</td>
</tr>
<tr>
<td>PD-L1 status</td>
<td>PD-L1− 71 (49.0) PD-L1+ 74 (51.0)</td>
</tr>
</tbody>
</table>

Figure 2. Kaplan-Meier estimate of clinical activity

CONCLUSIONS

• Avelumab showed clinical efficacy, including, 1 complete response (ORR: 18.7%, DCR: 51.8%), in patients with NSCLC.

• PD-L1 expression in tumor cell was associated with a pattern of clinical activity

• Further evaluation of PD-L1 expression as a predictive biomarker for treatment in lung cancer.

DISCLOSURES

• Authors disclose clinical trial: all authors involved in the study declare no financial disclosures.

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REFERENCES


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