Ociperlimab plus tislelizumab demonstrated antitumor activity as first-line treatment for patients with metastatic NSCLC with PD-L1 positive tumors (TC ≥1%).

Antitumor activity was observed in patients with tumors with PD-L1 TC 1-49% and PD-L1 TC ≥50%, with a higher response rate in patients with high PD-L1 TC ≥50%.

The combination of ociperlimab plus tislelizumab had an acceptable safety profile, with most TEAEs being grade 1 or 2 in severity.

In the ongoing phase 1/β, open-label AdvanTIG-105 dose-escalation/expansion (NCT04047882) study, ociperlimab plus tislelizumab was well tolerated in patients with advanced, unselectable solid tumors.

**Table 1. Summary of antitumor activity**

<table>
<thead>
<tr>
<th>PD-L1 TC (%)</th>
<th>PD-L1 TC 1-14%</th>
<th>PD-L1 TC 15-49%</th>
<th>PD-L1 TC ≥50%</th>
<th>Total (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unconfirmed ORR, n (%)</td>
<td>14 (40.0)</td>
<td>10 (34.5)</td>
<td>14 (28.6)</td>
<td>38 (23.9)</td>
</tr>
<tr>
<td>Unconfirmed DCR, n (%)</td>
<td>1 (2.5)</td>
<td>1 (3.4)</td>
<td>1 (2.0)</td>
<td>3 (1.8)</td>
</tr>
<tr>
<td>CR</td>
<td>0 (0.0)</td>
<td>1 (3.4)</td>
<td>1 (2.0)</td>
<td>2 (1.2)</td>
</tr>
<tr>
<td>PR</td>
<td>11 (46.0)</td>
<td>1 (3.4)</td>
<td>3 (6.0)</td>
<td>20 (12.5)</td>
</tr>
<tr>
<td>SD</td>
<td>1 (4.0)</td>
<td>2 (6.9)</td>
<td>1 (2.0)</td>
<td>4 (2.5)</td>
</tr>
<tr>
<td>DCR, n (%)</td>
<td>22 (57.1)</td>
<td>13 (45.1)</td>
<td>35 (69.7)</td>
<td></td>
</tr>
</tbody>
</table>

**Table 2. Summary of TEAEs and TRAEs (safety analysis set)**

<table>
<thead>
<tr>
<th>TEAEs</th>
<th>TRAEs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients with at least one AE</td>
<td>36 (62.0)</td>
</tr>
<tr>
<td>Patients with at least one ≥3 AE</td>
<td>11 (17.5)</td>
</tr>
</tbody>
</table>

**Table 3. Duration of treatment and response**

<table>
<thead>
<tr>
<th>Time since treatment initiation (weeks)</th>
<th>PD-L1 TC 1-49%</th>
<th>PD-L1 TC ≥50%</th>
<th>Total (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤12</td>
<td>34 (60.7)</td>
<td>13 (33.3)</td>
<td>47 (44.8)</td>
</tr>
<tr>
<td>&gt;12</td>
<td>4 (6.9)</td>
<td>1 (2.6)</td>
<td>5 (4.8)</td>
</tr>
</tbody>
</table>

**Table 4. Best change in target lesions**

<table>
<thead>
<tr>
<th>Best change in target lesions</th>
<th>PD-L1 TC 1-49%</th>
<th>PD-L1 TC ≥50%</th>
<th>Total (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Partial response</td>
<td>2 (3.3)</td>
<td>1 (2.6)</td>
<td>3 (2.9)</td>
</tr>
<tr>
<td>Complete response</td>
<td>11 (21.9)</td>
<td>3 (7.1)</td>
<td>14 (13.3)</td>
</tr>
<tr>
<td>Stable disease</td>
<td>40 (67.3)</td>
<td>22 (57.1)</td>
<td>62 (59.3)</td>
</tr>
</tbody>
</table>

**Table 5. Efficacy**

- The median age was 65.0 years (range 46-81), and 32.5% of patients were female.
- In total, 35.9% (14/39) of patients were PD-L1 TC ≥50%.
- The median follow-up was 23.0 weeks (range 3.0-61.7).

**Efficacy**

- Two patients were evaluable for efficacy.
- The unconfirmed ORR was 53.8% (95% CI 37.2-69.9). In patients with PD-L1 TC 1-49% and PD-L1 TC 250% subgroups, the unconfirmed ORR was 44.0% and 74.0%, respectively (Table 1).
- The median DoR was not evaluable (NE) (Table 1), and the median PFS was 5.4 months (95% CI 4.2-NE), with 5.2 months and 5.6 months in the PD-L1 TC 1-49% and PD-L1 TC 250% subgroups, respectively.
- The best change in target lesions and the duration of treatment and response are shown in Figures 2 and 3, respectively.

**Safety**

- The safety profiles of ociperlimab and tislelizumab are shown in Table 2.

**Figure 1. AdvanTIG-105 study design (Cohort 3)**

- Primary endpoints: 
  - Investigator-assessed CR or PR per RECIST v1.0
  - Objective response rate (ORR) for PD-L1 ≥1%
  - Duration of response (DoR) for PD-L1 ≥1%
- Secondary endpoints: 
  - Objective response rate (ORR) for PD-L1 ≥50% 
  - OS
  - Duration of response for PD-L1 ≥50%
  - PFS
  - ORR for PD-L1 ≥1%

**Figure 2. Best change in target lesions**

- **Best change in target lesions**
  - PD-L1 TC 1-14%: 34 (60.7%)
  - PD-L1 TC 15-49%: 13 (33.3%)
  - PD-L1 TC ≥50%: 3 (2.9%)

**Figure 3. Duration of treatment and response**

- **Time since treatment initiation (weeks)**
  - PD-L1 TC 1-49%: 34 (60.7%)
  - PD-L1 TC ≥50%: 13 (33.3%)
  - Total: 37 (23.9%)

**References**


**Acknowledgments**

This study was supported by BeiGene, Ltd. Medical writing and editorial support was provided by Adeline Lum Nde, PhD, of Ashfield GenomiCare, an affiliate company, and was funded by BeiGene, Ltd. The authors declare no competing interests.

**Disclosures**

ORR: Clinical, Oncology, Eli Lilly, F. Hoffmann-La Roche, Janssen, Menarini, Novo Nordisk, Pfizer, PTC Therapeutics, Puma Biotechnology, Sanofi, and Takeda. 

**Figure 4. Summary of antitumor activity**

- As of April 5, 2022, 40 patients were enrolled in Cohort 3 and comprised the safety analysis set, who received at least one dose of the study drug.

**Figure 5. Safety**

- Included criteria: 
  - ≥18 years of age
  - ≥12 weeks from prior systemic therapy or ≥2 receiving systemic therapy before the start of the study
  - Eastern Cooperative Oncology Group (ECOG) performance status ≤1
  - Adequate laboratory parameters

- Exclusion criteria: 
  - Previous treatment for NSCLC
  - Histological confirmation of NSCLC
  - Performance status >1
  - Uncontrolled intercurrent illness

**Figure 6. Efficacy**

Inhibition of T-cell immunoreceptor with immunoglobulin and ITIM domains (TIGIT) in combination with PD-1/PD-L1 inhibition has demonstrated early efficacy in NSCLC.

**Figure 7. Safety**

- No prior treatment for NSCLC profile,
- sRAF inhibitor activity
- PI3Kδ inhibitor activity
- No prior treatment to metastatic disease (ECOG PS 0-1)

**Figure 8. Conclusion**