In this updated analysis of RATIONALE-304, tislelizumab plus platinum-based chemotherapy as first-line treatment for advanced non-squamous NSCLC continued to demonstrate a clinically meaningful PFS benefit, higher ORR, and longer DoR versus platinum-based chemotherapy alone, and was generally well tolerated, with no new safety signals identified.

**Figure 1. IRC-Assessed PFS (ITT Analysis Set)**

![Figure 1](image-url)

**Table 1. IRC-Assessed Efficacy Outcomes by PD-L1 Expression Subgroup**

<table>
<thead>
<tr>
<th>PD-L1 Expression</th>
<th>Arm A (n=223)</th>
<th>Arm B (n=111)</th>
<th>HR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PD-L1 &lt;1%</td>
<td>7.6 (5.4, 9.7)</td>
<td>7.6 (4.3, 7.9)</td>
<td>0.81 (0.52, 1.26)</td>
</tr>
<tr>
<td>PD-L1 1-4%</td>
<td>9.7 (6.9, 11.7)</td>
<td>9.5 (6.8, 16.8)</td>
<td>0.90 (0.49, 1.63)</td>
</tr>
<tr>
<td>PD-L1 ≥50%</td>
<td>14.6 (11.5, 18.6)</td>
<td>14.6 (3.6, 4.7)</td>
<td>0.29 (0.16, 0.50)</td>
</tr>
<tr>
<td><strong>OS</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Arm A: Tislelizumab plus platinum-based chemotherapy</td>
<td>133 (59.6)</td>
<td>9.8 (8.9, 11.7)</td>
<td></td>
</tr>
<tr>
<td>Arm B: Platinum-based chemotherapy alone</td>
<td>68 (61.3)</td>
<td>7.6 (5.6, 8.0)</td>
<td></td>
</tr>
</tbody>
</table>

**Table 2. OS Analyses (ITT Analysis Set)**

<table>
<thead>
<tr>
<th>Median OS (months)</th>
<th>Arm A</th>
<th>Arm B</th>
<th>HR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arm A: Tislelizumab plus platinum-based chemotherapy</td>
<td>73.0 (61.4, 82.6)</td>
<td>41.7 (25.5, 64.7)</td>
<td>-</td>
</tr>
<tr>
<td>Arm B: Platinum-based chemotherapy alone</td>
<td>62.3 (47.9, 75.2)</td>
<td>44.4 (25.5, 64.7)</td>
<td>-</td>
</tr>
</tbody>
</table>

**References**

1. Tislelizumab, a monoclonal antibody with high affinity and binding specificity for programmed cell death ligand 1 (PD-L1).
2. Tislelizumab plus platinum-based chemotherapy and platinum-based chemotherapy alone were well tolerated, with no new safety signals identified.

**Methodology**

- **Patients aged 18-75 years with treatment-naive, stage IIIB (not amenable to curative surgery/radiotherapy) or stage IV non-NSCLC were enrolled.**
- **Patients were randomized (2:1) to open-label**
  - Arm A: Tislelizumab 200 mg intravenously every 3 weeks plus platinum-based chemotherapy for 4-6 cycles, followed by maintenance tislelizumab plus pembrolizumab or
  - Arm B: Platinum-based chemotherapy alone for 4-6 cycles, followed by maintenance pembrolizumab.
- **Primary endpoint:** PFS, assessed by independent review committee in the intent-to-treat (ITT) analysis set.
- **Secondary endpoints included:** overall survival (OS), IRC-assessed objective response rate (ORR), and safety.
- **Scan the QR code for full methodology from the previously published interim analysis**

**Results**

- **At the FA cutoff date (October 26, 2020),**
  - Median follow-up was 16.1 months (range: 0.0-27.2); 6.3 additional months compared with the interim analysis.
  - More patients remained on assigned treatment in Arm A (24.2%) than Arm B (5.4%).

**Efficacy**

**PFS**

- The study met its primary objective of prolonging IRC-assessed PFS in the tislelizumab plus chemotherapy arm (Arm A) versus chemotherapy alone (Arm B) at the FA cutoff date (October 26, 2020).
- The PFS improvement in Arm A versus Arm B remained consistent at the FA cutoff date (October 26, 2020); PFS hazard ratio (HR) (0.63; 95% confidence interval [CI]: 0.47, 0.86) (Figure 1).
- PFS benefit was observed in all PD-L1 expression subgroups (Table 1).

**OS**

- OS benefit was observed in Arm A vs B (72.4% of [42/58] crossed over to tislelizumab) and by 10.6% (242/223) of patients in Arm A.
- Of the patients from Arm B who crossed over to tislelizumab: 26.0% (61.9%) crossed over within one cycle
- The reduction in HR in the two-stage supportive analysis suggests the OS benefit for tislelizumab in combination with chemotherapy may have been partially obscured by in-study crossover.

**Safety**

- The tislelizumab plus chemotherapy combination (Arm A) was tolerable; no new safety signals were identified at the FA compared with the interim analysis.

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