HCC is one of the most commonly diagnosed cancers globally, and the proportion of patients affected in the ≥65 years age group is increasing each year. Tislelizumab, a monoclonal antibody with high affinity and binding specificity for programmed cell death protein 1, was specifically engineered to minimize Fc-γ receptor binding on macrophages.3,4

The longer median OS observed with tislelizumab in patients aged ≥65 years vs the overall population could be attributed to regional imbalances and more favorable baseline characteristics observed in this subgroup.

Figure 1. Primary Endpoint: OS (ITT Analysis Set)

### Results

#### Patient Disposition and Baseline Characteristics

- **At data cutoff (July 11, 2022), median survival follow-up in the ≥65 years subgroup was 38.9 months in the tislelizumab arm vs 39.6 months in the sorafenib arm.**
- In total, 255 (37.8%) of the 674 randomized patients were in the ≥65 years subgroup (tislelizumab: n=134, sorafenib: n=121), with median age of 71.0 years (range: 65-86).
- **Baseline demographics and disease characteristics in patients aged ≥65 years are shown in Table 1.**

#### Table 1. Baseline Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Tislelizumab (n=134)</th>
<th>Sorafenib (n=121)</th>
<th>Overall Population (Total n=255)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender, n (%)</td>
<td>Male: 107 (80.3)</td>
<td>Female: 27 (19.7)</td>
<td>Male: 214 (84.0)</td>
</tr>
<tr>
<td>Age, years (median)</td>
<td>71.0 (IQR: 65-86)</td>
<td>71.0 (IQR: 65-86)</td>
<td>71.0 (IQR: 65-86)</td>
</tr>
</tbody>
</table>

#### Table 2. Efficacy Endpoints (ITT Analysis Set)

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Overall Population (Total n=255)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median OS, months (95% CI)</td>
<td>18.2 (11.6, 24.2) vs 14.2 (10.5, 19.2)</td>
</tr>
<tr>
<td>Median progression-free survival, months</td>
<td>16.9 (11.6, 22.3) vs 13.0 (9.1, 17.1)</td>
</tr>
</tbody>
</table>

#### Efficacy

**OS (≥65 Years Subgroup):**

- Patients in the ≥65 years subgroup had a numerically longer median OS (18.2 months [95% CI: 11.6, 24.2] vs 14.2 months [95% CI: 10.5, 19.2]) in the tislelizumab vs sorafenib arm, respectively (Figure 1).
- **Median OS in the tislelizumab arm was longer in the ≥65 years subgroup than in the overall population (18.2 months for ≥65 years vs 16.9 months for overall population).**

#### Conclusion

In the subgroup of patients aged ≥65 years in the RATIONALE-301 trial, tislelizumab demonstrated numerically longer median overall survival (OS) and a higher objective response rate (ORR) vs sorafenib. Tislelizumab showed a favorable safety profile vs sorafenib in the ≥65 years subgroup, consistent with the overall population.

### References


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