Introduction
Unmet need in ESCC

- Esophageal cancer is the eighth most common cancer globally, with approximately 444,000 deaths in 2020, and is the sixth most common cause of cancer-related deaths.
- The most common cause of cancer-related deaths in ESCC patients is due to advanced disease.

PD-L1 may be a predictive biomarker for clinical benefit6

Methods

Study design and treatment

- AdvanTIG-203 is a randomized, Phase 2, double-blind study (NCT04732494) being conducted in approximately 100 patients with advanced or recurrent esophageal squamous cell carcinoma expressing programmed death-ligand 1 (PD-L1) with ≥ 10% (visually-estimated Combined Positive Score [vCPS] ≥ 10%).

Secondary endpoints are listed in Table 1

Table 1. Secondary and exploratory endpoints

<table>
<thead>
<tr>
<th>Exploratory endpoints</th>
<th>Secondary endpoints</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Safety and survival</td>
<td>- OS and survival</td>
</tr>
<tr>
<td>- PD-L1 expression</td>
<td>- ORR and OS</td>
</tr>
<tr>
<td>- Immunological safety</td>
<td></td>
</tr>
<tr>
<td>- Tumor biomarkers</td>
<td></td>
</tr>
</tbody>
</table>

Conclusions

- AdvanTIG-203 is an ongoing Phase 2 study investigating whether ociperlimab + tislelizumab combination therapy improves ORR and OS vs tislelizumab + placebo in adults with unresectable, locally advanced, recurrent, or metastatic ESCC.

Endpoints and assessments

- Co-primary endpoints are:
  - Investigation-assessed ORR in the intent-to-treat (ITT) analysis set, according to RECIST v1.1
  - OS in the ITT analysis set
- Secondary endpoints are listed in Table 1

Patients will be evaluated for adverse events (AEs) and serious AEs (SAEs), and immunemediated AEs. Vital signs, physical examinations, ECOG PS change, electrocardiogram results, and other examinations will be used for safety assessments (Table 1).

References

Acknowledgements

This study is sponsored by BeiGene, Ltd. Medical writing support, under the direction of the authors, was provided by Jessica Jones, PhD, and Tamsin Grewal, MSc, of Global Scientific Affairs, Adelphi能文/Adelphi能文

Author contact details: ruih@sysucc.org.cn (Rui-Hua Xu)