Tislelizumab Versus Chemotherapy as Second-line Treatment for Advanced or Metastatic Esophageal Squamous Cell Carcinoma (ESCC, RATIONALE 302): Impact on Health-Related Quality of Life

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Background

- Esophageal squamous cell carcinoma (ESCC) is the most common histological subtype of esophageal cancer, accounting for more than 90% of all esophageal cancer worldwide.1
- In addition, tislelizumab (teplizumab) is a humanized anti-programmed death-ligand 1 (PD-L1) monoclonal antibody with strong affinity and high potency.

Methods

The study included 462 patients (aged 18 years or older) with histologically confirmed ESCC who had advanced or metastatic disease that had progressed during or after first-line treatment.

Eligible patients were randomized (1:1) to receive tislelizumab (200 mg) every 3 weeks or the following single-agent chemotherapy: docetaxel, paclitaxel, or irinotecan (64 mg/m2) defining treatment. Treatment discontinuation was triggered upon disease progression, intolerable toxicity, or withdrawal for other reasons.

Health-related quality of life (HRQoL) was a secondary endpoint assessed using the EuroQol 5 Dimensions Five-levels (EQ-5D 5L) Visual Analog Scale (VAS) and the EQ-5D. The EQ-5D-5L is a descriptive method that uses a direct valuation method to derive a health status equivalence.

HRQoL Assessments and Endpoints

The EQ-5D-5L measures were collected at baseline and at every cycle 4 through 6 in tislelizumab treatment (whichever occurs first). The EQ-5D-5L is a standardized measure of HRQoL that assesses five dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression). The EQ-5D-5L index score (total symptoms, dyspnea, and weight loss) and VAS were included in the analysis.

Higher scores in EQ-5D-5L, physical function, and EORTC-OES18 scores were associated with greater HRQoL.

Statistical Analyses

The EQ-5D-5L and EORTC-OES18 were analyzed using the data cut-off at December 1, 2020.

Completion rate was defined as the number of patients included in the trial from the total number of patients in the relevant treatment arm.

Completion rate = number of patients with completed questionnaire/total number of patients in relevant treatment arm

Table 2

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Figure 1

Change From Baseline for EQ-5D-5L at Cycle 4 and Cycle 6

Figure 2

Change From Baseline for EORTC-OES18 at Cycle 4 and Cycle 6

Conclusions

- Tislelizumab as a second-line treatment for patients with advanced or metastatic ESCC was associated with more favorable HRQoL outcomes than investigator-chosen chemotherapy.
- The general health and quality of life of tislelizumab-treated patients remained stable while ICC-tREATED patients experienced declines.
- Overall, fewer patients experienced grade ≥3 adverse events in the tislelizumab arm compared to patients receiving ICC.
- These HRQoL data, together with the efficacy and safety results from the RATIONALE 302 trial, support the favorable risk-benefit ratio for tislelizumab as a second-line treatment for patients with advanced or metastatic ESCC.