Tislelizumab (TIS) plus chemotherapy (chemo) showed clinically meaningful improvements in overall survival (OS) and progression-free survival (PFS), and durable antitumor response, compared with placebo (PBO) plus chemo in the first-line (1L) treatment of advanced or metastatic esophageal squamous cell carcinoma (ESCC) after a minimum of 2 years of follow-up in RATIONALE-306.

Conclusions

ESCC is the predominant histologic subtype of esophageal cancer, accounting for 85% of cases worldwide. A recent meta-analysis showed that the 1-year OS rate in patients treated with PBO plus chemo for 24 months was 39.9%, and 37.9% in those treated with TIS plus chemo. This study evaluated the efficacy and safety of Tislelizumab (TIS) plus chemotherapy (chemo) versus placebo (PBO) plus chemo in patients with advanced or metastatic ESCC.

Methods

The study design has been described previously. For full details of the study design and primary analysis results, please see the primary publication at the QR code.

Results

ESCC is predominantly a histologic subtype of esophageal cancer, accounting for 85% of cases worldwide. Platinum-based chemotherapy has been used for 1L treatment of advanced or metastatic ESCC, but median survival remains poor at <1 year. TIS is a monoclonal antibody with high affinity and binding specificity for programmed cell death ligand 1 (PD-L1) tumor area positivity (TAP) score response rate (ORR), duration of response (DoR), OS in the subgroup with programmed death-ligand 1 (PD-L1) tumor area positivity (TAP) score ≥10%.

Figure 1. Kaplan-Meier Curves of OS for (A) All Patients; (B) Patients With PD-L1 TAP Score ≥10%; and (C) <10% (ITT Analysis Set)

Figure 2. Forest Plot of OS by Subgroup (ITT Analysis Set)

Table 1. Efficacy Endpoints (ITT Analysis Set)

Safety

Median exposure was longer for TIS plus chemo (6 months; range: 0.1-4.8) than for PBO plus chemo (4 months; range: 0.2-6.8), with 97 (10.5%) and 121 (18.9%) patients treated with TIS plus chemo and PBO plus chemo for ≥24 months, respectively.

Table 2. Summary of TEAEs and TRAEs (Safety Analysis Set)

Acknowledgments

This study is sponsored by BeiGene, Ltd. Medical writing support under the direction of the author was provided by Ashfield MedComms, an Inizio company.

Disclosures

Richard Hubner reports speaker fees from Eisai, and an advisory role for BeiGene, Novartis, and Ipsen.

Abbreviations

AEC, atelectasis; AEs, adverse events; CI, confidence interval; CRF, case report form; CT, computed tomography; DoR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance score; ES, esophageal squamous cell carcinoma; ESCC, esophageal squamous cell carcinoma; EUS, endoscopic ultrasound; FAS, full analysis set; HR, hazard ratio; ICC, investigator-chosen chemotherapy; ITT, intent-to-treat; L, left; OS, overall survival; PD-L1, programmed death-ligand 1; PFS, progression-free survival; PBO, placebo; R, right; RCT, randomized controlled trial; RR, response rate; S, subtotal; TAP, tumor area positivity; TRAE, treatment-related adverse event; TIS, tislelizumab; U, upper; TEAE, treatment-emergent adverse event; V, vertical; W, width; Y, young; Z, zero.