RATIONALE-302: Tislelizumab vs Chemotherapy as Second-Line Treatment for Patients with Advanced or Metastatic Esophageal Squamous Cell Carcinoma (ESCC): Impact on Health-Related Quality of Life (HRQoL) in Asian Patients

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Background

Analysis of the intent-to-treat (ITT) population of RATIONALE-302 (NCT03430843) found overall HRQoL, fatigue, and physical functioning were maintained in patients (pts) receiving tislelizumab, while worsening in pts receiving investigator-chosen chemotherapy (ICC). Post-hoc analysis examines HRQoL and ESCC symptoms in the Asian and non-Asian subgroups of pts in RATIONALE-302.

Methods

Patients with advanced or metastatic ESCC that progressed following systemic therapy were randomized 1:1 to receive either tislelizumab or ICC (paclitaxel, docetaxel, or irinotecan). HRQoL was measured using the EORTC QLQ-C30 and the QLQ-OES18. Least-squares mean score change from baseline to weeks 12 and 18 in HRQoL scores was assessed using a mixed model for repeated measurements. Reported nominal p-values are for descriptive purpose only.

Results

Of the total of 512 pts, this analysis was conducted in the subgroup of 392 Asian pts (tislelizumab N=192; ICC N=200). Tislelizumab pts had stable GHS/QoL, while fatigue scores worsened in both arms, though more so in ICC pts. Change from baseline was similar in both arms for physical functioning at weeks 12 and 18. The eating score remained stable in tislelizumab pts, while it worsened in ICC pts, particularly at week 18. Reflux improved at week 12 in the tislelizumab pts and worsened in ICC pts. Of note, a similar pattern of results was found in the smaller non-Asian subgroup (tislelizumab N=49; ICC N=47).

Conclusions

The HRQoL and ESCC-related symptoms of the Asian subgroup of tislelizumab pts remained stable or improved while ICC pts experienced worsening. These HRQoL results in Asian pts corroborate the HRQoL findings in the total population, suggesting tislelizumab is a potential new second-line treatment option for pts with advanced or metastatic ESCC.

Least-Squares (LS) Mean Change from Baseline in Asian Subgroup

		Week 12 LS mean change Tislelizumab vs ICC	Week 18 LS mean change Tislelizumab vs ICC
QLQ-30			
	GHS/QoL	0.01 vs -5.9, p=0.032	-0.8 vs -9.8, p=0.0011
	Physical functioning	-3.7 vs -5.7, p=0.2941	-3.7 vs -6.5, p=0.1492
	Fatigue	4.0 vs 10.3, p=0.0149	1.8 vs 7.0, p=0.0815
OES18			
	Eating	0.1 vs 3.3, p=0.1444	0.8 vs 5.8, p=0.0818
	Reflux	-2.3 vs 3.3, p=0.0068	-2.3 vs -1.2, p=0.6978