

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 (HRQOL)

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ABSTRACT

Introduction: The global phase 3 study RATIONALE 302 (NCT03430843) compared tislelizumab (tisle) with investigator-chosen chemotherapy (ICC) as second-line (2L) treatment for advanced or metastatic ESCC. Tisle had a significant and clinically meaningful improvement in overall survival (HR=0.70 [95% CI 0.57–0.85], $P=.0001$), and a favorable safety profile compared with ICC. This study assessed the health-related quality of life (HRQoL) and ESCC-related symptoms of patients (pts) in RATIONALE 302.

Methods: Adults with advanced or metastatic ESCC whose disease progressed after systemic therapy were randomized 1:1 to tisle 200 mg intravenously every 3 weeks or ICC (paclitaxel, docetaxel, or irinotecan). HRQoL was measured using EORTC QLQ-C30 global health status/quality of life (GHS/QoL), physical functioning, and fatigue scores, and EORTC QLQ-OES18 dysphagia, reflux, eating, and pain scores from

screening to Cycle 6 or treatment discontinuation. Least-squares mean HRQoL score change from baseline to Cycles 4 and 6 was assessed using a mixed model for repeated measurements. Time to deterioration (TTD) for GHS/QoL score and QLQ-OES18 symptom scales was examined with the Kaplan-Meier method.

Results: Overall, 512 pts (median age 62 y) were randomized to tisle (n=256) or ICC (n=256). Compared with ICC, the tisle arm maintained GHS/QoL and fatigue scores and had less decline in physical functioning at Cycles 4 and 6. Except for pain, the tisle arm had less severe OES18 symptoms relative to baseline than the ICC arm. TTD showed that risk of experiencing a deterioration event was lower in tisle pts compared to ICC for physical functioning (HR=0.67, [95% CI: 0.45–1.00]) and reflux (HR=0.50, [95% CI: 0.32–0.80]).

Conclusions: Pts with ESCC treated with 2L tisle had longer maintenance of HRQoL compared with ICC. These results, along with improved survival and a favorable safety profile, suggest tisle represents a potential new 2L treatment option for advanced or metastatic ESCC.