

Impact of Tislelizumab on Health-Related Quality of Life in Asian Patients with Esophageal Squamous Cell Carcinoma

Ken Kato, MD¹, Eric Van Cutsem, MD², Jaffer Ajani, MD³, Lin Shen, MD⁴, Gisoo Barnes, PhD⁵, Ningning Ding, MD⁶, Aiyang Tao, PhD⁷, Tianyu Xia, MS⁸, Lin Zhan, MS⁵, and Sung-Bae Kim, MD⁹

¹National Cancer Center Hospital, Tokyo, Japan

²University Hospitals Gasthuisberg Leuven and KU Leuven, Leuven, Belgium

³University of Texas MD Anderson Cancer Center, Houston, Texas

⁴Department of Gastrointestinal Oncology, Key Laboratory of Carcinogenesis and Translational Research (Ministry of Education/Beijing), Peking University Cancer Hospital & Institute, Beijing, China

⁵BeiGene, Ltd., Emeryville, CA, USA

⁶BeiGene (Shanghai) Co., Ltd., Shanghai, China

⁷BeiGene, Ltd., Ridgefield Park, NJ, USA

⁸BeiGene, Ltd., Beijing, China

⁹ Department of Oncology, Asan Medical Center, University of Ulsan College of Medicine, Seoul, South Korea

Background

Analysis of the intent-to-treat (ITT) population of RATIONALE-302 (NCT03430843) found overall HRQoL, fatigue, and physical functioning were maintained in esophageal squamous cell carcinoma (ESCC) patients (pts) receiving tislelizumab (TIS) while worsening in pts receiving investigator-chosen chemotherapy (ICC). This post-hoc analysis examined HRQoL and ESCC symptoms in the Asian subgroup of pts in RATIONALE-302.

Methods

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

Results

Analysis was conducted using the 392 pts in the Asian subgroup (TIS, N=192; ICC, N=200). For the GHS/QoL index score, LS mean change from baseline to week 12 (6.2 [95% CI: 2.2 to 10.2], $P=0.0025$) and week 18 (9.4 [95% CI: 4.1 to 14.7], $P=0.0006$) was significantly different between the arms with the TIS pts experiencing maintenance and the ICC pts worsening. Both arms experienced worsening in fatigue but change was significantly less in the TIS arm vs ICC pts particularly at week 12 (-6.4 [95% CI: -11.5 to -1.4], $P=0.0118$). TIS patients experienced less worsening in eating than ICC pts particularly at week 18 (-5.7 [95% CI: -11.3 to 0.0], $P=0.0510$). Reflux improved at week 12 in the TIS pts and worsened in ICC pts and the difference between the arms was significant (-5.7 [95% CI: -9.7 to -1.6], $P=0.0063$).

Conclusions

The HRQoL and ESCC-related symptoms of the Asian subgroup of TIS 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.