A PHASE 3, RANDOMIZED, OPEN-LABEL STUDY TO COMPARE THE EFFICACY OF TISLELIZUMAB (BGB-A317) VERSUS CHEMOTHERAPY AS SECOND-LINE THERAPY FOR ADVANCED UNRESECTABLE/METASTATIC ESOPHAGEAL SQUAMOUS CELL CARCINOMA (ESCC)

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METHODS

Overall Design and Study Objectives

- This phase 3, randomized, controlled, open-label study (NCT03430843) was designed to evaluate the efficacy and safety of tislelizumab compared with investigator-chosen chemotherapy for second-line treatment of advanced unresectable/metastatic ESCC (Figure 2)
- The primary objective will be to compare overall survival (OS) for tislelizumab with that for chemotherapy
- Secondary objectives will include a comparison of tislelizumab versus chemotherapy for objective response rate (ORR), progression-free survival (PFS), and duration of response (DoR), along with health-related quality of life, and safety and tolerability
- Approximately 450 patients will be enrolled globally

TREATMENT

- Patients will be randomized 1:1 to receive either tislelizumab 200 mg IV Q3W (Day 1 of each 21-day cycle) or investigator-chosen chemotherapy:
  - Paclitaxel 135–175 mg/m² IV Q3W (Day 1 of each 21-day cycle) or 100 mg/m² IV weekly for 6 weeks with 1 week of rest (Japan only); or
  - Docetaxel 75 mg/m² IV Q3W or 70 mg/m² IV Q2W (Japan only) (Day 1 of each 21-day cycle); or
  - Irinotecan 125 mg/m² Q3W (Day 1, Day 8 of each 21-day cycle)
- Randomization will be stratified by region, ECOG performance status, and chemotherapy option
- Treatment will be administered until disease progression, intolerable toxicity, or treatment discontinuation for other reasons. Patients on the tislelizumab arm will be permitted to continue tislelizumab treatment beyond radiological progression if clinical benefit is observed per investigator’s discretion
- There will be no dose reduction of tislelizumab in this study; dose delays or interruption of less than 12 weeks will be permitted
- A maximum of two dose reductions will be permitted for each chemotherapeutic agent. Chemotherapy-related toxicities (with the exception of alopecia or grade 2 fatigue) must have resolved to baseline or grade 0–1 prior to administration of the next chemotherapy dose

REFERENCES


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