TISLELIZUMAB VERSUS PLACEBO IN COMBINATION WITH CONCURRENT CHEMORADIOTHERAPY IN PATIENTS WITH LOCALIZED ESOPHAGEAL SQUAMOUS CELL CARCINOMA: A PHASE 3 TRIAL IN PROGRESS

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BACKGROUND
Esophageal squamous cell carcinoma (ESCC) is a common cancer type in China that is associated with a poor prognosis. At initial diagnosis, half of the patients present with locally advanced disease and many are unfit for surgery.

New therapeutic models for the treatment of gastrointestinal tumors have focused on targeting T-cell dysfunction. Antibodies targeting PD-1 have demonstrated antitumor activity in patients with advanced ESCC and have been approved for the treatment of ESCC in China.

Antibodies targeting PD-1 have demonstrated activity in both preclinical models and in clinical trials. Tislelizumab is a humanized anti-PD-1 monoclonal antibody which has shown high affinity to PD-1 and it is being evaluated in ESCC patients in a phase 3, randomized, double-blind, placebo-controlled study (NCT03957590).

METHODS
This phase 3, randomized, double-blind, placebo-controlled study (NCT03957590) is being conducted in approximately 316 patients from 35 centers. The study design is compared to the efficacy of tislelizumab or placebo in combination with concurrent chemoradiation therapy (cCRT) (Figure 1).

Study Population
- Adult patients aged 18-75 years with histologically confirmed localized ESCC with an Eastern Cooperative Oncology Group (ECOG) performance status of 0-1.
- ESCC with T3-4 N0-2 M0 per AJCC 8th Edition staging (up to 24 months)*
- Patients who received prior chemoradiotherapy (for stage IV ESCC only) are excluded.

Study Assessments and Statistical Analysis
Patients will be randomly assigned in a 1:1 ratio to receive either tislelizumab 200 mg every 3 weeks, cCRT (2 cycles) or placebo plus cCRT (2 cycles).

Endpoints:
- PFS (primary endpoint).
- OS.
- RFS.
- TTF.
- All-grade and grade ≥3 adverse events.
- Laboratory test (e.g., liver function).
- Safety and tolerability profile of tislelizumab in combination with cCRT.

REFERENCE

1. Reference that is based on patient-level data (using ORCID). This reference includes a systematic review and meta-analysis.

1. Reference that is related to a phase 3 clinical trial. This reference is based on RCT data.

9. Reference that is related to a phase 1 clinical trial. This reference is based on RCT data.

10. Reference that is related to a phase 2 clinical trial. This reference is based on RCT data.

11. Reference that is related to a phase 1 clinical trial. This reference is based on RCT data.

12. Reference that is related to a phase 2 clinical trial. This reference is based on RCT data.

13. Reference that is related to a phase 1 clinical trial. This reference is based on RCT data.

14. Reference that is related to a phase 2 clinical trial. This reference is based on RCT data.