ForPatients
by Roche

Esophageal Cancer

A Study of Atezolizumab Plus Tiragolumab in Combination With Paclitaxel and Cisplatin Compared With Paclitaxel and Cisplatin as First-Line Treatment in Participants With Unresectable Locally Advanced, Unresectable Recurrent, or Metastatic Esophageal Carcinoma

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	5 Countries	NCT04540211 YO42138

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A Phase III, Randomized, Double-Blind, Placebo-Controlled Study of Atezolizumab Plus Tiragolumab in Combination With Paclitaxel and Cisplatin Compared With Paclitaxel and Cisplatin as First-Line Treatment in Patients With Unresectable Locally Advanced, Unresectable Recurrent, or Metastatic Esophageal Squamous Cell Carcinoma

Trial Summary:

The purpose of this study is to evaluate the efficacy and safety of atezolizumab plus tiragolumab in combination with paclitaxel and cisplatin (PC) compared with atezolizumab matching placebo plus tiragolumab matching placebo plus PC as first-line treatment in participants with unresectable locally advanced, unresectable recurrent, or metastatic esophageal carcinoma (EC). Participants will be randomized in a 1:1 ratio to receive one of the following treatment regimens during induction phase: Arm A: Atezolizumab plus Tiragolumab and PC Arm B: Atezolizumab placebo plus Tiragolumab placebo and PC Following the induction phase, participants will continue maintenance therapy with either atezolizumab plus tiragolumab (Arm A) or atezolizumab matching placebo plus tiragolumab matching placebo (Arm B).

Hoffmann-La Roche	Phase 3
Sponsor	Phase

NCT04540211 YO42138
Trial Identifiers

Eligibility Criteria:

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Gender	Age	Healthy Volunteers
All	**#18 Years**	**No**

Inclusion Criteria:

- Histologically confirmed EC
- Unresectable locally advanced, unresectable recurrent, or metastatic disease
- Measurable disease per Response Evaluation Criteria in Solid Tumors version 1.1 (RECIST v1.1)
- Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1
- Adequate hematologic and end-organ function
- Female participants must be willing to avoid pregnancy and refrain from donating eggs during the treatment period and for 90 days after the final dose
- Male participants with partners of childbearing potential must commit to the use of two methods of contraception and must not donate sperm for the study duration and 90 days after the final dose

Exclusion Criteria:

- Palliative radiation treatment for EC within 4 weeks prior to initiation of study treatment
- Evidence of complete esophageal obstruction not amenable to treatment
- Symptomatic, untreated, or actively progressing central nervous system (CNS) metastases
- Uncontrolled tumor-related pain, uncontrolled pleural effusion, pericardial effusion, or ascites requiring recurrent drainage procedures
- Active or history of autoimmune disease or immune deficiency or leptomeningeal disease
- History of idiopathic pulmonary fibrosis, organizing pneumonia, drug-induced pneumonitis, or idiopathic pneumonitis, or evidence of active pneumonitis
- Malignancies other than EC within 2 years prior to screening with a negligible risk of metastasis or death adequately treated with expected curative outcome
- Severe infection within 4 weeks prior to initiation of study treatment or any active infection that, in the opinion of the investigator, could impact patient safety
- Positive test result for human immunodeficiency virus (HIV)
- Active hepatitis B or hepatitis C
- Prior treatment with CD137 agonists or immune checkpoint blockade therapies, anti-CTLA-4, anti-TIGIT, anti-PD-1, and anti-PD-L1 therapeutic antibodies
- Treatment with any investigational therapy prior to initiation of study treatment
- Poor peripheral venous access
- Prior allogeneic stem cell or solid organ transplantation
- Concurrent participation in another therapeutic clinical trial