ForPatients
*by Roche*

Small Cell Lung CancerSmall Cell Lung Carcinoma

# Study of Atezolizumab Plus Carboplatin and Etoposide With or Without Tiragolumab in Participants With Untreated Extensive-Stage Small Cell Lung Cancer (SKYSCRAPER-02C)

| Trial Status | Trial Runs In | Trial Identifier |
|---|---|---|
| Active, not recruiting | 1 Country | NCT04665856 YO42373 |

*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 Carboplatin and Etoposide With or Without Tiragolumab in Patients With Untreated Extensive-Stage Small Cell Lung Cancer

## *Trial Summary:*

The purpose of this multicenter study in China is to evaluate the safety and efficacy of tiragolumab plus atezolizumab and carboplatin and etoposide (CE) compared with placebo plus atezolizumab and CE in participants with untreated extensive-stage small cell lung cancer.

**Hoffmann-La Roche**
Sponsor

**Phase 3**
Phase

**NCT04665856 YO42373**
Trial Identifiers

## *Eligibility Criteria:*

| Gender | Age | Healthy Volunteers |
|---|---|---|
| All | #18 Years | No |

## *Inclusion Criteria:*

- Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1
- Histologically or cytologically confirmed Extensive-Stage Small Cell Lung Cancer (ES-SCLC) per the modified Veterans Administration Lung Study Group (VALG) staging system
- No prior systemic treatment for ES-SCLC

- For participants who have received prior chemoradiotherapy for limited-stage SCLC must have had treatment with curative intent and a treatment-free interval of at least 6 months between the last dose/ cycle of chemotherapy, thoracic radiotherapy, or chemoradiotherapy and the diagnosis of ES-SCLC
- Measurable diseases as defined by RECIST v1.1
- Submission of a pre-treatment tumor tissue sample
- Adequate hematologic and end-organ function
- Participants not receiving therapeutic anticoagulation with International Normalized Ratio (INR) and Activated Clotting Time (aPTT) </= 1.5 x ULN
- Participants receiving therapeutic anticoagulation: stable anticoagulant regimen
- Negative Human Immunodeficiency Virus (HIV) test at screening
- Negative hepatitis B surface antigen (HBsAg) test at screening
- Positive hepatitis B surface antibody (HBsAb) test at screening, or negative HBsAb at screening accompanied by either of the following: negative total hepatitis B core antibody (HBcAb) and/or positive total HBcAb test followed by a negative hepatitis B virus (HBV) DNA test
- Negative hepatitis C virus (HCV) antibody test at screening, or positive HCV antibody test followed by a negative HCV RNA test
- Negative Epstein-Barr virus (EBV) viral capsid antigen (VCA) IgM test or negative EBV polymerase chain reaction (PCR) test at screening
- For women of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraception, and agreement to refrain from donating eggs
- For men: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive methods, and agreement to refrain from donating sperm.

## *Exclusion Criteria:*

- Symptomatic or actively progressing central nervous system (CNS) metastases
- Spinal cord compression
- Leptomeningeal disease
- Uncontrolled pleural effusion, pericardial effusion, or ascites
- Uncontrolled or symptomatic hypercalcemia
- Known clinically significant liver disease, including active viral, alcoholic, or other hepatitis, cirrhosis, and inherited liver disease, or current alcohol abuse
- Malignancies other than SCLC within 5 years prior to randomization
- Active or history of autoimmune disease or immune deficiencies
- History of idiopathic pulmonary fibrosis, organizing pneumonia, drug-induced pneumonitis, or idiopathic pneumonitis, or evidence of active pneumonitis on screening chest Computer Tomography (CT) scan
- Known active tuberculosis, Current treatment with anti-viral therapy for HBV or HCV
- Severe chronic or active infection
- Treatment with therapeutic oral or IV antibiotics
- Significant cardiovascular disease
- Major surgical procedure other than for diagnosis
- Prior allogeneic bone marrow transplantation or solid organ transplant
- Any other diseases, metabolic dysfunction, physical examination finding, or clinical laboratory finding giving reasonable suspicion of a disease or condition
- Administration of a live, attenuated vaccine
- Prior treatment with CD137 agonists, T-cell co-stimulating, or immune checkpoint blockade therapies
- Treatment with systemic immunostimulatory agents
- Treatment with systemic immunosuppressive medications
- History of severe allergic anaphylactic reactions to chimeric or humanized antibodies or fusion proteins
- Known hypersensitivity to Chinese Hamster Ovary (CHO) cell products or to any component of the tiragolumab or atezolizumab formulations
- History of allergic reactions to carboplatin or etoposide

- Pregnancy or breastfeeding, or intention of becoming pregnant during study treatment or within 5 months after the final dose of atezolizumab or within 90 days after the final dose of tiragolumab or for 6 months after the final dose of carboplatin or etoposide.