ForPatients
by Roche

Small Cell Lung CancerSmall Cell Lung Carcinoma

A Study of Atezolizumab in Combination With Carboplatin Plus Etoposide to Investigate Safety and Efficacy in Patients With Untreated Extensive-Stage Small Cell Lung Cancer

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	NCT04028050 ML41118

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 IIIB, Single Arm, Multicenter Study of Atezolizumab (Tecentriq) in Combination With Carboplatin Plus Etoposide to Investigate Safety and Efficacy in Patients With Untreated Extensive-Stage Small Cell Lung Cancer - MAURIS

Trial Summary:

This is a phase IIIB, single-arm, single-country, multicenter study of the safety and efficacy of atezolizumab in combination with carboplatin plus etoposide in patients who have ES-SCLC and are chemotherapy-naive for their extensive-stage disease.

Hoffmann-La Roche	Phase 3
Sponsor	Phase

NCT04028050 ML41118
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Histologically or cytologically confirmed ES-SCLC per the Veterans Administration Lung Study Group (VALG) staging system
- Measurable disease, as defined by RECIST v1.1. Previously irradiated lesions can only be considered as measurable disease if disease progression has been unequivocally documented at that site since radiation and the previously irradiated lesion is not the only site of disease

- Eastern Cooperative Oncology Group (ECOG) performance status (PS) from 0 to 2
- Life expectancy > 12 weeks
- No prior systemic treatment for ES-SCLC
- Patients who have received prior chemoradiotherapy for limited-stage SCLC must have been treated with curative intent and experienced a treatment-free interval of at least 6 months since last chemotherapy, radiotherapy, or chemoradiotherapy cycle from diagnosis of ES-SCLC
- Patients where thoracic radiotherapy (consolidation RT) is clinically indicated could be enrolled providing they receive RT between the completion of induction phase and the beginning of maintenance phase
- Patients with Paraneoplastic syndromes can be enrolled if an autoimmune origin can be excluded
- Adequate hematologic and end organ function
- Negative human immunodeficiency virus (HIV) test at screening
- Negative hepatitis B surface antigen (HBsAg) test at screening
- Negative total hepatitis B core antibody (HBcAb) test at screening, or positive total HBcAb test followed by a negative hepatitis B virus (HBV) DNA test at screening
- Negative hepatitis C virus (HCV) antibody test at screening, or positive HCV antibody test followed by a negative HCV RNA test at screening. The HCV RNA test will be performed only for patients who have a positive HCV antibody test.
- For women of childbearing potential: agreement to remain abstinent or use of contraception
- For men: agreement to remain abstinent or use a condom, and agreement to refrain from donating sperm

Exclusion Criteria:

- Symptomatic or actively progressing central nervous system (CNS) metastases. Asymptomatic patients with treated or untreated CNS lesions are eligible, provided that all of the following criteria are met: (1) Measurable disease, per RECIST v1.1, must be present outside the CNS. (2) Patient has no history of intracranial hemorrhage or spinal cord hemorrhage. (3) Patient has not undergone stereotactic radiotherapy within 7 days prior to initiation of study treatment, whole-brain radiotherapy within 14 days prior to initiation of study treatment, or neurosurgical resection within 28 days prior to initiation of study treatment. (4) Patient has no ongoing requirement for corticosteroids as therapy for CNS disease. Anticonvulsant therapy at a stable dose is permitted. Metastases are limited to the cerebellum or the supratentorial region. (5) There is no evidence of interim progression between completion of CNS directed therapy and initiation of study treatment. (6) Asymptomatic patients with CNS metastases newly detected at screening are allowed at Investigator's discretion with no need to repeat the screening brain scan.
- History of leptomeningeal disease
- Uncontrolled tumor-related pain
- Uncontrolled pleural effusion, pericardial effusion, or ascites requiring recurrent drainage procedures. Patients with indwelling catheters are allowed regardless of drainage frequency.
- Uncontrolled or symptomatic hypercalcemia
- History of idiopathic pulmonary fibrosis, organizing pneumonia, drug-induced pneumonitis, idiopathic pneumonitis, or evidence of active pneumonitis on screening chest computerized tomography (CT) scan. History of radiation pneumonitis in the radiation field (fibrosis) is permitted.
- Active tuberculosis
- Significant cardiovascular disease within 3 months prior to initiation of study treatment, unstable arrhythmia, or unstable angina
- Major surgical procedure other than for diagnosis within 4 weeks prior to initiation of study treatment, or anticipation of need for a major surgical procedure during the study
- History of malignancy other than SCLC within 5 years prior to screening, with the exception of malignancies with a negligible risk of metastasis or death, such as adequately treated carcinoma in

situ of the cervix, non-melanoma skin carcinoma, localized prostate cancer, ductal carcinoma in situ, or Stage I uterine cancer
- Prior allogeneic stem cell or solid organ transplantation treatment, or anticipation of need for such a vaccine during atezolizumab treatment or within 5 months after the final dose of atezolizumab
- Current treatment with anti-viral therapy for HBV
- Treatment with investigational therapy within 28 days prior to initiation of study treatment
- Pregnancy or breastfeeding, or intention of becoming pregnant during study treatment or within 5 months after the final dose of study treatment