ForPatients
by Roche

Small Cell Lung CancerSmall Cell Lung Carcinoma

Study of Low-Dose Radiotherapy (LDRT) Concurrent Cisplatin/ Carboplatin Plus Etoposide With Atezolizumab for Patients With Extensive-Stage Small Cell Lung Cancer

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	NCT04622228 ML42391

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:

Phase II, Single-Arm Study of Low-Dose Radiotherapy (LDRT) Concurrent Cisplatin/Carboplatin Plus Etoposide With Atezolizumab for Patients With Extensive-Stage Small Cell Lung Cancer

Trial Summary:

This is a Phase II, single arm, multicenter study designed to evaluate the safety and efficacy of low-dose radiotherapy (LDRT) concurrent cisplatin/carboplatin plus etoposide with atezolizumab in participants who have extensive-stage small cell lung cancer (ES-SCLC) and are chemotherapy-navïe for their extensive-stage disease.

Hoffmann-La Roche
Sponsor

Phase 2
Phase

NCT04622228 ML42391
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Histologically or cytologically confirmed ES-SCLC
- No prior treatment for ES-SCLC

- Measurable disease, as defined by RECIST v1.1. Previously irradiated lesions can be considered as measurable disease only if progressive disease has been unequivocally documented at that site since radiation.
- ECOG performance status of 0 or 1
- Life expectancy >= 3 months
- Adequate hematologic and end-organ function
- For 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), or positive total HBcAb test followed by a negative hepatitis B virus (HBV) DNA test. The HBV DNA test must be performed for participants who have a negative HBsAg test, a negative HBsAb test, and a positive total HBcAb test.
- 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 must be performed for participants who have a positive HCV antibody test.
- For women of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraception
- For men: agreement to remain abstinent (refrain from heterosexual intercourse) or use a condom, and agreement to refrain from donating sperm

Exclusion Criteria:

- Symptomatic, untreated, or actively progressing central nervous system (CNS) metastases
- History of leptomeningeal disease
- Uncontrolled tumor-related pain
- Uncontrolled pleural effusion, pericardial effusion, or ascites requiring recurrent drainage procedures
- Uncontrolled or symptomatic hypercalcemia
- Active or history of autoimmune disease or immune deficiency
- History of idiopathic pulmonary fibrosis, organizing pneumonia, drug-induced pneumonitis, or idiopathic pneumonitis, or evidence of active pneumonitis on screening chest computed tomography (CT) scan
- Active tuberculosis
- Significant cardiovascular disease within 3 months prior to initiation of study treatment, unstable arrhythmia, or unstable angina
- History of malignancy other than small cell lung cancer (SCLC) within 5 years prior to initiation of study treatment, with the exception of the cancer under investigation in this study and malignancies with a negligible risk of metastasis or death