ForPatients
by Roche

Solid Tumors

A Study of Adjuvant Atezolizumab or Atezolizumab Plus Tiragolumab in Solid Tumors with Resectable Disease with Intermediate-High Risk of Recurrence and High Tumor Mutational Burden (TMB-H) or Microsatellite Instability (MSI-H)

Trial Status	Trial Runs In	Trial Identifier
Withdrawn	1 Country	NCT06331598 2022-003708-33 ML43332

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 II, Open Label, Randomized, Non-Comparative Cohorts Study of Adjuvant Atezolizumab or Atezolizumab Plus Tiragolumab in Solid Tumors with Resectable Disease with Intermediate-High Risk of Recurrence and High Tumor Mutational Burden (TMB-H) or Microsatellite Instability (MSI-H)

Trial Summary:

This study is being conducted to evaluate efficacy parameters (disease free survival [DFS] and overall survival [OS]) of atezolizumab and atezolizumab in combination with tiragolumab in TMB-H or MSI-H as adjuvant treatment after standard radical intended treatment in participants with intermediate-high risk of recurrence.

Hoffmann-La Roche
Sponsor

Phase 2
Phase

NCT06331598 2022-003708-33 ML43332
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1

- Any of the following solid tumors considered to be resectable with a curative intent: non-small cell lung cancer, skin melanoma, skin squamous cell carcinoma, urothelial carcinoma, colorectal cancer, gastric cancer, endometrial cancer, cervix cancer, head and neck cancer and any other tumor type with known high TMB (# 13 mut/MB) or MSI-H
- Participants must undergo standard treatment according to the stage of their disease and investigator´s choice
- All participants must be disease free after standard therapy to be included in this study
- Having TMB # 13 mut/MB or MSI-H in tumor tissue biopsy obtained prior to starting standard treatment or from surgical specimens and analyzed using F1 CDx
- Participants must be at intermediate/high risk of recurrence
- Adequate hematologic and organ function
- Female participants of childbearing potential and male participants with female partners of childbearing potential must be willing to avoid pregnancy
- Women who are not postmenopausal or surgically sterile must have a negative serum pregnancy test result within 8 days prior to initiation of study drug.

Exclusion Criteria:

- Previous malignancies within 3 years prior to enrollment, with the exception of those with a negligible risk of metastasis or death treated with expected curative outcome
- Prior cancer immunotherapy
- Women who are pregnant, lactating, or intending to become pregnant during the study
- History of autoimmune disease
- History of idiopathic pulmonary fibrosis, organizing pneumonia, drug-induced pneumonitis, idiopathic pneumonitis, or evidence of active pneumonitis on screening chest computed tomography (CT) scan
- Significant cardiovascular disease
- Treatment with systemic immunosuppressive medications within 2 weeks prior to inclusion
- Treatment with systemic immunostimulatory agents within 4 weeks or 5 drug-elimination half-lives of the drug, whichever is longer, prior to randomization.