ForPatients
by Roche

Non-Small Cell Lung Cancer (NSCLC)

A Study of the Efficacy and Safety of RO7198457 in Combination With Atezolizumab Versus Atezolizumab Alone Following Adjuvant Platinum-Doublet Chemotherapy in Participants Who Are ctDNA Positive After Surgical Resection of Stage II-III Non-Small Cell Lung Cancer

Trial Status	Trial Runs In	Trial Identifier
Withdrawn		NCT04267237 2019-003449-14 GO41836

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, Multicenter, Randomized Study of the Efficacy and Safety of RO7198457 in Combination With Atezolizumab Versus Atezolizumab Alone Following Adjuvant Platinum-doublet Chemotherapy in Patients Who Are ctDNA Positive After Surgical Resection of Stage II-III Non-small Cell Lung Cancer

Trial Summary:

This study will evaluate the efficacy, safety, pharmacokinetics, immunogenicity and biomarkers of RO7198457 plus atezolizumab compared with atezolizumab alone in patients with Stage II-III non-small cell lung cancer (NSCLC) who are circulating tumor DNA (ctDNA) positive following surgical resection and have received standard-of-care adjuvant platinum-doublet chemotherapy.

Hoffmann-La Roche Sponsor	**Phase 2** Phase

NCT04267237 2019-003449-14 GO41836
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

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Inclusion Criteria:

- Age >= 18 years;
- Resected Stage II-III Non-small Cell Lung Cancer (NSCLC) per American Joint Committee on Cancer staging criteria, 8th revised edition;
- Complete R0 resection of Stage II or III NSCLC prior to enrollment and adequate recovery from surgery;
- Pathological evaluation of mediastinal lymph nodes preoperatively or intraoperatively;
- ctDNA (circulating tumor DNA) identified in plasma after resection of Stage II-III NSCLC and prior to start of adjuvant platinum-doublet therapy, as determined by central testing;
- Treatment with at least two cycles of adjuvant platinum-doublet chemotherapy regimens for resected NSCLC;
- No unequivocal evidence of disease after surgery and adjuvant platinum-doublet chemotherapy, as assessed on imaging (computed tomography [CT] scan or magnetic resonance imaging [MRI]) within 28 days prior to randomization;
- Availability of adequate tumor material;
- Eastern Cooperative Oncology Group (ECOG) Performance Status 0 or 1;
- Adequate hematologic and end-organ function;
- Negative HIV test at screening;
- Negative hepatitis B test at screening;
- Negative hepatitis C test at screening.

Exclusion Criteria:

- Participants with a known mutation in exons 18-21 of epidermal growth factor receptor (EGFR) or with a known anaplastic lymphoma kinase (ALK) or reactive oxygen species (ROS) alteration;
- History of malignancy other than disease under study within 5 years prior to enrollment, 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 cancer, localized prostate cancer, ductal carcinoma in situ, or Stage I uterine cancer;
- Induction and neoadjuvant systemic therapy prior to resection of NSCLC;
- Radiotherapy prior to or after resection of NSCLC;
- Prior systemic investigational therapy;
- Prior anti-CTLA-4, anti-PD-1, and anti-PD-L1 therapeutic antibodies, or a cancer vaccine;
- Treatment with systemic immunostimulatory agents within 6 weeks or 5 drug elimination half-lives, prior to initiation of study treatment;
- Treatment with systemic immunosuppressive medication within 2 weeks prior to initiation of study treatment or anticipation of need for systemic immunosuppressive medication during study treatment;
- Treatment with monoamine oxidase inhibitors (MAOIs) within 3 weeks prior to initiation of study treatment or requirement for ongoing treatment with MAOIs;
- Active or history of autoimmune disease or immune deficiency;
- Known primary immunodeficiencies, either cellular or combined T-cell and B-cell immunodeficiencies;
- History of idiopathic pulmonary fibrosis, organizing pneumonia, drug-induced pneumonitis, or idiopathic pneumonitis, or evidence of active pneumonitis on screening chest CT scan;
- Significant cardiovascular disease;
- Major surgical procedure, other than for diagnosis or for resection of disease under current study, within 4 weeks prior to initiation of study treatment, or anticipation of need for a major surgical procedure during the study;
- Known active or latent tuberculosis infection;
- Recent acute infection;

- Treatment with a live, attenuated vaccine within 4 weeks prior to initiation of study treatment, or anticipation of need for such a vaccine during study treatment or within 5 months after the final dose of study treatment;
- Prior allogeneic stem cell or solid organ transplantation;
- Any other disease, metabolic dysfunction, physical examination finding, or clinical laboratory finding that contraindicates the use of an investigational drug, may affect the interpretation of the results, or may render the participants at high risk from treatment complications;
- Known clinically significant liver disease;
- Previous splenectomy;
- History of severe allergic anaphylactic reactions to chimeric or humanized antibodies or fusion proteins;
- Known hypersensitivity to Chinese hamster ovary cell products or any component of the atezolizumab formulation;
- Known allergy or hypersensitivity to any component of RO7198457;
- Pregnant or lactating women.