A PHASE III/IV, SINGLE ARM, MULTICENTER STUDY OF ATEZOLIZUMAB (TECENTRIQ) TO INVESTIGATE LONG-TERM SAFETY AND EFFICACY IN PREVIOUSLY-TREATED PATIENTS WITH LOCALLY ADVANCED OR METASTATIC NON-SMALL CELL LUNG CANCER (TAIL)

05/11/2025 05:42:44

Main Information

Primary registry identifying number
LBCTR2020033438

Protocol number
MO39171

MOH registration number

Study registered at the country of origin
Yes

Study registered at the country of origin: Specify

Type of registration
Retrospective

Type of registration: Justify
Study started before establishment of LBCTR

Date of registration in national regulatory agency
21/10/2017

Primary sponsor
F. HOFFMANN-LA ROCHE LTD

Primary sponsor: Country of origin
Switzerland

Date of registration in primary registry
18/10/2022

Date of registration in national regulatory agency
21/10/2017

Public title
A PHASE III/IV, SINGLE ARM, MULTICENTER STUDY OF ATEZOLIZUMAB (TECENTRIQ) TO INVESTIGATE LONG-TERM SAFETY AND EFFICACY IN PREVIOUSLY-TREATED PATIENTS WITH LOCALLY ADVANCED OR METASTATIC NON-SMALL CELL LUNG CANCER (TAIL)

Acronym
TAIL

Scientific title
A PHASE III/IV, SINGLE ARM, MULTICENTER STUDY OF ATEZOLIZUMAB (TECENTRIQ) TO INVESTIGATE LONG-TERM SAFETY AND EFFICACY IN PREVIOUSLY-TREATED PATIENTS WITH LOCALLY ADVANCED OR METASTATIC NON-SMALL CELL LUNG CANCER (TAIL)

Acronym
TAIL

Brief summary of the study: English

This study will evaluate the long-term safety and efficacy of atezolizumab in patients with locally advanced or metastatic NSCLC who have progressed following standard systemic chemotherapy (including if given in combination with anti-PD-1 therapy, after anti-PD-1 as monotherapy, or after tyrosine kinase inhibitor [TKI] therapy). Patients with a previously detected sensitizing EGFR mutation or ALK fusion oncogene must have received targeted therapy (TKI) followed by at least one line of standard systemic chemotherapy prior to receiving atezolizumab. Overall, patients should not have received more than two lines of standard systemic chemotherapy. Patients will also be eligible if they discontinued first-line or second-line therapy due to intolerance.

Brief summary of the study: Arabic

ان الهدف من هذه الدراسة هو اختبار سلامة دواء اتيزوليزوماب على المدى الطويل، واكتشاف تأثيرات اتيزوليزوماب، الايجابية او السلبية، علي المرضى وعلى سرطانهم.
وهذا الممرّ يساهم في ضبط الاستجابة المناعية .PD-L1 ان اتيزوليزوماب هو جسم مضاد (بروتين ينتجه جهاز المناعة في الجسم) يسدّ ممرّ PD-L1، الطبيعية لجسم المريض، غير ان الاورام يمكن ان تستفيد من هذا الضبط لتقاوم جزئياً او لتفلت من جهاز المناعة. من خلال سدّ ممرّ يمكن لدواء اتيزوليزوماب ان يساعد جهاز المناعة لدى المريض كي يوقف او يعكس نمو الاورام.
في الولايات المتحدة الاميركية لعلاج المرضى المصابين بسرطان الرئة ذي (FDA) ان دواء اتيزوليزوماب مُعتمَد من قبل ادارة الغذاء والدواء والذين عانوا من تفاقم للمرض خلال او بعد علاج كيميائي بلاتيني (لا بدّ ان يكون المرضى الذين لديهم (NSCLC) الخلايا غير الصغيرة قد اختبروا تفاقماً للمرض في ظل علاج ALK او (EGFR) انحرافات جينومية في الورم على مستوى مورّثة معدّل الترشيح الكلوي التقديري قبل ان يتلقوا اتيزوليزوماب FDA لهذه الانحرافات معتمد من قبل).

Health conditions/problem studied: Specify

Locally advanced or metastatic Non-Small Cell Lung Cancer (NSCLC) who have progressed following standard systemic chemotherapy (including if given in combination with anti-PD-1 therapy, after anti-PD-1 as monotherapy, or after tyrosine kinase inhibitor [TKI] therapy).

Interventions: Specify

The investigational medicinal product (IMP) for this study is Atezolizumab (Tecentriq).

Key inclusion and exclusion criteria: Inclusion criteria

Patients must meet the following criteria for study entry:
1.Signed Informed Consent Form
2.Age ≥ 18 years
3.Able to comply with the study protocol, in the investigator's judgment
4.Histologically or cytologically documented Stage IIIb or Stage IV NSCLC that has progressed following standard systemic chemotherapy (including if given in combination with anti-PD-1 therapy, after anti-PD-1 as monotherapy, or after TKI therapy). Patients with a previously detected sensitizing EGFR mutation or ALK fusion oncogene must have received targeted therapy (TKI), followed by at least one line of standard systemic chemotherapy, prior to receiving atezolizumab. Overall, patients should not have received more than two lines of standard systemic chemotherapy. Patients who have discontinued first-line or second-line therapy due to intolerance are also eligible
–Staging must be according to the UICC/AJCC system, 7th edition (Detterbeck et al. 2009) (see Appendix 8)
–Pathological characterization may be conducted on tumor specimens from earlier stage disease, but the tumor samples must be sufficient to distinguish squamous or non-squamous histology
–Chemotherapy regimens will be counted based on interval disease progression, and not on the number of agents or the number of switches in agents (e.g., a first-line or second-line therapy that consists of several cycles of a platinum doublet and subsequent maintenance therapy that introduces or switches to a new chemotherapy agent without interval disease progression will all be considered one chemotherapy regimen)
–Patients with a previously-detected sensitizing EGFR mutation must have experienced disease progression (during or after treatment) on an EGFR TKI (erlotinib, gefitinib, osimertinib, etc.)
–Patients with a previously detected ALK fusion oncogene must have experienced disease progression (during or after treatment) with crizotinib, alectinib, or another ALK inhibitor
–Prior radiation therapy is allowed, provided that the patient has recovered from any toxic effects thereof. Combined radiation/chemotherapy treatment constitutes a single regimen
–Combined radiation/chemotherapy treatment (chemoradiation) counts as one prior chemotherapy regimen if < 6 months have elapsed between the last dose and the date of recurrence
–Adjuvant/neoadjuvant chemotherapy is not counted as a line of treatment
–Debulking surgery and anticancer agents used for pleurodesis are not counted as lines of therapy

5.The last dose of prior systemic anticancer therapy must have been administered ≥ 21 days prior to study treatment initiation
6.The last dose of prior anti-PD-1 therapy must have been administered
–Nivolumab must have been discontinued ≥ 14 days and pembrolizumab ≥ 21 days prior to study treatment initiation, providing that these treatments were not administered in a clinical trial setting

7.Measurable disease, as defined by Response Evaluation Criteria for Solid Tumors, Version 1.1 (RECIST v1.1)
8.Patients with asymptomatic CNS metastases (treated or untreated), as determined by CT or MRI evaluation during screening and prior radiographic evaluation, are eligible
9.ECOG performance status 0, 1, or 2 [Appendix 7]
10.Life expectancy ≥ 12 weeks
11.Adequate hematologic and end-organ function, defined by the following laboratory results obtained within 2 weeks prior to the first study treatment:
–Absolute neutrophil count ≥ 1500 cells/µL (without granulocyte colony-stimulating factor support within 2 weeks prior to the first study

treatment)
–White blood cell count > 2500/µL
–Lymphocyte count ≥ 500/µL
–Platelet count ≥ 100,000/µL (without transfusion within 2 weeks prior to the first study treatment)
–Hemoglobin ≥ 9.0 g/dL (patients may be transfused or receive erythropoietic treatment to meet this criterion)
–Aspartate transaminase (AST), alanine transaminase (ALT), and alkaline phosphatase ≤ 2.5 times the upper limit of normal (ULN), with the following exceptions:
Patients with documented liver metastases: AST and/or ALT ≤ 5 × ULN
Patients with documented liver or bone metastases: alkaline phosphatase ≤ 5 × ULN

–Serum bilirubin ≤ 1.5 ×ULN. Patients with known Gilbert's Syndrome who have serum bilirubin level ≤ 3 × ULN may be enrolled.
–Calculated creatinine clearance ≥ 15 mL/min (Cockcroft-Gault formula)
–International normalized ratio (INR) and activated partial thromboplastin time (aPTT) ≤ 1.5 ×ULN. This applies only to patients who are not receiving therapeutic anticoagulation agents
–Patients receiving therapeutic anticoagulation agents must be on a stable dose
–HIV-positive patients are allowed, so long as they are on stable anti-retroviral therapy, have a CD4 count ≥ 200 cells/µL, and have an undetectable viral load at the time of screening

12.For women of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive methods that result in a failure rate of < 1% per year during the treatment period and for at least 5 months after the last dose of atezolizumab
–A woman is considered to be of childbearing potential if she is postmenarchal, has not reached a postmenopausal state (≥ 12 continuous months of amenorrhea with no identified cause other than menopause), and has not undergone surgical sterilization (removal of ovaries and/or uterus)
–Examples of contraceptive methods with a failure rate of □ 1% per year include bilateral tubal ligation, male sterilization, established, proper use of hormonal contraceptives that inhibit ovulation, hormone-releasing intrauterine devices, and copper intrauterine devices
–The reliability of sexual abstinence should be evaluated in relation to the duration of the clinical trial and the preferred and usual lifestyle of the patient. Periodic abstinence (e.g., calendar, ovulation, symptothermal, or postovulation methods) and withdrawal are not acceptable methods of contraception

13.Patients must have recovered (i.e., improvement to Grade 1 or better) from all acute toxicities from previous therapy, excluding alopecia and toxicities related to prior anti-PD-1-therapy

Key inclusion and exclusion criteria: Gender

Both

Key inclusion and exclusion criteria: Specify gender

Key inclusion and exclusion criteria: Age minimum

18

Key inclusion and exclusion criteria: Age maximum

100

Key inclusion and exclusion criteria: Exclusion criteria

Patients who meet any of the following criteria will be excluded from study entry:
1.Symptomatic CNS metastases
2.Spinal cord compression not definitively treated with surgery and/or radiation or previously diagnosed and treated spinal cord compression without evidence that disease has been clinically stable for ≥ 2 weeks prior to study treatment initiation
3.Leptomeningeal disease
4.Uncontrolled pericardial effusion or ascites requiring recurrent drainage procedures
5.Pregnant or lactating, or intending to become pregnant during the study
–Women who are not postmenopausal (postmenopausal defined as ≥ 12 months of non-drug-induced amenorrhea) or surgically sterile must have a negative serum pregnancy test result within 2 weeks prior to initiation of study drug

6.Evidence of significant uncontrolled concomitant disease that could affect compliance with the protocol, including significant liver disease (such as cirrhosis, uncontrolled major seizure disorder, or superior vena cava syndrome)
7.Significant cardiovascular disease, such as New York Heart Association cardiac disease ≥ Class III, myocardial infarction within 3 months, unstable arrhythmias, or unstable angina
–Patients with known coronary artery disease or left ventricular ejection fraction < 50% must be on a stable medical regimen that is optimized in the opinion of the treating physician, in consultation with a cardiologist if appropriate

8.Significant renal disorder requiring dialysis or indication for renal transplant
9.Treatment with any other investigational agent or participation in another clinical trial with therapeutic intent within 28 days prior to study treatment initiation
10.Major surgical procedure within 4 weeks prior to study treatment initiation or anticipation of need for a major surgical procedure during the course of the study other than for diagnosis
11.Inability to understand the local language(s) for which the EORTC QLQ-LC13 and EuroQol EQ-5D-5L questionnaires are available (see Appendix 4 for English versions)
12.History of severe allergic, anaphylactic, or other hypersensitivity reactions to chimeric or humanized antibodies or fusion proteins
13.Known hypersensitivity or allergy to biopharmaceuticals produced in Chinese hamster ovary cells or any component of the atezolizumab formulation
14.History of autoimmune disease (Appendix 5) are allowed if controlled and on stable treatment (i.e., same treatment, same dose) for the last 12 weeks, with the exception of:
–Patients taking concurrent abatacept or belatacept treatment, unless therapy has been withdrawn for > 8 weeks
–Patients with a history of serious or life threatening immune-related events
–No more than 1 concomitant autoimmune disease at the time of study entry is allowed unless one of them is:
Autoimmune-mediated hypothyroidism on a stable dose of thyroid replacement hormone

Controlled Type I diabetes mellitus on a stable dose of insulin regimen
A medical history of such entities as atopic disease or childhood arthralgias, where the clinical suspicion of autoimmune disease is low. In addition, transient autoimmune manifestations of an acute infectious disease that resolved upon treatment of the infectious agent are not excluded (e.g., acute Lyme arthritis)

15.Prior allogeneic stem cell or solid organ transplantation
16.History of idiopathic pulmonary fibrosis, including pneumonitis, drug-induced pneumonitis, organizing pneumonia (i.e., bronchiolitis obliterans, cryptogenic organizing pneumonia), or evidence of active pneumonitis on screening chest computed tomography (CT) scan
–History of radiation pneumonitis in the radiation field (fibrosis) is permitted

17.Active tuberculosis
–In patients who have a potentially high likelihood of latent tuberculosis (e.g., recent contact with an infectious carrier, residence in a locale with high TB burden), absence of Mycobacterium tuberculosis infection must be confirmed before enrollment according to local practice standards

18.Administration of a live, attenuated vaccine within 4 weeks prior to study treatment initiation
–Influenza vaccination should be given during influenza season only (e.g., approximately October to March in the Northern Hemisphere).
–Patients must not receive live, attenuated influenza vaccine (e.g., FluMist®) within 4 weeks prior to study treatment initiation or at any time during the study

19.Prior treatment with CD137 agonists or immune checkpoint blockade therapies other than anti-PD-1 therapy, including anti−PD-L1 therapeutic antibodies
20.Treatment with systemic immunostimulatory agents (including, but not limited to, interferons or interleukin-2) within 4 weeks or five half-lives of the drug, whichever is longer, prior to initiation of study treatment
–Prior cancer vaccines and cellular immunotherapy are permitted

21.Specifically for patients without autoimmune disease: treatment with systemic corticosteroids or other systemic immunosuppressive medications (including but not limited to prednisone, dexamethasone, cyclophosphamide, azathioprine, methotrexate, thalidomide, and anti−tumor necrosis factor [TNF] agents) within 2 weeks prior to study treatment initiation, or anticipated requirement for systemic immunosuppressive medications during the trial
–For patients with CNS metastases, use of prednisone at a stable dose (or dose equivalent) of ≤ 20 mg/day is acceptable
–The use of inhaled corticosteroids for chronic obstructive pulmonary disease, mineralocorticoids (e.g., fludrocortisone) for patients with orthostatic hypotension, and low-dose supplemental corticosteroids for adrenocortical insufficiency and topical steroids for cutaneous diseases are allowed

Type of study

Interventional

Type of intervention

Pharmaceutical

Type of intervention: Specify type

N/A

Trial scope

Other

Trial scope: Specify scope

Study design: Allocation

N/A: Single arm study

Study design: Masking

Open (masking not used)

Study design: Control

Uncontrolled

Study phase

3

Study design: Purpose

Treatment

Study design: Specify purpose

N/A

Study design: Assignment

Single

Study design: Specify assignment

N/A

IMP has market authorization

Yes, Lebanon and Worldwide

IMP has market authorization: Specify

Lebanon and 102 countries worldwide.

Name of IMP

Atezolizumab

Year of authorization

Month of authorization

Type of IMP

Immunological

Pharmaceutical class

TECENTRIQ (atezolizumab) is a humanized immunoglobulin (IgG1) monoclonal antibody that is produced in Chinese hamster ovary (CHO) cells.

Therapeutic indication

Locally advanced or metastatic Non-Small Cell Lung Cancer (NSCLC)

Therapeutic benefit

The results from studies evaluating atezolizumab as monotherapy in patients with locally advanced or metastatic NSCLC single-agent treatment with atezolizumab resulted in clinically meaningful overall survival (OS)improvement in the 2L/3L NSCLC intent to treat (ITT) population, in comparison with standard of care, in both non-squamous and squamous histologies, and across all PD-L1 expression subgroups.

Atezolizumab in combination with chemotherapy and other therapeutic agents was demonstrated to have benefit in the settings of small cell lung cancer and NSCLC. Clinical benefit was observed in patients with renal cell carcinoma (RCC) with the combination of atezolizumab and bevacizumab. Additionally, a clinically meaningful improvement in IRC-assessed progression-free survival (PFS) was observed with atezolizumab and bevacizumab compared with sunitinib in the IC1/2/3 population, and no difference in treatment effect was observed with atezolizumab monotherapy compared with sunitinib in either the IC1/2/3 or ITT populations.

Study model

N/A

Study model: Explain model

N/A

Study model: Specify model

N/A

Time perspective

N/A

Time perspective: Explain time perspective

N/A

Time perspective: Specify perspective

N/A

Target follow-up duration

Target follow-up duration: Unit

Number of groups/cohorts

Biospecimen retention

None retained

Biospecimen description

NA

Target sample size

10

Actual enrollment target size

10

Date of first enrollment: Type

Actual

Date of first enrollment: Date

13/04/2018

Date of study closure: Type

Actual

Date of study closure: Date

03/12/2021

Recruitment status

Complete

Recruitment status: Specify

Date of completion

04/12/2018

IPD sharing statement plan

Yes

IPD sharing statement description

During this study, health and personal information about subjects will be collected. This section describes the protection, use, and sharing of information, which consists of the following:
• Information in the medical record, which is held by Sites.
• Information that is collected or produced during this study ("study data"), which is held by sites, Roche, Roche affiliates, and Roche's representatives.
Subject privacy is very important, and Roche uses many safeguards to protect privacy, in accordance with applicable data privacy laws and laws related to the conduct of clinical trials.
Subject study data and samples will be labelled with a patient identification (ID) number that is unique and not related to or derived from information that identifies subject (such as name, picture, or any other personally identifying information). Roche, Roche affiliates, and Roche's representatives will only have access to study data and samples labelled with a patient ID number, except as described below. Subjects medical record, which includes personal information that can identify subjects, will not be accessed for the purposes of this study, except as described below:
Information (which includes information in medical record that can identify subjects) may need to be reviewed to make sure the study is being done properly or to check the quality of the information. This information will be kept private. The following people and groups of people may and/or copy this information:
• Study monitors of Roche and/or CRO, a company hired by Roche to perform certain study activities
• The Institutional Review Board or Ethics Committee
• Regulatory authorities

Roche, Roche affiliates, and Roche's collaborators and licensees (people and companies who partner with Roche) may use study data labelled with patient ID number for research purposes or to advance science and public health.
Study data may be submitted to government or other health research databases or shared with researchers, government agencies, companies, or other groups that are not participating in this study. These data may be combined with or linked to other data and used for research purposes, to advance science and public health, or for analysis, development, and commercialization of products to treat and diagnose disease. These data will not include information that identifies subjects, and extra steps will be taken to safeguard privacy.
Subject information will not be given to insurance company or employer, unless required by law. If the results from this study are published in a medical journal or presented at a scientific meeting, subjects will not be identified.
Information from this study will be retained by Sites for 15 years after the end of the study. In addition, Roche will retain the study data for up to 25 years after the end of the study.

Additional data URL

Admin comments

Trial status

Approved

Secondary Identifying Numbers

Full name of issuing authority	Secondary identifying number
NA	NA

Sources of Monetary or Material Support

Name
F. HOFFMANN-LA ROCHE LTD

Secondary Sponsors

Name
NA

Contact for Public/Scientific Queries

Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	Fadi ElKarak	Bellevue Medical Center, Mansourieh, El Metn, Beirut	Lebanon	+961 1 682666	felkarak@yahoo.com	Bellevue Medical Center
Scientific	Joseph Kattan	Hotel Dieu De France Hospital,ALFRED NACCACHE STREET, Beirut	Lebanon	++961 1 424942	jkattan62@hotmail.com	Hotel Dieu De France Hospital

Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
Hotel Dieu De France Hospital	Dr. Joseph Kattan	Oncology	Approved
Bellevue Medical Center	Dr. Fadi El Karak	Oncology	Approved

Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Hotel Dieu de France	31/10/2017	Georges Halaby	cue@usj.edu.lb	+9611421229
Bellevue Medical Center	25/10/2017	Ghassan Maalouf	cru@bmc.com.lb	+9611682666

Countries of Recruitment

Name
Argentina
Brazil
China
Colombia
Costa Rica
Denmark
Greece
Guatemala
Italy
Latvia
Lebanon
Malaysia
Mexico
Morocco
Netherlands
Panama
Peru

Health Conditions or Problems Studied

Condition	Code	Keyword
Non Small Cell Lung Cancer	Other disorders of lung (J98.4)	NSCLC

Interventions

Intervention	Description	Keyword
Atezolizumab	TECENTRIQ (atezolizumab) is a humanized immunoglobulin (IgG1) monoclonal antibody that is produced in Chinese hamster ovary (CHO) cells.	Tecentriq

Primary Outcomes

Name	Time Points	Measure
•To evaluate the long-term safety of atezolizumab in previously treated patients with advanced NSCLC	•Incidence of serious adverse events (SAEs) related to atezolizumab treatment	•Incidence of immune-related adverse events (irAEs) related to atezolizumab treatment

Key Secondary Outcomes

Name	Time Points	Measure
•To evaluate the efficacy of atezolizumab in previously treated patients with advanced NSCLC	•Overall survival (OS) rate at 2 years	defined as the proportion of patients remaining alive 2 years after initiation of study treatment
•To further evaluate the efficacy of atezolizumab in previously treated patients with advanced NSCLC	Overall Survival	defined as the time from initiation of study treatment to death from any cause
•To further evaluate the efficacy of atezolizumab in previously treated patients with advanced NSCLC	•Progression-free survival (PFS)	defined as the time from initiation of study treatment to the first occurrence of disease progression or death from any cause, whichever occurs first. PFS will be calculated based on disease status evaluated by the investigator according to Response Evaluation Criteria in Solid Tumors, Version 1.1 (RECIST v1.1) and also by disease status evaluated by the investigator according to modified RECIST
•To further evaluate the efficacy of atezolizumab in previously treated patients with advanced NSCLC	•OS rate at 3 years	defined as the proportion of patients remaining alive 3 years after initiation of study treatment
•To further evaluate the efficacy of atezolizumab in previously treated patients with advanced NSCLC	•Objective response rate (ORR)	defined as the percentage of patients who attain complete response (CR) or partial response (PR) according to RECIST v1.1 and also by disease status evaluated by the investigator according to modified RECIST
•To further evaluate the efficacy of atezolizumab in previously treated patients with advanced NSCLC	•Duration of response (DOR),	defined as the time from initial response to disease progression or death among patients who have experienced a CR or PR (unconfirmed) during the study. Duration of response will be calculated based on disease status evaluated by the investigator according to RECIST v1.1 and also by disease status evaluated by the investigator according to modified RECIST
•To further evaluate the long-term safety and efficacy of atezolizumab in previously treated patients with advanced NSCLC	•Safety and efficacy of atezolizumab in subgroups of the study population differentiated according to:	Presence of CNS metastases at baseline (yes vs. no) ECOG performance status (0 or 1 vs. 2) Histologic subtype (squamous vs. non-squamous) History of or current autoimmune disease (yes vs. no) Prior anticancer treatment
•To further evaluate the long-term safety and efficacy of atezolizumab in previously treated patients with advanced NSCLC	•Progression-free survival from start of new anti-cancer therapy	defined as the time from initiation of new anti-cancer therapy to objective tumor progression on next-line treatment or death from any cause
•To further evaluate the long-term safety and efficacy of atezolizumab in previously treated patients with advanced NSCLC	•Objective response rate from start of new anti-cancer therapy	defined as the percentage of patients who attain complete response (CR) or partial response (PR)
•To further evaluate the long-term safety and efficacy of atezolizumab in previously treated patients with advanced NSCLC	•Progression-free survival 2 (PFS2),	defined as the time from initiation of study treatment to objective tumor progression on next-line treatment or death from any cause

Trial Results

Summary results

Study results globally

Date of posting of results summaries

Date of first journal publication of results

Results URL link

Baseline characteristics

Participant flow

Adverse events

Outcome measures

URL to protocol files