IMReal

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Main Information

Primary registry identifying number
LBCTR2020033423

Protocol number
MO40653

MOH registration number

Study registered at the country of origin
Yes

Study registered at the country of origin: Specify

Type of registration
Prospective

Type of registration: Justify
N/A

Date of registration in national regulatory agency
07/01/2020

Primary sponsor
F. HOFFMANN-LA ROCHE LTD

Primary sponsor: Country of origin
Germany

Date of registration in primary registry
06/02/2024

Date of registration in national regulatory agency
07/01/2020

Public title
IMReal

Acronym
IMReal

Scientific title
A NON-INTERVENTIONAL, MULTICENTER, MULTIPLE COHORT STUDY INVESTIGATING THE OUTCOMES AND SAFETY OF ATEZOLIZUMAB UNDER REAL-WORLD CONDITIONS IN PATIENTS TREATED IN ROUTINE CLINICAL PRACTICE

Acronym
IMReal

Brief summary of the study: English

In the real world, the clinical benefit, and safety of atezolizumab have not yet been established. This study will contribute to the understanding of the short and long-term outcomes and safety of atezolizumab in patients with locally advanced/metastatic UC, locally advanced/metastatic NSCLC and ES-SCLC in the real-world setting.
The study aims to address the following research questions in patients treated with atezolizumab for the first time for the approved indications, in the real-world setting of routine clinical practice:
•What are the clinical outcomes of atezolizumab?
•What is the quality of life of patients treated with atezolizumab?
•What is the safety profile of atezolizumab?
•What is the sociodemographic and clinical profile of patients treated with atezolizumab?
•What are the characteristics of atezolizumab treatment (e.g. treatment duration,
•discontinuation, interruption, number of cycles)?
•What are the characteristics of prior and subsequent cancer-related therapies?
•What is the healthcare resource utilisation and associated cost of atezolizumab treatment?
•What are non-healthcare consequences and associated costs of atezolizumab?

Brief summary of the study: Arabic

ان الهدف من هذه الدراسة الرصدية معرفة كيف يعمل العلاج باتيزوليزوماب في "الحياة الحقيقية"، في سياق الممارسة الطبية الروتينية.
كذلك، بواسطة هذه الدراسة، يمكن الاستحصال على معلومات اضافية تتعلق بالمأمونية، اي معلومات حول مدى تحمّل المريض للدواء عندما يوصف له في اطار الممارسة الطبية اليومية.
هناك العديد من العوامل التي لا يمكن دراستها الا في الممارسة اليومية، على وجه الخصوص اذا كان عدد المرضى المشاركين كبيراً؛ على سبيل المثال، يمكن اكتشاف آثار جانبية غير معروفة كثيراً للدواء، كما يمكن ملاحظة تأثير تغيير الجرعات او الادوية المصاحبة، الخ. من شأن هذه المعلومات ان تساعد الاطباء ليعرفوا بصورة افضل كيفية استخدام اتيزوليزوماب، كما من شأنها ان تحسّن الى الحدّ الاقصى علاج المرضى المشاركين.

Health conditions/problem studied: Specify

Patients diagnosed with locally advanced/metastatic non-small cell lung cancer (NSCLC) after prior chemotherapy. Patients with epidermal growth factor receptor (EGFR) activating mutations or anaplastic lymphoma kinase (ALK)- positive tumor mutations should also have received targeted therapy

Interventions: Specify

Non-interventional study.

Key inclusion and exclusion criteria: Inclusion criteria

Patients must meet the following criteria for study entry:
1.Patient must have one of the following confirmed diagnoses for which atezolizumab is locally approved in the SmPC:
oAs monotherapy for the treatment of adult patients with locally advanced/metastatic UC after prior platinum-containing chemotherapy (Cohort 1 LOT2+ mUC).
oAs monotherapy for the treatment of adult patients with locally advanced/metastatic NSCLC after prior chemotherapy. Patients with EGFR activating mutations or ALK- positive tumour mutations should also have received targeted therapy (i.e. ALK /EGFR-TKIs) before receiving atezolizumab (Cohort 2 LOT2+ NSCLC).
oIn combination with bevacizumab, paclitaxel and carboplatin for the first line treatment of adult patients with metastatic non-squamous NSCLC. Patients with EGFR activating mutations or ALK- positive tumour mutations should also have received targeted therapy (i.e. ALK /EGFR-TKIs). (Cohort 3 LOT1 NSCLC).
oIn combination with carboplatin and etoposide, is indicated for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC) (Cohort 4 LOT1 ES-SCLC)
2.Patient is prescribed atezolizumab therapy for the first time
3.Decision to prescribe atezolizumab must be made and documented prior to inclusion into the study and must follow local clinical practice.
4.Patient is aged ≥ 18 years or older at the index date.
5.Patient has signed an informed consent form according to local regulations.
6.Data collection can only start after the signing of inform consent and not more than 28 days after initiation of atezolizumab. In countries where enrollment is only allowed after the treatment start, enrollment must be preceded by the administration of the first cycle of atezolizumab.

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.Patients not receiving treatment for a disease with atezolizumab according to standard of care and in line with the current summary of product characteristics (SPC) or local labelling *.
2.Concomitant anti-cancer therapy at the time of starting atezolizumab on the index date, not part of locally approved combination therapy with atezolizumab.
3.Treatment with atezolizumab as part of a clinical trial or for compassionate use as part of an access or compassionate use program.
4.Patients not receiving atezolizumab, but a biosimilar or non-original biologic.

Type of study

Observational

Type of intervention

N/A

Type of intervention: Specify type

N/A

Trial scope

N/A

Trial scope: Specify scope

N/A

Study design: Allocation

N/A

Study design: Masking

N/A

Study design: Control

Study phase

N/A

N/A

Study design: Purpose

N/A

Study design: Specify purpose

N/A

Study design: Assignment

N/A

Study design: Specify assignment

N/A

IMP has market authorization

IMP has market authorization: Specify

Name of IMP

Year of authorization

Month of authorization

Type of IMP

Pharmaceutical class

Therapeutic indication

Therapeutic benefit

Study model

Cohort

Study model: Explain model

The study will be split into separate cohorts based on the approved indications for atezolizumab treatment, excluding cisplatin ineligible patients receiving atezolizumab as first line of therapy (LOT1) for locally advanced/metastatic urothelial cancer (locally advanced/metastatic UC). The study may be amended for inclusion of new cohorts as these are approved in the participating countries. Patients will be included into each cohort based on their indication for receiving atezolizumab.

Lebanon is participating in Cohort 2 (NSCLC LOT2 plus later lines [LOT2+]): Patients diagnosed with locally advanced/metastatic non-small cell lung cancer (NSCLC) after prior chemotherapy. Patients with epidermal growth factor receptor (EGFR) activating mutations or anaplastic lymphoma kinase (ALK)- positive tumor mutations should also have received targeted therapy.

Study model: Specify model

N/A

Time perspective

Prospective

Time perspective: Explain time perspective

This is a non-interventional, multi-country, multi-centre, multiple cohort prospective study, with retrospective collection of prior medical/treatment history data from medical records, designed to assess the real-world outcomes and safety of atezolizumab for indications in the existing label in the real-world setting of routine clinical practice. The study will collect data before, during and after treatment with atezolizumab.

Time perspective: Specify perspective

N/A

Target follow-up duration

5

Target follow-up duration: Unit

years

Number of groups/cohorts

4

Biospecimen retention

None retained

Biospecimen description

Non retained

Target sample size
10

Actual enrollment target size

Date of first enrollment: Type
Anticipated

Date of first enrollment: Date
01/04/2020

Date of study closure: Type
Anticipated

Date of study closure: Date
01/06/2025

Recruitment status
Recruiting

Recruitment status: Specify

Date of completion
01/06/2025

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 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	Dani Abi Gerges	Middle East Institute of Health - University Hospita, Bsalim, Metn P.O. Box 60-387 Metn, Lebanon	Lebanon	009614712111	abgerges@idm.net.lb	Middle East Institute of Health - University Hospital
Scientific	Dani Abi Gerges	Middle East Institute of Health - University Hospita, Bsalim, Metn P.O. Box 60-387 Metn, Lebanon	Lebanon	009614712111	abgerges@idm.net.lb	Middle East Institute of Health - University Hospital
Public	Fadi Nasr	Mount Lebanon Hospital, Camille Chamoun Boulevard, Hazmieh	Lebanon	009613126606	nasrfadi@hotmail.com	Mount Lebanon Hospital
Scientific	Fadi Nasr	Mount Lebanon Hospital, Camille Chamoun Boulevard, Hazmieh	Lebanon	009613126606	nasrfadi@hotmail.com	Mount Lebanon Hospital
Public	Joseph Makdessi	Saint George Hospital	Lebanon	NA	josejoce@yahoo.fr	Saint George Hospital
Scientific	Joseph Makdessi	Saint George Hospital	Lebanon	NA	josejoce@yahoo.fr	Saint George Hospital

Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
Middle East Institute of Health Hospital	Dr. Dani Abigerges	Hemato-Oncology	Approved
Mount Lebanon Hospital	Dr. Fadi Nasr	Hemato-Oncology	Approved
Saint George Hospital	Dr. Joseph Makdessi	Hemato-Oncology	Approved

Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Middle East Institute of Health	07/01/2020	Dr. Rania Haddad	r_haddad@meih.org	009614712111 ext. 6063
Mount Lebanon Hospital	27/03/2020	Dr. Elie Gharios	mlh@mlh.com.lb	009615957000
Saint George Hospital University Medical Center	28/06/2021	Dr. Michel Daher	NA	009611566781

Countries of Recruitment

Name
Hungary
Argentina
France
Spain
Bulgaria
Austria
Belgium
United Kingdom
Netherlands
Lithuania
Italy
Croatia
Portugal
Poland
Slovenia
Lebanon

Health Conditions or Problems Studied

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

Interventions

Intervention	Description	Keyword
Non-interventional study	NA	NA

Primary Outcomes

Name	Time Points	Measure
•To estimate overall survival (OS) at two years and at the end of the study.	Overall Survival - OS	Time from index date until date of death from any cause
•To estimate overall survival (OS) at two years and at the end of the study.	OS at 2 years	Proportion of patients alive 2 years after the index date

Key Secondary Outcomes

Name	Time Points	Measure
To evaluate the clinical benefit of atezolizumab	Time to loss of clinical benefit	Time from the index date to loss of clinical benefit as assessed by the treating physician (single or multiple reasons possible: e.g. disease progression, deterioration in ECOG performance status, patient preference, death, etc.). Clinical benefit is defined as: • Absence of symptoms and signs indicating unequivocal progression of disease • No decline in ECOG performance status • Absence of tumour progression at critical anatomical sites that cannot be readily managed and stabilized by protocol-allowed medical interventions prior to repeat dosing • Evidence of clinical benefit as assessed by the physician according to local clinical standard of care
To estimate PFS	Progression-free survival - PFS	Time from index date to death or disease progression (DP; physician assessed according to local clinical standard of care or as per RECIST if available)
To estimate the ORR, DCR and DoR	Objective response rate - ORR	ORR is the proportion of patients who have a BOR of CR or PR. Best overall response (BOR) for each patient is the best response (physician assessed according to local clinical standard of care or as per RECIST if available) achieved after the index date prior to initiation of any subsequent treatment.
To estimate the ORR, DCR and DoR	Time to response	Time from index date to first objective tumour response, CR or PR (physician assessed according to local clinical standard of care or as per RECIST if available)
To estimate the ORR, DCR and DoR	Duration of response - DoR	Time from first documentation of CR or PR (whichever occurs first) after index until death or PD (physician assessed according to local clinical standard of care or as per RECIST if available)
To estimate the ORR, DCR and DoR	Disease control rate - DCR	Percentage of patients who have achieved CR, PR and stable disease (physician assessed according to local clinical standard of care or as per RECIST if available) at least 12 weeks after the index date
To estimate the ORR, DCR and DoR	Duration of DCR	Time from first documentation of CR, PR or stable disease (whichever occurs first) after index until death or PD.
To evaluate HRQoL	The EQ-5D-5L during and after atezolizumab treatment will be used to assess HRQoL	The EQ-5D-5L is a standardized instrument for measuring generic health status and has been used in the atezolizumab clinical trials. It includes two components, health state description and evaluation.
To describe baseline patient characteristics relevant to treatment and/or prognosis	Refer to protocol page 44 for table of patient characteristics	To describe baseline patient characteristics relevant to treatment and/or prognosis
To describe the characteristics of atezolizumab treatment, prior and subsequent cancer related therapies and estimate time to initiation of subsequent LOTs	Refer to protocol page 45,46,47 for Characteristics of atezolizumab treatment, and prior/subsequent cancer-related therapies	The time from diagnosis to the index date and time from last LOT to the index date will also be calculated.

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