Study of Efficacy and Safety of Pembrolizumab Plus Platinum-based Doublet Chemotherapy With or Without Canakinumab in Previously Untreated Locally Advanced or Metastatic Non-squamous and Squamous NSCLC Subjects (CANOPY 1)

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Main Information

Primary registry identifying number
LBCTR2019070214

Protocol number
CACZ885U2301

MOH registration number
11626/2019

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

Primary sponsor
Novartis Pharma Services Inc.

Primary sponsor: Country of origin
Novartis Pharmaceuticals

Date of registration in primary registry
29/05/2021

Date of registration in national regulatory agency

Public title
Study of Efficacy and Safety of Pembrolizumab Plus Platinum-based Doublet Chemotherapy With or Without Canakinumab in Previously Untreated Locally Advanced or Metastatic Non-squamous and Squamous NSCLC Subjects (CANOPY 1)

Acronym
CANOPY 1

Scientific title
A Randomized, Double-blind, Placebo-controlled, Phase III Study Evaluating the Efficacy and Safety of Pembrolizumab Plus Platinum -based Doublet Chemotherapy With or Without Canakinumab as First Line Therapy for Locally Advanced or Metastatic Non-squamous and Squamous Non-small Cell Lung Cancer Subjects (CANOPY-1)

Acronym

Brief summary of the study: English
This is a phase III study of pembrolizumab plus platinum-based doublet chemotherapy with or without canakinumab in previously untreated locally advanced or metastatic non-squamous and squamous NSCLC subjects.

The study will assess primarily the safety and tolerability (safety run -in part) of pembrolizumab plus platinum-based doublet chemotherapy with canakinumab and then the efficacy (double-blind, randomized, placebo controlled part) of pembrolizumab plus platinum-based doublet chemotherapy with or without canakinumab.

Brief summary of the study: Arabic

دراسة مرحلة ثالثة عشوائيّة التوزيع مزدوجة التعمية مرتكزة على المقارنة بدواء وهميّ لتقييم فعاليّة وسلامة دواء بمبروليزوماب بالإضافة إلى العلاج الكيميائي المزدوج القائم على البلاتين مع أو بدون كاناكينوماب كعلاج أساسيّ لدى المرضى المصابين بسرطان الرئة ذي الخلايا غير الصغيرة غير الحرشفي والحرشفي المتقدّم محليًّا أو النقيلي (كانوبي-1)

Health conditions/problem studied: Specify

Patients with Non-Small Cell Lung Cancer

Interventions: Specify

•Drug: canakinumab
canakinumab every 3 weeks (squamous and non-squamous)

Other Name: ACZ885

•Drug: canakinumab matching placebo
canakinumab placebo every 3 weeks (squamous and non-squamous)

•Drug: pembrolizumab
200 mg every 3 weeks (squamous and non-squamous)

•Drug: carboplatin
AUC 5 mg/mL*min every 3 weeks (non-squamous) or AUC 6 mg/mL*min (squamous)

•Drug: cisplatin
75 mg/m2 every 3 weeks (non-squamous)

•Drug: paclitaxel
200 mg/m2 every 3 weeks (squamous)

•Drug: nab-paclitaxel
100 mg/m2 every 3 weeks (squamous)

•Drug: pemetrexed
500 mg/m2 every 3 weeks (non-squamous)

Key inclusion and exclusion criteria: Inclusion criteria

Key inclusion criteria:
•Histologically confirmed locally advanced stage IIIB or stage IV NSCLC for treatment in the first-line setting
•Known PD-L1 status determined by a Novartis designated central laboratory. A newly obtained tissue biopsy or an archival biopsy (block or slides) is required for PD-L1 determination (PD-L1 IHC 22C3 pharmDx assay), prior to study randomization. Note: For the safety run-in part, known PD-L1 status is not required.
•Eastern Cooperative oncology group (ECOG) performance status of 0 or 1.
•At least 1 measurable lesion by RECIST 1.1

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

90

Key inclusion and exclusion criteria: Exclusion criteria

Key exclusion criteria:
•Previous immunotherapy (e.g. anti-PD-1, anti-PD-L1, anti-PD-L2, anti-CTLA-4 antibody, or any other antibody or drug specifically targeting T-cell co-stimulation or immune checkpoint pathways).
•Prior treatment with canakinumab or drugs of a similar mechanism of action (IL-1β inhibitor).
•Subjects with epidermal growth factor receptor (EGFR) sensitizing mutations (identified in exons 19, 20, or 21), and/or ALK rearrangement by locally approved laboratory testing.
•Previously untreated or symptomatic central nervous system (CNS) metastases or lepto-meningeal disease.
•Subject with suspected or proven immune-compromised state or infections.
•Subject has prior to starting study drug: received live vaccination ≤3 months, had major surgery ≤4 weeks prior to starting study drug, has thoracic radiotherapy: lung fields ≤ 4 weeks, other anatomic sites ≤ 2 weeks, palliative radiotherapy for bone lesions ≤ 2 weeks.

Other protocol-defined inclusion/exclusion criteria may apply.

Type of study

Interventional

Type of intervention

Pharmaceutical

Type of intervention: Specify type

N/A

Trial scope

Therapy

Trial scope: Specify scope

N/A

Study design: Allocation

Randomized controlled trial

Study design: Masking

Blinded (masking used)

Study design: Control

Placebo

Study phase

3

Study design: Purpose

Treatment

Study design: Specify purpose

N/A

Study design: Assignment

Parallel

Study design: Specify assignment

N/A

IMP has market authorization

Yes, Worldwide

IMP has market authorization: Specify

Argentina, Australia, Canada, Belgium, Bahrain, Brazil, Chile, Austria, Denmark, France, Germany, India, Italy, Japan...

Name of IMP

Canakinumab (ACZ885)

Year of authorization

Month of authorization

Type of IMP

Immunological

Pharmaceutical class

Monoclonal Antibody-IL1B Inhibitor

Therapeutic indication

Histologically confirmed locally advanced stage IIIB or stage IV NSCLC

Therapeutic benefit

Progression free survival (PFS) per investigator assessment using RECIST v1.1
Overall response rate (ORR) per investigator assessment using RECIST v1.

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

Biospecimen description

Samples with DNA**

Lab specimen and tissue will be shipped to Quintiles (Q2) Central Lab in the UK. ctDNA Biomarker testing on shipped blood smaples

Target sample size

10

Actual enrollment target size

8

Date of first enrollment: Type

Actual

Date of first enrollment: Date

05/11/2019

Date of study closure: Type

Actual

Date of study closure: Date

22/12/2022

Recruitment status

Other

Recruitment status: Specify

Recruitment closed however last patient in screening did not receive treament

Date of completion

23/11/2022

IPD sharing statement plan

No

IPD sharing statement description

Novartis is committed to sharing with qualified external researchers, access to patient-level data and supporting clinical documents from eligible studies. These requests are reviewed and approved by an independent expert panel on the basis of scientific merit. All data provided is anonymized to respect the privacy of patients who have participated in the trial in line with applicable laws and regulations.

This trial data is currently available according to the process described on www.clinicalstudydatarequest.com.

Additional data URL

https://clinicaltrials.gov/ct2/show/NCT03631199?term=CACZ885U2301&rank=1

Admin comments

Trial status

Approved

Secondary Identifying Numbers

Full name of issuing authority	Secondary identifying number
Clinical Trials. gov	NCT03631199

Sources of Monetary or Material Support

Name
Novartis Pharma Services Inc.

Secondary Sponsors

Name
NA

Contact for Public/Scientific Queries

Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	Fadi Farhat	Saida	Lebanon	03 753 155	drfadi.trials@gmail.com	Hammoud Hospital
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Public	Dany Abi Gerges	Bsalim	Lebanon	03 341 960	abigerges@gmail.com	Middle East Institute of Health

Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
Hammoud Hospital University Medical Center	Dr Fadi Farhat	Hematology Oncology	Approved
Hotel Dieu De France	Dr Joseph Kattan	Hematology Oncology	Approved
Bellevue Medical Center	Dr Fadi El karak	Hematology Oncology	Approved
Middle East Institute of Health	Dr Dany Abi Gerges	Hematology Oncology	Approved

Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Hammoud Hospital University Medical Center	20/12/2018	Ahmad Zaatari	zaatari@hammoudhospital.com	+961 (0) 7 723111 ext 1160
Hotel Dieu de France	05/12/2018	Sami Richa	cue@usj.edu.lb	961421229
Bellevue Medical Center	01/03/2019	Ghassan Maalouf	gmaalouf@bmc.com.lb	1 682666 ext 5006
Middle East Institute of Health	30/05/2019	Ahmad Ibrahim	ahmad_O_Ibrahim@hotmail.com	961 (0) 3 233 560

Countries of Recruitment

Name
Lebanon
Canada
France
Iceland
Germany
Japan
United States of America
Switzerland
Spain

Health Conditions or Problems Studied

Condition	Code	Keyword
Non-Small Cell Lung Cancer	Malignant neoplasm of bronchus and lung (C34)	NSCLC

Interventions

Intervention	Description	Keyword
Blood test (Hematology, Chemistry, Coagulation, PK, ct DNA, Biomarkers...), CT Scan, MRI, Whole body bone scan, Skin photography, Vital signs, Physical exam, Urinalysis, X-Ray	Blood test (Hematology, Chemistry, Coagulation, PK, ct DNA, Biomarkers...), CT Scan, MRI, Whole body bone scan, Skin photography, Vital signs, Physical exam, Urinalysis, X-Ray	ICF, IMP, Lab tests

Primary Outcomes

Name	Time Points	Measure
*To compare PFS by local investigator assessment as per RECIST1.1	6 months	6 months
Progression free survival	Duing the study	during the study

Key Secondary Outcomes

Name	Time Points	Measure
•Overall response rate (ORR) per investigator assessment using RECIST v1.1	baseline, 6 weekd and 12 wee	baseline, 6 weeks..
•Patient reported outcome (PRO)	baseline and every visit	baseline and every visit

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