



# 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 عشوائية التوزيع مزدوجة التعمية مركزة على المقارنة بدواء وهمي لتقييم فعالية وسلامة دواء بمبروليزوماب بالإضافة إلى العلاج الكيميائي المزدوج القائم على البلاتين مع أو بدون كاناكينوماب كعلاج أساسي لدى المرضى المصابين بسرطان الرئة ذي الخلايا غير-الصغيرة غير الحرشفي والحرشفي المتقدم محلياً أو النقلي (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/m<sup>2</sup> every 3 weeks (non-squamous)

•Drug: paclitaxel  
200 mg/m<sup>2</sup> every 3 weeks (squamous)

•Drug: nab-paclitaxel  
100 mg/m<sup>2</sup> every 3 weeks (squamous)

•Drug: pemetrexed  
500 mg/m<sup>2</sup> 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-1 $\beta$  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  $\leq$ 3 months, had major surgery  $\leq$ 4 weeks prior to starting study drug, has thoracic radiotherapy: lung fields  $\leq$  4 weeks, other anatomic sites  $\leq$  2 weeks, palliative radiotherapy for bone lesions  $\leq$  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 samples

**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 treatment

**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](http://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
Scientific	Hind Khairallah	Sin El Fil	Lebanon	+961 1 512002 Ext. 271	Hind.Khairallah@fattal.com.lb	Khalil Fattal et Fils s.a.l.
Public	Joseph Kattan	Beirut	Lebanon	03 635 913	jkattan62@hotmail.com	Hotel Dieu De France
Public	Fadi El Karak	Beirut	Lebanon	71 061 621	felkarak@yahoo.com	Bellevue Medical Center
Public	Dany Abi Gerges	Bsalim	Lebanon	03 341 960	abigeres@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	During 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