# 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 )

**18/08/2025 02:49:21**

## 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**
27/02/2023

**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**

07/11/2019

**Date of study closure: Type**

Actual

**Date of study closure: Date**

28/02/2024

**Recruitment status**

Complete

**Recruitment status: Specify**

Recruitment closed however last patient in screening did not receive treament

**Date of completion**

11/12/2019

**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 |
| 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 | 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**