



# Study of Efficacy and Safety of Canakinumab as Adjuvant Therapy in Adult Subjects With Stages AJCC/UICC v. 8 II-III A and IIIB (T>5cm N2) Completely Resected Non-small Cell Lung Cancer Acronym: CANOPY-A

22/11/2024 02:26:41

## Main Information

### Primary registry identifying number

LBCTR2019040221

### Protocol number

CACZ885T2301

### MOH registration number

7981/2018

### Study registered at the country of origin

Yes

### Study registered at the country of origin: Specify

### Type of registration

Retrospective

### Type of registration: Justify

LCTR was recently initiated, original file was previously submitted by Paper

### Date of registration in national regulatory agency

22/02/2018

### Primary sponsor

Novartis Pharma Services Inc.

### Primary sponsor: Country of origin

Novartis Pharmaceuticals

### Date of registration in primary registry

09/12/2022

### Date of registration in national regulatory agency

22/02/2018

### Public title

Study of Efficacy and Safety of Canakinumab as Adjuvant Therapy in Adult Subjects With Stages AJCC/UICC v. 8 II-III A and IIIB (T>5cm N2) Completely Resected Non-small Cell Lung Cancer Acronym: CANOPY-A

### Acronym

### Scientific title

A phase III, multicenter, randomized, double blind, placebocontrolled study evaluating the efficacy and safety of canakinumab versus placebo as adjuvant therapy in adult subjects with stages AJCC/UICC v. 8 II-III A and IIIB (T>5cm N2) completely resected (R0) non-small cell lung cancer (NSCLC)

### Acronym

### Brief summary of the study: English

The primary purpose of the study is to compare the efficacy and safety of canakinumab versus placebo as adjuvant therapy in adult subjects with stages AJCC/UICC v. 8 II-III A and the subset of IIIB (T>5cm N2 disease) completely resected (R0) non-small cell lung cancer (NSCLC).

### Brief summary of the study: Arabic

دراسة مرحلة ثالثة متعددة المراكز وعشوائية التوزيع ومزدوجة التعمية ومراقبة الدواء الوهمي لتقييم فعالية وسلامة دواء كاناكينوماب مقابل الدواء الوهمي كعلاج مساعد لدى مرضى بالغين مصابين بسرطان الرئة غير ذي الخلايا الصغيرة المستأصل كلياً في Canakinumab مراحل AJCC/UICC v. 8 II-III A و IIIB (T>5cm N2)

### Health conditions/problem studied: Specify

Non-Small Cell Lung Cancer



**Interventions: Specify**

•Drug: Canakinumab  
Canakinumab will be administered periodically for approximately 54 weeks.

Other Name: ACZ885

•Drug: Placebo  
Placebo will be administered periodically for approximately 54 weeks.

**Key inclusion and exclusion criteria: Inclusion criteria**

- Written informed consent must be obtained prior to any screening procedures
- Subjects must have recovered from all toxicities related to prior systemic therapy to grade  $\leq 1$  (CTCAE v 4.03). Exception to this criterion: subjects with any grade of alopecia and grade 2 or less neuropathy are allowed to enter the study
- ECOG performance status (PS) of 0 or 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**

- Subjects with unresectable or metastatic disease, positive microscopic margins on the pathology report, and/or gross disease remaining at the time of surgery
- Subjects who received neoadjuvant chemotherapy or neoadjuvant radiotherapy
- Presence or history of a malignant disease, other than the resected NSCLC, that has been diagnosed and/or required therapy within the past 3 years Exceptions to this exclusion include the following: completely resected basal cell and squamous cell skin cancers, completely resected carcinoma in situ of any type and hormonal maintenance for breast and prostate cancer > 3 years.
- Known active or recurrent hepatic disorder including cirrhosis, hepatitis B and C (positive or indeterminate central laboratory results)
- Subjects must be evaluated for tuberculosis as per local treatment guidelines or clinical practice. Subjects with active tuberculosis are not eligible.
- Subjects with suspected or proven immunocompromised state as described in the protocol
- Live and attenuated vaccination within 3 months prior to first dose of study drug (e.g. MMR, Yellow Fever, Rotavirus, Smallpox, etc.).

**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**

Single

**Study design: Specify assignment**

N/A

**IMP has market authorization**

Yes, Worldwide

**IMP has market authorization: Specify**

United Kingdom, United States, United Arab Emirates, Saudi Arabia, Sweden, Spain, Russia, Portugal, Japan, Greece, France, Canada, Brazil,

**Name of IMP**

Canakinumab

**Year of authorization**

**Month of authorization**

**Type of IMP**

Immunological

**Pharmaceutical class**

Anti-Inflammatory

**Therapeutic indication**

Non Small Cell Lung cancer

**Therapeutic benefit**

Disease free survival

**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**

Samples with DNA\*\*

**Biospecimen description**

DNA tumor circulating DNA, hematology, chemistry, urinalysis PK and PD are shipped to central lab Q2 Edinburgh, UK

**Target sample size**

16

**Actual enrollment target size**

11

**Date of first enrollment: Type**

Actual

**Date of first enrollment: Date**

08/10/2018

**Date of study closure: Type**

Actual

**Date of study closure: Date**

15/09/2025

**Recruitment status**

Complete

**Recruitment status: Specify****Date of completion**

29/11/2021

**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.

**Additional data URL**

<https://clinicaltrials.gov/ct2/show/record/NCT03447769?term=ACZ885&cntry=LB&rank=1&view=record>

**Admin comments****Trial status**

Approved

## Secondary Identifying Numbers

Full name of issuing authority	Secondary identifying number
Clinicaltrials.gov	NCT03447769

## 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	Joseph Kattan	Beirut	Lebanon	03635913	jkattan62@hotmail.com	Hotel Dieu De France
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Public	Jawad Makarem	Alchouf	Lebanon	03484288	Jawad.Makarem@awmedicalvillage.org	Ainwazein Medical Village

## Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
Hotel Dieu De France	Dr Joseph Kattan	Hematology Oncology	Approved
Hammoud Hospital University Medical Center	Dr Fadi Farhat	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
Nini Hospital	Dr Mona Ayoubi	Hematology Oncology	Approved
Ainwazein Medical Village	Dr Jawad Makarem	Hematology Oncology	Approved



Ethics Review				
Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Hotel Dieu de France	27/02/2018	Nancy Alam	nancy.alam@usj.edu.lb	961 (0) 1 421000 ext 2335
Bellevue Medical Center	05/03/2018	Ghassan Maalouf	gmaalouf@bmc.com.lb	961 (0) 1 682666 ext 7600
Ain w Zein Medical Village	16/02/2018	Khaled Abdel Baki	Khaled.abdelbaki@awmedicalvillage.org	961 (0) 5 509 001 ext 2000
Middle East Institute of Health	16/08/2018	Ahmad Ibrahim	ahmad_O_Ibrahim@hotmail.com	961 (0) 3 233 560
Nini Hospital	15/05/2018	Nabil Kabbara	Nabil.kabbara@hopitalnini.com	961 (0) 6 431 400 ext 1062
Hammoud Hospital University Medical Center	05/02/2018	Ahmad Zaatari	zaatari@hammoudhospital.com	961 (0) 7 723111 ext 1160

Countries of Recruitment
Name
Lebanon
Argentina
Austria
Bulgaria
Chile
France
Germany
India
Turkey
Jordan
United Kingdom
United States of America



## Health Conditions or Problems Studied

Condition	Code	Keyword
Non Small Cell Lung Cancer	Bronchus or lung, unspecified (C34.9)	NSCLC

## Interventions

Intervention	Description	Keyword
Lab, radiology, ICF , IMP administration	Lab, radiology, ICF , IMP administration	Lab, radiology, ICF , IMP administration

## Primary Outcomes

Name	Time Points	Measure
Disease Free Survival	5 years	5 years

## Key Secondary Outcomes

Name	Time Points	Measure
Overall Survival (OS)	5 years	5 years
•Lung Cancer Specific Survival (LCSS)	5 years	5 years



## 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**