



# 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

05/04/2025 09:22:06

## 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**

23/06/2021

**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**

26

**Actual enrollment target size**

9

**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**

Recruiting

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

15/09/2020

**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                       |
| 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       | Fadi Farhat       | Saida      | Lebanon | 03753155               | drfadi.trials@gmail.com            | Hammoud Hospital University Medical Center |
| Public       | Fadi El karak     | Beirut     | Lebanon | 71061621               | felkarak@yahoo.com                 | Bellevue Medical Center                    |
| Public       | Dany Abi Gerges   | Bsalim     | Lebanon | 03341960               | abigerges@idm.net.lb               | Middle East Institute Of Health            |
| Public       | Mona Ayoubi       | Tripoli    | Lebanon | 03280069               | ayoubi_mona@hotmail.com            | Nini Hospital                              |
| 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**