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

05/04/2025 02:01:38

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
07/01/2020

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-IIIA 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-IIIA 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 -IIIA 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 وعشوائيّة التوزيع ومزدوجة التعمية ومراقبة الدواء الوهمي لتقييم فعاليّة وسلامة دواء كاناكينوماب Canakinumab مقابل الدواء الوهمي كعلاج مساعد لدى مرضى بالغين مصابين بسرطان الرئة غير ذي الخلايا الصغيرة المستأصل كليًا في مراحل AJCC/UICC v. 8 II-IIIA 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 ≤ 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