



# Phase III Study Evaluating Efficacy and Safety of Canakinumab in Combination With Docetaxel in Adult Subjects With Non-small Cell Lung Cancers as a Second or Third Line Therapy (CANOPY-2)

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## Main Information

**Primary registry identifying number**

LBCTR2019030199

**Protocol number**

CACZ885V2301

**MOH registration number**

**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**

05/09/2019

**Date of registration in national regulatory agency**

**Public title**

Phase III Study Evaluating Efficacy and Safety of Canakinumab in Combination With Docetaxel in Adult Subjects With Non-small Cell Lung Cancers as a Second or Third Line Therapy (CANOPY-2)

**Acronym**

**Scientific title**

A Randomized, Double-blind, Placebo-controlled, Phase III Study Evaluating the Efficacy and Safety of Canakinumab in Combination With Docetaxel Versus Placebo in Combination With Docetaxel in Adult Subjects With Non-small Cell Lung Cancer (NSCLC) Previously Treated With PD-(L)1 Inhibitors and Platinum-based Chemotherapy (CANOPY 2)

**Acronym**

**Brief summary of the study: English**

This phase III study is designed to evaluate the role of IL-1 $\beta$  inhibition in combination with docetaxel in subjects with advanced NSCLC previously treated with PD-(L)1 inhibitors and platinum-based chemotherapy. The randomized III part will be preceded by a safety run-in part in which the recommended dose of the combination of canakinumab and docetaxel will be confirmed.

**Brief summary of the study: Arabic**

دراسة مرحلة ثالثة عشوائية التوزيع مزدوجة التعمية مرتكزة على المقارنة بدواء وهمي لتقييم فعالية وسلامة دواء كاناكينوماب بالاشتراك مع PD دوسيتاكسيل مقابل الدواء الوهمي مع دوسيتاكسيل لدى المرضى المصابين بسرطان الرئة ذي الخلايا غير الصغيرة المعالجين سابقًا بمنتجات (CANOPY-2) 2 وبالعلاج الكيميائي القائم على البلاتين (كانوبي- L)1

**Health conditions/problem studied: Specify**

Non Small Cell Lung Cancer (NSCLC)



**Interventions: Specify**

Camakinumab (ACZ885) plus Docetaxel vs Placebo Plus Docetaxel

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

- Histologically confirmed advanced (stage IIIB) or metastatic NSCLC.
- Subject has received one prior platinum-based chemotherapy and one prior PD-(L)1 inhibitor therapy for locally advanced or metastatic disease.
- Subject with ECOG performance status (PS) of 0 or 1.
- Subject with at least 1 evaluable (measurable or non-measurable) lesion by RECIST 1.1 in solid tumors criteria.

**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**

- Subject who previously received docetaxel, canakinumab (or another IL-1 $\beta$  inhibitor), or any systemic therapy for their locally advanced or metastatic NSCLC other than one platinum-based chemotherapy and one prior PD-(L)1 inhibitor.
- Subject with EGFR or ALK positive tumor.
- History of severe hypersensitivity reaction to monoclonal antibodies, taxanes or excipients of docetaxel or canakinumab.

Other protocol-defined inclusion/exclusion may apply.

**Type of study**

Interventional

**Type of intervention**

Pharmaceutical

**Type of intervention: Specify type**

N/A

**Trial scope**

Other

**Trial scope: Specify scope****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

**Therapeutic indication**



subjects with non-small cell lung cancer (NSCLC) previously treated with PD-(L)1 inhibitors and platinum-based chemotherapy

**Therapeutic benefit**

Progression-Free Survival (PFS)

**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**

Lab specimen and tissue will be shipped to Quintiles (Q2) Central Lab in the UK  
Blood will include hematology, biochemistry and blood for circulating tumor DNA

**Target sample size**

8

**Actual enrollment target size**

**Date of first enrollment: Type**

Anticipated

**Date of first enrollment: Date**

15/08/2019

**Date of study closure: Type**

Anticipated

**Date of study closure: Date**

20/10/2020

**Recruitment status**

Recruiting

**Recruitment status: Specify**

**Date of completion**

16/12/2020

**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.

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/record/NCT03626545?term=cacz885v2301&rank=1>

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

Approved

## Secondary Identifying Numbers

Full name of issuing authority	Secondary identifying number
ClinicalTrials.gov	NCT03626545

## 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	03 635 913	jkattan62@hotmail.com	Hotel Dieu De France
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Public	Fadi El karak	Beirut	Lebanon	961 3 061 621	felkarak@yahoo.com	Bellevue Medical Center



## 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

## Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Hotel Dieu de France	21/12/2018	Nancy Alam	nancy.alam@usj.edu.lb	+961 (0) 1 421000 ext 2335
Hammoud Hospital University Medical Center	20/12/2018	Ahmad Zaatari	zaatari@hammoudhospital.com	00961 (0) 7 723111 ext 1160
Bellevue Medical Center	21/12/2018	Ghassan Maalouf	gmaalouf@bmc.com.lb	01 682666 ext 7600

## Countries of Recruitment

Name
Lebanon
Belgium
France
Germany
Japan
Singapore
United States of America

## Health Conditions or Problems Studied

Condition	Code	Keyword
Non Small Cell Lung Cancer (NSCLC)	Bronchus or lung, unspecified (C34.9)	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
Incidence of dose limiting toxicities (DLTs)	6 months	6 months
Overall Survival (OS)	Randomization till 26 Months	Randomization till 26 Months

## Key Secondary Outcomes

Name	Time Points	Measure
•Overall response rate (ORR)	every 6 weeks	every 6 weeks
•Duration of response (DOR)	every 6 weeks	every 6 weeks
•Disease control rate (DCR)	every 6 weeks	every 6 weeks



## 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**