



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

q34124

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

12/12/2019

Primary sponsor

Novartis Pharma Services Inc.

Primary sponsor: Country of origin

Novartis Pharmaceuticals

Date of registration in primary registry

23/05/2022

Date of registration in national regulatory agency

12/12/2019

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 β 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 سابقاً بمثبطات (L)1 (CANOPY-2) 2وبالعلاج 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 β 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

5

Actual enrollment target size

3

Date of first enrollment: Type

Actual

Date of first enrollment: Date

28/08/2019

Date of study closure: Type

Actual

Date of study closure: Date

04/04/2022

Recruitment status

Complete

Recruitment status: Specify**Date of completion**

04/03/2020

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.

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 |
| 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 | 03 753 155 | drfadi.trials@gmail.com | Hammoud Hospital University Medical Center |
| Public | Fadi El karak | Beirut | Lebanon | 961 3 061 621 | felkarak@yahoo.com | Bellevue Medical Center |
| Public | Anas Mugharbil | Beirut | Lebanon | 03 776 142 | anasml@hotmail.com | Makassed General Hospital |

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 |
| Makassed General Hospital | Dr Anas Mugharbil | Hematology Oncology | Approved |

Ethics Review

| Ethics approval obtained | Approval date | Contact name | Contact email | Contact phone |
|--|---------------|-----------------|-------------------------------|-----------------------------|
| Hotel Dieu de France | 21/12/2018 | Sami Richa | cue@usj.edu.lb | 961421229 |
| 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 5006 |
| Makassed General Hospital | 30/04/2019 | Mariam Rajab | Research.makassed@hotmail.com | 01636941 |



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