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
20/10/2021

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-1β 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 عشوائيّة التوزيع مزدوجة التعمية مرتكزة على المقارنة بدواء وهميّ لتقييم فعاليّة وسلامة دواء كاناكينوماب بالاشتراك مع دوسيتاكسيل مقابل الدواء الوهمي مع دوسيتاكسيل لدى المرضى المصابين بسرطان الرئة ذي الخلايا غير الصغيرة المعالجين سابقًا بمثبّطات PD (L)1 -كانوبي) بالعلاج الكيميائي القائم على البلاتين (CANOPY-2)

Health conditions/problem studied: Specify
Non Small Cell Lung Cancer (NSCLC)

Interventions: Specify

Camakinumab (ACZ885) plus Docetaxel vs Palcebo 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-1β 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 EGFRor 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

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

20/10/2020

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
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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