

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

14/12/2025 09:03:44

Main Information

Primary registry identifying number

LBCTR2019030199

MOH registration number

q34124

Study registered at the country of origin

Type of registration

Prospective

Date of registration in national regulatory

12/12/2019

Primary sponsor

Novartis Pharma Services Inc.

Date of registration in primary registry

17/12/2019

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)

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)

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 platinumbased 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 بالإشتراك مع PD دُوسيناكسيل مقابل الدوّاء الوهميّ مع دُوسيناكسيل لدى المرّضي المصابين بسرطان الرّئة ذي الخلايا غير الصغيرة المعالجين سابقًا بمثبّطات (L)1 -وبالعلاج الكيميائي القائم على البلاتين (كانوبي- 1)2وبالعلاج

Health conditions/problem studied: Specify

Non Small Cell Lung Cancer (NSCLC)

Protocol number

CACZ885V2301

Study registered at the country of origin: Specify

Type of registration: Justify

Primary sponsor: Country of origin

Novartis Pharmaceuticals

Date of registration in national regulatory agency

12/12/2019

Acronym

Acronym



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

Key inclusion and exclusion criteria: Specify gender

Roth

Key inclusion and exclusion criteria: Age minimum

Key inclusion and exclusion criteria: Age maximum

90

Study phase

N/A

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 Type of intervention: Specify type

Pharmaceutical N/A

Trial scope Trial scope: Specify scope

Other

Study design: AllocationStudy design: MaskingRandomized controlled trialBlinded (masking used)

Study design: Control

Placebo

Study design: Purpose Study design: Specify purpose

Treatment

Study design: Assignment Study design: Specify assignment

Parallel

IMP has market authorization IMP has market authorization: Specify

Yes, Worldwide Argentina, Australia, Canada, Belgium, Bahrain, Brazil, Chile, Austria, Denmark, France, Germany, India, Italy, Japan...

Name of IMP Year of authorization Month of authorization

Type of IMP

Immunological

Pharmaceutical class

Canakinumab (ACZ885)

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 Study model: Explain model

N/A N/A

Study model: Specify model

N/A

Time perspective Time perspective: Explain time perspective

N/A N/A

Time perspective: Specify perspective

Target follow-up duration Target follow-up duration: Unit

Number of groups/cohorts

Biospecimen retention Biospecimen description

Samples with DNA** 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 Actual enrollment target size

Date of first enrollment: Date Date of first enrollment: Type

28/08/2019 Actual

Date of study closure: Type Date of study closure: Date

20/10/2020 Actual

Recruitment status **Recruitment status: Specify**

Recruiting

Date of completion

16/12/2020

IPD sharing statement plan IPD sharing statement description

No



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.	

Seco	ndary	/ Snc	onsors

Name

NA



Contac	Contact for Public/Scientific Queries					
Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	Joseph Kattan	Beirut	Lebanon	03 635 913	jkattan62@hotm ail.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
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	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
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		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	