Study of JDQ443 in Comparison With Docetaxel in Participants With Locally Advanced or Metastatic KRAS G12C Mutant Non-small Cell Lung Cancer

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Main Information

Primary registry identifying number
LBCTR2022055019

Protocol number
CJDQ443B12301

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 Pharmaceuticals

Primary sponsor: Country of origin
Novartis Pharmaceuticals

Date of registration in primary registry
29/11/2022

Date of registration in national regulatory agency

Public title
Study of JDQ443 in Comparison With Docetaxel in Participants With Locally Advanced or Metastatic KRAS G12C Mutant Non-small Cell Lung Cancer

Acronym
KontRASt-02

Scientific title
A Randomized, Controlled, Open Label, Phase III Study Evaluating the Efficacy and Safety of JDQ443 Versus Docetaxel in Previously Treated Subjects With Locally Advanced or Metastatic KRAS G12C Mutant Non-small Cell Lung Cancer

Acronym
KontRASt-02

Brief summary of the study: English
This is a phase III open label study designed to compare JDQ443 as monotherapy to docetaxel in participants with advanced non-small cell lung cancer (NSCLC) harboring a KRAS G12C mutation who have been previously treated with a platinum-based chemotherapy and immune checkpoint inhibitor therapy either in sequence or in combination.

Brief summary of the study: Arabic
مقابل دوسيتاكسيل لدى أشخاص معالجين سابقًا مصابين بسرطان الرئة JDQ443 دراسة مرحلة ثالثة ومفتوحة التسمية تقيّم فعاليّة وسلامة دواء ذي الخلايا غير الصغيرة المتقدّم محليًا أو المنتشر مع الطفرة الجينيّة KRAS G12C

Health conditions/problem studied: Specify
Non-Small Cell Lung Cancer

Interventions: Specify
Drug: JDQ443
JDQ443 tablets, orally administered

Drug: docetaxel
docetaxel concentrated solution for infusion, intravenously administered

Key inclusion and exclusion criteria: Inclusion criteria

- Participant has histologically confirmed locally advanced/metastatic (stage IIIB/IIIC or IV)
- Participant has a KRAS G12C mutation present in tumor tissue prior to enrollment, as determined by a Novartis designated central laboratory.
- Participants has received one prior platinum-based chemotherapy regimen and one prior immune checkpoint inhibitor therapy for locally advanced or metastatic disease
- Participant has at least 1 evaluable (measurable or non-measurable) lesion by RECIST 1.1 at the screening visit.

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

99

Key inclusion and exclusion criteria: Exclusion criteria

- Participant has previously received docetaxel, KRAS G12C inhibitor or any other systemic therapy for their locally advanced or metastatic NSCLC other than one platinum-based chemotherapy and one prior immune check point inhibitor
- Participant has EGFR-sensitizing mutation and/or ALK rearrangement by local laboratory testing
- Participant has known active central nervous system (CNS) metastases and/or carcinomatous meningitis
- Participant has an history of interstitial lung disease or pneumonitis grade > 1.

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

Open (masking not used)

Study design: Control

Active

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

No

IMP has market authorization: Specify

Name of IMP

JDQ443

Year of authorization

Month of authorization

Type of IMP

Gene therapy

Pharmaceutical class

KRAS G12C inhibitors

Therapeutic indication

Locally Advanced or Metastatic KRAS G12C Mutant Non-small Cell Lung Cancer

Therapeutic benefit

To determine if JDQ443 is safe and effective for better controlling NSCLC, with KRAS G12C mutation, compared to docetaxel

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

Samples will be shipped to Q2 for lab tests and Navigate biopharma for biomarker assessment

Target sample size

6

Actual enrollment target size

Date of first enrollment: Type

Anticipated

Date of first enrollment: Date

27/06/2022

Date of study closure: Type

Anticipated

Date of study closure: Date

29/05/2025

Recruitment status

Recruiting

Recruitment status: Specify

Date of completion

IPD sharing statement plan

Yes

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 review 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 availability is according to the criteria and process described on https://www.clinicalstudydatarequest.com/.

Additional data URL

https://clinicaltrials.gov/ct2/show/record/NCT05132075?term=CJDQ443B12301&draw=2&rank=1

Admin comments

Trial status

Approved

Secondary Identifying Numbers

Full name of issuing authority	Secondary identifying number
clinicaltrials.gov	NCT05132075

Sources of Monetary or Material Support

Name
Novartis Pharmaceuticals

Secondary Sponsors

Name
NA

Contact for Public/Scientific Queries

Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	Fadi Farhat	Saida	Lebanon	+961 3 753155	drfadi.trials@gmail.com	Hammoud Hospital University Medical Center
Scientific	Hind Khairallah	Sin El Fil	Lebanon	01512002 ext. 271	hind.khairallah@fattal.com.lb	Khalil Fattal et Fils s.a.l.
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Public	Arafat Tfayli	Hamra	Lebanon	+961 71194294	at35@aub.edu.lb	American University of Beirut Medical Center

Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
Hammoud Hospital University Medical Center	Fadi Farhat	Oncology	Approved
Hotel Dieu de France	Fadi El Karak	Oncology	Approved
Hopital Saint Joseph	Hampig Raphael Kourie	Oncology	Approved
American University of Beirut Medical Center	Arafat Tfayli	Hematology - Oncology	Approved

Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Hammoud Hospital University Medical Center	28/01/2022	Ibrahim Omeis	iomeis@hammoudhospital.org	+961 (0) 7 723111 ext 1222/1223
Hotel Dieu de France	03/05/2022	Nancy Alam	nancy.alam@usj.edu.lb	+961 (0) 1 421000 ext 2335
Psychiatric Hospital of the Cross	08/09/2022	Christiane Abi Elias	irghpc@gmail.com	+961 (0) 3 953794
American University of Beirut Medical Center	13/10/2022	Rami Mahfouz	rm11@aub.edu.lb	+961 (0) 1 350 000 ext:5445

Countries of Recruitment

Name
Czech Republic
Lebanon

Health Conditions or Problems Studied

Condition	Code	Keyword
locally advanced or metastatic KRAS G12C mutant non-small cell lung cancer	Malignant neoplasm of bronchus and lung (C34)	non-small cell lung cancer

Interventions

Intervention	Description	Keyword
IMP administration , ICF, visit assessment and schedule	IMP administration , ICF, visit assessment and schedule	IMP administration , ICF, visit assessment and schedule

Primary Outcomes

Name	Time Points	Measure
Progression free survival (PFS)	Approximately up to 24 months	PFS is the time from date of randomization/start of treatment to the date of event defined as the first documented progression or death due to any cause. PFS is based on central assessment and using RECIST 1.1 criteria

Key Secondary Outcomes

Name	Time Points	Measure
Overall Survival (OS)	Approximately up to 33 months	OS is defined as the time from date of randomization to date of death due to any cause
Overall Response Rate (ORR)	Approximately up to 33 months	ORR is defined as the proportion of patients with best overall response of complete response (CR) or partial response (PR) based on central and local investigator's assessment according to RECIST 1.1.
Disease Control Rate (DCR)	Approximately up to 33 months	DCR is defined as the proportion of participants with Best Overall Response (BOR) of Complete Response (CR), Partial Response (PR), Stable Disease (SD) or Non-CR/Non-PD.
Time To Response (TTR)	Approximately up to 33 months	TTR is defined as the time from the date of randomization to the date of first documented response (CR or PR, which must be confirmed subsequently)
Duration of Response (DOR)	Approximately up to 33 months	DOR is calculated as the time from the date of first documented response (complete response (CR) or partial response (PR)) to the first documented date of progression or death due to underlying cancer.
Progression-Free Survival after next line therapy (PFS2)	Approximately up to 33 months	PFS2 (based on local investigator assessment) is defined as time from date of randomization to the first documented progression on next line therapy or death from any cause, whichever occurs first.
Concentration of JDQ443 and its metabolite in plasma	Approximately up to 33 months	To characterize the pharmacokinetics of JDQ443 and its metabolite HZC320
Time to definitive deterioration of Eastern Cooperative Group of Oncology Group (ECOG) performance status	Approximately up to 33 months	Deterioration of Eastern Cooperative Oncology Group (ECOG) Performance Status (PS)
Time to definitive 10-point deterioration symptom scores of chest pain, cough and dyspnea per QLQ-LC13	Approximately up to 33 months	The EORTC QLQ LC13 is a 13-item, lung cancer specific questionnaire module, and it comprises both multi-item and single-item measures of lung cancer-associated symptoms (i.e. coughing, hemoptysis, dyspnea and pain) and side-effects from conventional chemo- and radiotherapy (i.e. hair loss, neuropathy, sore mouth and dysphagia). The time to definitive 10-point deterioration is defined as the time from the date of randomization to the date of event, which is defined as at least 10 points absolute increase from baseline (worsening), with no later change below the threshold or death due to any cause

Time to definitive deterioration in global health status/QoL, shortness of breath and pain per QLQ-C30	Approximately up to 33 months	The EORTC QLQ-C30 is a questionnaire developed to assess the health-related quality of life of cancer participants. The questionnaire contains 30 items and is composed of both multi-item scales and single-item measures based on the participants experience over the past week. These include five domains (physical, role, emotional, cognitive and social functioning), three symptom scales (fatigue, nausea/vomiting, and pain), six single items (dyspnea, insomnia, appetite loss, constipation, diarrhea and financial impact) and a global health status/HRQoL scale. The time to definitive 10-point deterioration is defined as the time from the date of randomization to the date of event, which is defined as at least 10 points absolute increase from baseline (worsening) of the corresponding scale score, with no later change below the threshold or death due to any cause
Change from baseline in EORTC-QLQ-C30	Approximately up to 33 months	The EORTC QLQ-C30 is a questionnaire developed to assess the health-related quality of life of cancer participants. The questionnaire contains 30 items and is composed of both multi-item scales and single-item measures based on the participants experience over the past week. These include five domains (physical, role, emotional, cognitive and social functioning), three symptom scales (fatigue, nausea/vomiting, and pain), six single items (dyspnea, insomnia, appetite loss, constipation, diarrhea and financial impact) and a global health status/HRQoL scale. A higher score indicates a higher presence of symptoms.
Change from baseline in EORTC-QLQ-LC13	Approximately up to 33 months	The EORTC QLQ LC13 is a 13-item, lung cancer specific questionnaire module, and it comprises both multi-item and single-item measures of lung cancer-associated symptoms (i.e. coughing, hemoptysis, dyspnea and pain) and side-effects from conventional chemo- and radiotherapy (i.e. hair loss, neuropathy, sore mouth and dysphagia). A higher score indicates a higher presence of symptoms.
Change from baseline in EORTC-EQ-5D-5L	Approximately up to 33 months	The EQ-5D-5L is a generic instrument for describing and valuing health. It is based on a descriptive system that defines health in terms of 5 dimensions: Mobility, Self-Care, Usual Activities, Pain/Discomfort, and Anxiety/Depression.
Change from baseline in NSCLC-SAQ	Approximately up to 33 months	The Non-Small Cell Lung Cancer Symptom Assessment Questionnaire (NSCLC-SAQ) is a 7-item, patient-reported outcome measure which assess patient-reported symptoms associated with advanced NSCLC. It contains five domains and accompanying items that were identified as symptoms of NSCLC: cough (1 item), pain (2 items), dyspnea (1 item), fatigue (2 items), and appetite (1 item).
PFS based on KRAS G12C mutation status in plasma.	Approximately up to 33 months	To compare the clinical outcomes for JDQ443 vs docetaxel based on KRAS G12C mutation status in plasma
OS based on KRAS G12C mutation status in plasma.	Approximately up to 33 months	To compare the clinical outcomes for JDQ443 vs docetaxel based on KRAS G12C mutation status in plasma
ORR based on KRAS G12C mutation status in plasma	Approximately up to 33 months	To compare the clinical outcomes for JDQ443 vs docetaxel based on KRAS G12C mutation status in plasma

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