



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

11/09/2025 16:25:06

## 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

12/10/2022

### 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 سابقاً مصابين بسرطان الرئة JDQ443 دراسة مرحلة ثالثة ومفتوحة التسمية تقيم فعالية وسلامة دواء KRAS G12C ذي الخلايا غير الصغيرة المتقدم محلياً أو المنتشر مع الطفرة الجينية

### 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.               |
| Public       | Fadi El Karak         | Beirut     | Lebanon | +961 3 061621     | felkarak@yahoo.com            | Hopital Dieu de France                     |
| Public       | Hampig Raphael Kourie | Dora       | Lebanon | +961 3 321899     | hampig.kourie@usj.edu.lb      | Hopital Saint Joseph                       |



## 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         |

## 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               |

## 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