



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

28/02/2023

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

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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 |
|--|---------------|----------------------|----------------------------|---------------------------------|
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| 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