

# RAStik: A Retrospective Cohort Analysis of Survival and Treatment Outcomes of Docetaxel in KRAS G12C Mutated Locally Advanced or Metastatic NSCLC (20190411)

**First published:** 09/12/2020

**Last updated:** 26/07/2023

Study

Finalised

## Administrative details

### **PURI**

<https://redirect.ema.europa.eu/resource/49082>

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### **EU PAS number**

EUPAS38357

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### **Study ID**

49082

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### **DARWIN EU® study**

No

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## Study countries

Germany

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## Study description

This is a retrospective, observational cohort study of KRAS G12C mutated locally advanced or metastatic non-small cell lung cancer (NSCLC) patients. Patients are identified from Network Genomic Medicine (NGM) Network Database. The study period is from 01 July 2015 through to 31 December 2019. Approximately 150 patients will be randomly selected from the NGM (Network Genomic Medicine) database. The patients will be over the age of 18 with a pathologically documented locally advanced or metastatic NSCLC, who have a record of treatment with docetaxel (monotherapy or combination) in  $\geq$ second-line. The primary objectives of the study are to evaluate the real-world effectiveness of docetaxel (monotherapy or combination) and estimate overall and progression-free survival.

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## Study status

Finalised

# Research institutions and networks

## Institutions

Amgen

United States

**First published:** 01/02/2024

**Last updated:** 21/02/2024

Multiple centres: 300 centres are involved in the study

## Contact details

### Study institution contact

Global Development Leader Amgen Inc.

Study contact

[medinfo@amgen.com](mailto:medinfo@amgen.com)

### Primary lead investigator

Global Development Leader Amgen Inc.

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 25/06/2020

Actual: 25/06/2020

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### Study start date

Planned: 31/10/2020

Actual: 31/10/2020

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### **Data analysis start date**

Planned: 01/03/2021

Actual: 23/05/2022

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### **Date of final study report**

Planned: 31/07/2023

Actual: 25/07/2023

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Amgen

## Study protocol

[Protocol-Published Original Sotorasib 20190411 .pdf\(649.17 KB\)](#)

## Regulatory

### **Was the study required by a regulatory body?**

No

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### **Is the study required by a Risk Management Plan (RMP)?**

Not applicable

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Human medicinal product

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Disease epidemiology

Effectiveness study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**Main study objective:**

The main objectives of this study are to evaluate the real-world effectiveness of docetaxel (monotherapy or combination) and estimate the overall survival and progression-free survival in ? second-line treatment of patients with KRAS G12C mutated locally advanced or metastatic NSCLC.

## Study Design

**Non-interventional study design**

Cohort

Other

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**Non-interventional study design, other**

Retrospective observational study

## Study drug and medical condition

## **Study drug International non-proprietary name (INN) or common name**

DOCETAXEL

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### **Medical condition to be studied**

Non-small cell lung cancer

## **Population studied**

### **Short description of the study population**

Patients aged 18 years or older diagnosed with locally advanced or metastatic non-small cell lung cancer (NSCLC) received treatment with docetaxel (monotherapy or combination) between 1 July 2015 to 31 December 2019 identified from the Network Genomic Medicine (NGM) network database.

Inclusion criteria:

1. Adults (aged  $\geq 18$ ) patients diagnosed between 1 July 2015 to 30 June 2019 with pathologically documented locally advanced or metastatic NSCLC from the Colonge center
2. Have a record of treatment with docetaxel (monotherapy or combination) in  $\geq$ second line (eg. 2nd line, 3rd line, 4th line, or 4th line+)
3. Have a molecular test results of KRAS G12C somatic mutation recorded before start date of treatment with docetaxel
4. Have FFPE tumor samples with adequate material available for biomarker testing (ie.  $>10\%$  of tumor cells are available on sample) that was archived before start date of treatment with docetaxel
5. Have CT-scan or MRI documentation of measurable disease at treatment baseline for docetaxel (ie.,  $\leq 4$  weeks before start date of treatment)
6. Have documented consent that their medical data and residual tissue samples can be used for research purposes

Exclusion criteria:

1. Have a history of treatment with chemotherapy, immunotherapies, targeted therapies, or anti-angiogenic agents as part of a clinical trial.

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### **Age groups**

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

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### **Special population of interest**

Other

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### **Special population of interest, other**

Patients with non-small cell lung cancer

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### **Estimated number of subjects**

150

## Study design details

### **Outcomes**

• Real-world Objective Response Rate • Duration of overall response (DOR) • Disease control rate (DCR) • Duration of Treatment (DOT) • Time to Next Therapy (TTNT) • Time to Progression (TTP) • Overall survival (OS) • real-world Progression-free survival (rwPFS), • Patient Characteristics

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## Data analysis plan

The primary outcomes are rwORR, OS and rwPFS. Non-parametric methods will be used to estimate OS and rwPFS. To describe time-to-event (rwORR, CR, PR, SD, PD, rwPFS, and OS), Kaplan-Meier (KM) curves will be plotted, and survival probabilities 95% confidence intervals (CIs) will be presented (eg, 6 months and 12 months). Median OS and rwPFS and 95% CI will be presented. Survival differences may be assessed for statistical significance using two-sided Log-Rank in Kaplan-Meier. The level of significance will be set at 0.05. For analyses of rwORR and survival, the index date will be determined by the start date of the type of treatment or start date of LOT, depending on the analysis. Duration or time to events (DOR, DCR, TTNT, and TTP) will be summarized (mean, median, standard deviation, range). Patient characteristics of patients with locally advanced or metastatic NSCLC will be described using summary statistics.

## Documents

### Study results

[20190411\\_ORSR\\_Abstract\\_Redacted.pdf](#)(121.5 KB)

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## Data management

## Data sources

### Data sources (types)

[Other](#)

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## **Data sources (types), other**

Medical Database

## Use of a Common Data Model (CDM)

### **CDM mapping**

No

## Data quality specifications

### **Check conformance**

Unknown

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No