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

EU PAS number

EUPAS38357

Study ID

49082

DARWIN EU® study

No

Study countries

Germany

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 ≥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.

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

Last updated: 21/02/2024

Institution

Multiple centres: 300 centres are involved in the study

Contact details

Study institution contact

Global Development Leader Amgen Inc.

Study contact

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

Study start date

Planned: 31/10/2020

Actual: 31/10/2020

Data analysis start date
Planned: 01/03/2021

Actual: 23/05/2022

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

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

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

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

Non-interventional study design, other

Retrospective observational study

Study drug and medical condition

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

DOCETAXEL

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 ≥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 ≥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., ≤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.

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)

Special population of interest

Other

Special population of interest, other

Patients with non-small cell lung cancer

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

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)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Medical Database

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No