Vargatef in 2nd-line therapy of advanced or metastatic adenocarcinoma of the lung (VARGADO)

First published: 14/03/2016

Last updated: 04/07/2024

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/38264

EU PAS number

EUPAS12795

Study ID

38264

DARWIN EU® study

No

Study countries

☐ Germany

Study description

This observational study will investigate the efficacy and tolerability of Vargatef (Nintedanib) plus docetaxel in daily routine second-line treatment in patients with locally advanced, metastatic or locally recurrent NSCLC. Treatment with Vargatef in eligible NSCLC patients, for whom the treating physician has decided to initiate treatment with Vargatef in second line according to the local label, will be observed for up to 24 months. Survial follow-up will be done until the end of the study.

Study status

Ongoing

Research institutions and networks

Institutions

Boehringer Ingelheim

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Boehringer Ingelheim Pharma GmbH Boehringer Ingelheim Pharma GmbH

Study contact

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Primary lead investigator

Boehringer Ingelheim Pharma GmbH Boehringer Ingelheim Pharma GmbH

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 31/01/2015

Actual: 31/01/2015

Study start date
Planned: 27/04/2015

Actual: 27/04/2015

Date of final study report
Planned: 31/12/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim Pharma GmbH

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 type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

Assess 1-year survival rate

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

VARGATEF

Medical condition to be studied

Lung adenocarcinoma

Population studied

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)

Estimated number of subjects

700

Study design details

Outcomes

Assess 1-year survival rate, Assess 1-year progression-free survival rate in patients with early progression of first-line therapy. Median overall survival. Median progression free survival. Tumor controll rate. Duration of therapy and modifications. Incidence of adverse events related to Vargatef

Data analysis plan

All analyses are descriptive, SAS software will be used. Frequency tables for categorial variables will depict all possible categories and will report the

number of observations and the percentage per characteristic feature. The number of patients with missing values and the percentage of the total patient population will also be presented (if necessary).All analyses are presented in the overall population. These analyses are also performed additionally according to further subgroups in the event of special interests. The details of the statistical analyses are described in the statistical analysis plan (TSAP) which is produced in a completed form before database lock.The main diagnosis must be met. The primary endpoint of this NIS is the survival rate one year after the beginning of treatment with Vargatef® + docetaxel. Relative frequency of patients who have not died after 12 months will be presented, together with the 95% confidence interval.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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