A non-interventional biomarker study in patients with Non-Small Cell Lung Cancer (NSCLC) of adenocarcinoma tumour histology eligible for treatment with Vargatef® according to the approved label (LUME BioNIS)

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Study Finalised

Administrative details

EU PAS number

EUPAS11885

Study ID

37252

DARWIN EU® study

No

Study countries

- Austria
- Belgium
- Denmark
- Germany
- Greece
- Hungary
- Italy
- Lithuania
- Luxembourg
- Netherlands
- Spain
- Sweden
- United Kingdom

Study description

To explore whether genetic/genomic markers (alone or combined with clinical covariates) could be used to predict overall survival (OS) in NSCLC patients eligible for treatment with Vargatef® according to the approved label.

Study status

Finalised

Research institutions and networks

Institutions

Multiple centres: 71 centres are involved in the study

Contact details

Study institution contact

Boehringer Ingelheim clintriage.rdg@boehringer-ingelheim.com

Study contact

clintriage.rdg@boehringer-ingelheim.com

Primary lead investigator

Martin Reck

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 12/06/2015

Study start date

Planned: 09/03/2016

Actual: 09/03/2016

Data analysis start date

Planned: 01/11/2019

Actual: 14/03/2016

Date of final study report

Planned: 30/06/2020

Actual: 08/07/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Biomarker assessment

Data collection methods:

Primary data collection

Study design:

Non-interventional, multi-national, multi-site study

Main study objective:

Overall Survival in relation to exploratory biomarker assessment, including gene-expressions and genomic alterations.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

VARGATEF

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

NINTEDANIB

Medical condition to be studied

Non-small cell lung cancer stage IIIB

Population studied

Short description of the study population

NSCLC patients eligible for treatment with Vargatef®.

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

Non-small cell lung cancer patients

Estimated number of subjects

260

Study design details

Outcomes

Overall Survival, Disease progression

Data analysis plan

Biomarkers will be investigated by univariate and multivariate prediction models and regression analysis.For all univariate screening approaches, multiplicity correction of p-values will be performed.Model performances will be

quantified and uncertainty will be evaluated by resampling methods.Categorical biomarkers will only be investigated provided there are sufficient patient numbers within the subgroups defined by the categorical biomarkers. For all selected categorical biomarkers the estimate of the HR/odds ratio and its 95% confidence interval (CI) will be presented. For continuous biomarkers the HR/odds ratio for a change per unit will be presented.

Summary results

In the non-interventional LUME-BioNIS study, Vargatef® plus docetaxel demonstrated real-world clinical effectiveness in patients with adenocarcinoma NSCLC previously treated with chemotherapy as well as both immunotherapy and chemotherapy.

The post hoc, exploratory analysis of the subgroup of patients with prior immunotherapy suggests that the Vargatef® plus docetaxel combination treatment yields greater efficacy when administered after immune checkpoint inhibitors than administered without prior immunotherapy.

Safety findings were as expected and consistent with the known safety profile of Vargatef® plus docetaxel in patients with advanced NSCLC.

Despite comprehensive biomarker analyses(both clinical and molecular) using various analytic approaches, no new prognostic marker was identified for the OS outcome. Hence, no possible new predictive marker for OS was identified as well.

Given the efficacy and safety results of this non-interventional study, the benefit-risk balance of Vargatef® plus docetaxel remains unchanged in the approved indication.

Documents

Study results

1199.223_Synopsis.pdf (312.33 KB)

Data management

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

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