VARGADO - Vargatef in 2nd-line Therapy of Non-Small Cell Lung Cancer (NSCLC)

This study is currently recruiting participants. (see Contacts and Locations)

Verified November 2016 by Boehringer Ingelheim

Sponsor:
Boehringer Ingelheim

Information provided by (Responsible Party):
Boehringer Ingelheim

ClinicalTrials.gov Identifier:
NCT02392455

First received: March 17, 2015
Last updated: November 21, 2016
Last verified: November 2016
History of Changes

Purpose

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.

Condition	Intervention
Carcinoma, **Non-Small-Cell Lung**	Drug: **treatment**

Study Type: Observational
Study Design: Observational Model: Cohort
Time Perspective: Prospective

Official Title: **Vargatef in 2nd-line Therapy** of Advanced or Metastatic Adenocarcinoma of the **Lung**

Resource links provided by NLM:

Genetics Home Reference related topics: lung cancer

Drug Information available for: Nintedanib Nintedanib esylate

Genetic and Rare Diseases Information Center resources: Lung Adenocarcinoma

U.S. FDA Resources

Further study details as provided by Boehringer Ingelheim:

Primary Outcome Measures:

- Percentage of patients alive one year after start of **therapy** with **Vargatef** and Docetaxel (1-year survival rate) [Time Frame: up to 24 months] [Designated as safety issue: No]

Secondary Outcome Measures:

- One year survival rate of patients with first line progression within 9 months after start of first line **therapy** [Time Frame: up to 24 months] [Designated as safety issue: No]
- Progression-free survival of patients with first line progression within 9 months after start of first line **therapy** [Time Frame: up to 24 months] [Designated as safety issue: No]
- Median overall survival [Time Frame: up to 24 months] [Designated as safety issue: No]
- Progression-free survival [Time Frame: up to 24 months] [Designated as safety issue: No]
- **Tumour** control rate (complete response, partial response, stable disease) [Time Frame: up to 24 months] [Designated as safety issue: No]
- Incidence of side effects [Time Frame: up to 24 months] [Designated as safety issue: Yes]

Estimated Enrollment:	400
Study Start Date:	March 2015
Estimated Study Completion Date:	December 2020
Estimated Primary Completion Date:	March 2019 (Final data collection date for primary outcome measure)

Groups/Cohorts	Assigned Interventions
A	Drug: **treatment** Docetaxel plus **nintedanib** until progression or intolerability

Eligibility

Ages Eligible for Study:	18 Years and older (Adult, Senior)
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No
Sampling Method:	Probability Sample

Study Population
NSCLC patients

Criteria

Inclusion criteria:

- age 18 or older
- men and women locally advanced, metastastic and/or recurrent NSCLC with adenocarcinoma histology for which vargatef treatment is indicated according to Summary of Product Characteristics (SmPC)
- after first line therapy; second-line therapy not yet started
- standard 21-day-cycles docetaxel treatment according to SmPC possible
- written informed consent

Exclusion criteria:

- contraindications according to the SmPC of Vargatef or Docetaxel
- more than one chemotherapy for treatment of NSCLC in palliative setting
- current partcipation in a clinical trial
- pregnancy
- breastfeeding

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02392455

Contacts

Contact: Boehringer Ingelheim Call Center 1-800-243-0127 clintriage.rdg@boehringer-ingelheim.com

Locations

Germany

Boehringer Ingelheim Investigational Site **Recruiting**
one or multiple Investigational sites, Germany

Sponsors and Collaborators

Boehringer Ingelheim

Investigators

Study Chair: Boehringer Ingelheim Boehringer Ingelheim

More Information

Responsible Party:	Boehringer Ingelheim
ClinicalTrials.gov Identifier:	NCT02392455 History of Changes
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Study First Received:	March 17, 2015

Last Updated:	November 21, 2016
Health Authority:	Germany: Ethics Commission

Additional relevant MeSH terms:

Carcinoma, **Non-Small-Cell Lung**	**Lung** Diseases
Bronchial **Neoplasms**	**Nintedanib**
Lung Neoplasms	Carcinoma, Bronchogenic
Respiratory Tract **Neoplasms**	Respiratory Tract Diseases
Thoracic **Neoplasms**	Antineoplastic Agents
Neoplasms by Site	Enzyme Inhibitors
Neoplasms	Molecular Mechanisms of Pharmacological Action

ClinicalTrials.gov processed this record on November 22, 2016