**Trial Description**

**Title**

A Burden-of Illness Study in Patients With Stage IB-IIIA Non-Small Cell Lung Cancer (NSCLC)

**Trial Acronym**

LuCaBIS

**URL of the trial**

[---]*

**Brief Summary in Lay Language**

The aim of this observational study is to identify and quantify the humanistic and economic burden of illness of patients with complete resection (no residual disease) of stage IB-IIIA NSCLC in three European countries (France, Germany, and the United Kingdom [UK]). Data collection will be conducted through patient medical record abstraction and patient survey.

**Brief Summary in Scientific Language**

The study procedures will have no effect on the medical care delivered to enrolled patients. Physicians will continue to provide usual medical care to patients. There is no study intervention, and no drug or other intervention will be provided to the site as part of the study.

**Methodology:** The study will consist of two components:

- Medical record abstraction. Medical records of eligible patients (both living and deceased) will be reviewed, and data will be extracted for the study. Data collected will include patient demographic and disease characteristics, details of medical care received (including adjuvant treatment), and information about disease recurrence/progression.
- Patient survey. Living patients will be asked to participate in a patient survey.

Living patients who agree to participate will be administered a brief patient questionnaire to collect information that is not available in the clinical sites' medical records [e.g., local medical care, patient out-of-pocket expenses, work loss, and health-related quality of life (HRQOL)]. The site may exclude individual patients from the survey if site staff feel that it would be inappropriate for that individual; the study will not collect patient survey information from the families of deceased patients.

Informed consent will be collected from living patients who participate in the patient survey, apart from the abstraction of their medical records. Country-specific requirements will be followed.

The medical records of patients (living or deceased) with complete resection of stage IB-IIIA NSCLC between 01 August 2009 and 31 July 2012 will be identified. No vaccine or drug was administered during this study.

Organizational Data

- DRKS-ID: DRKS00005783
- Date of Registration in DRKS: 2014/02/17
- Date of Registration in Partner Registry or other Primary Registry: 2013/01/17
- Investigator Sponsored/Initiated Trial (IST/IIT): no
- Ethics Approval/Approval of the Ethics Committee: [---]*
- (leading) Ethics Committee Nr.: [---]*

Secondary IDs

- Primary Registry-ID: NCT01772225 (ClinicalTrials.gov)
- Sponsor-ID: 116913 (GlaxoSmithKline)

Health condition or Problem studied

- Free text: Lung Cancer, Non-Small Cell
- ICD10: C34 - Malignant neoplasm of bronchus and lung
Interventions/Observational Groups

- Arm 1: **Other: Data collection**

Characteristics

- **Study Type**: Non-interventional
- **Study Type Non-Interventional**: Observational study
- **Allocation**: [---]*
- **Blinding**: [---]*
- **Who is blinded**: [---]*
- **Control**: [---]*
- **Purpose**: [---]*
- **Assignment**: [---]*
- **Phase**: N/A
- **Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels)**: [---]*

Primary Outcome

- Determination of the adjuvant therapies used in routine practice in the target countries along with the durations of treatment, doses, dose reduction rates, discontinuation rates, and reasons for discontinuation.; time frame: Observation of retrospective data between 2009-2012.
- Determinations of the proportions of patients receiving each type of adjuvant chemotherapy and proportions receiving no adjuvant chemotherapy.; time frame: Observation of retrospective data between 2009-2012.
- Determination of the level of medical resource utilization and the direct healthcare costs of managing these patients during adjuvant treatment, prior to disease recurrence/progression, and post disease recurrence/progression.; time frame: Observation of retrospective data between 2009-2012.

Secondary Outcome

- Determination of the characteristics of patients receiving chemotherapy compared with those not receiving chemotherapy.; time frame: Observation of retrospective data between 2009-2012.
- Determination of the proportion of patients with selected co morbidities (e.g., chronic obstructive pulmonary disease [COPD], cardiovascular disease, asthma).; time frame: Observation of retrospective data between 2009-2012.
- Determination of indirect costs incurred.; time frame: Observation of retrospective data between 2009-2012.
- Determination of the effect of the disease on Health related quality of life (HRQOL) based on EuroQol 5 Dimensions quality-of-life questionnaire (EQ-5D).; time frame: Observation of retrospective data between 2009-2012.
- Estimation of overall and disease-free survival of patients with resected stage IB-IIIA NSCLC observed retrospectively; time frame: Between 01 Aug 2009 and 31 July 2012.

**Countries of recruitment**

- DE Germany

**Locations of Recruitment**

- University Medical Center *Freiburg im Breisgau*

**Recruitment**

- Planned/Actual: [--]*
- (Anticipated or Actual) Date of First Enrollment: 2013/06/30
- Target Sample Size: 900
- Monocenter/Multicenter trial: [--]*
- National/International: National

**Inclusion Criteria**

- Gender: Both, male and female
- Minimum Age: 18 Years
- Maximum Age: no maximum age

**Additional Inclusion Criteria**

Patient medical records will be screened using the following criteria:

- Patients must be aged 18 years or older at the time of first presentation with clinical stage IB-IIIA NSCLC.
- Patients must have complete resection of pathologic stage IB-IIIA NSCLC at least 1 calendar month prior to the date of screening, according to the current classification recommended by the International Association for the Study of Lung Cancer (2009). The investigator/study site must have been the main care provider for the patient during the period of treatment or management of the patient's NSCLC.
Exclusion criteria

- Patients who underwent wedge resection.
  - Patients whose resection was less than 1 calendar month before the date of screening.
  - Patients who received adjuvant systemic treatment within a clinical trial if the type of adjuvant treatment is either unknown or is not recommended by international clinical guidelines [European Society for Medical Oncology (ESMO), National Comprehensive Cancer Network (NCCN)].
  - Patients who are lost to follow-up:
    - Living patients who are no longer under the care of the site or can no longer be contacted.
    - Deceased patients who were transferred to another NSCLC treatment centre before death.

Patients with concomitant malignancies who received treatment for other cancers at any time during their treatment or follow-up for NSCLC.

Addresses

- **Primary Sponsor**
  GlaxoSmithKline
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  E-mail: [---]*
  URL: [---]*

- **Contact for Scientific Queries**
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Contact for Public Queries

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Collaborator, Other Address

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Sources of Monetary or Material Support

[---]*

Bitte wenden Sie sich an den Sponsor / Please refer to primary sponsor

Telephone: [---]*  
Fax: [---]*  
E-mail: [---]*  
URL: [---]*

Status

Recruitment Status: Recruiting planned  
Study Closing (LPLV): [---]*

Trial Publications, Results and other documents

The parameters in ClinicalTrials.gov and DRKS are not identical. Therefore the data import from ClinicalTrials.gov required adjustments. For full details please see the DRKS FAQs.
- Translation on version: 4
- Last processed date by ClinicalTrials.gov: 2014/02/13

* This entry means the parameter is not applicable or has not been set.
*** This entry means that data is not displayed due to insufficient data privacy clearing.