PLEASE NOTE: *This study has been imported from ClinicalTrials.gov without additional data checks.*

Trial Description

Title

Study of GSK2302032A Antigen-Specific Cancer Immunotherapeutic in Patients With Resectable Non-Small Cell Lung Cancer

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

The purpose of this clinical study is to assess the safety and immunogenicity of the immunotherapeutic product GSK 2302032A when given to Non-Small Cell Lung Cancer (NSCLC) patients, after tumor removal by surgery.

Brief Summary in Scientific Language

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Organizational Data

- DRKS-ID: **DRKS00003850**
- Date of Registration in DRKS: **2012/09/28**
- Date of Registration in Partner Registry or other Primary Registry: **2010/07/08**
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- Primary Registry-ID: **NCT01159964 (ClinicalTrials.gov)**
- Sponsor-ID: **113174 (GlaxoSmithKline)**

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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: **Biological: Immunotherapeutic GSK2302032A, different formulations**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Non-randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **[---]***
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **I**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

- Occurrence of dose-limiting toxicities during study treatment; time frame: During the study treatment period (up to 112 weeks, approximately 2 years and 2 months)
- Occurrence of dose-limiting toxicities during study follow-up; time frame: 12 months after concluding visit (week 112)
- Anti-PRAME humoral immune response; time frame: Assessed post-dose 4 (Week 12)
- Anti-PRAME humoral immune response; time frame: Throughout the study (Day 0 until 12 months after concluding visit (week 112))

Secondary Outcome

- Occurrence of adverse events (AEs) and serious adverse events; time frame: During the whole study treatment period until 30 days after the last treatment administration.

- The anti-PRAME cellular (T-cell) response; time frame: At 6 defined time-points during the study (Week 0, 12, 24, 72 and 112) and follow-up period (6 months later).
- The anti-PRAME humoral immunogenicity; time frame: At 10 defined timepoints during the study (Week 0, 6, 12, 24, 48, 72, 96, 112), and follow-up period (6 and 12 months later).

Countries of recruitment

- US **United States**
- FR **France**
- DE **Germany**
- IT **Italy**
- PL **Poland**
- RU **Russian Federation**

Locations of Recruitment

- **GSK Investigational Site, Freiburg**
- **GSK Investigational Site, Heidelberg**
- **GSK Investigational Site, Muenchen**
- **GSK Investigational Site, Regensburg**
- **GSK Investigational Site, Regensburg**
- **GSK Investigational Site, Immenhausen**
- **GSK Investigational Site, Koeln**
- **GSK Investigational Site, Moers**
- **GSK Investigational Site, Velbert**
- **GSK Investigational Site, Leipzig**
- **GSK Investigational Site, Berlin**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2010/07/31**
- Target Sample Size: **45**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

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

Additional Inclusion Criteria

1. Male or female patient with completely resected (R0 resection), pathologically proven stage IB, II or IIIA NSCLC. Patients are allowed to receive adjuvant platinum-based chemotherapy for the treatment of the current NSCLC between surgery and enrolment.

2. Written informed consent for PRAME gene expression screening on resected tumor tissue has been obtained from the patient prior to shipment of the sample for expression testing, and written informed consent for the complete study participation has been obtained before the performance of any other protocol specific procedure.

3. Patient is >= 18 years of age at the time of signature of the first informed consent form.

4. The patient's tumor shows expression of the PRAME gene.

5. The surgical technique for resection of the patient's tumor is anatomical, involving at least a lobectomy or a sleeve lobectomy. The first ASCI administration will be given, either within 12 weeks after surgery or within 8 weeks after day 1 of last chemotherapy cycle and within 32 weeks after resection.

6. The patient is free of metastasis, as confirmed by a negative baseline computer tomogram (CT scan) of the chest and upper abdomen as well as CT scan or magnetic resonance imaging (MRI) of the brain. These tests are to be performed within 6 weeks for the CT scan of the chest and upper abdomen and within 12 weeks for the brain CT scan or MRI before first ASCI administration.

7. ECOG performance status of 0, 1 or 2.

8. Adequate bone-marrow reserve, renal, adrenal and hepatic function as assessed by standard laboratory criteria

9. Female patients of non-childbearing potential may be enrolled in the study.

Non-childbearing potential is defined as current tubal-ligation, hysterectomy, ovariectomy or post-menopause.

10. Female patient of childbearing potential may be enrolled in the study, if the patient:

- has practiced adequate contraception for 30 days prior to study product administration, and

- has a negative pregnancy test on the day of administration, and

- has agreed to continue adequate contraception during the entire treatment period and for 2 months after completion of the study product administration series.

11. In the view of the investigator, the patient can and will comply with the requirements of the protocol.

Exclusion criteria

1. The primary tumor was removed by segmentectomy or wedge resection.

2. The patient has received any anti-cancer specific treatment, including radiotherapy, immunotherapy, chemotherapy or neo-adjuvant chemotherapy, except for the treatment of previous malignancies allowed by the protocol.

3. The patient requires concomitant treatment (more than 7 consecutive days) with systemic corticosteroids or any other immunosuppressive agents.

4. Use of any investigational or non-registered product (drug or vaccine, except influenza vaccine in the context of H1N1 mass-vaccination) other than the study product within the 30 days preceding the first dose of study product, or planned use during the study period.

5. The patient has previous or concomitant malignancies at other sites, except effectively treated non-melanoma skin cancers or carcinoma in situ of the cervix or effectively treated malignancy that has been in remission for more than 3 years and highly likely to have been cured.

6. History of allergic disease or reactions likely to be exacerbated by any component of the study investigational product.

7. History of confirmed adrenal dysfunction.

8. The patient has an autoimmune disease such as, but not limited to, multiple sclerosis, lupus, and inflammatory bowel disease. Patients with vitiligo are not excluded.

9. The patient has received a major organ allograft.

10. The patient is known to be Human Immunodeficiency Virus (HIV) - positive.

11. The patient has an uncontrolled bleeding disorder.

12. The patient has uncontrolled congestive heart failure or uncontrolled hypertension, unstable heart disease (coronary artery disease or myocardial infarction) or uncontrolled arrhythmia at the time of enrolment.

13. The patient needs home oxygenation.

14. The patient has psychiatric or addictive disorders that may compromise his/her ability to give informed consent, or to comply with the trial procedures.

15. The patient has other concurrent severe medical problems, unrelated to the malignancy, that would significantly limit full compliance with the study or expose the patient to unacceptable risk.

16. For female patients: the patient is pregnant or lactating.

Addresses

- **Primary Sponsor**

  GlaxoSmithKline

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

- **Contact for Scientific Queries**

  GlaxoSmithKline
  GSK Clinical Trials

Contact for Scientific Queries

GlaxoSmithKline
GSK Clinical Trials

Telephone: **[---]***
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- **Contact for Public Queries**

GlaxoSmithKline
GSK Clinical Trials

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

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 complete, follow-up continuing**
- 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: 113

- Last processed date by ClinicalTrials.gov: 2013/10/30

* *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.*