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

Trial Description

Title

GSK 2132231A Antigen-Specific Cancer Immunotherapeutic as Adjuvant Therapy in Patients With Resected Melanoma

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

**The purpose of this clinical trial is to evaluate the benefit of the immunotherapeutic
product GSK 2132231A in preventing disease relapse when given to melanoma patients, after
surgical removal of their tumor.**

**This Protocol Posting has been updated following Amendments 1 of the Protocol, March 2010.
The impacted sections are outcome measures and entry criteria.**

Brief Summary in Scientific Language

**"http://www.immunotherapyforcancer.info provides information on the cancer immunotherapeutic
approach in an easy-to-understand format" "http://www.ascitrials.com gives practical
information on the MAGRIT clinical study"**

Organizational Data

- DRKS-ID: **DRKS00003615**
- Date of Registration in DRKS: **2012/04/16**
- Date of Registration in Partner Registry or other Primary Registry: **2008/11/21**
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **[---]***

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Ethics Approval/Approval of the Ethics Committee: **[---]***

- (leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- Primary Registry-ID: **NCT00796445 (ClinicalTrials.gov)**
- Sponsor-ID: **111482 (GlaxoSmithKline)**

Health condition or Problem studied

- Free text: **Melanoma**
- ICD10: **C43 - Malignant melanoma of skin**

Interventions/Observational Groups

- Arm 1: **Drug: GSK 2132231A**
- Arm 2: **Drug: Placebo**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **patient/subject, investigator/therapist, assessor**
- Control: **Placebo**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **III**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

- Disease Free Survival; time frame: Once the pre-defined number of events is reached

Secondary Outcome

- Overall Survival; time frame: At the time of analysis
- Disease-free specific survival; time frame: At the time of analysis
- Distant metastasis-free survival; time frame: At the time of analysis
- Anti-MAGE-A3 and anti-protein D seropositivity status.; time frame: Post-treatment and 1 year after concluding visit.
- Occurrence of adverse events including abnormal haematological and biochemical parameters.; time frame: Up to 30 days after each study dose.
- Occurrence of serious adverse events and autoimmunity events.; time frame: During the whole study duration up to 30 days after the last administration of study treatment.
- Health-related quality of life (utility) assessment using the EuroQoL 5D (EQ-5D) questionnaire.; time frame: At regular intervals from Visit 1 (baseline) till 6 months after the concluding visit or 1 year post-recurrence.

Countries of recruitment

- US **United States**
- AR **Argentina**
- AU **Australia**
- AT **Austria**
- BE **Belgium**
- BR **Brazil**
- BG **Bulgaria**
- CA **Canada**
- CZ **Czech Republic**
- EE **Estonia**
- FR **France**
- DE **Germany**
- GR **Greece**
- IE **Ireland**
- IL **Israel**
- IT **Italy**
- JP **Japan**
- KR **Korea, Republic of**

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- MX **Mexico**
- NL **Netherlands**
- NZ **New Zealand**
- NO **Norway**
- PL **Poland**
- RO **Romania**
- RU **Russian Federation**
- RS **Serbia**
- ES **Spain**
- SE **Sweden**
- CH **Switzerland**
- TW **Taiwan, Province of China**
- UA **Ukraine**
- UK **United Kingdom**

Locations of Recruitment

- **GSK Investigational Site, Freiburg**
- **GSK Investigational Site, Heidelberg**
- **GSK Investigational Site, Mannheim**
- **GSK Investigational Site, Tuebingen**
- **GSK Investigational Site, Ulm**
- **GSK Investigational Site, Muenchen**
- **GSK Investigational Site, Muenchen**
- **GSK Investigational Site, Nuernberg**
- **GSK Investigational Site, Regensburg**
- **GSK Investigational Site, Wuerzburg**
- **GSK Investigational Site, Frankfurt**
- **GSK Investigational Site, Kassel**
- **GSK Investigational Site, Marburg**
- **GSK Investigational Site, Wiesbaden**
- **GSK Investigational Site, Greifswald**
- **GSK Investigational Site, Schwerin**

- **GSK Investigational Site, Buxtehude**
- **GSK Investigational Site, Hannover**
- **GSK Investigational Site, Oldenburg**
- **GSK Investigational Site, Bochum**
- **GSK Investigational Site, Bonn**
- **GSK Investigational Site, Duesseldorf**
- **GSK Investigational Site, Essen**
- **GSK Investigational Site, Koeln**
- **GSK Investigational Site, Minden**
- **GSK Investigational Site, Muenster**
- **GSK Investigational Site, Ludwigshafen**
- **GSK Investigational Site, Mainz**
- **GSK Investigational Site, Homburg**
- **GSK Investigational Site, Magdeburg**
- **GSK Investigational Site, Quedlinburg**
- **GSK Investigational Site, Dresden**
- **GSK Investigational Site, Leipzig**
- **GSK Investigational Site, Kiel**
- **GSK Investigational Site, Luebeck**
- **GSK Investigational Site, Erfurt**
- **GSK Investigational Site, Jena**
- **GSK Investigational Site, Berlin**
- **GSK Investigational Site, Berlin**
- **GSK Investigational Site, Berlin**
- **GSK Investigational Site, Berlin**
- **GSK Investigational Site, Hamburg**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2008/12/31**
- Target Sample Size: **1300**
- 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

- Written informed consent signed.

- Male or female patient with histologically proven stage IIIB or IIIC cutaneous melanoma presenting with macroscopic lymph node involvement suitable for surgery.

- The patient must have been surgically rendered free of disease before the randomization.

- Patient is ≥ 18 years old at the time of signing the informed consent form.

- The patient's lymph node tumor shows expression of the MAGE-A3 gene.

- The patient has fully recovered from surgery.

- ECOG performance status of 0 or 1 at the time of randomization.

- The patient must have adequate organ functions as assessed by standard laboratory criteria.

- If the patient is female, she must be of non-childbearing potential, or practice adequate contraception.

- In the opinion of the investigator, the patient can and will comply with all the requirements of the protocol.

Exclusion criteria

- The patient suffers from a mucosal or ocular melanoma.

- The patient has or has had any history of in-transit metastases

- The patient has been treated or is scheduled to be treated with an adjuvant anticancer therapy after the surgery that qualifies the patient for inclusion in the present trial.

- The patient requires concomitant chronic treatment with systemic corticosteroids or any other immunosuppressive agents.

- Use of any investigational or non-registered product (drug or vaccine) other than the study treatment.

- The patient has a history of autoimmune disease.

- The patient has a family history of congenital or hereditary immunodeficiency.

- The patient is known to be positive for Human Immunodeficiency Virus (HIV) or has another confirmed or suspected immunosuppressive or immunodeficient condition.

- History of allergic disease or reactions likely to be exacerbated by any component of the treatments.

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

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

- 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 over 5 years and is highly likely to have been cured.

- The patient has an uncontrolled bleeding disorder.

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

Addresses

■ **Primary Sponsor**

GlaxoSmithKline

Telephone: **[---]***
Fax: **[---]***

Primary Sponsor

GlaxoSmithKline

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

- **Contact for Scientific Queries**

GlaxoSmithKline
GSK Clinical Trials

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

- **Contact for Public Queries**

GlaxoSmithKline
GSK Clinical Trials

Telephone: **[---]***
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

- Further trial documents **gives practical information on the MAGRIT clinical study**
- Further trial documents **provides information on the cancer immunotherapeutic approach in an easy-to-understand format**