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

Trial Description

Title

A Randomized, Controlled Phase III Study Investigating IMA901 Multipeptide Cancer Vaccine in Patients Receiving Sunitinib as First-line Therapy for Advanced/Metastatic Renal Cell Carcinoma

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

**The primary objective of the phase III study is to investigate whether IMA901 can prolong
overall survival in patients with metastatic and/or locally advanced renal cell carcinoma
(RCC) when added to standard first-line therapy with sunitinib.**

**Secondary objectives include a subgroup analysis of overall survival in patients defined by
a certain biomarker signature, the investigation of progression-free survival, best tumor
response, safety, and immunological parameters.**

Brief Summary in Scientific Language

**This is a multicenter, open-label, randomized phase III study to investigate whether
therapeutic vaccination with IMA901, a mult-peptide cancer vaccine (TUMAP), can prolong
overall survival in patients with metastatic and/or locally advanced RCC when added to
standard first-line therapy with sunitinib (primary endpoint).**

**Secondary endpoints include a subgroup analysis of overall survival in patients who are
positive for a prospectively defined primary biomarker signature (identified as being
predictive for improved clinical outcome in IMA901-vaccinated patients in the previous phase
II study), progression-free survival (PFS), best overall response, cellular**

immunomonitoring
in a subset of patients, and safety. Safety analysis will be based on adverse events (AEs),
physical examinations, vital signs, hematology, clinical chemistry, urinalysis and ECG
changes.

Further endpoints include subgroup analyses of overall survival in patients who are positive
for further prospectively defined biomarkers (identified in the previous phase II study),
and exploratory screening of new biomarkers (to be investigated in patients' blood and
paraffin sections from tumor tissue) to predict better clinical outcome as response to
vaccination with IMA901. Biomarker sets will not be used for patient selection in this
study.

Organizational Data

- DRKS-ID: **DRKS00004109**
- Date of Registration in DRKS: **2013/06/06**
- Date of Registration in Partner Registry or other Primary Registry: **2010/12/22**
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- EudraCT-No.
  (for studies acc. to Drug Law): **2010-022459-45**
- Primary Registry-ID: **NCT01265901 (ClinicalTrials.gov)**
- Sponsor-ID: **IMA901-301 (immatics Biotechnologies GmbH)**
- Other Secondary-ID: **2010-022459-45**

Health condition or Problem studied

- Free text: **Metastatic Renal Cell Carcinoma**
- ICD10: **C64 - Malignant neoplasm of kidney, except renal pelvis**

Interventions/Observational Groups

- Arm 1: **Drug: Sunitinib**
- Arm 2: **Biological: IMA901 plus GM-CSF**
- Arm 3: **Drug: Cyclophosphamide**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control (effective treament of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **III**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

- Overall survival; time frame: 2015 (estimated)

Secondary Outcome

- Overall survival in biomarker-defined subgroup; time frame: 2015 (estimated)
- Progression-free survival; time frame: 2014 (estimated)
- Best tumor response; time frame: 2014 (estimated)
- Safety and tolerability; time frame: continuously
- Cellular immunomonitoring; time frame: 2014 (estimated)

Countries of recruitment

- US **United States**
- FR **France**
- DE **Germany**
- HU **Hungary**
- IT **Italy**
- NL **Netherlands**
- NO **Norway**
-

PL **Poland**

- RO **Romania**
- RU **Russian Federation**
- UK **United Kingdom**

Locations of Recruitment

- **Universitätsmedizin Berlin, Charité Campus Benjamin Franklin, Urologische Klinik und Hochschulambulanz, Berlin**
- **Klinik für Hämatologie und internistische Onkologie, Augusta-Krankenanstalt gGmbH, Bochum**
- **Medizinische Klinik III für Hämatologie und Onkologie, Universitätsklinikum Bonn, Bonn**
- **Universitätsklinikum Essen, Klinik für Innere Medizin (Tumorforschung), Essen**
- **Klinik für Hämatologie, Hämostaseologie, Onkologie und Stammzelltransplantation, Medizinische Hochschule Hannover, Hannover**
- **Nationales Centrum für Tumorerkrankungen (NCT), Medizinische Onkologie, Heidelberg**
- **Klinik und Poliklinik für Urologie, Abteilung für Operative Medizin, Universitätsklinikum Leipzig, Leipzig**
- **Klinikum rechts der Isar, Urologischen Klinik und Poliklinik, Technische Universität München, Munich**
- **Urologische Klinik Dr. Castringius, München-Planegg, Planegg**
- **Klinikum St. Elisabeth Straubing GmbH, Straubing**
- **Klinik für Urologie, Universitätsklinikum Tübingen, Tübingen**
- **Klinik für Innere Medizin III, Hämatologie - Onkologie - Rheumatologie - Infektionskrankheiten, Universitätsklinikum Ulm, Ulm**
- **Schwarzwald-Baar Klinikum Villingen-Schwenningen, Abteilung Hämatologie und Onkologie, Villingen-Schwenningen**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2010/12/31**
- Target Sample Size: **330**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**

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Minimum Age: **18 Years**

- Maximum Age: **no maximum age**

Additional Inclusion Criteria

1. Aged at least 18 years.

2. HLA type: HLA-A*02-positive

3. Metastatic and/or locally advanced RCC with clear cell histology (histological confirmation by local pathologist required). NOTE: prior nephrectomy is NOT required.

4. Measurable and/or non-measurable tumor lesions as per RECIST 1.1

5. Patients who are candidates for a first-line therapy with sunitinib.

6. Favorable or intermediate risk according to the 6-score risk criteria in patients treated with VEGF-targeted agents according to Heng [Heng et al. 2009]. The patient has a favorable risk if none, or intermediate risk if one or two of the following criteria apply (if three or more criteria apply the patient is not eligible):

1. Hemoglobin < LLN,

2. Serum corrected calcium > ULN,

3. Karnofsky performance status < 80%,

4. Time from initial diagnosis to initiation of therapy < 1 year,

5. Absolute neutrophil count > ULN,

6. Platelets > ULN.

7. Able to understand the nature of the study and give written informed consent.

8. Willingness and ability to comply with the study protocol for the duration of the study.

9. Female patients who are post menopausal (no menstrual period for a minimum of 1 year), or surgically sterile (bilateral tubal ligation, bilateral oophorectomy, or hysterectomy) or practice a medically acceptable method of birth control.

10. Male patients willing to use contraception (upon study entry and during

the course of the study or have undergone vasectomy.

Exclusion criteria

1. Prior systemic therapy for metastatic disease. (Note: prior adjuvant treatment for non-metastatic disease is allowed, however adjuvant therapy must have been stopped ≥ 1 year before Visit C).

2. History of or current brain metastases.

3. Abnormal ≥ CTC Grade 3 laboratory values for hematology (Hb, WBC, neutrophils, lymphocytes, platelets), liver (serum bilirubin, ALAT or ASAT) and renal function (serum creatinine).

4. Metastatic second malignancy.

5. Localized second malignancy expected to influence the patient's life span.

6. Patients with a history or evidence of systemic autoimmune disease, e.g., rheumatoid arthritis, multiple sclerosis, systemic lupus erythematodes (SLE), scleroderma, Sjögren's syndrome, Wegener's granulomatosis, Guillain-Barre syndrome.

7. Known active hepatitis B or C infection.

8. Known HIV infection.

9. Active infections requiring oral or intravenous antibiotics.

10. Any other known infection with a biological agent that can cause a severe disease and poses a severe danger to lab personnel working on patients' blood or tissue.

11. Received study drug within any clinical study (including approved and experimental drugs) within 4 weeks before sunitinib start.

12. Serious intercurrent illness, which according to the investigator, poses an undue risk for the patient when participating in the trial, including, but not limited to, any of the following:

- **Clinically significant cardiovascular disease (e.g., uncontrolled hypertension; clinically significant cardiac arrhythmia, clinically significant QT-prolongation),**
- **New York Heart Association class III-IV congestive heart failure,**

- Symptomatic peripheral vascular disease,

- Severe pulmonary dysfunction,

- Psychiatric illness or social situation that would preclude study compliance.

13. Less than 12 months since any of the following:

- Myocardial infarction,

- Severe or unstable angina,

- Coronary or peripheral artery bypass graft,

- Cerebrovascular event incl. transient ischemic attack,

- Pulmonary embolism / deep vein thrombosis (DVT).

14. Pregnancy or breastfeeding.

15. Any condition which in the judgment of the investigator would place the patient at undue risk or interfere with the results of the study.

Addresses

■ **Primary Sponsor**

immatics Biotechnologies GmbH

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

■ **Contact for Scientific Queries**

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Cleveland Clinic Taussig Cancer Institute
Brian Rini, MD

Contact for Public Queries

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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 complete, follow-up complete**
- Study Closing (LPLV): **2015/07/01**

Trial Publications, Results and other documents