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

Trial Description

Title

Open-label, Multi Center PET/CT (Positron Emission Tomography/Computed Tomography) Study for Investigation of Safety, Tolerability, Biodistribution and Diagnostic Performance of the 68Ga Labeled PET Tracer BAY86-7548 Following a Single Intravenous Administration of 140 MBq (Corresponding to ≤ 28 µg Mass Dose) in Patients With Prostate Cancer as Well as Radiation Dosimetry, Plasma Pharmacokinetics, Biodistribution, Safety and Tolerability of the Tracer in PET/CT in Healthy Volunteers

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Visual assessment of diagnostic PET/CT (positron emission tomography/computed tomography)
images obtained after a single intravenous injection of BAY86-7548 in patients with cancer.

Brief Summary in Scientific Language

[---]*

Organizational Data

- DRKS-ID: **DRKS00004044**
- Date of Registration in DRKS: **2012/07/16**
- Date of Registration in Partner Registry or other Primary Registry: **2010/09/17**
- 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): **2008-008315-25**
- Primary Registry-ID: **NCT01205321 (ClinicalTrials.gov)**
- Sponsor-ID: **14269 (Bayer)**
- Other Secondary-ID: **2008-008315-25**

Health condition or Problem studied

- Free text: **Diagnostic Imaging**
- ICD10: **C61 - Malignant neoplasm of prostate**

Interventions/Observational Groups

- Arm 1: **Drug: Bombesin (68Ga) labeled (BAY86-7548)**
- Arm 2: **Drug: Bombesin (68Ga) labeled (BAY86-7548)**

Characteristics

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

Primary Outcome

- Visual assessment of lesions; time frame: Day of study drug administration

Secondary Outcome

- Quantitative analysis of BAY86-7548 uptake into lesions (Standardized Uptake Values = SUVs); time frame: Day of study drug administration
- ECG (significant abnormalities); time frame: At least 3 times until one day after treatment

- Blood pressure; time frame: At least 3 times until one day after treatment
- Serum protein; time frame: At least 3 times until one day after treatment
- Serum creatinine; time frame: At least 3 times until one day after treatment
- Serum GOT (Glutamat-Oxalacetat-Transaminase); time frame: At least 3 times until one day after treatment
- Adverse events collection; time frame: Continuously for at least 5 days after treatment

Countries of recruitment

- FI **Finland**
- DE **Germany**
- CH **Switzerland**

Locations of Recruitment

- **Ulm**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2010/11/30**
- Target Sample Size: **19**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Male**
- Minimum Age: **45 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

- Healthy volunteers:

- males, >/=50 and </= 65 years of age

- Cancer patients:

- males >/= 45 years of age

- Patients had an MRI of the prostate and/or a positive choline or acetate

PET/CT for diagnosis (Note: MRI, choline and acetate PET/CT are optional for primary prostate cancer patients) of recurrence prostate cancer and the primary cancer disease is/ will be histologically confirmed.

- The prostate cancer is histologically confirmed and results of histology are available.

- Patients with primary prostate cancer: >/= 20 percent of biopsy material should be affected by cancer in the histopathological evaluation.

- Patients with primary prostate cancer: Patient is scheduled to undergo prostatectomy.

Exclusion criteria

- Concurrent severe and/or uncontrolled and/or unstable other medical disease (e.g. poorly controlled diabetes, congestive heart failure, myocardial infarction within 12 months prior to planned injection of BAY86-7548, unstable and uncontrolled hypertension, chronic renal or hepatic disease, severe pulmonary disease) which could compromise participation in the study

- Known sensitivity to the study drug or components of the preparation.

Addresses

■ **Primary Sponsor**

Piramal Imaging SA

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

■ **Contact for Scientific Queries**

Bayer
Bayer Study Director

Contact for Scientific Queries

Bayer
Bayer Study Director

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

- **Contact for Public Queries**

Bayer
Bayer Study Director

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 complete**
- Study Closing (LPLV): **2011/12/01**

Trial Publications, Results and other documents

- Further trial documents **Click here and search for drug information provided by the FDA.**
- Further trial documents **Click here and search for information on any recalls, market or product safety alerts by the FDA which might have occurred with this product.**

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: 5

- Last processed date by ClinicalTrials.gov: 2016/01/14

Please note:
There are additional attributes available concerning this trial. To open an extended view please click here.