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

Trial Description

Title

A Phase 3, Randomized, Double-blind, Controlled Study of Cabozantinib (XL184) Versus Prednisone in Metastatic Castration-resistant Prostate Cancer Patients Who Have Received Prior Docetaxel and Prior Abiraterone or MDV3100

Trial Acronym

COMET-1

URL of the trial

[---]*

Brief Summary in Lay Language

This study will evaluate the effect of cabozantinib compared to prednisone on overall survival in men with previously treated metastatic castration-resistant prostate cancer with bone-dominant disease who have experienced disease progression on docetaxel-containing chemotherapy and abiraterone or MDV3100.

Brief Summary in Scientific Language

[---]*

Organizational Data

- DRKS-ID: **DRKS00005167**
- Date of Registration in DRKS: **2013/08/06**
- Date of Registration in Partner Registry or other Primary Registry: **2012/05/22**
- 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): **2012-001834-33**
- Primary Registry-ID: **NCT01605227 (ClinicalTrials.gov)**
- Sponsor-ID: **XL184-307 (Exelixis)**
- Other Secondary-ID: **2012-001834-33**

Health condition or Problem studied

- Free text: **Prostate Cancer**
- Free text: **Castration Resistant Prostate Cancer**
- Free text: **Pain**
- Free text: **Prostatic Neoplasms**
- ICD10: **C61 - Malignant neoplasm of prostate**

Interventions/Observational Groups

- Arm 1: **Drug: cabozantinib**
- Arm 2: **Drug: prednisone**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **patient/subject, caregiver, investigator/therapist, assessor**
- 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: Through 21 months after study start

Secondary Outcome

- Bone scan response; time frame: End of Week 12; Bone scans will be evaluated by an independent radiology facility for response

Countries of recruitment

- US **United States**
- AU **Australia**
- AT **Austria**
- BE **Belgium**
- CA **Canada**
- FR **France**
- DE **Germany**
- IE **Ireland**
- IT **Italy**
- NL **Netherlands**
- PR **Puerto Rico**
- ES **Spain**
- SE **Sweden**
- UK **United Kingdom**

Locations of Recruitment

- **Aachen**
- **Aachen**
- **Berlin**
- **Berlin**
- **Braunschweig**
- **Dresden**
- **Dusseldorf**
- **Frankfurt am Main**
- **Freiburg**
- **Furth**
- **Gütersloh**
- **Hamburg**

- **Hamburg**
- **Hamburg**
- **Hannover**
- **Heidelberg**
- **Homburg**
- **Kassel**
- **Kempen**
- **Kirchheim**
- **Koln**
- **Mannheim**
- **Munchen**
- **Munster**
- **Nurtingen**
- **Offenburg**
- **Traunstein**
- **Tubingen**
- **Weiden**
- **Wuppertal**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2012/06/30**
- Target Sample Size: **960**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Male**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

- Histological or cytological diagnosis of castration resistant prostate cancer (serum testosterone less than 50 ng/dL).

- Evidence of bone metastasis related to prostate cancer on bone scans.

- Received prior docetaxel (minimum cumulative dose of 225 mg/m2) and either abiraterone or MDV3100 treatment and has evidence of prostate cancer progression on each agent independently.

- Maintenance of LHRH agonist or antagonist unless treated with orchiectomy.

- Recovered from toxicities related to any prior treatments, unless the toxicities are clinically non significant or easily manageable.

- Adequate organ and marrow function.

- Capable of understanding and complying with the protocol requirements and signed the informed consent form.

- Sexually active fertile patients and their partners must agree to use medically accepted methods of contraception (eg, barrier methods, including male condom, female condom, or diaphragm with spermicidal gel) during the course of the study and for 4 months after the last dose of study treatment.

Exclusion criteria

- Prior treatment with cabozantinib.

- Treatment with docetaxel, abiraterone, or MDV3100 in the last 2 weeks; or with any other type of cytotoxic or investigational anticancer agent in the last 2 weeks.

- Radiation within 4 weeks (excluded if to mediastinum) or radionuclide treatment within 6 weeks of randomization.

- Known brain metastases or cranial epidural disease.

- Requires concomitant treatment, in therapeutic doses, with anticoagulants.

- Requires chronic concomitant treatment of strong CYP3A4 inducers (eg, dexamethasone, phenytoin, carbamazepine, rifampin, rifabutin, rifapentin, phenobarbital, and St. John's Wort).

- Uncontrolled, significant intercurrent illness including, but not limited to, cardiovascular disorders, gastrointestinal disorders, active infections, non-healing

wounds, recent surgery.

- Clinically significant hematemesis or hemoptysis, or other signs indicative of pulmonary hemorrhage in the last 3 months, or history of other significant bleeding in the past 6 months.

- Cavitating pulmonary lesion(s) or a lesion invading or encasing a major blood vessel.

- QTcF > 500 ms within 7 days of randomization.

- Unable to swallow capsules or tablets.

- Previously-identified allergy or hypersensitivity to components of the study treatment formulations.

- Another diagnosis of malignancy requiring systemic treatment within 2 years of randomization.

Addresses

■ **Primary Sponsor**

Exelixis

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): **2015/03/01**

Trial Publications, Results and other documents

Additional Trial Attributes

- *Urological disease:* ***prostate cancer***
- *If other, please specify:* ***[---]****
- *Onset of therapy:* ***second-line***
- *If other, please specify:* ***[---]****
- *If other, please specify:* ***[---]****
- *Study recommendations:* ***[---]****
- *If other, please specify:* ***[---]****
- *German director of clinical investigation:*

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  Fax: **+49 (0) 30 8445 4448**
  E-mail: **[---]***
  URL: **http://urologie.charite.de/**

- *Further contact:*

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

- *Function of contact:* ***[---]****
- *Non-interventional study:* ***No***
- *Stage:* ***metastasized, castration-resistent***

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: 70

- Last processed date by ClinicalTrials.gov: 2016/07/17

** 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.*