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

Trial Description

Title

YM598 Added to Mitoxantrone/Prednisone to Control Pain in Metastatic Prostate Cancer Patients No Longer Responding to Hormone Therapy

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

The purpose of this study is to determine if patients who take YM598 in addition to mitoxantrone and prednisone (standard therapy) experience improvement in the pain associated with prostate cancer metastases in the bone.

Brief Summary in Scientific Language

[---]*

Organizational Data

- DRKS-ID: **DRKS00009648**
- Date of Registration in DRKS: **2015/11/11**
- Date of Registration in Partner Registry or other Primary Registry: **2002/11/04**
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- Primary Registry-ID: **NCT00048659 (ClinicalTrials.gov)**
- Sponsor-ID: **598-CL-008 (Astellas Pharma Inc)**

Sponsor-ID: **598-CL-008 (Astellas Pharma Inc)**

Health condition or Problem studied

- Free text: **Hormone-Refractory Prostate Cancer**
- Free text: **Prostatic Neoplasms**
- ICD10: **C61 - Malignant neoplasm of prostate**

Interventions/Observational Groups

- Arm 1: **Drug: YM598**

Characteristics

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

Primary Outcome

[---]*

Secondary Outcome

[---]*

Countries of recruitment

- AU **Australia**
- BE **Belgium**
-

FR **France**

- DE **Germany**
- IE **Ireland**
- NL **Netherlands**
- PL **Poland**
- ES **Spain**
- UK **United Kingdom**
- US **United States**

Locations of Recruitment

- **Krankenhause am Urban, Urologie Dieffenfachstr, Berlin**
- **Dept Urology University of Essen, Essen**
- **Urologische Klinik der MHH, Hannover**
- **Klinikum Mannheim Urology, Mannheim**

Recruitment

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

Inclusion Criteria

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

Additional Inclusion Criteria

[---]*

Exclusion criteria

[---]*

Addresses

- **Primary Sponsor**

  Astellas Pharma Inc

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **[---]***
- **Collaborator, Other Address**

  Astellas Pharma US, Inc.

  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 stopped after recruiting started**
- Study Closing (LPLV): **2004/06/01**

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: 2

- Last processed date by ClinicalTrials.gov: 2015/11/10

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