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

Trial Description

Title

Randomized, Open Label, Multi-Center Study Comparing Cabazitaxel at 25 mg/m2 and at 20 mg/m² in Combination With Prednisone Every 3 Weeks to Docetaxel in Combination With Prednisone in Patients With Metastatic Castration Resistant Prostate Cancer Not Pretreated With Chemotherapy

Trial Acronym

FIRSTANA

URL of the trial

[---]*

Brief Summary in Lay Language

Primary Objective:

- To demonstrate the superiority of cabazitaxel plus prednisone at 25 mg/m² (Arm A) or 20 mg/m² (Arm B) versus docetaxel plus prednisone (Arm C) in term of overall survival (OS) in patients with metastatic castration resistant prostate cancer (mCRPC) and not previously treated with chemotherapy.

Secondary Objectives:

- To evaluate safety in the 3 treatment arms.

- To compare efficacy of cabazitaxel at 20 mg/m² and 25 mg/m² to docetaxel for:

- Progression Free Survival (PFS) (RECIST 1.1)

- Tumor progression free survival (RECIST 1.1)

- Tumor response in patients with measurable disease (RECIST 1.1),

- PSA response

- PSA-Progression free survival (PSA-PFS).

- Pain response in patients with stable pain at baseline

- Pain progression free survival

- **Time to occurrence of any skeletal related events (SRE)**

- **To compare Health-Related Quality of Life (HRQL).**

- **To assess the pharmacokinetics and pharmacogenomics of cabazitaxel.**

Brief Summary in Scientific Language

Patients will be treated until progressive disease, unacceptable toxicity, or patient's refusal of further study treatment. All patients will be followed when on study treatment and after completion of study treatment during follow up period until death or the study cutoff date, whichever comes first.

Organizational Data

- DRKS-ID: **DRKS00006504**
- Date of Registration in DRKS: **2015/01/09**
- Date of Registration in Partner Registry or other Primary Registry: **2011/03/03**
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- Universal Trial Number (UTN): **U1111-1117-8356**
- EudraCT-No.
  (for studies acc. to Drug Law): **2010-022064-12**
- Primary Registry-ID: **NCT01308567 (ClinicalTrials.gov)**
- Sponsor-ID: **EFC11784 (Sanofi)**
- Other Secondary-ID: **2010-022064-12**
- Other Secondary-ID: **U1111-1117-8356**

Health condition or Problem studied

- Free text: **Prostate Cancer**
- ICD10: **C61 - Malignant neoplasm of prostate**

Interventions/Observational Groups

- Arm 1: **Drug: Cabazitaxel (XRP6258)**
- Arm 2: **Drug: Docetaxel (XRP6976)**
- Arm 3: **Drug: Prednisone**

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: up to 57 months

Secondary Outcome

- Progression Free Survival (PFS); time frame: up to 57 months

Countries of recruitment

- US **United States**
- AU **Australia**
- BY **Belarus**
- BR **Brazil**
- CA **Canada**
- CN **China**
- CZ **Czech Republic**
- DK **Denmark**

DK **Denmark**

- FI **Finland**
- FR **France**
- DE **Germany**
- IL **Israel**
- IT **Italy**
- JP **Japan**
- MX **Mexico**
- PE **Peru**
- PL **Poland**
- PT **Portugal**
- RO **Romania**
- RU **Russian Federation**
- ES **Spain**
- SE **Sweden**
- TW **Taiwan, Province of China**
- TR **Turkey**
- UA **Ukraine**

Locations of Recruitment

- **Investigational Site Number 276003, Aachen**
- **Investigational Site Number 276005, Berlin**
- **Investigational Site Number 276001, Düsseldorf**
- **Investigational Site Number 276004, Erlangen**
- **Investigational Site Number 276002, Homburg**
- **Investigational Site Number 276006, München**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2011/05/31**
- Target Sample Size: **1170**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

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

Additional Inclusion Criteria

Inclusion criteria :

- I 01. Histologically- or cytologically-confirmed prostate adenocarcinoma.

- I 02. Metastatic disease.

- I 03. Progressive disease while receiving hormonal therapy or after surgical castration .

Exclusion criteria

Exclusion criteria:

- E 01. Prior chemotherapy for prostate cancer,

- E 02. Less than 28 days elapsed from prior treatment with estramustine, radiotherapy or surgery to the time of randomization. Patients may be on biphosphonates prior to study entry.

- E 03. Prior isotope therapy, whole pelvic radiotherapy, or radiotherapy to >30% of bone marrow.

- E 04. Adverse events (excluding alopecia and those listed in the specific exclusion criteria) from any prior anticancer therapy of grade >1(National Cancer Institute Common Terminology Criteria [NCI CTCAE] v4.03) at the time of randomization.

- E 05. Less than 18 years (or country's legal age of majority if the legal age is >18 years).

- E 06. Eastern Cooperative Oncology Group (ECOG) performance status >2.

- E 07. History of brain metastases, uncontrolled spinal cord compression, or carcinomatous meningitis or new evidence of brain or leptomeningeal disease.

- E 08. Prior malignancy.

- E 09. Participation in another clinical trial and any concurrent treatment with any investigational drug within 30 days prior to randomization.

- E 10. Any of the following within 6 months prior to study enrollment: myocardial infarction, severe/unstable angina pectoris, coronary/peripheral artery bypass graft, NYHA class III or IV congestive heart failure, stroke or transient ischemic attack.

- E 11. Any of the following within 3 months prior to randomization: treatment resistant peptic ulcer disease, erosive esophagitis or gastritis, infectious or inflammatory bowel disease, diverticulitis, pulmonary embolism, or other uncontrolled thromboembolic event.

- E 12. Acquired immunodeficiency syndrome (AIDS-related illnesses) or known HIV disease requiring antiretroviral treatment.

- E 13. Any severe acute or chronic medical condition which could impair the ability of the patient to participate to the study or interfere with interpretation of study results, or patient unable to comply with the study procedures.

- E 14. Absence of signed and dated Institutional Review Board (IRB)-approved patient informed consent form prior to enrollment into the study.

- E 15. Patients with reproductive potential who do not agree to use accepted and effective method of contraception during the study treatment period.

- E 16. History of hypersensitivity to docetaxel, or polysorbate 80.

- E 17. Inadequate organ and bone marrow function

- E 18. Contraindications to the use of corticosteroid treatment.

- E 19. Symptomatic peripheral neuropathy grade >2 (National Cancer Institute Common Terminology Criteria [NCI CTCAE] v.4.03).

The above information is not intended to contain all considerations relevant to a patient's potential participation in a clinical trial.

Addresses

■ **Primary Sponsor**

Sanofi

Primary Sponsor

Sanofi

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

- **Contact for Scientific Queries**

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Clinical Sciences & Operations

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URL: **[---]***

- **Contact for Public Queries**

Sanofi
Clinical Sciences & Operations

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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

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: 3

- 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.