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

Trial Description

Title

A Phase 3 Randomized, Placebo-controlled Double-blind Study of JNJ-56021927 in Combination With Abiraterone Acetate and Prednisone Versus Abiraterone Acetate and Prednisone in Subjects With Chemotherapy-naive Metastatic Castration-resistant Prostate Cancer (mCRPC)

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

The purpose of this study is to compare the radiographic progression-free survival (rPFS) of JNJ56021927 in combination with abiraterone acetate (AA) plus prednisone or prednisolone (AAP) and AAP in participants with chemotherapy-naive (participants who did not receive any chemotherapy [treatment of cancer using drugs]) metastatic castration-resistant prostate cancer (mCRPC) (cancer of prostate gland [gland that makes fluid that aids movement of sperm]).

Brief Summary in Scientific Language

This is a randomized (study drug assigned by chance), double-blind (neither the Investigator nor the participant know the treatment) placebo-controlled and multicenter (when more than 1 hospital or medical school team work on a medical research study) study to determine if participants with chemotherapy-naive mCRPC will benefit from the addition of JNJ56021927 to AAP compared with AAP alone. The study consists of 3 phases: Screening phase; Treatment phase, and Follow-up phase. Participants' safety will be monitored throughout the study.

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00007764**
- Date of Registration in DRKS: **2015/02/18**
- Date of Registration in Partner Registry or other Primary Registry: **2014/10/02**
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- Primary Registry-ID: **NCT02257736 (ClinicalTrials.gov)**
- Sponsor-ID: <style fontName='DejaVu Sans' isBold='true'>CR105505 (Janssen Research & Development, LLC)</style>
- Other Secondary-ID: **56021927PCR3001**

Health condition or Problem studied

- Free text: **Prostatic Neoplasms**
- ICD10: **C61 - Malignant neoplasm of prostate**

Interventions/Observational Groups

- Arm 1: **Drug: JNJ56021927**
- Arm 2: **Drug: Abiraterone acetate**
- Arm 3: **Drug: Prednisone**
- Arm 4: **Drug: Placebo**

Characteristics

- Study Type: **Interventional**

Study Type: **Interventional**

- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **patient/subject, investigator/therapist**
- Control: **Placebo**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **III**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

- Radiographic Progression-free Survival (rPFS).; time frame: Time from randomization until death or lost to follow-up or withdrawal of consent or study termination, whichever occurs first, up to 5 years; Radiographic progression of bone is determined if there are more than or equal (>=) to 2 new lesions if less than (<) 12 weeks from randomization and there are 2 additional new lesions when observed 6 weeks later or, >= 2 new lesions after more than 12 weeks from randomization and the same is confirmed 6 weeks later or, progression of soft tissue lesion as per Response Evaluation Criteria in Solid Tumors (RECIST) Version 1.1.

Secondary Outcome

- Overall Survival (OS); time frame: Time from randomization until death or lost to follow-up or withdrawal of consent or study termination, whichever occurs first, up to 5 years; The OS is defined as the time from randomization to date of death from any cause.
- Time to Chronic Opioid Use; time frame: Baseline up to 5 years; Time to chronic opioid use is defined as the time from date of randomization to the first date of opioid use.
- Time to Initiation of Cytotoxic Chemotherapy; time frame: Baseline up to 5 years; Time to initiation of cytotoxic chemotherapy is defined as the time from date of randomization to the date of initiation of cytotoxic chemotherapy.
- Time to Pain Progression; time frame: Baseline up to 5 years; Time to pain progression is defined as time from randomization to progression in worst pain over the last 24 hours (item 3) in the Brief pain inventory-short form (BPI-SF). BPI-SF is a self-evaluated pain assessment form consisting of 15 items. The Worst Pain-item 3 of the BPI-SF scale is used to assess pain on 11-point Likert scale which has range: 0 (no pain) to 10 (pain as bad as you can imagine).

Countries of recruitment

- AR **Argentina**
- AU **Australia**
- BE **Belgium**
- BR **Brazil**
- CA **Canada**
- FR **France**
- DE **Germany**
- JP **Japan**
- KR **Korea, Republic of**
- MX **Mexico**
- NL **Netherlands**
- RU **Russian Federation**
- ZA **South Africa**
- ES **Spain**
- UK **United Kingdom**
- US **United States**

Locations of Recruitment

- **Berlin**
- **Braunschweig**
- **Dresden**
- **Frankfurt**
- **Freiburg**
- **Hamburg**
- **Heidelberg**
- **Homburg**
- **Muenchen**
- **Muenster**
- **Nuertingen**
- **Tübingen**
- **Wuppertal**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2014/11/30**
- 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

- Adenocarcinoma of the prostate

- Metastatic disease as documented by technetium-99m (99mTc) bone scan or metastatic lesions by computed tomography (CT) or magnetic resonance imaging (MRI) scans (visceral or lymph node disease). If lymph node metastasis is the only evidence of metastasis, it must be greater than or equal to (>=) 2 centimeter (cm) in the longest diameter

- Castration-resistant prostate cancer demonstrated during continuous androgen deprivation therapy (ADT), defined as 3 rises of PSA, at least 1 week apart with the last androgen deprivation therapy (PSA) >= 2 nanogram per milliliters (ng/mL)

- Participants who received a first generation anti-androgen (eg, bicalutamide, flutamide, nilutamide) must have at least a 6-week washout prior to randomization and must show continuing disease (PSA) progression (an increase in PSA) after the washout period

- Prostate cancer progression documented by prostate-specific antigen (PSA) according to the Prostate Cancer Clinical Trials Working Group (PCWG2) or radiographic progression of soft tissue according to modified Response Evaluation Criteria in Solid Tumors, version 1.1 (RECIST) modified based on PCWG2, or radiographic progression of bone according to PCWG2

Exclusion criteria

- Small cell or neuroendocrine carcinoma of the prostate

- Known brain metastases

- Prior chemotherapy for prostate cancer, except if administered in the adjuvant/neoadjuvant setting

- Previously treated with ketoconazole for prostate cancer for greater than 7 days

- Therapies that must be discontinued or substituted at least 4 weeks prior to randomization include the following: a) Medications known to lower the seizure threshold, b) Herbal and non-herbal products that may decrease PSA levels (example [eg], saw palmetto, pomegranate) or c) Any investigational agent

- At Screening need for parenteral or oral opioid analgesics (eg, codeine, dextropropoxyphene)

Addresses

■ **Primary Sponsor**

Janssen Research & Development, LLC

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

■ **Contact for Scientific Queries**

Janssen Research & Development, LLC
Janssen Research & Development, LLC Clinical Trial

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

■ **Contact for Public Queries**

Use link at the bottom of the page to see if you qualify for an enrolling site (see list). If you still have questions:

Contact for Public Queries

Use link at the bottom of the page to see if you qualify for an enrolling site (see list). If you still have questions:

Telephone: **[---]***
Fax: **[---]***
E-mail: **JNJ.CT at sylogent.com**
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 ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

- Further trial documents **To learn how to participate in this trial please click here.**

Additional Trial Attributes

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

German director of clinical investigation:

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

- *Further contact:*

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

- *Function of contact: **[---]****
- *Non-interventional study: **[---]****
- *Stage: **[---]****

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: 9
- Last processed date by ClinicalTrials.gov: 2016/04/10

* *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.*