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

Trial Description

Title

A Phase 3b Multicenter, Open-label Abiraterone Acetate Long-term Safety Study

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

The purpose of this study is to collect follow-up safety data from participants in completed abiraterone acetate studies for a maximum duration of 6 years.

Brief Summary in Scientific Language

This is a nonrandomized (individuals will not be assigned by chance to study treatments), open-label (individuals will know the identity of study treatments), long-term safety follow-up study of abiraterone acetate in approximately 300 patients from other completed abiraterone acetate clinical studies. Patients must have received at least 3 months of treatment with abiraterone acetate and a low-dose corticosteroid and, based on investigator assessment, may benefit from continued treatment. This study will consist of a screening period followed by open-label treatment of continued abiraterone acetate access. The patients will continue with the same abiraterone acetate and low-dose corticosteroid dosing regimen they were receiving in the previous abiraterone acetate clinical study until the investigator determines that the patient is no longer receiving benefit or the sponsor terminates the study. Patients can be withdrawn from the study if an alternative access (eg, patient-assistance program or commercial source of abiraterone acetate) is available and feasible. Each cycle of treatment will be 28 days. Investigators will monitor

and assess the patients for response to treatment or progression according to routine practice or as clinically indicated to determine whether continued treatment with abiraterone acetate is warranted. No efficacy data are being collected. Safety will be monitored throughout the study for a maximum duration of 6 years. End-of-study assessments will be performed at least 30 days after the last dose of abiraterone or upon early withdrawal.

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00006473**
- Date of Registration in DRKS: **2014/09/19**
- Date of Registration in Partner Registry or other Primary Registry: **2012/01/23**
- 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): **2011-005243-28**
- Primary Registry-ID: **NCT01517802 (ClinicalTrials.gov)**
- Sponsor-ID: <style fontName='DejaVu Sans' isBold='true'>CR100797 (Janssen Research & Development, LLC)</style>
- Other Secondary-ID: **212082PCR3010**
- Other Secondary-ID: **2011-005243-28**

Health condition or Problem studied

- Free text: **Metastatic Castration-resistant Prostate Cancer**
- Free text: **Metastatic Breast Cancer**
- ICD10: **C61 - Malignant neoplasm of prostate**

ICD10: **C61 - Malignant neoplasm of prostate**

- ICD10: **C50 - Malignant neoplasm of breast**

Interventions/Observational Groups

- Arm 1: **Drug: Abiraterone acetate**
- Arm 2: **Drug: Prednisone**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Treatment**
- Assignment: **Single (group)**
- Phase: **III**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

- The number of participants affected by a serious adverse event; time frame: Up to 30 days after the last dose of study drug

Secondary Outcome

[---]*

Countries of recruitment

- US **United States**
- AU **Australia**
- BE **Belgium**
- DE **Germany**
- ES **Spain**
- UK **United Kingdom**

Locations of Recruitment

- **Hamburg**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2012/03/31**
- Target Sample Size: **300**
- Monocenter/Multicenter trial: **[---]***
- National/International: **[---]***

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **no minimum age**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

- Currently participating in an abiraterone acetate clinical study considered complete and had received at least 3 months of treatment with abiraterone acetate tablets.

Exclusion criteria

- Medical conditions that require hospitalization.

- Any condition or situation which, in the opinion of the investigator, may put the patient at significant risk, may confound the study results, or may interfere significantly with the patient's participation in the study.

Addresses

- **Primary Sponsor**

  Janssen Research & Development, LLC

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**

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

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 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: 4

- 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.