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

## Trial Description

### Title

**A Randomized, Double Blind, Placebo-Controlled, Phase IIIb Study of the Efficacy and Safety of Continuing Enzalutamide in Chemotherapy Naïve Metastatic Castration Resistant Prostate Cancer Patients Treated With Docetaxel Plus Prednisolone Who Have Progressed on Enzalutamide Alone**

### Trial Acronym

**PRESIDE**

### URL of the trial

**[---]***

### Brief Summary in Lay Language

**The purpose of the study is to understand if there is benefit in continued treatment with a medicine called enzalutamide, when starting treatment with docetaxel and prednisolone (a standard chemotherapy for prostate cancer), after the prostate cancer has gotten worse when treated with enzalutamide alone.**

### Brief Summary in Scientific Language

**The study will be conducted in consecutive periods of open label treatment with enzalutamide followed by randomized double-blind treatment with continued enzalutamide or placebo, in combination with docetaxel and prednisolone.**

**Open Label (Period 1) At Week 13, all subjects will be assessed by prostate-specific antigen (PSA) and imaging. Subjects with no confirmed PSA response or evidence of radiographic progression will be ineligible for participation in Period 2 and will typically have safety follow up; however, Period 1 treatment may continue for some subjects as long as the investigator considers it to be of clinical benefit (stopping on initiation of any new antineoplastic therapy). Subjects with confirmed PSA response will continue Period 1 until**

**disease progression.**

**Randomization (Period 2) 274 subjects with confirmed disease progression on enzalutamide alone who continue to meet all eligibility criteria may proceed to randomization. Treatment allocation will be in a 1:1 ratio, stratified by disease progression in Period 1 to the following treatments:**

- **Enzalutamide with docetaxel and prednisolone**
- **Placebo with docetaxel and prednisolone**

## Organizational Data

- DRKS-ID: **DRKS00008812**
- Date of Registration in DRKS: **2015/06/25**
- Date of Registration in Partner Registry or other Primary Registry: **2014/11/07**
- 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): **2013-004711-50**
- Primary Registry-ID: **NCT02288247 (ClinicalTrials.gov)**
- Sponsor-ID: **9785-MA-1001 (Astellas Pharma Europe Ltd.)**
- Other Secondary-ID: **2013-004711-50**

## Health condition or Problem studied

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

## Interventions/Observational Groups

- Arm 1: **Drug: Enzalutamide**
- Arm 2: **Drug: Docetaxel**
- Arm 3: **Drug: Prednisolone**
-

Arm 4: **Drug: Placebo**

## Characteristics

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

### Primary Outcome

**- Progression free survival (PFS); time frame: Until subject discontinuation (up to 3 years); PFS is defined as the time from randomization to the earliest objective evidence of radiographic progression, unequivocal clinical progression, or death on study, whichever occurs first**

### Secondary Outcome

**- Time to prostate-specific antigen (PSA) progression; time frame: Until subject discontinuation (up to 3 years); Time (in months) from randomization to the date of the first PSA value in Period 2 demonstrating progression (Period 2)**
**- PSA response; time frame: Until subject discontinuation (up to 3 years); Percentage change in PSA from randomization to Week 13 (or earlier for those that discontinue therapy), as well as the maximum decline in PSA that occurs at any point after treatment**
**- Objective response rate; time frame: Until subject discontinuation (up to 3 years); Best overall radiographic response after randomization as per the Investigator assessments of response for soft tissue disease per RECIST 1.1, in subjects who have a measurable tumor**
**- Time to pain progression; time frame: Until subject discontinuation (up to 3 years); Time (in months) to an increase of >= 30% from randomization in the mean of Brief Pain Inventory Short Form (BPI-SF) pain intensity item scores**
**- Time to opiate use for cancer-related pain; time frame: Until subject discontinuation (up to 3 years); Time (in months) to initiation of chronic administration of opiate analgesia**
**- Time to first skeletal-related event (SRE); time frame: Until subject discontinuation (up to 3 years); Time (in months) from randomization to radiation therapy or surgery to bone, pathologic bone fracture, spinal cord compression, or change of antineoplastic therapy to treat bone pain**
**- Quality of life; time frame: Until subject discontinuation (up to 3 years); Assessed using Functional Assessment of Cancer Therapy - Prostate (FACT-P) and EuroQol 5**

**dimension, 5 level health state utility index (EQ-5D-5L)**

## Countries of recruitment

- AT **Austria**
- BE **Belgium**
- CZ **Czech Republic**
- FR **France**
- DE **Germany**
- GR **Greece**
- IT **Italy**
- NL **Netherlands**
- NO **Norway**
- PL **Poland**
- RU **Russian Federation**
- ES **Spain**
- SE **Sweden**
- CH **Switzerland**
- TR **Turkey**
- UK **United Kingdom**

## Locations of Recruitment

- **Site DE49008, Aachen**
- **Site DE49010, Bergisch Gladbach**
- **Site DE49001, Hannover**
- **Site DE49006, Heidelberg**
- **Site DE49003, Mannheim**
- **Site DE49002, Muenster**
- **Site DE49018, Nuertingen**
- **Site DE49015, Tuebingen**
- **Site DE49017, Ulm**
- **Site DE49004, Wuppertal**

## Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2014/11/30**
- Target Sample Size: **650**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

### Inclusion Criteria

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

### Additional Inclusion Criteria

**- Histologically confirmed adenocarcinoma of the prostate without neuroendocrine differentiation or small cell features;**

**- Ongoing androgen deprivation therapy (ADT) with a luteinizing hormone-releasing hormone (LHRH) agonist or antagonist at a stable dose and schedule within 4 weeks of initiation of investigational medicinal product (IMP), or bilateral orchiectomy (i.e., surgical or medical castration);**

**- Metastatic disease documented by at least 2 bone lesions on bone scan, or soft tissue disease documented by computed tomography (CT)/magnetic resonance imaging (MRI);**

**- Progressive disease at study entry defined as the following occurring in the setting of castrate levels of testosterone: Prostate specific antigen (PSA) progression defined by a minimum of three rising PSA levels with an interval of ≥ 1 week between each determination.**

**- Asymptomatic or minimally symptomatic prostate cancer (Brief Pain Inventory - Short Form (BPI-SF) question 3 score of < 4);**

**- Eastern Cooperative Oncology Group (ECOG) performance score of 0-1;**

**- Estimated life expectancy of ≥ 12 months;**

**- Be suitable and willing to receive chemotherapy as part of the trial;**

**- Able to swallow the IMP and comply with study requirements;**

**- Subject agrees not to participate in another interventional study while on treatment.**

**Exclusion criteria**

**- Prior treatment with the following agents for the treatment of prostate cancer: Aminoglutethimide; Ketoconazole; Abiraterone; Enzalutamide or participation in a clinical trial of enzalutamide; 223Ra, 89Sr, 153Sm, 186Re/188Re; Immunomodulatory therapies; Cytotoxic chemotherapy; Participation in a clinical trial of an investigational agent that inhibits the AR or androgen synthesis unless the treatment was placebo;**

**- Current or prior treatment within 4 weeks prior to initiation of IMP with the following agents for the treatment of prostate cancer: Antiandrogens; 5-α reductase inhibitors; Estrogens; Anabolic steroids; Drugs with antiandrogenic properties; Progestational agents;**

**- Subject has received investigational therapy within 28 days or 5 half-lives whichever is longer, prior to initiation of IMP;**

**- Use of opiate analgesia for pain from prostate cancer within 4 weeks prior to initiation of IMP;**

**- Radiation therapy to bone lesions or prostatic bed within 4 weeks prior to initiation of IMP;**

**- Major surgery within 4 weeks prior to initiation of IMP;**

**- History of seizure or any condition that may predispose to seizures at any time in the past. History of loss of consciousness or transient ischemic attack within 12 months prior to Screening;**

**- Known or suspected brain metastasis or active leptomeningeal disease;**

**- History of another malignancy within the previous 5 years other than non-melanoma skin cancer;**

**- Clinically significant cardiovascular disease;**

**- Gastrointestinal disorders affecting absorption;**

**- Medical contraindications to the use of prednisolone or docetaxel;**

- **Allergies to any of the active ingredients or excipients in the study drugs**

## Addresses

■ **Primary Sponsor**

**Astellas Pharma Europe Ltd.**

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

■ **Contact for Scientific Queries**

**Astellas Pharma Europe Ltd.**
**Medical Director**

Telephone: **[---]***
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**Medical Affairs Europe**

Telephone: **+44(0)20 3379 8000**
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E-mail: **Astellas.registration at astellas.com**
URL: **[---]***

■ **Collaborator, Other Address**

**Medivation, Inc.**

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

## Sources of Monetary or Material Support

■ **[---]***

**Bitte wenden Sie sich an den Sponsor / Please refer to primary sponsor**

**[---]***

**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

*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.*