Safety and Efficacy Study of Enzalutamide in Patients With Nonmetastatic Castration-Resistant Prostate Cancer (PROSPER)

This study is currently recruiting participants. (see Contacts and Locations)

Verified June 2015 by Medivation, Inc.

Sponsor:
Medivation, Inc.

Collaborator:
Astellas Pharma Inc

Information provided by (Responsible Party):
Medivation, Inc.

ClinicalTrials.gov Identifier:
NCT02003924

First received: December 3, 2013
Last updated: June 17, 2015
Last verified: June 2015
History of Changes

Purpose

The purpose of this study is to assess the safety and efficacy of **enzalutamide** in patients with non metastatic prostate cancer.

Condition	Intervention	Phase
Nonmetastatic Castration-Resistant Prostate Cancer Prostate Cancer Cancer of the Prostate	Drug: **Enzalutamide** Drug: Placebo	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
Primary Purpose: Treatment

Official Title: A Multinational, Phase 3, Randomized, Double Blind, Placebo Controlled, Efficacy and Safety Study of **Enzalutamide** in Patients With Nonmetastatic Castration Resistant Prostate Cancer

Resource links provided by NLM:

Genetics Home Reference related topics: prostate cancer

MedlinePlus related topics: Cancer Prostate Cancer

Drug Information available for: Enzalutamide

U.S. FDA Resources

Further study details as provided by Medivation, Inc.:

Primary Outcome Measures:

- Metastasis Free Survival (MFS) [Time Frame: ≥ 16 weeks] [Designated as safety issue: No]

Secondary Outcome Measures:

- Overall Survival (OS) [Time Frame: ≥ 16 weeks] [Designated as safety issue: No]
- Time to Pain Progression [Time Frame: ≥ 16 weeks] [Designated as safety issue: No]
- Time to Opiate Use for Prostate Cancer Pain [Time Frame: ≥ 16 weeks] [Designated as safety issue: No]
- Time to First Use of Cytotoxic Chemotherapy [Time Frame: ≥ 16 weeks] [Designated as safety issue: No]
- Time to First Use of New Antineoplastic Therapy [Time Frame: ≥ 16 weeks] [Designated as safety issue: No]
- Time to Prostate-Specific Antigen (PSA) Progression [Time Frame: ≥ 16 weeks] [Designated as safety issue: No]
- FACT-P Global Score [Time Frame: ≥ 16 weeks] [Designated as safety issue: No]
- Quality of Life as assessed by EQ-5D-5L and QLQ-PR25 [Time Frame: ≥ 16 weeks] [Designated as safety issue: No]

Estimated Enrollment:	1560
Study Start Date:	December 2013
Estimated Study Completion Date:	December 2019
Estimated Primary Completion Date:	June 2019 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Sham Comparator: Placebo Sugar pill manufactured to mimic **Enzalutamide** 40 mg capsule	Drug: Placebo Sugar pill to mimic **enzalutamide**
Experimental: **Enzalutamide** 160 mg by mouth once daily	Drug: **Enzalutamide** 160 mg by mouth once daily Other Names: • **MDV3100** • **Xtandi**

Eligibility

Ages Eligible for Study:	18 Years and older
Genders Eligible for Study:	Male
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Histologically or cytologically confirmed adenocarcinoma of the prostate without neuroendocrine differentiation, signet cell, or small cell features;
- Ongoing androgen deprivation therapy with a GnRH agonist/antagonist or prior bilateral orchiectomy (medical or surgical castration);
- Testosterone ≤ 50 ng/dL (≤ 1.73 nmol/L) at screening;
- Progressive disease on androgen deprivation therapy at enrollment;
- PSA and the screening PSA assessed by the central laboratory (central PSA) should be ≥ 2 µg/L (2 ng/mL:
- PSA doubling time ≤ 10 months;
- No prior or present evidence of metastatic disease;
- Asymptomatic prostate cancer;
- Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1;
- Estimated life expectancy ≥ 12 months.

Exclusion Criteria:

- Prior cytotoxic chemotherapy;
- Use of hormonal therapy or biologic therapy for prostate cancer (other than approved bone targeting agents and GnRH agonist/antagonist therapy) or use of an investigational agent within 4 weeks of randomization;
- Known or suspected brain metastasis or active leptomeningeal disease;
- History of another invasive cancer within 3 years of randomization;
- Absolute neutrophil count < 1000/µL, platelet count < 100,000/µL, or hemoglobin < 10 g/dL (6.2 mmol/L) at screening;
- Total bilirubin ≥ 1.5 times the upper limit of normal;
- Creatinine > 2 mg/dL (177 µmol/L) at screening;
- Albumin < 3.0 g/dL (30 g/L) at screening;

- History of seizure or any condition that may predispose to seizure;
- Clinically significant cardiovascular disease;
- Gastrointestinal disorder affecting absorption;
- Major surgery within 4 weeks of randomization;
- Hypersensitivity reaction to the active pharmaceutical ingredient or any of the capsule components, including Labrasol, butylated hydroxyanisole, and butylated hydroxytoluene;
- Any concurrent disease, infection, or comorbid condition that interferes with the ability of the patient to participate in the trial, which places the patient at undue risk, or complicates the interpretation of data, in the opinion of the investigator or medical monitor.

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02003924

Contacts

Contact: Mohammad Hirmand, MD	415-543-3470	mohammad.hirmand@medivation.com
Contact: Kristina Wilson	415-543-3470	kristina.wilson@medivation.com

Show 251 Study Locations

Sponsors and Collaborators

Medivation, Inc.

Astellas Pharma Inc

More Information

No publications provided

Responsible Party:	Medivation, Inc.
ClinicalTrials.gov Identifier:	NCT02003924 History of Changes
Other Study ID Numbers:	**MDV3100-**14
Study First Received:	December 3, 2013
Last Updated:	June 17, 2015
Health Authority:	United States: Food and Drug Administration

Additional relevant MeSH terms:

Prostatic Neoplasms	Neoplasms by Site
Genital Diseases, Male	Prostatic Diseases
Genital Neoplasms, Male	Urogenital Neoplasms
Neoplasms	

ClinicalTrials.gov processed this record on July 12, 2015