Purpose

This is a phase 3 study to compare the clinical benefit of **MDV3100** versus placebo in patients with castration-resistant prostate cancer who have been previously treated with docetaxel-based chemotherapy.

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<th>Condition</th>
<th>Intervention</th>
<th>Phase</th>
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<td>Castration-Resistant Prostate Cancer</td>
<td>Drug: <strong>Enzalutamide</strong> Drug: Placebo</td>
<td>Phase 3</td>
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Study Type: Interventional

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

Official Title: AFFIRM: A Multinational Phase 3, Randomized, Double-Blind, Placebo-Controlled Efficacy and Safety Study of Oral **MDV3100** in Patients With Progressive Castration-Resistant Prostate Cancer Previously Treated With Docetaxel-Based Chemotherapy

Resource links provided by NLM:
- MedlinePlus related topics: Cancer Prostate Cancer
- Drug Information available for: Docetaxel
- U.S. FDA Resources

Further study details as provided by Medivation, Inc.:

Primary Outcome Measures:
- Overall Survival [ Time Frame: During study period (up to 3 years) ] [ Designated as safety issue: No ]

Survival is defined as time from randomization to death due to any cause. The duration of overall survival was right-censored for patients who were lost to follow-up since randomization or not known to have died at the data analysis cutoff date (this included patients who were known to have died after the data analysis cutoff date).

Secondary Outcome Measures:
- Radiographic Progression-free Survival [ Time Frame: During study period (up to 3 years) ] [ Designated as safety issue: No ]

Radiographic progression-free survival was defined as time from randomization to the earliest objective evidence of radiographic progression or death due to any cause. Patients were assessed for objective disease progression at regularly scheduled visits. The consensus guidelines of the Prostate Cancer Clinical Trials Working Group 2 were taken into consideration for the determination of disease progression. Radiographic disease progression was defined by RECIST 1.1 for soft tissue disease, or the appearance of two or more new bone lesions on bone scan.
Progression at the first scheduled reassessment at Week 13 required a confirmatory scan 6 or more weeks later. Patients who did not reach the endpoint were right censored at their last assessment.

- Time to First Skeletal-related Event [Time Frame: During study period (up to 3 years)] [Designated as safety issue: No]
  The time to first skeletal-related event was defined as time from randomization to the occurrence of the first skeletal-related event. Patients were assessed for skeletal-related events at regularly scheduled visits. A skeletal-related event was defined as radiation therapy or surgery to bone, pathologic bone fracture, spinal cord compression, or change of antineoplastic therapy to treat bone pain. Patients who did not reach the endpoint were right censored at their last assessment.

- Functional Assessment of Cancer Therapy - Prostate (FACT-P) [Time Frame: During study period (up to 3 years)] [Designated as safety issue: No]
  The FACT-P questionnaire is a 39-item questionnaire consisting of 5 domains: “physical well-being,” “social/family well-being,” “emotional well-being,” “functional well-being,” and “additional concerns” (consisting of items relating to prostate cancer and its treatment). Each item can be answered on a scale of 0-4. The sum of scores on all 5 domains constitutes the FACT-P.
  Patients were defined as having a quality of life response if they had a 10-point improvement in their global FACT-P score, as compared with baseline, on two consecutive measurements obtained at least 3 weeks apart.

- Time to Prostate-specific Antigen (PSA) Progression [Time Frame: Baseline and at every study visit from week 13 while on study drug (up to 3 years)] [Designated as safety issue: No]
  Time to PSA progression was defined as time from randomization to PSA progression. Patients who did not reach the endpoint were right censored at their last assessment or for patients with no post-baseline PSA assessment, date of randomization.
  For patients with PSA declines at Week 13, the PSA progression date was defined as the date that a ≥ 25% increase and an absolute increase of ≥ 2 ng/mL above the nadir was documented, which was confirmed by a second consecutive value obtained 3 or more weeks later (required only if PSA progression did not occur at last PSA assessment). For patients with no PSA declines at Week 13, PSA progression date was defined as the date that a ≥ 25% increase and an absolute increase of ≥ 2 ng/mL above the baseline was documented, which was confirmed by a second consecutive value 3 or more weeks later (required only if PSA progression did not occur at last PSA assessment).

- Percentage of Patients With Soft-tissue Objective Response [Time Frame: During study period (up to 3 years)] [Designated as safety issue: No]
  The proportion of patients with pain palliation was assessed for patients with a stable and sufficient pain burden at study entry. Pain burden was measured by question #3 of the Brief Pain Inventory (Short Form). This scale measures pain on a 0 to 10 scale with 0 indicating no pain and 10 indicating pain as bad as you can imagine. Pain palliation at Week 13 was determined for the proportion of men with baseline bone metastasis(es) who had baseline pain attributable to the metastasis(es). Palliation was defined as ≥ 30% reduction in average pain score at Week 13 compared to baseline without a ≥ 30% increase in analgesic use.

- Percentage of Patients With Prostate Specific Antigen (PSA) Response [Time Frame: During study period (up to 3 years)] [Designated as safety issue: No]
  Patients were evaluable for PSA response rate if they had a PSA level measured at baseline and at least 1 post-baseline assessment. Both PSA responses of > 50% and > 90% were determined. PSA responses required confirmation with a subsequent assessment that was conducted at least 3 weeks later.

- Percentage of Patients With Soft-tissue Objective Response [Time Frame: During study period (up to 3 years)] [Designated as safety issue: No]
  The best overall soft tissue response as assessed using RECIST v1.1 during the study was summarized using the Investigators’ response assessments and also the derived response assessments by treatment group. Only patients with measurable soft tissue disease at screening were included in this analysis. Patients with measurable disease at screening are patients who had at least 1 target lesion identified per RECIST v1.1 at screening.
  Percentage of Participants summarizes the number of patients with complete or partial objective response (%).

- European Quality of Life Five-Domain Scale (EQ-5D) [Time Frame: At Week 13 visit] [Designated as safety issue: No]
  RESULTS FOR EQ-5D WILL BE REPORTED in Q4 2013.
  The EQ-5D is a standardized instrument for use as a measure of quality of life. Five parameters (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) were assessed on 3-point categorical scales ranging from “no problem” to “severe problem.” Higher scores reflect worse quality of life.

- Circulating Tumor Cell (CTC) Conversion Rate [Time Frame: During study period (up to 3 years)] [Designated as safety issue: No]
  RESULTS FOR CTC WILL BE REPORTED IN 2014

Enrollment: 1199
Study Start Date: September 2009
Estimated Study Completion Date: November 2012
Safety and Efficacy Study of MDV3100 in Patients With Castration-Resistant Prostate Cancer

**Eligibility**

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

**Inclusion Criteria:**
- Progressive prostate cancer  
- Medical or surgical castration with testosterone less than 50 ng/dl  
- One or two prior chemotherapy regimens. At least one chemotherapy regimen must have contained docetaxel  
- ECOG performance status 0-2  
- Adequate bone marrow, hepatic, and renal function  
- Able to swallow the study drug and comply with study requirements  
- Informed consent

**Exclusion Criteria:**
- Metastases in the brain or active epidural disease  
- Another malignancy within the previous 5 years  
- Clinically significant cardiovascular disease  
- GI disorder affecting absorption

**Contacts and Locations**

Please refer to this study by its ClinicalTrials.gov identifier: NCT00974311

**Sponsors and Collaborators**

Medivation, Inc.  
Astellas Pharma Inc

**More Information**

No publications provided by Medivation, Inc.

Additional publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

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[Safety and Efficacy Study of MDV3100 in Patients With Castration-Resistant Prostate Cancer](http://clinicaltrials.gov/ct2/show/NCT00974311?term=MDV+3100&rank=7)