Trial record **1 of 1** for: BAY 17777

Previous Study | Return to List | Next Study

ODM-201 in Addition to Standard ADT and Docetaxel in Metastatic Castration Sensitive Prostate Cancer (ARASENS)

This study is currently recruiting participants.

See Contacts and Locations

Verified July 2017 by Bayer

Sponsor:
Bayer

Collaborator:
Orion Corporation, Orion Pharma

Information provided by (Responsible Party):
Bayer

ClinicalTrials.gov Identifier:
NCT02799602

First received: June 6, 2016
Last updated: July 21, 2017
Last verified: July 2017
History of Changes

Full Text View | Tabular View | No Study Results Posted | Disclaimer

How to Read a Study Record

Purpose

The purpose of the study is to assess the efficacy and safety of **BAY**1841788 (darolutamide (ODM-201)) in combination with standard androgen deprivation therapy (ADT) and docetaxel in patients with metastatic hormone sensitive prostate cancer.

Condition	Intervention	Phase
Prostatic Neoplasms	Drug: **BAY**1841788 / darolutamide (ODM-201) Drug: Standard ADT (androgen deprivation therapy) Drug: Docetaxel	Phase 3

	Drug: Placebo	

Study Type: Interventional
Study Design: Allocation: Randomized
Intervention Model: Parallel Assignment
Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)
Primary Purpose: Treatment

Official Title: A Randomized, Double-blind, Placebo Controlled Phase III Study of ODM-201 Versus Placebo in Addition to Standard Androgen Deprivation Therapy and Docetaxel in Patients With Metastatic Hormone Sensitive Prostate Cancer

Resource links provided by NLM:

Genetics Home Reference related topics: prostate cancer

MedlinePlus related topics: Allergy Hormones Prostate Cancer

Drug Information available for: Docetaxel

U.S. FDA Resources

Further study details as provided by Bayer:

Primary Outcome Measures:

- Overall survival [Time Frame: approximately 70 months]

  From date of randomization until death from any cause, during treatment and during active and long term follow-up

Secondary Outcome Measures:

- Time to castration resistant prostate cancer [Time Frame: approximately 70 months]

  Approximately every 12 weeks (according to standards of care) up to the time of PSA progression by soft tissue lesions or progression by bone lesions, whatever come first.

- Time to initiation of subsequent antineoplastic therapy [Time Frame: approximately 70 months]

  Every 12 weeks up to the date of first subsequent antineoplastic therapy for prostate cancer.

- Symptomatic skeletal event free survival (SSE-FS) [Time Frame: approximately 70 months]

  Every 12 weeks up to the first occurrence of SSE or death from any cause, whatever comes first SSE is defined as external beam radiation therapy (EBRT) to relieve skeletal symptoms, or new symptomatic pathologic bone fracture, or occurrence of spinal cord compression or tumor-related orthopedic surgical intervention, whichever comes first.

- Time to first symptomatic skeletal event (SSE) [Time Frame: approximately 70 months]

Every 12 weeks up to the first occurrence of SSE. SSE is defined as EBRT to relieve skeletal symptoms, or new symptomatic pathologic bone fracture, or occurrence of spinal cord compression or tumor-related orthopedic surgical intervention, whichever comes first.

- Time to initiation of opioid use [Time Frame: approximately 70 months]

  Every 12 weeks up to the opiod use.

- Time to pain progression [Time Frame: approximately 70 months]

  Every 12 weeks up to the first date a subject experiences a pain progression. Pain to be assessed with a patient reported questionaire.

- Time to worsening of physical symptoms of disease [Time Frame: approximately 70 months]

  Every 12 weeks up to the first date a subject experiences an increase in physical symptoms.

  Physical symptoms of disease to be assessed with a patient reported questionaire.

- Number of participants with adverse events as a measure of safety and tolerability [Time Frame: approximately 70 months]

Estimated Enrollment:	1300
Actual Study Start Date:	November 30, 2016
Estimated Study Completion Date:	August 1, 2022
Estimated Primary Completion Date:	August 1, 2022 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: **BAY**1841788 /darolutamide (ODM-201)+standard ADT+Docetaxel Co-administration of **BAY** 1841788 / darolutamide (ODM-201), standard ADT and docetaxel	Drug: **BAY**1841788 / darolutamide (ODM-201) 600 mg (2 x 300 mg tables) BID with food to a daily dose of 1200 mg in addition to standard ADT (luteinizing hormone releasing hormone (LHRH) agonist/antagonist or orchiectomy) and 6 cycles of docetaxel Drug: Standard ADT (androgen deprivation therapy) As prescribed by the treating physician. Drug: Docetaxel As prescribed by the treating physician.
Placebo Comparator: Placebo + standard ADT + Docetaxel Co-administration of Placebo matching **BAY** 1841788 / darolutamide (ODM-201) tablets, standard ADT and docetaxel	Drug: Standard ADT (androgen deprivation therapy) As prescribed by the treating physician. Drug: Docetaxel As prescribed by the treating physician. Drug: Placebo Placebo matching darolutamide (ODM-201) tablets in appearance, bid orally with food, in addition to standard ADT (luteinizing hormone releasing

	hormone [LHRH] agonist/antagonist or orchiectomy) and 6 cycles of docetaxel.

Detailed Description:

This is a randomized, double-blind, placebo-controlled, multicenter phase III study. The study population will consist of approximately 1300 subjects with metastatic hormone sensitive prostate cancer (mHSPC), who will be randomized (1:1 ratio) to receive either darolutamide (ODM-201) 600 mg (2 x 300 mg tablets) bid orally with food or placebo, in addition to standard androgen deprivation therapy (ADT) and docetaxel. Subjects will be stratified at randomization for the extent of disease and for Alkaline Phosphatase levels. All subjects will be treated with ADT as standard therapy. Six cycles of docetaxel will be administered after randomization.

The subjects considered for inclusion in the study will have metastatic prostate cancer and will be candidates for ADT and docetaxel.

Treatment with darolutamide (ODM-201)/placebo will be administered until symptomatic progressive disease, change of antineoplastic therapy, unacceptable toxicity, until subject withdraws consent, withdrawal from the study at the discretion of the Investigator or his/her designated associate(s), death, non-compliance, or if Sponsor terminates the study.

Eligibility

Ages Eligible for Study:	18 Years and older (Adult, Senior)
Sexes Eligible for Study:	Male
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Histologically or cytologically confirmed adenocarcinoma of prostate.
- Metastatic disease
- Candidates for ADT and docetaxel. Started ADT with or without first generation anti androgen, but no longer than 12 weeks before randomization
- An Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
- Adequate bone marrow, liver and renal function

Exclusion Criteria:

- Prior treatment with: LHRH agonist/antagonists; second generation androgen receptor (AR) inhibitors such as enzalutamide, ARN-509, ODM-201; other investigational AR inhibitors; CYP17 enzyme inhibitor such as abiraterone acetate or oral ketoconazole as antineoplastic treatment for prostate cancer, chemotherapy or immunotherapy for prostate cancer prior to randomization.
- Treatment with radiotherapy/radiopharmaceuticals within 2 weeks before randomization.
- Had any of the following within 6 months before randomization: stroke, myocardial infarction, severe/unstable angina pectoris, coronary/peripheral artery bypass graft, congestive heart failure (New York Heart Association Class III or IV)
- Had a prior malignancy. Adequately treated basal cell or squamous cell carcinoma of skin or superficial bladder cancer that has not spread behind the connective tissue layer (i.e., pTis, pTa, and pT1) is allowed, as well as any other cancer for which treatment has been completed 5 years before randomization and from which the subject has been disease-free

- Gastrointestinal disorder or procedure which is expected to interfere significantly with absorption of study treatment.
- Inability to swallow oral medications

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: NCT02799602

Contacts

Contact: Bayer Clinical Trials Contact clinical-tria

Contact: For trial location information (Phone Menu Options '3' or '4') (+)1-888-84 22937

Show 331 Study Locations

Sponsors and Collaborators

Bayer

Orion Corporation, Orion Pharma

Investigators

Study Director: Bayer Study Director Bayer

More Information

Additional Information:

Click here and search for drug information provided by the FDA. EXIT

Click here and search for information on any recalls, market or product safety alerts by the FDA which might have occurred with this product. EXIT

Responsible Party:	Bayer
ClinicalTrials.gov Identifier:	NCT02799602 History of Changes
Other Study ID Numbers:	**17777** 2015-002590-38 (EudraCT Number)
Study First Received:	June 6, 2016
Last Updated:	July 21, 2017

Studies a U.S. FDA-regulated Drug Product:	Yes
Studies a U.S. FDA-regulated Device Product:	No
Product Manufactured in and Exported from the U.S.:	No

Keywords provided by Bayer:
Metastatic hormone sensitive prostate cancer

Additional relevant MeSH terms:

Prostatic Neoplasms
Hypersensitivity
Genital Neoplasms, Male
Urogenital Neoplasms
Neoplasms by Site
Neoplasms
Genital Diseases, Male
Prostatic Diseases
Immune System Diseases
Docetaxel
Hormones
Prolactin Release-Inhibiting Factors
Androgens
Antineoplastic Agents
Tubulin Modulators
Antimitotic Agents
Mitosis Modulators
Molecular Mechanisms of Pharmacological Action
Hormones, Hormone Substitutes, and Hormone Antagonists
Physiological Effects of Drugs

ClinicalTrials.gov processed this record on August 22, 2017