Efficacy and Safety Study of BAY1841788 (ODM-201) in Men With High-risk Non-metastatic Castration-resistant Prostate Cancer (ARAMIS)

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

Verified June 2015 by Bayer

Sponsor:
Bayer

Information provided by (Responsible Party):
Bayer

ClinicalTrials.gov Identifier:
NCT02200614

First received: July 22, 2014
Last updated: June 18, 2015
Last verified: June 2015
History of Changes

Purpose

The purpose of this study is to assess the safety and efficacy of BAY1841788 (ODM-201) in patients with non-metastaticcastration-resistant prostate cancer.

Condition	Intervention	Phase
Prostate Cancer Non-Metastatic Castration-Resistant	Drug: BAY1841788 (ODM-201) Drug: Placebo	Phase 3

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

Official Title: A MULTINATIONAL, RANDOMISED, DOUBLE-BLIND, PLACEBO-CONTROLLED, PHASE III EFFICACY AND SAFETY STUDY OF ODM-201 IN MEN WITH HIGH-RISK NON-METASTATIC CASTRATION-RESISTANT PROSTATE CANCER

Resource links provided by NLM:

Genetics Home Reference related topics: prostate cancer

MedlinePlus related topics: Prostate Cancer

U.S. FDA Resources

Further study details as provided by Bayer:

Primary Outcome Measures:

- Metastasis-Free Survival [Time Frame: Up to 72 months] [Designated as safety issue: No]

  Time from randomisation to evidence of metastasis or death from any cause, whichever occurs first

Secondary Outcome Measures:

- Overall Survival [Time Frame: Up to 72 months] [Designated as safety issue: No]

  Date of death and primary cause of death will be recorded

- Time to first symptomatic skeletal event (SSE) [Time Frame: Up to 72 months] [Designated as safety issue: No]

Date of first SSE will be recorded

- Time to initiation of first cytotoxic chemotherapy [Time Frame: Up to 72 months] [Designated as safety issue: No]

  Name and start date of cytotoxic chemotherapy treatment will be recorded

- Time to pain progression [Time Frame: Up to 72 months] [Designated as safety issue: No]

  Date of pain progression will be recorded

Estimated Enrollment:	1500
Study Start Date:	September 2014
Estimated Study Completion Date:	June 2020
Estimated Primary Completion Date:	March 2018 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: BAY1841788 (ODM-201)	Drug: BAY1841788 (ODM-201) BAY1841788 (ODM-201) tablets 2 x 300mg bid
Placebo Comparator: Placebo	Drug: Placebo Matching placebo tablets x 2 bid

Detailed Description:

This study was transferred from ORION to Bayer in February 2015. Former ORION product ODM-201 has been renamed to BAY1841788.

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 prostate without neuroendocrine differentiation or small cell features.
- Castration-resistant prostate cancer (CRPC) with castrate level of serum testosterone.
- Prostate-specific antigen doubling time of ≤ 10 months and PSA > 2ng/ml.
- Eastern Cooperative Oncology Group (ECOG) performance status of 0-1.
- Blood counts at screening: haemoglobin ≥ 9.0 g/dl,absolute neutrophil count ≥ 1500/µl, platelet count ≥ 100,000/µl.
- Screening values of serum alanine aminotransferase (ALT) and/or aspartate transaminase (AST) ≤ 2.5 x upper limit of normal (ULN), total bilirubin ≤ 1.5 x ULN, creatinine ≤ 2.0 x ULN.
- Sexually active patients, unless surgically sterile, must agree to use condoms as an effective barrier method and refrain from sperm donation during the study treatment and for 3 months after the end of the study treatment.

Exclusion Criteria:

- History of metastatic disease or presence of detectable metastases.
- Acute toxicities of prior treatments and procedures not resolved to grade ≤ 1 or baseline before randomisation.
- Prior treatment with: second generation androgen receptor (AR) inhibitors, other investigational AR inhibitors, or CYP17 enzyme inhibitor.
- Use of estrogens, 5-α reductase inhibitors or AR inhibitors.
- Prior chemotherapy or immunotherapy for prostate cancer.
- Use of systemic corticosteroid.
- Radiation therapy within 12 weeks before randomisation.
- Severe or uncontrolled concurrent disease, infection or co-morbidity.
- Ttreatment with bisphosphonate or denosumab within 12 weeks before randomisation.
- Known hypersensitivity to the study treatment or any of its ingredients.
- Major surgery within 28 days before randomisation.
- Any of the following within 6 months before randomisation: stroke, myocardial infarction, severe/unstable angina pectoris, coronary/peripheral artery bypass graft; congestive heart failure New York Heart Association (NYHA) Class III or IV.

- Uncontrolled hypertension.
- Prior malignancy.
- Gastrointestinal disorder or procedure which expects to interfere significantly with absorption of study treatment.
- Active viral hepatitis, active human immunodeficiency virus (HIV) or chronic liver disease.
- Any condition that in the opinion of the investigator would impair the patients' ability to comply with the study procedures.

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: NCT02200614

Contacts

Contact: Bayer Clinical Trials Contact clinical-trials-contact@bayerhealthcare.com

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

Show 374 Study Locations

Sponsors and Collaborators

Bayer

Investigators

Study Director: Bayer Study Director Bayer

More Information

Additional Information:

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

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

No publications provided

Responsible Party:	Bayer
ClinicalTrials.gov Identifier:	NCT02200614 History of Changes
Other Study ID Numbers:	17712, 2013-003820-36
Study First Received:	July 22, 2014
Last Updated:	June 18, 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