An Efficacy and Safety Study of Apalutamide (JNJ-56021927) in Combination With Abiraterone Acetate and Prednisone Versus Abiraterone Acetate and Prednisone in Participants With Chemotherapy-naive Metastatic Castration-resistant Prostate Cancer (mCRPC)

This study is ongoing, but not recruiting participants.

Sponsor:
Aragon Pharmaceuticals, Inc.

Information provided by (Responsible Party):
Aragon Pharmaceuticals, Inc.

ClinicalTrials.gov Identifier:
NCT02257736

First received: October 2, 2014
Last updated: November 18, 2016
Last verified: November 2016
History of Changes

Purpose

The purpose of this study is to compare the radiographic progression-free survival (rPFS) of apalutamide in combination with abiraterone acetate (AA) plus prednisone or prednisolone (AAP) and AAP in participants with chemotherapy-naive (participants who did not receive any chemotherapy [treatment of cancer using drugs]) metastatic castration-resistant prostate cancer (mCRPC) (cancer of prostate gland [gland that makes fluid that aids movement of sperm]).

Condition	Intervention	Phase
Prostatic Neoplasms	Drug: Apalutamide Drug: Abiraterone acetate Drug: Prednisone Drug: Placebo	Phase 3

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

Official Title: A Phase 3 Randomized, Placebo-controlled Double-blind Study of JNJ-56021927 in Combination With Abiraterone Acetate and Prednisone Versus Abiraterone Acetate and Prednisone in Subjects With Chemotherapy-naive Metastatic Castration-resistant Prostate Cancer (mCRPC)

Resource links provided by NLM:

Genetics Home Reference related topics: prostate cancer

MedlinePlus related topics: Cancer Prostate Cancer Steroids

Drug Information available for: Prednisone Abiraterone acetate

U.S. FDA Resources

Further study details as provided by Aragon Pharmaceuticals, Inc.:

Primary Outcome Measures:

- Radiographic Progression-free Survival (rPFS). [Time Frame: Time from randomization until death or lost to follow-up or withdrawal of consent or study termination, whichever occurs first, up to 5 years] [Designated as safety issue: No]

  Radiographic progression of bone is determined if there are more than or equal (>=) to 2 new lesions if less than (<) 12 weeks from randomization and there are 2 additional new lesions when observed 6 weeks later or, >= 2 new lesions after more than 12 weeks from randomization and the same is confirmed 6 weeks later or, progression of soft tissue lesion as per Response Evaluation Criteria in Solid Tumors (RECIST) Version 1.1.

Secondary Outcome Measures:

- Overall Survival (OS) [Time Frame: Time from randomization until death or lost to follow-up or withdrawal of consent or study termination, whichever occurs first, up to 5 years] [Designated as safety issue: No]

  The OS is defined as the time from randomization to date of death from any cause.

- Time to Chronic Opioid Use [Time Frame: Baseline up to 5 years] [Designated as safety issue: No]

  Time to chronic opioid use is defined as the time from date of randomization to the first date of opioid use.

- Time to Initiation of Cytotoxic Chemotherapy [Time Frame: Baseline up to 5 years] [Designated as safety issue: No]

  Time to initiation of cytotoxic chemotherapy is defined as the time from date of randomization to the date of initiation of cytotoxic chemotherapy.

- Time to Pain Progression [Time Frame: Baseline up to 5 years] [Designated as safety issue: No]

  Time to pain progression is defined as time from randomization to progression in worst pain over the last 24 hours (item 3) in the Brief pain inventory-short form (BPI-SF). BPI-SF is a self-evaluated pain assessment form consisting of 15 items. The Worst Pain-item 3 of the BPI-SF scale is used to assess pain on 11-point Likert scale which has range: 0 (no pain) to 10 (pain as bad as you can imagine).

Enrollment:	983
Study Start Date:	November 2014
Estimated Study Completion Date:	December 2018
Estimated Primary Completion Date:	December 2018 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Group 1: AAP and apalutamide Participants will receive 240 milligram (mg) tablet of apalutamide and 1000 mg (four 250 mg tablets) of abiraterone acetate (AA) once daily on an empty stomach and 5 mg prednisone (P), AAP, twice daily, until disease progression, unacceptable toxicity, or end of treatment, whichever occurs first.	Drug: Apalutamide Participants will receive 240 milligram (mg) tablet of apalutamide once daily until disease progression, unacceptable toxicity, or end of treatment, whichever occurs first. Drug: Abiraterone acetate Participants will receive 1000 mg (four 250 mg tablets) of abiraterone acetate (AA) once daily on an empty stomach until disease progression, unacceptable toxicity, or end of treatment, whichever occurs first. Other Name: ZYTIGA Drug: Prednisone Participants will receive 5 mg tablet prednisone twice daily until disease progression, unacceptable toxicity, or end of treatment, whichever occurs first.
Placebo Comparator: Group 2: AAP and Placebo Participants will receive matching Placebo of apalutamide and 1000 mg (four 250 mg tablets) of abiraterone acetate (AA)once daily on an empty stomach and 5 mg prednisone (P), AAP, twice daily until disease progression, unacceptable toxicity, or end of treatment, whichever occurs first.	Drug: Abiraterone acetate Participants will receive 1000 mg (four 250 mg tablets) of abiraterone acetate (AA) once daily on an empty stomach until disease progression, unacceptable toxicity, or end of treatment, whichever occurs first. Other Name: ZYTIGA Drug: Prednisone Participants will receive 5 mg tablet prednisone twice daily until disease progression, unacceptable toxicity, or end of treatment, whichever occurs first. Drug: Placebo Participants will receive matching placebo to apalutamide once daily until study drug discontinuation.

Detailed Description:
This is a randomized (study drug assigned by chance), double-blind (neither the Investigator nor the participant know the treatment) placebo-controlled and multicenter (when more than 1 hospital or medical school team work on a medical research study) study to determine if participants with chemotherapy-naive mCRPC will benefit from the addition of apalutamide to AAP compared with AAP alone. The study consists of 3 phases: Screening phase; Treatment phase, and Follow-up phase. Participants' safety will be monitored throughout the study.

Eligibility

Ages Eligible for Study:	18 Years and older (Adult, Senior)
Genders Eligible for Study:	Male

Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Adenocarcinoma of the prostate
- Metastatic disease as documented by technetium-99m (99mTc) bone scan or metastatic lesions by computed tomography (CT) or magnetic resonance imaging (MRI) scans (visceral or lymph node disease). If lymph node metastasis is the only evidence of metastasis, it must be greater than or equal to (>=) 2 centimeter (cm) in the longest diameter
- Castration-resistant prostate cancer demonstrated during continuous androgen deprivation therapy (ADT), defined as 3 rises of PSA, at least 1 week apart with the last androgen deprivation therapy (PSA) >= 2 nanogram per milliliters (ng/mL)
- Participants who received a first generation anti-androgen (eg, bicalutamide, flutamide, nilutamide) must have at least a 6-week washout prior to randomization and must show continuing disease (PSA) progression (an increase in PSA) after the washout period
- Prostate cancer progression documented by prostate-specific antigen (PSA) according to the Prostate Cancer Clinical Trials Working Group (PCWG2) or radiographic progression of soft tissue according to modified Response Evaluation Criteria in Solid Tumors, version 1.1 (RECIST) modified based on PCWG2, or radiographic progression of bone according to PCWG2

Exclusion Criteria:

- Small cell or neuroendocrine carcinoma of the prostate
- Known brain metastases
- Prior chemotherapy for prostate cancer, except if administered in the adjuvant/neoadjuvant setting
- Previously treated with ketoconazole for prostate cancer for greater than 7 days
- Therapies that must be discontinued or substituted at least 4 weeks prior to randomization include the following: a) Medications known to lower the seizure threshold, b) Herbal and non-herbal products that may decrease PSA levels (example [eg], saw palmetto, pomegranate) or c) Any investigational agent
- At Screening need for parenteral or oral opioid analgesics (eg, codeine, dextropropoxyphene)

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: NCT02257736

Show 186 Study Locations

Sponsors and Collaborators

Aragon Pharmaceuticals, Inc.

Investigators

Study Director: Janssen Research & Development, LLC Clinical Trial Janssen Research & Development, LLC

More Information

Responsible Party:	Aragon Pharmaceuticals, Inc.
ClinicalTrials.gov Identifier:	NCT02257736 History of Changes
Other Study ID Numbers:	CR105505 56021927**PCR3001** 2014-001718-25
Study First Received:	October 2, 2014
Last Updated:	November 18, 2016
Health Authority:	United States: Food and Drug Administration Belgium: Federal Agency for Medicines and Health Products, FAMHP Japan: Pharmaceuticals and Medical Devices Agency Canada: Health Canada South Africa: Medicines Control Council France: Agence Nationale de Sécurité du Médicament et des produits de santé Brazil: National Health Surveillance Agency Great Britain: Medicines and Healthcare Products Regulatory Agency Netherlands: The Central Committee on Research Involving Human Subjects (CCMO) Argentina: Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica Germany: Federal Institute for Drugs and Medical Devices Mexico: Federal Commission for Sanitary Risks Protection Australia: Department of Health and Ageing Therapeutic Goods Administration Canada: Health Canada - TPD

Keywords provided by Aragon Pharmaceuticals, Inc.:

Prostatic neoplasms
JN56021927
ZYTIGA
Prednisone
Abiraterone acetate
Apalutamide

Additional relevant MeSH terms:

Prostatic Neoplasms
Genital Neoplasms, Male
Urogenital Neoplasms
Neoplasms by Site
Neoplasms
Genital Diseases, Male
Prostatic Diseases
Prednisone
Abiraterone Acetate
Anti-Inflammatory Agents
Glucocorticoids
Hormones
Hormones, Hormone Substitutes, and Hormone Antagonists
Physiological Effects of Drugs
Antineoplastic Agents, Hormonal
Antineoplastic Agents
Steroid Synthesis Inhibitors
Enzyme Inhibitors
Molecular Mechanisms of Pharmacological Action
Hormone Antagonists
Cytochrome P-450 Enzyme Inhibitors

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