ForPatients
by Roche

Prostate Cancer

A Study of Atezolizumab (Anti-PD-L1 Antibody) in Combination With Enzalutamide in Participants With Metastatic Castration-Resistant Prostrate Cancer (mCRPC) After Failure of an Androgen Synthesis Inhibitor And Failure of, Ineligibility For, or Refusal of a Taxane Regimen

Trial Status	Trial Runs In	Trial Identifier
Completed	21 Countries	NCT03016312 2016-003092-22 CO39385

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A Phase III, Multicenter, Randomized Study of Atezolizumab (Anti-PD-L1 Antibody) in Combination With Enzalutamide Versus Enzalutamide Alone in Patients With Metastatic Castration-Resistant Prostate Cancer After Failure of an Androgen Synthesis Inhibitor and Failure of, Ineligibility for, or Refusal of a Taxane Regimen

Trial Summary:

This Phase III, multicenter, randomized, open-label study will evaluate the safety and efficacy of atezolizumab (anti-programmed death-ligand 1 [anti-PD-L1] antibody) in combination with enzalutamide compared with enzalutamide alone in participants with mCRPC after failure of an androgen synthesis inhibitor (e.g., abiraterone) and failure of, ineligibility for, or refusal of a taxane regimen. Participants will be randomized to one of the two treatment arms (atezolizumab in combination with enzalutamide, and enzalutamide alone) in a 1:1 ratio (experimental to control arm) in global randomized phase. Participants will receive treatment until investigator-assessed confirmed radiographic disease progression per Prostate Cancer Working Group 3 (PCWG3) criteria or unacceptable toxicity.

Hoffmann-La Roche	Phase 3
Sponsor	Phase

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Eligibility Criteria:

Gender	Age	Healthy Volunteers
Male	**# 18 Years**	**No**

Inclusion Criteria:

- Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
- Life expectancy greater than or equal to (>/=) 3 months
- Histologically confirmed adenocarcinoma of the prostate
- Known castrate-resistant disease with serum testosterone level less than or equal to (</=) 50 nanograms per deciliter (ng/dL) with prior surgical castration or ongoing androgen deprivation for the duration of the study
- Progressive disease prior to screening by PSA or imaging per PCWG3 criteria during or following the direct prior line of therapy in the setting of medical or surgical castration
- One prior regimen/line of a taxane-containing regimen for mCRPC or refusal or ineligibility of a taxane-containing regimen
- Progression on a prior regimen/line of an androgen synthesis inhibitor for prostate cancer
- Availability of a representative tumor specimen from a site not previously irradiated that is suitable for determination of programmed death-ligand 1 (PD-L1) status via central testing
- Adequate hematologic and end organ function

Exclusion Criteria:

- Prior treatment with enzalutamide or any other newer hormonal androgen receptor inhibitor (e.g., apalutamide, ODM-201)
- Treatment with any approved anti-cancer therapy, including chemotherapy, immunotherapy, radiopharmaceutical or hormonal therapy (with the exception of abiraterone), within 4 weeks prior to initiation of study treatment
- Treatment with abiraterone within 2 weeks prior to study treatment
- Structurally unstable bone lesions suggesting impending fracture
- Known or suspected brain metastasis or active leptomeningeal disease
- Major surgical procedure other than for diagnosis within 4 weeks prior to initiation of study treatment or anticipation of need for a major surgical procedure during the course of the study
- Active or history of autoimmune disease or immune deficiency
- Prior allogeneic stem cell or solid organ transplantation
- History of idiopathic pulmonary fibrosis, organizing pneumonia (e.g., bronchiolitis obliterans), drug-induced pneumonitis, or idiopathic pneumonitis, or evidence of active pneumonitis on screening chest computed tomography (CT) scan
- Positive human immunodeficiency virus (HIV) test, active tuberculosis, active hepatitis B virus (HBV) or hepatitis C virus (HCV) infection
- Prior treatment with cluster of differentiation (CD)137 agonists or immune checkpoint blockade therapies, including anti Cytotoxic T Lymphocyte-Associated 4 (CTLA4), anti-programmed death 1 (PD-1), and anti-PD-L1 therapeutic antibodies
- Treatment with systemic immunostimulatory agents within 4 weeks or five half-lives of the drug, whichever is shorter, prior to initiation of study treatment
- Treatment with systemic immunosuppressive medication within 2 weeks prior to initiation of study
- History of seizure or any condition that may predispose to seizure within 12 months prior to study treatment, including history of unexplained loss of consciousness or transient ischemic attack