ForPatients
by Roche

Prostate Cancer

Safety and Tolerability of Atezolizumab (ATZ) in Combination With Radium-223 Dichloride (R-223-D) in Metastatic Castrate-Resistant Prostate Cancer (CRPC) Progressed Following Treatment With an Androgen Pathway Inhibitor

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	NCT02814669 2015-003606-17 BO30013

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 Ib, Open-Label Study of the Safety and Tolerability of Atezolizumab in Combination With Radium-223 Dichloride in Patients With Castrate-Resistant Prostate Cancer Who Have Progressed Following Treatment With an Androgen Pathway Inhibitor

Trial Summary:

This study is designed to assess the safety and tolerability of atezolizumab when given in combination with radium-223 dichloride in participants with metastatic CRPC who have progressed after treatment with an androgen pathway inhibitor. This adaptive design study includes a cohort phase and a potential randomization phase. An initial concurrent dosing evaluation will evaluate the safety and tolerability of a treatment regimen that employs a concurrent start time for atezolizumab and radium-223 dichloride (Cohort 1). If concurrent dosing is found to be safe and tolerable in Cohort 1, additional participants will be enrolled and eligible participants will be randomized in a 1:1:1 ratio to Arms A, B, and C. If concurrent dosing is not tolerated in Cohort 1, new participants will be enrolled in a staggered dosing evaluation: Cohort 2 (28-day radium-223 dichloride run-in, atezolizumab will begin on Day 1 of Cycle 2) and Cohort 3 (56-day radium-223 dichloride run-in, atezolizumab will begin on Day 1 of Cycle 3). If the Cohort 2 schedule is tolerable, then additional participants will be enrolled using this treatment schedule; If the Cohort 2 schedule is not tolerable, subsequent participants will be enrolled in Cohort 3. If the Cohort 3 schedule is tolerable, then additional participants will be enrolled using this treatment schedule. If Cohort 3 schedule is not tolerable, no additional participant will be enrolled in the study.

Hoffmann-La Roche	Phase 1
Sponsor	Phase

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Trial Identifiers

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 (>/=) 12 weeks
- Histologically confirmed, castrate-resistant adenocarcinoma of the prostate
- Measurable disease according to RECIST v1.1
- Multiple bone metastases within 12 weeks prior to study drug
- Participants receiving bisphosphonate or denosumab therapy must have been on a stable dose for at least 4 weeks
- Visceral metastasis and/or lymphadenopathy
- Tumors that are amenable to serial biopsy
- Disease progression according to Prostate Cancer Working Group 2 (PCWG2) criteria during or following treatment with at least one second generation androgen pathway inhibitor (for example, enzalutamide, abiraterone) for metastatic prostate cancer
- Adequate hematologic and end-organ function
- One prior taxane-containing regimen for mCRPC, or refusal or ineligibility of a taxane-containing regimen

Exclusion Criteria:

- History of small-cell or neuroendocrine prostate carcinoma
- Treatment with approved anti-cancer therapy (with the exception of abiraterone) within 3 weeks of study drug. Abiraterone must not be administered within 2 weeks prior to initiation of study treatment
- Participation in another clinical trial/investigation within 28 days prior to study drug
- Brain metastases or active leptomeningeal disease (with the exception of participants with treated epidural disease and no other epidural progression)
- Uncontrolled tumor-related pain
- Uncontrolled hypercalcemia
- Significant cardiovascular disease
- History of autoimmune disease except controlled/treated hypothyroidism, type 1 diabetes mellitus, or certain skin disorders
- Prior allogeneic stem cell or solid organ transplant
- History of pulmonary fibrosis/inflammation, including active tuberculosis
- Human immunodeficiency virus (HIV) or hepatitis B or C
- Prior treatment with cluster of differentiation (CD) 137 agonist, anti-programmed death (PD) 1, or anti-programmed death ligand (PD-L) 1 therapeutic antibody or pathway-targeting agents
- Immunostimulants within 4 weeks or immunosuppressants within 14 days prior to study drug
- Prior radium-223 dichloride or hemibody external radiotherapy
- Systemic strontium-89, samarium-153, rhenium-186, or rhenium-188 for bone metastases within 24 weeks prior to initiation of study treatment

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- Spinal compression or structurally unstable bone lesions suggesting impending pathologic fractures based on clinical findings and/or magnetic resonance imaging (MRI)
- Bone marrow dysplasia
- Unmanageable fecal incontinence

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