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 Countries	NCT02814669 2015-003606-17 BO30013

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

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 Sponsor	**Phase 1** Phase

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Trial Identifiers

Eligibility Criteria:

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Gender	Age	Healthy Volunteers
Male	**>=18 Years**	**No**