ForPatients
by Roche

Metastatic Prostate CancerAdvanced Prostate Cancer

A Study Evaluating the Safety, Pharmacokinetics, and Activity of RO7656594 In Participants With Advanced or Metastatic Prostate Cancer

Trial Status	Trial Runs In	Trial Identifier
Recruiting	6 Countries	NCT05800665 2023-504013-68-00 GO44537

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 1, Open-Label, Multicenter, Dose-Escalation and Expansion Study Evaluating the Safety, Pharmacokinetics, and Activity of RO7656594 in Patients With Advanced or Metastatic Prostate Cancer

Trial Summary:

The purpose of this study is to evaluate the safety, tolerability, pharmacokinetics, and preliminary activity of RO7656594 in participants with advanced or metastatic prostate cancer. It will also identify recommended doses and regimens for RO7656594 for subsequent studies.

Genentech, Inc.	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 #1.
- Metastatic prostate adenocarcinoma without small-cell carcinoma or neuroendocrine features.
- Prior therapy with a second-generation androgen receptor (AR)-targeted therapy (e.g., abiraterone, enzalutamide, apalutamide, darolutamide).

- Prior therapy with a taxane regimen or are considered ineligible for treatment with a taxane regimen or have refused treatment with a taxane regimen, unless otherwise specified.
- For participants with a known pathogenic breast cancer gene 1 (BRCA1) or BRCA2 mutation: prior therapy with a poly (adenosine diphosphate (ADP)-ribose) polymerase (PARP) inhibitor, or are considered ineligible for treatment with a PARP inhibitor, if such therapy is approved and available.

Exclusion Criteria:

- Treatment with any approved systemic anti-cancer therapy within 14 days or 5 drug elimination half-lives (whichever is longer, not to exceed 28 days) prior to the first study treatment.
- Treatment with any investigational agent within 28 days prior to the first study treatment.
- Treatment with any previous AR protein degrader.
- Untreated central nervous system (CNS) metastases or leptomeningeal disease.

Note: Other protocol specified inclusion/exclusion criteria may apply.