

ForPatients

by Roche

Metastatic Prostate Cancer Advanced Prostate Cancer

A Study Evaluating the Safety, Pharmacokinetics, and Preliminary Activity of GDC-1261 in Participants With Advanced or Metastatic Prostate Cancer

Trial Status
Recruiting

Trial Runs In
1 Country

Trial Identifier
NCT07567846 GO46445

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 I/II Dose-escalation and Expansion Study Evaluating the Safety, Pharmacokinetics, and Preliminary Activity of GDC-1261 in Patients With Advanced or Metastatic Prostate Cancer

Trial Summary:

The purpose of this study is to evaluate the safety, pharmacokinetics (PK), and preliminary activity of GDC-1261 in participants with advanced or metastatic prostate cancer. It's also to identify a recommended dose(s) and regimen for GDC-1261 for subsequent studies.

Genentech, Inc.
Sponsor

Phase 1/Phase 2
Phase

NCT07567846 GO46445
Trial Identifiers

Eligibility Criteria:

Gender
Male

Age
#18 Years

Healthy Volunteers
No

Inclusion Criteria:

- Eastern Cooperative Oncology Group (ECOG) Performance Status of ≤ 1
- Life expectancy is ≥ 3 months
- Histologically or cytologically confirmed prostate adenocarcinoma
- Disease progression during or following the direct prior line of therapy
- Ongoing androgen deprivation therapy (ADT) with gonadotropin-releasing hormone (GnRH) agonist or antagonist, or have had bilateral orchiectomy

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- Metastatic disease
- Adequate end organ function

Exclusion Criteria:

- Treatment with any approved systemic anti-cancer therapy within 14 days or 5 drug elimination half-lives
- Structurally unstable bone lesions suggest an impending fracture
- Untreated central nervous system (CNS) metastases or leptomeningeal disease
- Uncontrolled pain
- History of malignancy within 5 years
- Infection requiring systemic IV antibiotics within 14 days or oral antibiotics within 7 days prior to screening, or any evidence of current infection
- Any medical condition or abnormal clinical laboratory finding that, in the investigator's judgment, would preclude the individual's safe participation in and completion of the study or could affect the interpretation of the results