ForPatients
by Roche

Metastatic castration-resistant prostate cancer

A Study to Test Inavolisib Treatment in Participants With Metastatic Castration-Resistant Prostate Cancer

Trial Status	Trial Runs In	Trial Identifier
Not yet recruiting		NCT07287150 2025-521327-67-00 CO45813

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 II, Randomized, Multicenter, Open-Label Study Evaluating the Efficacy and Safety of the Combination of Inavolisib Plus Enzalutamide Versus Physician's Choice of ARPI or Docetaxal in Patients With Metastatis Castration-Resistant Prostate Cancer

Trial Summary:

This study will evaluate the efficacy and safety of the combination of inavolisib plus enzalutamide compared with physician's choice of alternative androgen receptor pathway inhibitor (ARPi) or docetaxel in biomarker-selected participants with metastatic castrate-resistant prostate cancer (mCRPC) who have received one prior second-generation ARPi.

Hoffmann-La Roche
Sponsor

Phase 2
Phase

NCT07287150 2025-521327-67-00 CO45813
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
Male	#18 Years	No

Inclusion Criteria:

- Histologically or cytologically confirmed adenocarcinoma of the prostate without small-cell or neuroendocrine features
- Progressive metastatic CRPC, defied as any of the following: PSA progression, defined by a minimum of two rising PSA values from three consecutive assessments with an interval of at least 7 days

between assessments and with a minimal starting value of PSA >=1 ng/mL; The most recent qualifying PSA value must be determined within 14 days of enrollment; Soft tissue disease progression, defined by Response Evaluation Criteria in Solid Tumors, Version 1.1 (RECIST v1.1); Bone disease progression, defined by PCWG3 criteria, with two or more new metastatic bone lesions on a whole-body radionuclide bone scan
- Treatment with at least one, but no more than one, prior second-generation ARPi (abiraterone, apalutamide, enzalutamide, darolutamide) for hormone- sensitive prostate cancer (HSPC) or CRPC
- Availability of a tumor tissue specimen that is suitable (e.g., adequate quality and quantity) for use in determining biomarker status
- Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1
- Fasting glucose </= 100 mg/dL and HbA1c < 5.7%

Exclusion Criteria:

- Presence of liver metastasis
- Prior treatment with any phosphatidylinositol-3-kinase (PI3K), protein kinase B (AKT), or mammalian target of rapamycin (mTOR) inhibitor, or with any agent with a mechanism of action of inhibiting the PI3K/AKT/mTOR pathway
- Type 1 or Type 2 diabetes mellitus
- Prior treatment for mCRPC with cytotoxic chemotherapy or novel hormonal treatments (e.g., androgen receptor degraders, CYP11 inhibitors), with the following treatments permitted: Prior docetaxel in mHSPC, providing no evidence of disease progression occurred during treatment or within 6 months of treatment completion; Prior docetaxel in the adjuvant or neoadjuvant setting providing no evidence of disease progression occurred during treatment or within 12 months of treatment completion; Prior treatment with sipuleucel-T, with the last dose administered >28 days prior to start of treatment; Prior PARPi therapy, as per local prescribing information, with the last dose administered >14 days prior to start of treatment; One prior RLT or radiotherapeutic agent (e.g., PSMA-targeted RLT, Radium 223) with the last dose administered >8 weeks prior to start of treatment
- One prior RLT or radiotherapeutic agent (e.g., PSMA-targeted RLT, Radium 223) with the last dose administered > 8 weeks prior to start of treatment
- Other concurrent anti-cancer therapy except for androgen deprivation therapy
- Treatment with strong CYP2C8 inhibitors, strong or moderate CYP2C8 inducers, or strong CYP3A4 inducers within 1 week or 5 drug-elimination half-lives, whichever is longer, prior to initiation of study treatment
- Transfusion of any blood product for the sole purpose of making a potential participant eligible for study inclusion or within 28 days of enrollment