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# A Study to Learn How PF-06821497 (Mevrometostat) Works in Men With Metastatic Castration-resistant Prostate Cancer.

Pfizer

**Status and phase**

Enrolling Phase 3

**Conditions**

Metastatic Castration-Resistant Prostate Cancer

**Treatments**

Drug: PF-06821497 | Drug: Placebo | Drug: Enzalutamide

**Study type**

Interventional

**Funder types**

Industry

**Identifiers**

NCT06629779

2024-511652-40-00 (Registry Identifier)

C2321003

**Take notes**

**View 105 locations**

**Contact trial**

## Timeline

Last updated: Mar 12, 2025

**Start date**
Oct 22, 2024 • 4 months ago

**Today**
Mar 21, 2025

**End date**
Jul 24, 2026 • in 1 year and 4 months

## Sponsor of this trial

**Lead Sponsor**

Pfizer

## Details and patient eligibility

**About**

This study will explore whether a combination of the investigational drug PF-06821497 and enzalutamide will work better than taking enzalutamide alone in participants with mCRPC who are ARSi or abiraterone naïve.

**Full description**

This is a global, multicenter, randomized Phase 3 study evaluating PF-06821497 (mevrometostat) in combination with enzalutamide versus placebo in combination with enzalutamide in participants with mCRPC where no systemic anti-cancer treatments have been initiated after documentation of mCRPC with the exception of ADT (androgen deprivation therapy) and first-generation anti-androgen agents. Prior treatment with any of the ARSi's enzalutamide, darolutamide, apalutamide, or abiraterone acetate, is not permitted in any setting. Chemotherapy is permitted in the castrate sensitive setting.

This study consists of a Screening Phase, Randomization, Treatment Phase, Safety Follow-up, and Long-Term Follow-up. Participants will be randomized on a 1:1 basis to receive (Arm A) PF-06821497 in combination with enzalutamide, or (Arm B) placebo in combination with enzalutamide.

Hide

| Enrollment | Sex |
| --- | --- |
| 900 estimated patients | Male |
| **Ages** | **Volunteers** |
| 18+ years old | No Healthy Volunteers |

**Inclusion criteria**

- Male participants aged ≥18 years (or the minimum age of consent in accordance with local regulations) at screening.
- Histologically or cytologically confirmed adenocarcinoma of the prostate without small cell features.
- Metastatic disease in bone documented on bone scan, or in soft tissue documented on CT/MRI scan.
- Surgically or medically castrated, with serum testosterone ≤50 ng/dL (≤1.73 nmol/L) at screening.
- Metastatic disease in bone documented on bone scan, or in soft tissue documented on CT/MRI scan.
- Progressive disease in the setting of medical or surgical castration.

**Exclusion criteria**

- Any medical or psychiatric condition including recent (within the past year) or active suicidal ideation/behavior or laboratory abnormality that may increase the risk of study participation or, in the investigator's judgment, make the participant inappropriate for the study.
- Clinically significant cardiovascular disease.
- Known or suspected brain metastasis or active leptomeningeal disease.
- Participants must be treatment naïve at the mCRPC stage, eg, participants cannot have received any cytotoxic chemotherapy with the following exceptions: Treatment with first-generation antiandrogen (ADT) agents and. Docetaxel treatment is allowed for mCSPC.
- Previous administration with an investigational product (drug or vaccine) within 30 days.
- Current use or anticipated need for drugs that are known strong CYP3A4/5 inhibitors and inducers (with exception of enzalutamide as part of this study).
- Major surgery or palliative localized radiation therapy within 14 days before randomization.
- Inadequate organ function.

## Trial design

**Primary purpose**

Treatment

**Allocation**

Randomized

**Interventional model**

Parallel Assignment

**Masking**

Quadruple Blind

900 participants in 2 patient groups

### Arm A

Experimental group

**Description:**
Participants will receive PF-06821497 (875 mg) BID (twice daily) + enzalutamide 160 mg QD (once daily)

**Treatment:**
Drug: Enzalutamide
Drug: PF-06821497

### Arm B

daily)

**Treatment:**
Drug: Enzalutamide
Drug: Placebo

## Trial contacts and locations 105

**All locations**

### A Asan Medical Center | Clinical Trial Center
Veeva-enabled site

88 Olympic-ro 43 gil, Songpa-gu, Seoul, Seoul 5505

Not yet enrolling

### V Vejle Sygehus

Vejle, Syddanmark, Denmark, 7100

Not yet enrolling

### C Centre Jean Perrin - Centre Régional de Lutte contre le Cancer d'Auvergne

Clermont-Ferrand, France, 63011

Not yet enrolling

### S Studienpraxis Urologie

Nürtingen, Baden-württemberg, Germany, 72622

Not yet enrolling

### A Asociación de Beneficencia Hospital Sirio Libanés

Buenos Aires, Argentina, C1419AHN

Not yet enrolling

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**Central trial contact**

**Pfizer CT.gov Call Center**

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Data sourced from clinicaltrials.gov