

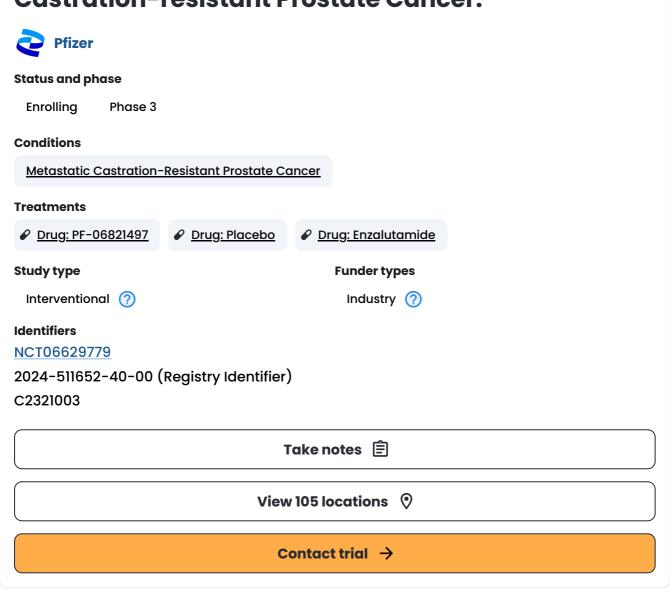


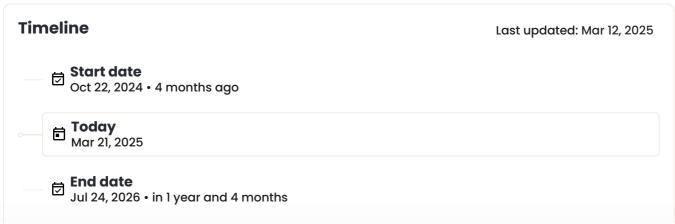
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A Study to Learn How PF-06821497 (Mevrometostat) Works in Men With Metastatic Castration-resistant Prostate Cancer.









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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.

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 Allocation

Treatment Randomized

Interventional model Masking

Parallel Assignment 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



Asan Medical Center | Clinical Trial Center

A 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

View more

Central trial contact

Pfizer CT.gov Call Center





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