



Record 1 of 1



The U.S. government does not review or approve the safety and science of all studies listed on this website.

Read our full [disclaimer](https://www.clinicaltrials.gov/about-site/disclaimer) (<https://www.clinicaltrials.gov/about-site/disclaimer>) for details.

Active, not recruiting ⓘ

Targeted Alpha Therapy With 225Actinium-Prostate Specific Membrane Antigen (PSMA)-I&T of Castration-resISTant Prostate Cancer (TATCIST). (TATCIST)

ClinicalTrials.gov ID ⓘ NCT05219500

Sponsor ⓘ Fusion Pharmaceuticals Inc.

Information provided by ⓘ Fusion Pharmaceuticals Inc. (Responsible Party)

Last Update Posted ⓘ 2025-10-08

Study Details Tab

Study Overview

Brief Summary

The treatment regimen will consist of 4 doses of FPI-2265

Detailed Description

The treatment regimen will consist of 4 doses of FPI-2265, administered at 8 ± 1 week intervals, with an initial activity of 100 kilobecquerel (kBq)/kg (±10%).

Additional doses will be administered at 100 kBq/kg (±10%) with the following exceptions:

- Participants who experience dose-modifying events.
- Participants with a confirmed decline in PSA>=50%.

Official Title

PSMA-directed Targeted Alpha Therapy With FPI-2265 (225Ac-PSMA-I&T) for the Treatment of Metastatic Castration-resISTant Prostate Cancer (TATCIST). A Phase II Clinical Trial.

Conditions ⓘ

Metastatic Castration Resistant Prostate Cancer

Intervention / Treatment ⓘ

- Drug: FPI-2265

Study Start (Actual) ⓘ

2021-12-16

Primary Completion (Actual) ⓘ

2025-05-30

Study Completion (Estimated) ⓘ

2026-07-31

Enrollment (Estimated) ⓘ

115

Study Type ⓘ

Interventional

Phase ⓘ

Phase 2

Patent Owner Exhibit 2088
IPR2025-01582

Other Study ID Numbers

- FPI-2265-201

Resource links provided by the National Library of Medicine **NLM**

[FDA Drug and Device Resources](https://www.clinicaltrials.gov/fda-links) (<https://www.clinicaltrials.gov/fda-links>).

Contacts and Locations

This section provides contact details for people who can answer questions about joining this study, and information on where this study is taking place.

To learn more, please see the [Contacts and Locations section in How to Read a Study Record](https://www.clinicaltrials.gov/study-basics/how-to-read-study-record#contacts-and-locations) (<https://www.clinicaltrials.gov/study-basics/how-to-read-study-record#contacts-and-locations>).

This study has 2 locations

United States**Nebraska Locations**

 Omaha, Nebraska, United States, 68130
XCancer Omaha/Urology Cancer Center

Texas Locations

 Houston, Texas, United States, 77042
Excel Diagnostics and Nuclear Oncology Center

Participation Criteria

Researchers look for people who fit a certain description, called [eligibility criteria](#). Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read [Learn About Studies](https://www.clinicaltrials.gov/study-basics/learn-about-studies) (<https://www.clinicaltrials.gov/study-basics/learn-about-studies>).

Eligibility Criteria**Description****Inclusion Criteria:**

- Participants aged ≥ 18 years.
- Participants must have the ability to understand and sign an approved informed consent (ICF).
- Participants must have the ability to understand and comply with all protocol requirements.
- Adenocarcinoma of prostate proven by histopathology.
- Life expectancy of 6 months or more.
- Unresectable metastases.
- Documented progressive disease (PD); progressive mCRPC will be based on at least 1 of the following criteria:
 - Serum PSA progression is defined as 2 consecutive increases in PSA over a previous reference value measured at least 1 week prior. The minimal starting value is 1.0 ng/mL, if PSA is the only indication of progression.
 - Soft-tissue progression defined as an increase $\geq 20\%$ in the sum of the diameter (SOD) (short axis for nodal lesions and long axis for non-nodal lesions) of all target lesions based on the smallest SOD since treatment started or the appearance of one or more new lesions.
 - Progression of bone disease: evaluable disease or new bone lesions(s) by bone scan (2+2 PCWG3 criteria).
- If known Breast Cancer gene (BRCA) mutations are present, participants should have received FDA approved therapies such as poly-ADP ribose polymerase (PARP) inhibitors and progressed.
- Castration resistant disease with confirmed testosterone level ≤ 50 ng/dL under prior androgen deprivation therapy (ADT). Must have a castrate level of serum testosterone (< 50 ng/dL or < 1.7 nmol/L).
- Positive PSMA PET/CT scans, obtained with approved PSMA-ligands, defined as at least one PSMA-positive metastatic lesion and no PSMA-negative lesions.
- ECOG-PS 0 to 1.
- Hemoglobin (Hgb) concentration ≥ 9.0 g/dL.
- Platelet counts $\geq 100 \times 10^9/L$.
- White blood cell (WBC) count $\geq 2.0 \times 10^9/L$, absolute neutrophil count (ANC) $> 1.5 \times 10^9/L$.
 - Hematological criteria cannot be met with ongoing or recent blood transfusions (within 7 days prior to the scheduled first dose of study treatment) or require growth factor support (within 21 days prior to the scheduled first dose of study treatment).
- Alanine aminotransferase or aspartate aminotransferase $\leq 3.0 \times$ upper limit of normal (ULN).
- Serum total bilirubin $\leq 1.5 \times$ ULN; in participants with Gilbert's syndrome, a total bilirubin ≤ 3 times ULN and direct bilirubin within normal limits are permitted.
- Albumin ≥ 2.5 g/dL.
- Serum/plasma creatinine $\leq 1.5 \times$ ULN or creatinine clearance ≥ 60 mL/min based on the Cockcroft-Gault formula.
- Prothrombin time, international normalized ratio or prothrombin time test $< 1.5 \times$ ULN.
- Received ≥ 1 androgen receptor axis-targeted therapies (ARAT).
- Participants on anti-androgen therapy are allowed to continue their treatment at the discretion of their treating physician.

Exclusion Criteria:

- Less than 6 weeks from enrollment since last myelosuppressive therapy (including Docetaxel, Cabazitaxel, 223Ra, 153Sm, 177Lu-PSMA-617/other Lu-PSMA RLT or any other radionuclide therapy). Participants who received previous treatment with Ac-225 are excluded.
- Participants who received more than 4 prior lines of systemic therapy for CRPC.
- Urinary tract obstruction as evidenced by Tc-99m DTPA renal scan with diuretics.
- Participants with skeletal metastases presenting as a superscan on a 99m Tc-MDP Bone Scan.

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

Male

Accepts Healthy Volunteers

No

- Superscan is defined as a bone scan which demonstrates markedly increased skeletal radioisotope uptake relative to soft tissues in association with absent or faint renal activity (absent kidney sign).
5. Persistent baseline dry eye or dry mouth > Grade 1 from prior RLT.
 6. Persistent prior AEs > Grade 1 from prior anti-cancer therapies.
 7. Abnormal renal function (estimated glomerular filtration rate < 60 mL/min), baseline Hgb < 9g/dL, ANC < $1.5 \times 10^9/L$, platelets < $100 \times 10^9/L$, and prothrombin time, international normalized ratio or prothrombin time test $\geq 1.5 \times$ ULN.
 8. Administration of an investigational agent $\leq$ 60 days or 5 half-lives, whichever is shorter, prior to Cycle 1, Week 0.
 9. Known presence of central nervous system (CNS) metastases or liver metastases.
 10. Active malignancy other than low-grade non-muscle-invasive bladder cancer and non-melanoma skin cancer.
 11. Concurrent illness that may jeopardize the participant's ability to undergo study procedures as determined by the Investigator.
 12. Symptomatic cord compression, or clinical or radiologic findings indicative of impending cord compression.
 13. Concurrent serious (as determined by the investigator) medical conditions, including, but not limited to, New York Heart Association Class III or IV congestive heart failure, unstable ischemia, uncontrolled symptomatic arrhythmia, history of congenital prolonged QT syndrome, uncontrolled infection, known active hepatitis B or C, or other significant co-morbid conditions that in the opinion of the Investigator would impair study participation or cooperation.
 14. Major surgery $\leq$ 30 days prior to enrollment.
 15. Planning to conceive pregnancy during the treatment and up to 6 months after the last treatment.

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment

Allocation : N/A

Interventional Model : Single Group Assignment

Masking : None (Open Label)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: FPI-2265 All patients will receive FPI-2265, administered at 8 ± 1 -week interval, with the initial activity of 100 kBq/kg ($\pm 10\%$).	Drug: FPI-2265 - Small molecule capable of binding to the domain of PSMA radiolabeled with Ac225 - Other Names: - Ac225-PSMA I&T

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
To evaluate the effect of FPI-2265 on prostate-specific antigen (PSA) in participants with mCRPC.	Frequency and proportion of participants with PSA50, defined as $\geq 50\%$ decline in PSA level by 12-weeks after the first treatment.	From start of treatment until 12 weeks after the first treatment.

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
To evaluate the safety and tolerability of FPI- 2265.	- Frequency, duration and severity of treatment emergent adverse events (TEAEs) evaluated according to the National Cancer Institute Common Terminology Criteria for Adverse Events version 5.0 (NCI-CTCAE v5.0). - Changes in clinical laboratory, electrocardiograms (ECGs) and physical examinations compared to baseline.	From first treatment dose to up to 24 months after last treatment.
To evaluate the anti-tumor activity of FPI-2265.	- Maximum % PSA decline. - PSA progression free survival (PFS). - Time to best PSA response - Objective response rate (ORR) per Response Evaluation Criteria in Solid Tumors version 1.1 (RECIST v1.1). - Disease control rate (DCR) per RECIST v1.1. - Duration of response (DoR) based on RECIST v1.1/Prostate Cancer Clinical Trials Working Group 3 (PCWG3) criteria. - Radiographic progression-free survival (rPFS) per PCWG3 criteria. - Overall survival (OS).	From first treatment until date of radiographic progression or date of death from any cause, whichever comes first, assessed up to 24 months after last treatment.
To assess the impact of FPI-2265 on participant reported outcomes.	- The frequency and proportion of participants with an improvement in bone pain levels. - Change in quality of life (QoL) over time.	From first treatment until 24 months after last treatment.

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Fusion Pharmaceuticals Inc.

Investigators

- Study Director: Keith Barnett, Fusion Pharmaceuticals Inc.

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates**First Submitted** ⓘ

2021-12-20

First Submitted that Met QC Criteria ⓘ

2022-01-27

First Posted ⓘ

2022-02-02

[HHS Vulnerability Disclosure](#)**Study Record Updates****Last Update Submitted that met QC Criteria** ⓘ

2025-10-08

Last Update Posted (Estimated) ⓘ

2025-10-08

Last Verified ⓘ

2025-02

More Information**Drug and device information, study documents, and helpful links****Studies a U.S. FDA-Regulated Drug Product**

Yes

Studies a U.S. FDA-Regulated Device Product

No