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Record 1 of 1

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Recruiting

FPI-2265 (225Ac-PSMA-I&T) for Patients With PSMA-Positive Metastatic Castration-Resistant Prostate Cancer (mCRPC) (AlphaBreak)

ClinicalTrials.gov ID NCT06402331

Sponsor Fusion Pharmaceuticals Inc.

Information provided by Fusion Pharmaceuticals Inc. (Responsible Party)

Last Update Posted 2025-10-09

Study Details Tab

Study Overview

Brief Summary

This is an open-label, randomized, multicenter study of FPI-2265 (225Ac-PSMA-I&T). Patient population is adult participants with PSMA positive mCRPC who have had previous treatment with with 177Lu-PSMA-617 or another 177Lu-PSMA radioconjugate (RC). The purpose of the study is to determine the safety and tolerability, and recommended dose and regiment of FPI-2265.

Detailed Description

This is an open-label, randomized, multicenter study of FPI-2265 (225Ac-PSMA-I&T). The purpose of this dose optimization study is to determine the recommended FPI-2265 dose and regimen. Conclusions will be based on safety, tolerability, and anti-tumor activity.

Screening Period: At screening, participants will be assessed for eligibility and undergo a positron emission tomography (PET)/computed tomography (CT) scan to evaluate PSMA positivity. Only participants with PSMA positive cancer and confirmed eligibility criteria will be randomized.

Participants randomized will enter the treatment period and receive investigational doses of FPI2265 according to the dose level and schedule as specified per proposed dose arm.

Part A participants will enroll 1:1:1 at three dose level/schedules, to arms 1, 2 or 3

Part B participants will enroll after completion of part A, in a 1:1 randomization scheme to arms 6 or 7.

Study Start (Actual)
2024-03-05

Primary Completion (Estimated)
2026-07-23

Study Completion (Estimated)
2031-01-23

Enrollment (Estimated)
100

Study Type
Interventional

Phase
Phase 2

Patent Owner Exhibit 2087
IPR2025-01582

Feedback

Once Part A is fully enrolled and participants have been followed for at least 12 weeks, data from Arm 1 and 2 will be analyzed to assess the feasibility of enrolling participants to arms 4 and 5.

All participants will be monitored and assessed for efficacy response, disease progression and adverse events.

Supportive care will be allowed in all arms at the discretion of the investigator and includes available care for the eligible participant according to best institutional practice for mCRPC treatment, including androgen deprivation therapy (ADT).

Follow-up after end of treatment visit will proceed for 5 years.

5 participants will be enrolled into a dosimetry substudy (open at select sites only). Dosimetry substudy participants will be administered one dose at of FPI2265 and proceed with dosimetric assessments will be taken at a number of timepoints after dose administration.

Official Title

A Phase 2, Randomized, Open-Label, Multicenter Study to Evaluate the Safety and Efficacy of FPI-2265 (225Ac-PSMA-I&T) in Patients With PSMA-Positive Metastatic Castration-Resistant Prostate Cancer (mCRPC)

Conditions

Metastatic Castration-resistant Prostate Cancer

Intervention / Treatment

- Drug: FPI-2265

Other Study ID Numbers

- FPI-2265-202

Resource links provided by the National Library of Medicine NIH NLM

FDA Drug and Device Resources (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).

Study Contact

Name: Clinical Trials Fusion Pharmaceuticals Inc.
Phone Number: 1 (888) 506-4215
Email: clinicaltrials@fusionpharma.com

This study has 18 locations

United States

California Locations

Duarte, California, United States, 91010
Recruiting

City of Hope Comprehensive Cancer Center
Contact : Jennifer Simpson
+ (626) 218 5087 jSimpson@coh.org
Contact : Jessica Liu
+ (626) 218 0473 jesliu@coh.org
Principal Investigator : Jeffrey Wong, MD

Irvine, California, United States, 92618
Recruiting
Hoag Health Center Irvine
Contact : Gary Ulaner, MD
949-557-0285 gary.ulaner@hoag.org
Principal Investigator : Gary Ulaner, MD

Los Angeles, California, United States, 90073
Recruiting
VA Greater Los Angeles Healthcare System
Contact : Gholam Berenji, MD
310-268-3547 gholam.berenji@va.gov
Contact : Janake Wijesuriya
310-977-5209 janake.wijesuriya@va.gov
Principal Investigator : Gholam Berenji, MD

Los Angeles, California, United States, 90095
Recruiting
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Contact : Stephanie Lira
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Principal Investigator : Jeremie Calais, MD

San Francisco, California, United States, 94143
Recruiting
UCSF School of Medicine
Contact : Maya Aslam
+1 (415) 514 8987 maya.aslam@ucsf.edu
Contact : Lisa Kody
+ (310) 983 1444 Lisa.kody@ucsf.edu
Principal Investigator : Ivan De Kouchkovsky, MD

Florida Locations

Miami, Florida, United States, 33165
Recruiting
Biogenix Molecular, LLC
Contact : Jerry Joseph, Site Administrator
786-791-1799 jjoseph@cira-health.com
Principal Investigator : Frankis Almaguel, MD, PhD

Iowa Locations

Iowa City, Iowa, United States, 52242
Recruiting
University of Iowa Hospitals and Clinics
Contact : Debra OConnell-Moore
319-356-1693 debra-oconnell-moore@uiowa.edu
Principal Investigator : Yusuf Menda, MD

Maryland Locations

Glen Burnie, Maryland, United States, 21061
Active, not recruiting
United Theranostics

Michigan Locations

Grand Rapids, Michigan, United States, 49503
Recruiting
BAMF Health
Contact : Brandon Mancini, MD
(616) 330-3343 brandon.mancini@@bamfhealth.com
Contact : Harshad Kulkarni, MD
harshad.kulkarni@bamfhealth.com
Principal Investigator : Brandon Mancini, MD

Missouri Locations

St Louis, Missouri, United States, 63104
Recruiting
SSM Health Saint Louis University Hospital

Contact : Chelsea Webb, CNMT
(314) 617-2899 chelsea.may@health.slu.edu
Principal Investigator : Razi Muzaffar, DO

Nebraska Locations

Omaha, Nebraska, United States, 68130
Recruiting
XCancer
Contact : Luke Nordquist, MD
402-991-8468 drluke@xcancer.com
Contact : Tony Romero
402-697-2229 tony@xcancer.com
Principal Investigator : Luke Nordquist, MD

New Mexico Locations

Albuquerque, New Mexico, United States, 87109
Recruiting
New Mexico Oncology Hematology Consultants Ltd.
Contact : Kimberly Demos
505 -317-2605 KimberlyD@nmohc.com
Principal Investigator : Gregg Franklin, MD

New York Locations

New York, New York, United States, 10016
Recruiting
Laura and Isaac Perlmutter Cancer Center at NYU Langone
Contact : Scarlett Rodriguez
929-334-6980 Scarlett.Rodriguez@nyulangone.org
Contact : Carol Fernandez Guerra
917-696-0226 Carol.FernandezGuerra@nyulangone.org
Principal Investigator : David Wise, MD

New York, New York, United States, 10065
Recruiting
Memorial Sloan Kettering Cancer Center - NYC
Contact : MSKCC Clinical Trials Contact
888-906-0432 neemuci@mskcc.org
Principal Investigator : Michael Morris, MD

Oregon Locations

Portland, Oregon, United States, 97239-3098
Recruiting
Oregon Health and Science University (OHSU, Knight Cancer Center)
Contact : Justina Lynch
+ (503) 418 9737 lynchjus@ohsu.edu
Principal Investigator : Alexandra Sokolova, MD

Texas Locations

Dallas, Texas, United States, 75216
Recruiting
VA North Texas Health Care System, Nuclear Medicine Service
Contact : Jessica Bhatti
+ (512) 341 8724 jessica.bhatti@va.gov
Contact : Maximillian Masuda
+ (214) 742 8387 maximillian.masuda@va.gov
Principal Investigator : Irfan Farukhi

Dallas, Texas, United States, 75390
Recruiting
The University of Texas Southwestern Medical Center
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214-648-5984 Michael.Fulkerson@UTSouthwestern.edu
Principal Investigator : Orhan OZ, Prof

Houston, Texas, United States, 77030
Recruiting
U.T. MD Anderson Cancer Center
Contact : Virginia Bayer
+ (713) 517 0790 VRBayer@mdanderson.org
Contact : Emily Batton
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Principal Investigator : Amado Zurita-Saavedra, MD

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).

Eligibility Criteria

Description

Key Inclusion Criteria:

- Eastern Cooperative Oncology Group (ECOG) Performance Status 0 or 1
- Diagnosis of adenocarcinoma of prostate proven by histopathology.
- Must have had prior orchiectomy and/or ongoing androgen-deprivation therapy and a castrate level of serum/plasma testosterone
- Progressive mCRPC at time of study entry.
- Must have been previously treated with lutetium-PSMA therapy (lutetium-177 vipivotide tetraxetan or other lutetium-177-PSMA RLT). Treatment must have been completed >6 weeks prior to the first dose of study drug.
- Participants with known BRCA mutations should have received FDA-approved therapies such as PARP inhibitors, per Investigator discretion.
- Positive PSMA PET/CT scan
- Adequate organ function
- For participants who have partners of childbearing potential: Partner and/or participant must not be planning to conceive and must use a method of birth control with adequate barrier protection deemed acceptable by the Principal Investigator during the study treatment and for six months after last study drug administration.

Key Exclusion Criteria:

- Participants who received more than two prior lines of cytotoxic chemotherapy for CRPC.
- Participants who progress prior to administration of the 3rd cycle of prior treatment with 177Lu-PSMA therapy
- All prior treatment-related adverse events must have resolved to Grade ≤1 (CTCAE v5.0). Alopecia and stable persistent Grade 2 peripheral neuropathy may be allowed at the discretion of the Investigator.
- Participants with known, unresolved, urinary tract obstruction are excluded.
- Administration of any systemic cytotoxic or investigational therapy ≤30 days of the first dose of study treatment or five half-lives, whichever is shorter. Completion of large-field external beam radiotherapy ≤four weeks of the first dose of study treatment.
- Participants with a history of central nervous system (CNS) metastases are excluded except those who have received therapy
- Participants with any liver metastases will be excluded
- Participants with skeletal metastases presented as a superscan on a ^{99m}Tc bone scan.
- Previous or concurrent cancer that is distinct from the cancer under investigation in primary site or histology, except treated cutaneous basal cell carcinoma or squamous cell carcinoma and superficial bladder tumors. Any cancer curatively treated >two years prior to the first dose of treatment is permitted.
- Concurrent serious (as determined by the investigator) medical conditions
- Major surgery ≤30 days prior to the first dose of study treatment.

Gender-based Eligibility

Yes

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

Male

Accepts Healthy Volunteers

No

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 : Randomized
Interventional Model : Parallel Assignment
Masking : None (Open Label)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: Part A Arm 1	Drug: FPI-2265 • Investigational treatment FPI2265 is a PSMA ligand radiolabelled with 225Ac. Other Names: 225Ac-PSMA-I&T
Experimental: Part A Arm 2	Drug: FPI-2265 • Investigational treatment FPI2265 is a PSMA ligand radiolabelled with 225Ac. Other Names: 225Ac-PSMA-I&T
Experimental: Part A Arm 3	Drug: FPI-2265 • Investigational treatment FPI2265 is a PSMA ligand radiolabelled with 225Ac. Other Names: 225Ac-PSMA-I&T
Experimental: Part B Arm 4 to be utilized based on analysis of Part A	Drug: FPI-2265 • Investigational treatment FPI2265 is a PSMA ligand radiolabelled with 225Ac. Other Names: 225Ac-PSMA-I&T
Experimental: Part B Arm 5 to be utilized based on analysis of Part A	Drug: FPI-2265 • Investigational treatment FPI2265 is a PSMA ligand radiolabelled with 225Ac. Other Names: 225Ac-PSMA-I&T
Experimental: Part B Arm 6	Drug: FPI-2265 • Investigational treatment FPI2265 is a PSMA ligand radiolabelled with 225Ac. Other Names: 225Ac-PSMA-I&T

Experimental: Part B Arm 7	Drug: FPI-2265 • Investigational treatment FPI2265 is a PSMA ligand radiolabelled with 225Ac. Other Names: 225Ac-PSMA-I&T

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Frequency, duration, and severity of treatment-emergent adverse events (TEAEs)	Frequencies and percentages of participants with TEAEs will be summarized. Analysis will also be completed regarding duration of TEAEs and their severity.	From first dose until end of long-term follow-up, 5 years from end of treatment visit.
Frequency and proportion of participants with PSA50 response	PSA50 response is defined as a decline in PSA levels by at least 50% and is used to evaluate anti-tumor activity.	From first dose until 12 weeks after the first administered dose of FPI-2265.

Collaborators and Investigators

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

Sponsor — HHS Vulnerability Disclosure

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
2024-04-26

First Submitted that Met QC Criteria
2024-05-02

First Posted
2024-05-07

Study Record Updates

Last Update Submitted that met QC Criteria
2025-10-07

Last Update Posted (Estimated)
2025-10-09

Last Verified
2025-10

More Information

Terms related to this study

Keywords Provided by Fusion Pharmaceuticals Inc.

mCRPC
225Ac-PSMA-I&T
Radioligand therapy

Plan for Individual Participant Data (IPD)

Plan to Share Individual Participant Data (IPD)?

No

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

Product Manufactured in and Exported from the U.S.

No