



# National Library of Medicine

## National Center for Biotechnology Information

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 ⓘ

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

ClinicalTrials.gov ID ⓘ NCT06909825

Sponsor ⓘ Fusion Pharmaceuticals Inc.

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

Last Update Posted ⓘ 2025-10-27

## Study Details Tab

### Study Overview

#### Brief Summary

This study is an open-label, multicenter study designed to investigate the efficacy, safety and tolerability of FPI-2265 (225Ac-PSMA-I&T) in combination with Olaparib in participants with mCRPC. The dose optimization Phase 2 part will be investigating the safety, tolerability, and anti-tumor activity of novel dosing regimens of FPI-2265 and Olaparib in participants with metastatic castration-resistant prostate cancer.

#### Detailed Description

This study is an open-label, multicenter study designed to investigate the efficacy, safety and tolerability of FPI-2265 (225Ac-PSMA-I&T) in combination with Olaparib in participants with mCRPC. The study will be conducted in two parts, with Part A enrolling participants who have been previously treated with lutetium-177 (177Lu) vipivotide tetraxetan or other 177Lu-PSMA radioligand therapy (RLT) and Part B enrolling participants who have not been previously treated with lutetium-177 (177Lu) vipivotide tetraxetan or other 177Lu-PSMA radioligand therapy. For each part of the study, a Simon 2-stage design will be used to evaluate two dosing regimens. The purpose of this investigation is to determine the recommended FPI-2265 dose and regimen. Conclusions from this Phase 2 study will be based on safety, tolerability, and anti-tumor activity data. Participants with PSMA-positive mCRPC will be allocated to Arm 1 and Arm 2 in a singular, alternating fashion, until all Stage 1 participants are enrolled into each of the two regimens:

Arm 1: Will consist of up to six doses of FPI-2265 every six weeks at Dose A and olaparib twice a day on days 1 to 14 of each cycle.

#### Study Start (Actual) ⓘ

2025-02-26

#### Primary Completion (Estimated) ⓘ

2030-01-29

#### Study Completion (Estimated) ⓘ

2030-08-12

#### Enrollment (Estimated) ⓘ

85

#### Study Type ⓘ

Interventional

#### Phase ⓘ

Phase 2

Patent Owner Exhibit 2086  
IPR2025-01582

Feedback

Arm 2: Will consist of up to nine doses of FPI-2265 every four weeks at Dose B and olaparib twice a day on days 1 to 14 of each cycle. Participants will be monitored and assessed for efficacy response, disease progression, and adverse events.

Official Title

A Phase 2, Open-label, Multi-centre Study of FPI-2265 (225Ac-PSMA-I&T) and Olaparib in Participants With Metastatic Castration Resistant Prostate Cancer (mCRPC)

Conditions ⓘ

Metastatic Castration-resistant Prostate Cancer

Intervention / Treatment ⓘ

- Drug: FPI-2265
- Drug: Olaparib

Other Study ID Numbers ⓘ

- FPI-2265-203
- CT-2024-CTN-00137-1 ( Other Identifier ) (OTHER: TGA Clinical Trial Notification (CTN))

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

[Drug Information](https://dailymed.nlm.nih.gov/dailymed/) (<https://dailymed.nlm.nih.gov/dailymed/>), available for: [Olaparib](https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Olaparib) (<https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Olaparib>).

[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 4 locations

Australia

New South Wales Locations

-  Macquarie Park, New South Wales, Australia, 2113  
Macquarie University Hospital

Queensland Locations

-  Woolloongabba, Queensland, Australia, 4102  
Princess Alexandra Hospital

South Australia Locations

-  Kurralta Park, South Australia, Australia, 5037  
Icon Cancer Centre Kurralta Park

Victoria Locations

-  Melbourne, Victoria, Australia, 3000  
Peter MacCallum Cancer 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:

1. Adult male participants with mCRPC that is progressing at the time of study entry

2. ECOG performance status 0-1 and life expectancy of at least three months

3. Must have received at least one novel anti-androgen deprivation therapy

4. Participants with known BRCA mutations should have received approved therapies such as PARP inhibitors, per Investigator discretion.

5. All prior treatment-related AEs must have resolved to CTCAE Grade ≤1 (except alopecia).

6. Participants must have had prior orchiectomy and/or ongoing androgen deprivation therapy and a castrate level of serum testosterone (<50 ng/dL or <1.7 nmol/L)

7. Positive PSMA PET/CT scans .

8. Participants must have adequate organ and bone marrow function:

Hgb >= 9g/dL

Platelets >= 100 x 10^9/L

ANC <= 1.5 x 10^9/L

CrCL >= 50 mL/min

Exclusion Criteria:

1. Previous treatment with any of the following within 6 months of first dose: Samarium-153, Rhenium-186, Rhenium-188, Radium-223, hemi-body irradiation.

2. Participants who received more than two (2) prior lines of cytotoxic chemotherapy for CRPC.

3. Participants with known unresolved urinary tract obstruction.

4. Transfusion- or growth factor-dependent participants.

5. Participants with a history of CNS metastases are excluded, except those who have received therapy (and are neurologically stable, asymptomatic, and not receiving corticosteroids for the purposes of maintaining neurologic integrity.

6. Symptomatic cord compression, or clinical or radiologic findings indicative of impending cord compression.

7. Participants with any liver metastases.

8. Participants with skeletal metastases presenting as a superscan .

9. Previous history of interstitial lung disease or non-infectious pneumonitis.

10. Participants with a history or clinical and/or laboratory features suggestive of MDS/AML.

11. Major surgery ≤28 days prior to the first dose of study treatment.

12. Planning to conceive a pregnancy during the treatment and up to six months after the last treatment.

13. Participants unable to swallow orally administered medications or with malabsorptive gastrointestinal disorders.

14. Concomitant use of known strong or moderate CYP3A inhibitors or inducers

Ages Eligible for Study

18 Years and older (Adult, Older Adult )

Sexes Eligible for Study

Male

Accepts Healthy Volunteers

No

Gender-based Eligibility

Yes

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** : Non-Randomized

**Interventional Model** : Parallel Assignment

**Masking** : None (Open Label)

### Arms and Interventions

| Participant Group/Arm                                                                                                                                                                                                                                                                                          | Intervention/Treatment                                                                                                                                                                                                            |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>Experimental: Part A</p> <p>Regimen 1: FPI-2265 (Dose A intravenously [IV] every six weeks) plus olaparib (twice daily [BID], on Days 1 to 14 of each cycle).</p> <p>Regimen 2: . FPI-2265 (Dose B intravenously [IV] every 4 weeks) plus olaparib (twice daily [BID], on Days 1 to 14 of each cycle)</p>   | <p>Drug: FPI-2265</p> <ul style="list-style-type: none"> <li>PSMA ligand radiolabeled with Ac225</li> </ul> <p>Drug: Olaparib</p> <ul style="list-style-type: none"> <li>Poly (ADP-ribose) polymerase (PARP) inhibitor</li> </ul> |
| <p>Experimental: Part B</p> <p>Regimen 1: FPI-2265 (Dose A intravenously [IV] every six weeks) plus olaparib (g twice daily [BID], on Days 1 to 14 of each cycle).</p> <p>Regimen 2: . FPI-2265 (Dose B intravenously [IV] every 4 weeks) plus olaparib (twice daily [BID], on Days 1 to 14 of each cycle)</p> | <p>Drug: FPI-2265</p> <ul style="list-style-type: none"> <li>PSMA ligand radiolabeled with Ac225</li> </ul> <p>Drug: Olaparib</p> <ul style="list-style-type: none"> <li>Poly (ADP-ribose) polymerase (PARP) inhibitor</li> </ul> |

## What is the study measuring?

Primary Outcome Measures

| Outcome Measure                                                                            | Measure Description                                                                                                                                                                                                                                                                                                                                                                                                          | Time Frame                                                                                            |
|--------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------|
| Evaluate anti-tumour activity of FPI-2265 administered in combination with olaparib        | The frequency and proportion of participants with PSA50 response will be summarized, where PSA50 is defined as ≥50% decline in PSA level from pre-treatment.                                                                                                                                                                                                                                                                 | From first dose until approximately 12 weeks after the first administered dose of FPI-2265            |
| Evaluate the safety and tolerability of FPI-2265 administered in combination with olaparib | Safety will be assessed by percentage of patient with treatment emergent adverse events and serious adverse events; percentage of patients with SAEs during the first year of the long term follow up and the number of AEs during the 5 year follow up period. Percentage of patients with interruption of FPI-2265; percentage of patients who discontinue treatment; number and grade for AEs related to study treatment. | From first dose until end of long-term follow-up, 5 years from the last administered dose of FPI-2265 |

Collaborators and Investigators

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

Sponsor

Fusion Pharmaceuticals Inc.

Investigators

- Study Director: Dipti Shoop, 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

2025-03-21

First Submitted that Met QC Criteria

2025-03-27

First Posted

2025-04-04

Study Record Updates

Last Update Submitted that met QC Criteria

2025-10-24

Last Update Posted (Estimated)

2025-10-27

Last Verified

2025-10

More Information

Terms related to this study

Keywords Provided by Fusion Pharmaceuticals Inc.

mCRPC

Additional Relevant MeSH Terms

[HHS Vulnerability Disclosure](#)

225Ac-PSMA-I&T  
RLT  
Radioligand Therapy  
FPI-2265  
Olaparib  
Radioconjugate

#### 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.

Yes