



Record 1 of 1



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Recruiting ⓘ

Open-label Study Comparing AAA817 Versus Standard of Care in the Treatment of Previously Treated PSMA-positive mCRPC Adults Who Have Disease Progressed on or After [177Lu]Lu-PSMA Targeted Therapy (PSMAcTION)

ClinicalTrials.gov ID ⓘ NCT06780670

Sponsor ⓘ Novartis Pharmaceuticals

Information provided by ⓘ Novartis (Novartis Pharmaceuticals) (Responsible Party)

Last Update Posted ⓘ 2025-11-12

Study Details Tab

Study Overview

Brief Summary

This is a Phase II/III study. Patient population is adult participants with PSMA-positive mCRPC who had treatments with androgen receptor pathway inhibitor (ARPI) and taxane-based chemotherapy and progressed on or after [177Lu]Lu-PSMA targeted therapy.

Treatment of interest: the investigational treatment is AAA817 regardless of subsequent anti-neoplastic treatment. The control treatment is investigator's choice of Standard of Care, regardless of subsequent anti-neoplastic treatment

Detailed Description

Study CAAA817A12201 consists of 2 parts: a randomized, open-label, international, multicenter, phase II study (Phase II) to collect more information to support the proposed dose of AAA817 and a randomized, open-label, international, multicenter, 2- arm phase III study (Phase III) aimed to evaluate the efficacy and safety of proposed dose of AAA817 vs. investigator's choice of standard of care (SoC) in the treatment of adult participants with PSMA-positive metastatic castration-resistant prostate cancer (mCRPC) who had treatments with ARPI and taxane-based chemotherapy, and progressed on or after [177Lu]Lu-PSMA targeted therapy. The purpose of the phase II part (Phase II) of this study is to collect additional information to support proposed phase III dose of AAA817.

Official Title

Study Start (Actual) ⓘ

2025-02-27

Primary Completion (Estimated) ⓘ

2028-06-27

Study Completion (Estimated) ⓘ

2033-07-19

Enrollment (Estimated) ⓘ

432

Study Type ⓘ

Interventional

Phase ⓘ

Phase 2
Phase 3

**Patent Owner Exhibit 2085
IPR2025-01582**



PSMAcTION: A Phase II/III, Open-label, International, Multicenter, Randomized Study of AAA817 Versus Standard of Care in the Treatment of Adult Participants With PSMA Positive Metastatic Castration-resistant Prostate Cancer Who Progressed on or After [177Lu]Lu-PSMA Targeted Therapy

Conditions ⓘ

Prostate Cancer

Intervention / Treatment ⓘ

- Drug: Investigators choice of SoC
- Drug: AAA817
- Drug: AAA817
- Drug: AAA817

Other Study ID Numbers ⓘ

- CAAA817A12201
- 2024-512342-42-00 (Other Identifier) (OTHER: EU CTIS)

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

[MedlinePlus](https://medlineplus.gov/) (<https://medlineplus.gov/>), related topics: [Prostate Cancer](https://medlineplus.gov/prostatecancer.html) (<https://medlineplus.gov/prostatecancer.html>)

[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>).

Study Contact ⓘ

Name: Novartis Pharmaceuticals
Phone Number: 1-888-669-6682
Email: novartis.email@novartis.com

Study Contact Backup

Name: Novartis Pharmaceuticals
Phone Number: +41613241111

This study has 28 locations

United States

Massachusetts Locations

 **Boston, Massachusetts, United States, 02115**
Recruiting
Dana Farber Cancer Institute
Contact : Jenna Baumeister
617-632-5136 jenna_baumeister@dfci.harvard.edu
Principal Investigator : Xiao Wei

Missouri Locations

 **St Louis, Missouri, United States, 63110**
Recruiting
WA Uni School Of Med
Contact : Ashley Murray
314-454-8293 ashley.murray@wustl.edu
Principal Investigator : Jeff Michalski

Australia

New South Wales Locations

 **Darlinghurst, New South Wales, Australia, 2010**
Recruiting
Novartis Investigative Site

Queensland Locations

 **Herston, Queensland, Australia, 4029**
Recruiting
Novartis Investigative Site

Brazil

São Paulo Locations

 **São Paulo, São Paulo, Brazil, 05652-000**
Recruiting
Novartis Investigative Site

China

 **Beijing, China, 100036**
Recruiting
Novartis Investigative Site

 **Shanghai, China, 200032**
Recruiting
Novartis Investigative Site

 **Tianjin, China, 300308**
Recruiting
Novartis Investigative Site

Hubei Locations

 **Wuhan, Hubei, China, 430022**
Recruiting
Novartis Investigative Site

 **Wuhan, Hubei, China, 430030**
Recruiting
Novartis Investigative Site

Jiangsu Locations

 **Nanjing, Jiangsu, China, 210006**
Recruiting
Novartis Investigative Site

 **Nanjing, Jiangsu, China, 210029**
Recruiting
Novartis Investigative Site

Sichuan Locations

 **Chengdu, Sichuan, China, 610041**
Recruiting
Novartis Investigative Site

Israel

 **Petah Tikva, Israel, 4941492**
Recruiting
Novartis Investigative Site

 **Ramat Gan, Israel, 5265601**
Recruiting
Novartis Investigative Site

 **Tel Aviv, Israel, 6423906**
Recruiting
Novartis Investigative Site

Japan

 **Kyoto, Japan, 606 8507**
Recruiting
Novartis Investigative Site

Chiba Locations

 Kashiwa, Chiba, Japan, 277 8577
Recruiting
Novartis Investigative Site

Hokkaido Locations

 Sapporo, Hokkaido, Japan, 060 8648
Recruiting
Novartis Investigative Site

Hyōgo Locations

 Kobe, Hyōgo, Japan, 650-0047
Recruiting
Novartis Investigative Site

Ishikawa-ken Locations

 Kanazawa, Ishikawa-ken, Japan, 920 8641
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Kanagawa Locations

 Yokohama, Kanagawa, Japan, 236-0004
Recruiting
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Singapore

 Singapore, Singapore, 119228
Recruiting
Novartis Investigative Site

 Singapore, Singapore, 168583
Recruiting
Novartis Investigative Site

South Korea

 Seoul, South Korea, 03080
Recruiting
Novartis Investigative Site

 Seoul, South Korea, 05505
Recruiting
Novartis Investigative Site

Taiwan

 Taipei, Taiwan, 10002
Recruiting
Novartis Investigative Site

 Taipei, Taiwan, 103616
Recruiting
Novartis Investigative Site

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:

- adults ≥ 18 years of age.
- ECOG performance status of 0 to 2.
- histopathological and/or cytological confirmation of adenocarcinoma of the prostate.
- PSMA-positive disease as assessed by PSMA PET/CT scan using an approved PSMA imaging agent as protocol instructed,
- castrate level of serum/plasma testosterone (< 50 ng/dL or < 1.7 nmol/L).
- Prior treatments with an androgen receptor pathway inhibitor (ARPI) and taxane-based chemotherapy, and progressed on or after [177Lu]Lu-PSMA targeted therapy.
- ≥ 1 metastatic lesion that is present on screening/baseline CT, MRI, or bone scan imaging obtained ≤ 28 days prior to randomization
- eGFR as requested by the sponsor

Exclusion Criteria:

- Any investigational agents within 28 days prior to the day of randomization.
- Any 225Ac-based investigational compound used prior to the day of randomization.
- Participants with a history of CNS metastases who are neurologically unstable, symptomatic, or receiving corticosteroids for the purpose of maintaining neurologic integrity.
- Concurrent acute kidney injury (renal failure developed between 48 hours to 7 days) or chronic kidney disease (at least 3 months of ongoing renal injury)
- Baseline xerostomia ≥ Grade 2 by CTCAE v.5
- History of uncontrolled hypertension, myocardial infarction (MI), angina pectoris, or coronary artery bypass graft (CABG) within 6 months prior to ICF signature and/or clinically active significant cardiac disease
- History of lymphoproliferative disease or any known malignancy or history of malignancy of any organ system within the past 5 years (except for basal cell carcinoma or actinic keratosis that have been treated with no evidence of recurrence in the past 3 months, non-invasive malignant colon polyps that have been removed).

Other protocol-defined inclusion/exclusion criteria may apply.

Ages Eligible for Study

18 Years to 100 Years (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 ¹	Intervention/Treatment ¹
Experimental: Phase II: AAA817 Dose B AAA817 will be given for a number of cycles; a cycle = 8 weeks	Drug: AAA817 - Investigational treatment is the Dose B of AAA817 - Other Names: [225Ac]Ac-PSMA-617
Active Comparator: Phase III: Investigator's choice of SoC Participants will be given Standard of Care (SOC) treatment per Investigator's choice.	Drug: Investigators choice of SoC The control treatment in Phase III is investigator's choice of SoC
Experimental: Phase II: AAA817 Dose A AAA817 Dose A will be given for a number of cycles: a cycle = 8 weeks	Drug: AAA817 - The investigational treatment is AAA817 - Other Names: [225Ac]Ac-PSMA-617)
Experimental: Phase III: Recommended Phase 3 Dose of AAA817 Rp3D of AAA817 will be given for a number of cycles; a cycle = 8 weeks	Drug: AAA817 - The investigational treatment is AAA817 - Other Names: [225Ac]Ac-PSMA-617)

What is the study measuring?

Primary Outcome Measures ¹

Outcome Measure	Measure Description	Time Frame
Biochemical response rate (Phase II)	Biochemical response rate as defined as the percentage of participants who achieved a $\geq 50\%$ decrease from baseline that is confirmed by a second measurement	from date of randomization up to approximately 24 months
Adverse Events (AEs) and Serious Adverse Events (SAEs), and deaths - Phase II	Safety defined as the type, incidence and severity of AEs and SAEs, and deaths	from day of randomization to 30 days after End of Treatment or (last AAA817 dose date + 55 days, last dose date of SoC + 30 days), whichever is later
Tolerability of the proposed dose of AAA817- Phase II	Percentage of participants who experienced Dose interruptions, reductions, discontinuation, dose intensity and duration of exposure	From on-treatment period which start from the first dose of study treatment

		until 30 days post-last dose date for SoC and 55 days post last-dose for AAA817
Radiographic progression-free survival (rPFS)- Phase III	Percentage of participants who are alive without radiographic progression or who are lost to follow-up at the time of analysis	from date of randomization up to approximately 24 months
Overall survival (OS)- Phase III	Percentage of participants who are alive or who are lost to follow-up at the time of analysis	from date of randomization up to approximately 24 months

Secondary Outcome Measures ⓘ

Outcome Measure	Measure Description	Time Frame
Radiographic progression-free survival (rPFS)- Phase II	Percentage of participants who are alive without radiographic progression or who are lost to follow-up at the time of analysis	from date of randomization up to approximately 24 months
Progression free survival (PFS)- Phase II	Percentage of Participants meeting Progression Free Survival	from date of randomization up to approximately 24 months
Overall response rate (ORR)- Phase II	Percentage of participants with best overall response (BOR) of complete response (CR) or partial response (PR)	from date of randomization up to approximately 24 months
Disease control rate (DCR)- Phase II	Percentage of participants with BOR of CR, PR, stable disease (SD) or non-CR/non-PD	from date of randomization up to approximately 24 months
Overall survival (OS)- Phase II	Percentage of participants who are alive or who are lost to follow-up at the analysis data cut-off	from date of randomization up to approximately 24 months
Progression free survival (PFS) - Phase III	Percentage of participants with PFS -defined as the time from date of randomization to first documented progression	from date of randomization up to approximately 24 months
Overall response rate (ORR)- Phase III	ORR is defined as the percentage of participants with best overall response (BOR) of confirmed complete response (CR) or partial response (PR)	from date of randomization up to approximately 24 months

Disease control rate (DCR) -Phase III	DCR is defined as the percentage of participants with BOR of confirmed CR, PR, stable disease (SD) or Non-CR/Non progressive disease (PD)	from date of randomization up to approximately 24 months
Duration of response (DoR)- Phase III	Percentage of participants with confirmed DoR defined as duration of time between the date of first documented response (CR or PR) and progression or death due to any cause, whichever occurs first.	from date of randomization up to approximately 24 months
Time to first radiographic soft tissue progression (TTSTP)- Phase III	Percentage of participants with confirmed first radiographic progression in soft tissue	from date of randomization up to approximately 24 months
First symptomatic skeletal event (TTSSE)_Phase III	Percentage of participants with confirmed skeletal event is defined as new symptomatic pathological bone fracture, spinal cord compression, tumor-related orthopedic surgical intervention, or requirement for radiation therapy to relieve bone pain, or death due to any cause, whichever occurs first	from date of randomization up to approximately 24 months
Prostate specific antigen (PSA) response -Phase III	PSA50 is defined as the percentage of participants who achieved a confirmed $\geq 50\%$ decrease from baseline	from date of randomization up to approximately 24 months
Patient reported disease related symptoms and health-related quality of life (HRQoL): Phase III	Percentage of participants who had a Change from baseline on FACT-P Prostate Cancer Subscale (PCS)	from date of randomization up to approximately 24 months
Time to worsening on the Worst Pain: Phase III	Time to worsening on the Worst Pain defined as the time from randomization to the first occurrence of worsening on the Worst Pain item (brief pain inventory - short form (BPI-SF)) of at least 30% of baseline or minimum of 2 points increase from baseline, or death due to any cause, whichever occurs first. BPI-SF is a self-reported questionnaire to evaluate pain intensity (severity) and impact of pain on the participant's daily functioning (interference).	from date of randomization up to approximately 24 months

Collaborators and Investigators

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

Sponsor ⓘ

Novartis Pharmaceuticals

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 ⓘ

Study Record Updates

Last Update Submitted that met QC Criteria ⓘ

2024-12-17

First Submitted that Met QC Criteria ⓘ

2025-01-16

First Posted ⓘ

2025-01-17

2025-11-07

Last Update Posted (Estimated) ⓘ

2025-11-12

Last Verified ⓘ

2025-11

More Information

Terms related to this study

Keywords Provided by Novartis (Novartis Pharmaceuticals)

post [177Lu]Lu-PSMA targeted therapy
PSMA-positive
mCRPC adults
Metastatic castration-resistant prostate cancer
AAA817
[225Ac]Ac-PSMA-617
PSMA-based targeted therapy
Standard of Care
SOC

Additional Relevant MeSH Terms

Genital Neoplasms, Male
Urogenital Neoplasms
Neoplasms by Site
Neoplasms
Genital Diseases, Male
Genital Diseases
Urogenital Diseases
Prostatic Diseases
Male Urogenital Diseases
Prostatic Neoplasms
(225)Ac-PSMA-617

[HHS Vulnerability Disclosure](#)

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