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

Last Update: Mar 03, 2025
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
ClinicalTrials.gov Identifier:
NCT06780670
Novartis Reference Number:CAAA817A12201
See if you Pre-qualify
All compounds are either investigational or being studied for (a) new use(s). Efficacy and safety have not been established. There is no guarantee that they will become commercially available for the use(s) under investigation.

Study Description

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 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.

Condition
Prostate Cancer
Phase
Phase2, Phase3
Overall Status
Recruiting
Number of Participants

432
Start Date
Feb 27, 2025
Completion Date
May 31, 2033
Gender
Male
Age(s)
18 Years - 100 Years (Adult, Older Adult)

Interventions

Drug

AAA817

Investigational treatment is the Dose B of AAA817
Drug

Investigators choice of SoC

The control treatment in Phase III is investigator's choice of SoC

Eligibility Criteria

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.

Singapore

Novartis Investigative Site

Recruiting

Singapore,168583,Singapore

Worldwide Contacts

If the location of your choosing does not feature any contact detail, please reach out using the information below.

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Source URL: *https://prod1.novartis.com/clinicaltrials/study/nct06780670*

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