An Open-label Study Comparing Lutetium (177Lu) Vipivotide Tetraxetan Versus Observation in PSMA Positive OMPC.

Last Update: May 21, 2025
An International, Prospective, Open-label, Multi-center, Randomized Phase III Study Comparing Lutetium (177Lu) Vipivotide Tetraxetan (AAA617) Versus Observation to Delay Castration or Disease Recurrence in Adult Male Patients With Prostate-specific Membrane Antigen (PSMA) Positive Oligometastatic Prostate Cancer (OMPC)
ClinicalTrials.gov Identifier:
NCT05939414
Novartis Reference Number:CAAA617D12302
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

The purpose of this study is to evaluate the efficacy and safety of lutetium (177Lu) vipivotide tetraxetan (AAA617) in participants with oligometastatic prostate cancer (OMPC) progressing after definitive therapy to their primary tumor. The data generated from this study will provide evidence for the treatment of AAA617 in early-stage prostate cancer patients to control recurrent tumor from progressing to fatal metastatic disease while preserving quality of life by delaying treatment with androgen deprivation therapy (ADT). All participants will be assessed for eligibility and will undergo baseline disease assessments including a mandatory gallium (68Ga) gozetotide (also known as \[68Ga\]Ga-PSMA-11) or piflufolastat (18F) (also known as\[18F\]DCFPyL) PET/CT scan and conventional imaging (i.e., CT/MRI and bone scans).

Piflufolastat (18F) PET/CT scan will be performed in countries where it is approved.

Stereotactic Body Radiation Therapy (SBRT) will be administered to all metastatic Prostate Cancer (PC) lesions after randomization and before the start of treatment with AAA617 or observation.

* The duration of SBRT procedures is approximately 3 weeks.
* For participants randomized to the investigational arm (AAA617), the treatment duration will be up to 4 cycles of AAA617. For participants randomized to the control arm (observation) the treatment duration will end at the last fraction of SBRT administration.
* The visit frequency will be every week 1 and 3 of each of the 4 cycles and every 16 weeks thereafter (for both arms) until first event of disease progression (RECIST 1.1)
* The study duration is approximately 6.5 years.

Condition
Oligometastatic Prostate Cancer (OMPC)
Phase

Phase3
Overall Status
Recruiting
Number of Participants
450
Start Date
Mar 12, 2024
Completion Date
Jul 09, 2030
Gender
Male
Age(s)
18 Years - 100 Years (Adult, Older Adult)

Interventions

Drug

AAA617

Stereotactic Body Radiation Therapy (SBRT) followed by AAA617 will be administered once every 6 weeks (1 cycle) for a planned 4 cycles to participants randomized to the Investigational arm

Eligibility Criteria

Key Inclusion criteria:

1. Histologically confirmed prostate cancer prior to randomization
2. Participants must have biochemically recurrent disease after definitive treatment to prostate by Radical Prostatectomy ((RP), (alone or with post-operative radiation to prostate bed/pelvic nodes)) or External beam Radiation Therapy (XRT), (prostate alone or prostate with seminal vesicle and/or pelvic nodes) and/or brachytherapy prior to randomization. Biochemical recurrence is defined as: nadir PSA + 2 ng/mL post XRT (if participant received-radiation therapy to intact prostate) and PSA \> 0.2 ng/mL and rising post RP (with or without post-operation Radiation Therapy (RT))
3. Participants must have OMPC with =\< 5 PSMA-positive metastatic lesions on screening PSMA PET/CT scan (with either gallium (68Ga) gozetotide or piflufolastat (18F)) as visually assessed by BIRC based on the methodology proposed in the Prostate Cancer Molecular Imaging Standardized Evaluation (PROMISE v2) (Seifert et al 2023); for further details, please refer to Section 8.1 and the Imaging Manual. Metastatic lesions may include regional/pelvic lymph nodes (N1), distant lymph nodes (M1a), bone (M1b), lung and others visceral (M1c) except liver and brain classified using AJCC 8. When counting the number of oligometastatic lesions, each lesion is counted as distinct metastasis irrespective of its anatomical location (e.g., one pelvic and one extra-pelvic lymph node will be counted as two metastatic lesions)
4. At least 1 PSMA-positive lesion should be a distant metastasis (M1) per AJCC8 classification at screening. For AJCC M staging, PSMA PET information should be used
5. Participants must have a negative conventional imaging for M1 disease at screening.

Note:
* For a participant not to be eligible, CI positive M1 lesions should be unequivocal in CI scans, i.e., potentially not attributable to findings thought to represent something other than tumor (e.g., degenerative, or post-

traumatic changes or Paget's disease in bone lesions). For conventional imaging assessments, bone lesions must be assessed by bone scan only and soft tissue lesions must be assessed by CT/MRI scans only at screening.
* Prior knowledge of PSMA PET positivity should not influence the radiologist (reader) in determination of CI positivity. Two different readers will be involved, one reader for PSMA PET scan and one reader for CI: Reader will be blinded to PSMA PET scan results while reading CI scans. Reader should not modify their assessment of CI scans (e.g. changing a lesion previously identified as equivocal in CI to unequivocal) after reading the PSMA PET scan. Similarly, biopsy positivity should not influence the reader in the assessment of CI positivity. More details on the reading paradigm will be provided in the imaging charter
* MRI for radiation treatment planning may show M1 disease but this will not exclude the participant from the study if the lesion is deemed negative per baseline CT or bone scans
* Participants with pelvic disease (N1) seen in conventional imaging are allowed if the local spread is below common iliac bifurcation (per AJCC 8 definition of local disease)
* Distant lymph node disease (M1a) that is visible per CI and less than 10mm in the short axis is not exclusionary irrespective of PSMA PET positivity.
* If a previously surgically removed lesion was unequivocal for M1 by bone scan or CT, the participant is not eligible.
6. All metastatic lesions detected at screening should be amenable to SBRT
7. Non-castration testosterone level \>100 ng/dL at screening

Key Exclusion criteria:

1. Participants with de novo OMPC at screening
2. Unmanageable concurrent bladder outflow obstruction or urinary incontinence at screening. Note: participants with bladder outflow obstruction or urinary incontinence, which is manageable and controlled with best available standard of care (incl. pads, drainage) are allowed
3. Prior therapy with:

1. ADT including bilateral orchiectomy

* Participants who had XRT or RP and completed adjuvant ADT (or ADT+ARPI) prior to recurrence are eligible to participate if the last dose of ADT (or ADT+ARPI) was before 12 months from randomization. Participants who had prior SBRT with short term ADT (3-6 months) are also allowed if the ADT was stopped at least 12 months before randomization.
* Participants who discontinued ADT due to disease progression are not allowed (i.e., Castration-Resistant Prostate Cancer (CRPC) participants)
2. Other hormonal therapy. e.g.,

* Use of estrogens, 5-α reductase inhibitors (finasteride, dutasteride), other steroidogenesis inhibitors (aminoglutethimide) if used in the context of prostate cancer treatment. Same medications are allowed if used for other indications: e.g., Benign Prostatic Hyperplasia (BPH), if stopped at least 5 half-lives before randomization.
* First-generation anti-androgens (bicalutamide, flutamide, nilutamide, cyproterone)
* Second generation anti-androgens (e.g., enzalutamide, apalutamide and darolutamide)
* CYP17 inhibitors (e.g., abiraterone acetate, orteronel, galeterone, ketoconazole). Short term ketoconazole treatment (\<28 days) is permitted
3. Radiopharmaceutical agents (e.g., Strontium-89, PSMA-targeted radioligand therapy)
4. Immunotherapy (e.g., sipuleucel-T)
5. Chemotherapy, except if administered in the adjuvant/neoadjuvant setting completed \> 12 months before randomization

6. Any other investigational or systemic agents for metastatic disease
4. Radiation therapy external beam radiation therapy (EBRT) and brachytherapy within 28 days before randomization
5. Concurrent cytotoxic chemotherapy, immunotherapy, radioligand therapy, hormonal therapy (see ADT initiation guidance in Section 6.8.2), Poly Adenosine Diphosphate-Ribose Polymerase (PARP) inhibitor, biological therapy or investigational therapy
6. Diagnosed at screening with other malignancies that are expected to alter life expectancy or may interfere with disease assessment. However, participants with a prior history of malignancy that has been adequately treated and who have been disease/treatment free for more than 3 years are eligible, as are participants with adequately treated non-melanoma skin cancer and superficial bladder cancer.
7. History or current diagnosis of ECG abnormalities indicating significant risk of safety for participants participating in the study such as:

* Concomitant clinically significant cardiac arrhythmias, e.g. sustained ventricular tachycardia, and clinically significant second or third degree Atrioventricular (AV) block without a pacemaker
* History of familial long QT syndrome or known family history of Torsades de Pointe
8. Participants in immediate need of ADT as assessed by the investigator.

Other protocol defined Inclusion/Exclusion may apply.

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