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A Study of Radiation Dosimetry, Safety, and Tolerability of Extended Lutetium (177Lu) Vipivotide Tetraxetan Treatment in Chemo-naïve Adults With Metastatic Castration-resistant Prostate Cancer: RADIOpharmaceutical DOSimetry Evaluation (RADIODOSE) Study

Last Update: Apr 18, 2025

A Phase I, Open-label, Multi-center Study of Radiation Dosimetry, Safety, and Tolerability of Extended Lutetium (177Lu) Vipivotide Tetraxetan Treatment in Chemo-naïve Adults With Metastatic Castration-resistant Prostate Cancer

ClinicalTrials.gov Identifier:
NCT06531499

Novartis Reference Number:CAAA617A12101

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 the study is to assess and evaluate dosimetry, safety, and tolerability following administration of up to 12 cycles of (177Lu) vipivotide tetraxetan (also referred to as \[177Lu\]Lu-PSMA-617 or 177Lu-PSMA-617 and hereafter identified as AAA617) in taxane-naïve adult participants with PSMA-positive mCRPC who progressed on a prior ARPI treatment with normal renal function or mild renal impairment (eGFR ≥ 60ml/min). The study includes screening period, treatment period, and a post-treatment follow-up period.

Screening Period: Approximately 106 participants will be enrolled to receive up to12 consecutive cycles of AAA617. Potential participants will be assessed for eligibility by verifying their baseline PSMA PET scan for mandatory confirmation of PSMA positivity prior to first cycle by local review.

Treatment Period: Eligible participants will be treated with up to 12 cycles of 7.4 GBq AAA617 intravenously every 6 weeks, until radiographic progression, toxicity leading to treatment discontinuation, death, loss to follow-up, or withdrawal of consent, whichever occurs first. During treatment period, all participants who complete the initial 6 cycles of AAA617 treatment will undergo an additional PSMA-PET scan after Cycle 6 to re-assess PSMA expression level and to reassess eligibility of participants to receive additional AAA617 treatment cycles.

Post-Treatment Follow-Up: All participants will undergo a PSMA-PET scan at end of treatment (EOT). The post-treatment follow-up period will consist of EOT; 42-days safety; EOT RLI; safety, survival and rPFS follow-up visits.

The planned duration of treatment period is up to 74 weeks with treatment given every 6 weeks. Participants may be discontinued from treatment earlier due to unacceptable toxicity or disease progression, and/or at the discretion of the Investigator or the participant.

Condition
Metastatic Castration-Resistant Prostate Cancer
Phase
Phase1
Overall Status
Recruiting
Number of Participants
106
Start Date
Nov 11, 2024
Completion Date
Feb 09, 2028
Gender
Male
Age(s)
18 Years - 100 Years (Adult, Older Adult)

Interventions

Drug

AAA617

\[177Lu\]Lu-PSMA-617 will be administered as an intravenous infusion at a dose of 7.4 GBq (200mCi) (+/- 10%), every 6 weeks for up to 12 cycles.
Drug

Gonadotropin-releasing hormone (GnRH) analogues

Anatomical Therapeutic Chemical \[ATC\] code L02AE
Drug

Gonadotropin-releasing hormone (GnRH) antagonists

Degarelix, Relugolix

Eligibility Criteria

Key Inclusion Criteria:

* Signed informed consent must be obtained prior to participation in the study.
* Participants must be adults ≥ 18 years of age.
* Participants must have an ECOG performance status ≤ 1.
* Participants must have histological confirmation of adenocarcinoma of the prostate.
* Participants must be PSMA-positive per 68Ga-PSMA PET/CT scans at baseline

* Participants must have a castrate level of serum/plasma testosterone (\< 50 ng/dL or \< 1.7 nmol/L) either by pharmaceutical or surgical methods.
* Participants must have progressed only once on prior second generation ARPIs
* Documented progressive mCRPC
* Participants must have ≥ 1 metastatic lesion by conventional imaging that is present on screening/baseline CT, MRI, or bone scan
* Renal: eGFR ≥ 60 mL/min/1.73m2 using the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation.
* Participants must have recovered to ≤ Grade 2 from all clinically significant toxicities related to prior therapies except alopecia.

Key exclusion Criteria:

* Previous treatment with any of the following within 6 months of study enrollment: Strontium 89, Samarium-153, Rhenium-186, Rhenium-188, Radium-223, hemi-body irradiation
* Any previous radioligand therapy.
* Prior treatment with cytotoxic chemotherapy for metastatic castration-resistant or metastatic hormone-sensitive prostate cancer (mHSPC) (e.g., taxanes, platinum, estramustine, vincristine, methotrexate, etc.), immunotherapy or biological therapy \[including monoclonal antibodies\]. \[Note: Taxane exposure (maximum 6 cycles) in the adjuvant or neoadjuvant setting is allowed if 12 months have elapsed since completion of this adjuvant or neoadjuvant therapy. Prior treatment with sipuleucel-T is allowed\].
* Concurrent therapies: cytotoxic chemotherapy, immunotherapy, radioligand therapy, PARP inhibitor, biological, or investigational therapy
* History of 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
* Concurrent serious acute or chronic nephropathy and/or moderate to severe renal impairment as determined by the principal investigator.
* Diagnosed with other active malignancies that are expected to alter life expectancy or may interfere with disease assessment
* Sexually active males unwilling to use a condom during intercourse while taking study treatment and for 14 weeks after stopping study treatment.
* Concurrent urinary outflow obstruction or unmanageable urinary incontinence
* History of somatic or psychiatric disease/condition that may interfere with the aims and assessments of the study.

Other protocol-defined inclusion/exclusion criteria may apply.

Netherlands

Novartis Investigative Site

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