Study of 177Lu-PSMA-617 In Metastatic Castrate-Resistant Prostate Cancer in Japan

Last Update: May 22, 2025
A Prospective, Open Label, Multicenter, Single Arm, Phase 2 Study of 177Lu-PSMA-617 in the Treatment of Participants With Progressive PSMA- Positive Metastatic Castration-resistant Prostate Cancer (mCRPC) in Japan
ClinicalTrials.gov Identifier:
NCT05114746
Novartis Reference Number:CAAA617A11201
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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 assess the efficacy, tolerability, safety, pharmacokinetic (PK) and dosimetry of 177Lu-PSMA-617, in participants with progressive prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) in Japan. Furthermore, the safety, PK and dosimetry of 68Ga-PSMA-11 (PSMA imaging agent) are assessed in the same study.

Another purpose of this study is to provide humanistic perspective access to study treatment (68Ga-PSMA-11 and 177Lu-PSMA-617) for the eligible patients with PSMA-positive mCRPC until marketed products are available in Japan.

Furthermore, if data availability PK and dose rate of 177 Lu-PSMA-617 will be evaluated to refine discharge criteria in Japan.

After obtaining manufacturing and marketing approval in Japan, this clinical trial will continue as a post marketing trial. This study is an open label, multicenter, single arm, phase II study to evaluate the efficacy, tolerability, safety, PK and dosimetry of 177Lu-PSMA-617 in participants with progressive PSMA-positive mCRPC in Japan. Furthermore, the safety, PK, and dosimetry of 68Ga-PSMA-11 (PSMA imaging agent) are also evaluated in this study.

This study consists of two populations:

1. Post-taxane population:

The post-taxane population will include men with PSMA-positive mCRPC who received at least one ARDT (for example enzalutamide, abiraterone etc.) and were previously treated with at least one, but no more than two taxane regimens. Participants treated with only 1 prior taxane regimen are eligible if the participant's physician deems the participants unsuitable to receive a second taxane regimen.
2. Pre-taxane population; The pre-taxane population will include men with PSMA-positive mCRPC who were previously treated with one ARDT as last treatment and have not been exposed to a taxane-containing regimen in the CRPC or HSPC settings and for whom it is considered appropriate to delay taxane-based

chemotherapy.

This is a 4-part study: Part 1 (a safety run-in part), Part 2 (post-taxane part), Part 3 (pre-taxane part) and Part 4 (expanded trial part).

1. Part 1 (safety run-in part) will confirm the tolerability and safety of recommended regimen, once every 6-weeks, 7.4 GBq of the 177Lu-PSMA-617. Minimum of 3 participants as 177Lu-PSMA-617 tolerability evaluable participants will be enrolled. Dosimetry and PK assessments of 177Lu-PSMA-617 are mandatory for participants enrolled in this part.
2. Part 2 (post-taxane part) will evaluate the efficacy, safety, PK and dosimetry of 177Lu-PSMA-617 plus BSC/BSoC, as well as safety, PK, and dosimetry of 68Ga-PSMA-11 in post-taxane participants with PSMA-positive mCRPC.
3. Part 3 (pre-taxane part) will evaluate the efficacy, safety, PK and dosimetry of 177Lu-PSMA-617, as well as safety, PK, and dosimetry of 68Ga-PSMA-11 in taxane naïve participants with PSMA-positive mCRPC
4. Part 4 (expanded trial part) will provide humanistic perspective access of study treatment (68Ga-PSMA-11 and 177Lu-PSMA-617) for the Japanese post-taxane participants with PSMA-positive mCRPC until marketed products are available in Japan. Additional safety and efficacy of 68Ga-PSMA-11 and of 177Lu-PSMA-617 will be evaluated.

Additionally, PK and dose rate will be evaluated (PK is optional and dose rate is mandatory in Part 4).

Approximately 80 eligible participants will be enrolled in Part 4 and approximately 10 evaluable participants PK data will be collected.

This study will consist of 3 periods: screening period, treatment period, and long term follow up.

Condition
Prostate Cancer
Phase
Phase2
Overall Status
Recruiting
Number of Participants
110
Start Date
Jan 25, 2022
Completion Date
Jan 31, 2028
Gender
Male
Age(s)
20 Years - 100 Years (Adult, Older Adult)

Interventions

Radiation

177Lu-PSMA-617

administered intravenously at a dose of 7.4 GBq (+/- 10%). 7.4 GBq dose is equivalent to 200 mCi or 7400

MBq.
Radiation

68Ga-PSMA-11

68Ga-PSMA-11 is manufactured by radiolabeling of PSMA-11 precursor with 68Ga directly at clinical trial sites immediately prior to administration into participants. The 68Ga used for radiolabeling will be eluted from the 68Ge/68Ga generator. 68Ga-PSMA-11 will be prepared as a sterile solution and administered intravenously at a dose of 111 - 259 MBq (3 - 7 mCi).
Other

Best supportive/best standard of care

Best supportive/best standard of care as defined by the local investigator (Post taxane population only)

Eligibility Criteria

Key Inclusion Criteria:

* ECOG performance status:

1. Post-taxane population only: 0 to 2.
2. Pre-taxane population only: 0 to 1.

* Participants must have a previous histological, pathological, and/or cytological confirmation of prostate cancer.
* Part 1/2/3 only; Participants must have a positive 68Ga-PSMA-11 PET/CT scan, as determined by the sponsor's central reader, before the enrollment to 177Lu-PSMA-617 treatment period.
* Participants must have a positive 68Ga-PSMA-11 PET/CT scan, as determined by the local investigator, before the enrollment to 177Lu-PSMA-617 treatment period.
* Participants must have a castrate level of serum/plasma testosterone (\<50 ng/dL or \<1.7 nmol/L).
* Post-taxane population only: Participants must have received at least one ARDT (for example enzalutamide, abiraterone, apalutamide, or darolutamide, etc.) in either the hormone-sensitive/castrate-resistant or non-metastatic/metastatic prostate cancer setting.
* Pre-taxane population only: Participants must have progressed only once on prior second generation ARDT (abiraterone, enzalutamide, darolutamide, or apalutamide) and be a candidate for change in ARDT as assessed by the treating physician.

1. first generation androgen receptor inhibitor therapy (e.g. bicalutamide) is allowed but not considered as prior ARDT therapy
2. second generation ARDT must be the most recent therapy received.

* Post-taxane population only: Participants must have been previously treated with at least 1, but no more than 2 prior taxane regimens. A taxane regimen is defined as a minimum exposure of 2 cycles of a taxane. If a participant has received only 1 taxane regimen, the participant is eligible if :

a. The participant's physician deems him unsuitable to receive a second taxane regimen (e.g., frailty assessed by geriatric or health status evaluation or intolerance, etc.).

* Participants must have progressive mCRPC. Documented progressive mCRPC will be based on at least 1 of the following criteria:

1. Serum PSA progression defined as 2 consecutive increases in PSA over a previous reference value

measured at least 1 week prior. 1.0 ng/mL is the minimal starting value if confirmed rise in PSA is the only indication of progression.
2. Soft-tissue progression defined as an increase \>= 20% in the sum of the diameter (SOD) (short axis for nodal lesions and long axis for non-nodal lesions) of all target lesions based on the smallest SOD since treatment started or the appearance of one or more new lesions.
3. Progression of bone disease: two new lesions; only positivity on the bone scan defines metastatic disease to bone (PCWG3 criteria, Scher et al 2016).
* Part 1/2/3 only; Participants must have at least one measurable lesion per PCWG3-modified RECIST v1.1 on CT or MRI.

Key Exclusion Criteria:

* Previous treatment with any of the following within 6 months of the enrollment: Strontium-89, Samarium-153, Rhenium-186, Rhenium-188, Radium-223, hemi-body irradiation. Previous PSMA-targeted therapy is not allowed.
* Post-taxane population: Any systemic anti-cancer therapy (e.g. chemotherapy, immunotherapy or biological therapy \[including monoclonal antibodies\], ARDT is not included) within 28 days prior to day of the enrollment.
* Pre-taxane population: Prior treatment with PARP inhibitor, cytotoxic chemotherapy for castration resistant or castrate sensitive prostate cancer (e.g., taxanes, platinum, estramustine, vincristine, methotrexate, etc.), immunotherapy or biological therapy \[including monoclonal antibodies\]) \[Note: Taxane exposure (maximum 6 cycles) in the adjuvant or neoadjuvant setting is allowed if 12 months have elapsed since completion of this adjuvant or neoadjuvant therapy\]
* Known hypersensitivity to the components of 177Lu-PSMA-617, 68Ga-PSMA-11 or excipients or to drugs of similar classes.
* Concurrent cytotoxic chemotherapy, immunotherapy, radioligand therapy, PARP inhibitors, biological, AKT inhibitors or investigational therapy.
* Participants with a history of CNS metastases must have received therapy (surgery, radiotherapy, gamma knife) and be neurologically stable, asymptomatic, and not receiving corticosteroids for the purposes of maintaining neurologic integrity.
* Symptomatic cord compression, or clinical or radiologic findings indicative of impending cord compression.

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