# Long-Term Safety of Lutetium (177Lu) Vipivotide Tetraxetan in Participants With Prostate Cancer

Last Update: Apr 24, 2025
A Phase IV, Post-Authorization Safety Study to Investigate the Long-Term Safety of Lutetium (177Lu) Vipivotide Tetraxetan in Adult Participants With Prostate Cancer
ClinicalTrials.gov Identifier:
NCT05803941
Novartis Reference Number:CAAA617A12402
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 post-marketing study is to further characterize the long-term outcome of known or potential risks of lutetium (177Lu) vipivotide tetraxetan also known as \[177Lu\]Lu-PSMA-617 or 177Lu-PSMA-617 and hereinafter referred to as AAA617. The study also seeks to further characterize (as possible) any other AAA617 causally related serious adverse event(s) in the long-term in adults with prostate cancer who received at least one dose of AAA617 from interventional, Phase I-IV Novartis sponsored clinical trials. This is a global, prospective, multi-center, long-term follow-up (LTFU) safety study of adult participants with prostate cancer that have received at least one dose of AAA617 from interventional, Phase I-IV Novartis sponsored clinical trials.

There will be no study treatment administered to participants in this study. Participants will have visits every 6-8 months for monitoring of selected AEs and laboratory parameters. The study periods include a Baseline and Follow-up Period (up to 10 years after first dose of AAA617 in parent treatment study).

Participants should enroll into the LTFU study after parent treatment study requirements are fulfilled (refer to the parent treatment study protocol for requirements, including any additional requirements after participant enters this LTFU safety study).

The schedule of activities for this LTFU study is designed to start from date of informed consent for this LTFU study. Participants should be followed every 6 to 8 months for up to a total of 10 years starting from first dose of AAA617 in the parent treatment study. Participants entering the LTFU study will have already completed a variable portion of the required 10-year follow-up within the parent treatment study. The specific number of visits required in this LTFU study will depend upon the time of enrollment into this LTFU study following the first dose of AAA617 in the parent treatment study.

The total number of participants to be enrolled and the duration of this LTFU study will depend upon the total number treated in the parent treatment studies and their duration.

Condition
Prostate Cancer

Phase
Phase4
Overall Status
Recruiting
Number of Participants
700
Start Date
Aug 14, 2023
Completion Date
Jul 21, 2033
Gender
Male
Age(s)
18 Years - 100 Years (Adult, Older Adult)

# Interventions

Drug

### AAA617

Long-term follow-up (LTFU) safety study of adult participants with prostate cancer that have received at least one dose of AAA617 from parent interventional Novartis sponsored clinical trials.

# Eligibility Criteria

Inclusion Criteria:

* Signed informed consent must be obtained prior to participation in the study
* Must have received at least one dose of AAA617 within an interventional, Phase I-IV Novartis sponsored clinical trial in prostate cancer and have fulfilled the trial's requirements that allows them to participate in this study.

Exclusion Criteria:

- Inability to complete the needed investigational examinations due to any reason.

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