Real-world Experience With Lutetium Vipivotide Tetraxetan in Metastatic Castration Resistant Prostate Cancer

Last Update: Jan 14, 2025
Real-world Experience With Lutetium (177Lu) Vipivotide Tetraxetan in Metastatic Castration Resistant Prostate Cancer, an Observational, Multicenter, Prospective Cohort Study
ClinicalTrials.gov Identifier:
NCT06517719
Novartis Reference Number:CAAA617A1DE04
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 describe routine clinical practice with lutetium (177Lu) vipivotide tetraxetan on Health related quality of life (HRQoL) at baseline, on treatment, and post progression. This non-interventional observational, prospective cohort study is using primary data collection to describe the routine clinical practice and HRQoL of patients with Metastatic castration-resistant prostate cancer (mCRPC) initiating lutetium (177Lu) vipivotide tetraxetan using patient questionnaires.

Data will be collected at the following time points: pre-index (if patient is eligible), index date (first application of lutetium (177Lu) vipivotide tetraxetan), during treatment, at EoT, and during follow-up.

The duration of a treatment cycle is 6 weeks (± 1 week). Patients will be treated for up to 6 cycles (as per local label).

EoT visit / assessments will be performed after the last lutetium (177Lu) vipivotide tetraxetan application.

Follow-up period: patient data will be collected if available up to 1 year after EoT.

Condition
Metastatic Castration Resistant Prostate Cancer
Overall Status
Recruiting
Number of Participants
500
Start Date
Sep 04, 2024
Completion Date
Feb 01, 2028
Gender
Male

Age(s)
18 Years - 99 Years (Adult, Older Adult)

Interventions

Other

lutetium (177Lu) vipivotide tetraxetan

This is an observational study. There is no treatment allocation. The decision to initiate lutetium vipivotide tetraxetan will be based solely on clinical judgement.

Eligibility Criteria

Inclusion Criteria:

All patients must meet the following inclusion criteria during the identification period:

* Adult male patients diagnosed with mCRPC and initiating lutetium (177Lu) vipivotide tetraxetan by treating physician as per local label. After treatment decision enrollment is allowed before date of cycle 1 or within 2 weeks after the date of Cycle 1.
* ≥ 18 years old at the time of enrollment
* Written informed consent must be obtained prior to any data collection
* Willing to participate in Quality of Life post treatment date collection for 1 year

Exclusion Criteria:

Patients must not meet the following exclusion criterion during the identification period:

- Simultaneous participation in any investigational trial or simultaneous participation in another Novartis-sponsored non-interventional study with lutetium (177Lu) vipivotide tetraxetan

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Source URL: *https://prod1.novartis.com/clinicaltrials/study/nct06517719*

List of links present in page

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2. #trial-eligibility
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