Understanding drug utilisation, treatment patterns, clinical outcomes, and profile of the patients receiving lutetium (177Lu) vipivotide tetraxetan for the treatment of metastatic prostate cancer: a multicountry, AI-powered registry (PULSE)

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Study Planned

Administrative details

EU PAS number

EUPAS1000000935

Study ID

1000000935

DARWIN EU® study

No

Study countries

Canada

Germany

Italy

Portugal

Switzerland

Study description

This study is planned as a multicountry, non-interventional, longitudinal registry using language processing technology, to periodically extract and structure clinical data documented in electronic health records (EHR) of patients with mPC who are treated with lutetium (177Lu) vipivotide tetraxetan as part of routine clinical care.

Study status

Planned

Research institutions and networks

Institutions

Novartis Pharmaceuticals

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Institution

Contact details

Study institution contact

Novartis Clinical Disclosure Officer

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Study contact

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Primary lead investigator

Novartis Clinical Disclosure Officer

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 26/03/2025

Study start date

Planned: 01/08/2026

Data analysis start date

Planned: 31/07/2031

Date of final study report

Planned: 28/11/2031

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novartis Pharma AG

Study protocol

Protocol_-_Redacted_16 Mar 2026.pdf (1.39 MB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Other study registration identification numbers and links

CAAA617A02001

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

This study is planned as a non-interventional, longitudinal cohort study

Main study objective:

The primary objective of the study is to describe the real-world drug utilisation of lutetium (177Lu) vipivotide tetraxetan in patients diagnosed with metastatic prostate cancer

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

PLUVICTO

Study drug International non-proprietary name (INN) or common name

LUTETIUM (177LU) VIPIVOTIDE TETRAXETAN

Anatomical Therapeutic Chemical (ATC) code

(V10XX05) lutetium (177Lu) vipivotide tetraxetan

lutetium (177Lu) vipivotide tetraxetan

Medical condition to be studied

Prostate cancer metastatic

Population studied

Short description of the study population

The study will include patients diagnosed with metastatic prostate cancer and who meet the following criteria

Inclusion criteria

• Age ≥ 18 years at index date

• Diagnosis of mPC

• PSMA positive

• Received at least one dose of lutetium (177Lu) vipivotide tetraxetan on or after mPC diagnosis date

Exclusion criterion

• Current or prior participation in an investigational study within the 30-day period immediately prior to and including the index date, or within five half-lives of the investigational product (whichever is longer)

Age groups

- **Adult and elderly population (≥18 years)**

Estimated number of subjects

753

Study design details

Setting

Clinical routine care treatment

Outcomes

The proportion and number of patients who receive any given number of lutetium (177Lu) vipivotide tetraxetan cycles

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Data analysis plan

This study is observational, and all data analyses will be descriptive in nature as there are no prespecified hypotheses. The primary analysis is the number and proportion of patients with any given number of lutetium (177Lu) vipivotide tetraxetan cycles (e.g., 1 cycle, two cycles, ... 6 cycles), described using counts and percentages.

Secondary analyses will be as follows:

• Patient profile (demographic and clinical characteristics), which will be reported as the number of non-missing observations, mean, SD, median, minimum, maximum, and IQR for continuous variables and counts and percentages for categorical variables.

• Survival outcomes (rwOS, median rwOS, five-year rwOS, rwPFS, median rwPFS, five-year rwPFS) will be assessed using time-to-event Kaplan-Meier methodology and will be reported as descriptive statistics (e.g., median time to event, IQR) with 95% CIs. Hazard ratio from Cox proportional hazards

regression will be presented with 95% CIs. A p-value of less than 0.05 will be considered significant.

• Treatment response-related outcomes based on PSA level cutoffs will be reported as counts and percentages. Time to treatment response will be assessed using Kaplan-Meier methodology. Best overall response, overall response rate (complete response + partial response) and duration of response will be described.

• AESIs will be reported as counts and percentages.

• Changes in drug utilisation and treatment patterns will be described by reporting the number of non-missing observations, mean, SD, median, minimum, maximum, and IQR for continuous variables, and counts and percentages for categorical variables. TTNT,TTI, persistence and time to first change in dose or frequency of lutetium (177Lu) vipivotide tetraxetan outcomes will be analysed using Kaplan-Meier methodology and will be reported as descriptive statistics

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data source(s), other

Study database based on extraction of electronic health records

Data sources (types)

Electronic healthcare records (EHR)

Non-interventional study

Use of a Common Data Model (CDM)

CDM mapping

Yes

CDM Mappings

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

No