A multicentre, non-interventional, cohort analysis describing the patients’ experience focusing on safety events among metastatic hormone-sensitive prostate cancer patients treated with Androgen Receptor Pathway Inhibitors (ARPIs) followed through a Telemonitoring tool funded by the French national healthcare insurance complemented with a chart review (ESPERANTO)

First published: 07/10/2025

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Study Ongoing

Administrative details

EU PAS number

EUPAS1000000759

Study ID

1000000759

DARWIN EU® study

No

Study countries

France

Study description

Currently, there is a significant lack of real-world data regarding the use, tolerability, and patient experiences during ARPI treatment.
The data that exists is often collected from databases that rely on using proxies for the patient experience such as claims or physician notes.
While this approach can convey valuable information it may not fully represent the patient experience.

This study offers a unique and innovative approach to understanding the patients experience by leveraging the Cureety remote monitoring platform to collect information directly from the patient perspective without proxies. The dual approach of also leveraging the charts allows for collection of disease specific factors which are best identified from clinicians and also collection of additional data such as treatment duration. This dual data collection strategy—leveraging both the Cureety remote monitoring platform and patient medical records—will yield a richer, more nuanced understanding of the mHSPC patient experience during ARPI treatment.

Study status

Ongoing

Research institutions and networks

Institutions

Astellas Pharma Europe Ltd.

Contact details

Study institution contact

Clinical Trial Registration Department
clinicaltrialregistration@astellas.com

Study contact

clinicaltrialregistration@astellas.com

Primary lead investigator

Trevor Stanbury

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 21/05/2025

Study start date

Planned: 31/10/2025

Actual: 15/10/2025

Data analysis start date

Planned: 28/02/2026

Actual: 04/03/2026

Date of final study report
Planned: 31/10/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Astellas Pharma Europe Ltd.

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

9785-MA-3673

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

Evaluation of patient-reported outcomes

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

Study design: French, multicenter, non-interventional cohort study with secondary data. Review of medical records of participants/participant-reported events from French medical centers from Jul 2019-Sep 2026. Study for collecting information only. Individual’s doctor decides treatment, not sponsor.

Main study objective:

The main aims of this study are to collect safety information on different ARPIs given to men with mHSPC in France. Other aims are to learn how long the men use ARPIs, if they tolerate treatment and reasons for stopping treatment.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

XTANDI

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

ENZALUTAMIDE

Anatomical Therapeutic Chemical (ATC) code

(L02BB04) enzalutamide

enzalutamide

Medical condition to be studied

Prostate cancer metastatic

Hormone-dependent prostate cancer

Additional medical condition(s)

metastatic hormone-sensitive prostate cancer (mHSPC)

Population studied

Short description of the study population

Prostate cancer affects the prostate gland in men and needs male sex hormones such as testosterone, to grow. Androgen receptor pathway inhibitors (ARPIs) are a type of hormone therapy used to treat men with prostate cancer. They work by reducing the amount of testosterone in the body. The ARPIs are usually given with other prostate cancer treatments.

This study is for men in France who are treated with ARPIs for their prostate cancer. The men have metastatic hormone-sensitive prostate cancer (mHSPC). Metastatic means the cancer has spread to other parts of the body. Hormone

sensitive means the cancer needs male sex hormones such as testosterone to grow.

Age groups

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

Estimated number of subjects

950

Study design details

Outcomes

Primary

• Rate of treatment discontinuation due to Adverse Events (AEs).

Data analysis plan

AE rates will be calculated overall and for each ARPI along with the 2-sided 95% CI using the Clopper-Pearson method (exact CI for a binomial proportion as computed by default by the FREQ procedure using the EXACT option). For rates per person-year, Poisson regression or negative binomial (GENMOD) will be considered.

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 data source

Data source(s), other

Chart Review (Medical Health Records)

Cureety Remote Monitoring Tool

Data sources (types)

Electronic healthcare records (EHR)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown