A non-interventional, real-world study of HRRm testing, treatment patterns, and overall survival among patients with metastatic castration-resistant prostate cancer initiating treatment with talazoparib plus enzaluatime in the US.

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Study Ongoing

Administrative details

EU PAS number

EUPAS1000000963

Study ID

1000000963

DARWIN EU® study

No

Study countries

United States

Study description

On the basis of the positive results from the TALAPRO-2 clinical trial, talazoparib in combination with enzalutamide was approved for treating adults with HRR gene mutated mCRPC. Current National Comprehensive Cancer Network (NCCN) clinical practice guidelines recommend germline and somatic tumor testing for HRR gene alterations in all patients with metastatic, regional, or high-risk localized prostate cancer to identify eligibility for ARPIs. However, studies have shown that HRRm testing rates in mCRPC have been suboptimal. Additionally, as this is a newly approved therapy, the real-world treatment patterns are not well understood. The current study aims to assess the patient demographics, clinical characteristics, HRRm testing, treatment patterns, rwTTNT, rwTTD, duration of treatment, and rwOS among patients with mCRPC treated with talazoparib plus enzalutamide.

Study status

Ongoing

Research institutions and networks

Institutions

Genesis Research Group

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Neo Su

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 11/03/2025

Actual: 11/03/2025

Study start date

Planned: 02/06/2025

Actual: 02/06/2025

Data analysis start date

Planned: 01/12/2026

Date of final study report

Planned: 30/03/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer Inc

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

C3441072

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

Non-interventional, retrospective cohort study of US patients with mCRPC treated with talazoparib plus enzalutamide, using Flatiron Health’s longitudinal, demographically and geographically diverse EHR-derived database to identify treatments between 20Jun2023 and 28Feb2025.

Main study objective:

What are the treatment patterns and characteristics of mCRPC patients initiating treatment with talazoparib plus enzalutamide combination in the real world?

Among patients with mCRPC initiating talazoparib plus enzalutamide combination therapy in the US:

To describe patient demographics and clinical characteristics including HRR testing and mutation status

To assess treatment patterns in the metastatic setting including prior treatments, rwToT, reason for dose discontinuation, and dosing patterns

To describe rwTTNT, rwTTD, and rwOS

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

TALZENNA

XTANDI

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

TALAZOPARIB

ENZALUTAMIDE

Anatomical Therapeutic Chemical (ATC) code

(L02BB04) enzalutamide

enzalutamide

Population studied

Short description of the study population

Study period: January 1, 2013, August 31, 2025 (or most recent available data).

Diagnosis date: date of first diagnosis record for mCRPC.

Treatment identification period: June 20, 2023, February 28, 2025.

Index date: defined as the first initiation date of the line of therapy (LOT) containing talazoparib plus enzalutamide.

Baseline period: defined as any time prior to the index date during the study period.

Follow-up period: defined as the time from index date (inclusive) until the earliest of death, administrative end date, or loss to follow-up.

The following selection criteria have been applied by the data provider, Flatiron

Health in order to define the patients included in the mCRPC spotlight data delivery:

Inclusion criteria:

Patients must meet all of the following inclusion criteria to be eligible for inclusion in the study:

Included in Flatiron’s Health Research Database

Has two or more visits on distinct dates in Flatiron’s network

Has evidence of diagnosis of metastatic prostate cancer on or after January 1, 2013, as identified by a natural language processing (NLP)-based machine-learning (ML) model

Has evidence of treatment with enzalutamide and talazoparib on or after January 1, 2023, as identified by an NLP-based ML model or structured medication administrations or non-cancelled orders

Has evidence of mCRPC on or after January 1, 2013, as confirmed via unstructured documentation

Has histology of adenocarcinoma or not otherwise specified (NOS), as confirmed via unstructured documentation

Has evidence of treatment with talazoparib in combination with enzalutamide on or after January 1, 2023, as defined per Flatiron’s LOT business rules

Exclusion criteria:

Lacking relevant unstructured documents in the Flatiron database for review by the abstraction team

Birth sex is female or unknown

Additional study-specific eligibility criteria:

Inclusion criteria:

≥18 years of age on metastatic prostate cancer (mPC) diagnosis date

Has evidence of treatment with talazoparib in combination with enzalutamide on or after June 20, 2023 (ie, the approval date for enzalutamide and talazoparib in HRRm for mCRPC)

2.Exclusion criteria:
Evidence of enrollment in a clinical trial during study period
Evidence of enzalutamide and talazoparib initiation prior to the mCRPC diagnosis date (ie, off-label use)
Patients who discontinued treatment with talazoparib plus enzalutamide in less than 7 days of any initiation (ie, <7 days from the treatment initiation date to the discontinuation date) during the study period will be excluded. Reasons for discontinuation will be reported
Patients with other secondary malignancies or benign neoplasm during the study period

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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)

Special population of interest

Other

Special population of interest, other

Oncology patients, specifically with metastatic castration-resistant prostate cancer

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Estimated number of subjects

253

Study design details

Setting

Patients treated with talazoparib plus enzalutamide with HRRm mCRPC on or after 01Jan2023

Comparators

No comparator

Outcomes

Treatment pattern, dosing pattern, rw survival outcomes

Data analysis plan

Analyses will be conducted using the Flatiron Health mCRPC Spotlight dataset. Data preparation will include assessments of duplicate records, variable formats, missingness, allowable ranges, implausible values, temporal sequencing, and logical consistency across related variables. Identified inconsistencies or errors will be addressed using prespecified programming rules documented in the protocol or programming specifications.

Study variables, including the index date, baseline and follow-up periods, HRRm testing variables, treatment regimens, lines of therapy, exposures, covariates, and clinical outcomes, will be derived using protocol-specified algorithms. No missing data will be imputed. The number and percentage of missing observations will be reported for relevant variables, and analysis denominators will be clearly identified.

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

Flatiron Health Database

Data sources (types)

Electronic healthcare records (EHR)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Unknown

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Unknown