Therapy of metastatic castration-resistant prostate cancer with Talazoparib + Enzalutamide under real world conditions in Germany – an observational medical chart review study (PROTEGE study)

First published: 17/12/2025

Last updated: 09/01/2026

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000593

Study ID

1000000593

DARWIN EU® study

No

Study countries

Germany

Study description

This is a non-interventional, observational, retrospective, multicenter study with secondary data collection and human review of medical charts in patients with mCRPC, who received talazoparib + enzalutamide under daily routine conditions in hospitals or practices in Germany.

The primary objective of the study is to describe the effectiveness of talazoparib + enzalutamide in mCRPC patients treated in real-world clinical settings in Germany.

For patients aged 18 and older with a confirmed diagnosis of mCRPC, whose treatment with talazoparib and enzalutamide was already initiated according to routine clinical practice, EHR data will be extracted retrospectively at multiple timepoints for up to 24 months after index date (date of talazoparib + enzalutamide initiation), or until loss to follow up, death, or study termination, whichever occurs the earliest.

Study status

Ongoing

Research institutions and networks

Institutions

Pfizer

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Institution

GermanOncology GmbH

Contact details

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Study contact

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Primary lead investigator

Giovanni Zanotti

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 30/10/2024

Actual: 30/10/2024

Study start date

Planned: 29/12/2025

Actual: 16/12/2025

Date of final study report

Planned: 31/05/2028

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

C3441071

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

This is a non-interventional, observational, retrospective, multicenter, study with secondary data collection and human review of medical charts in patients with mCRPC, who received a therapy with talazoparib + enzalutamide under daily routine conditions in hospitals or practices in Germany.

Main study objective:

Primary Objective, To describe the real-world progression-free survival (rwPFS) of talazoparib + enzalutamide

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

(L01XK04) talazoparib

talazoparib

(L02BB04) enzalutamide

enzalutamide

Medical condition to be studied

Prostate cancer metastatic

Additional medical condition(s)

metastatic castration-resistant prostate cancer mCRPC

Population studied

Short description of the study population

The patient population eligible for this study includes any patient with mCRPC who have already initiated talazoparib and enzalutamide according to the locally approved label, as well as: Participants age ≥18 years of age and assigned male sex at birth with diagnosis of mCRPC, as defined by histologically or cytologically confirmed adenocarcinoma of the prostate (ICD.revision 10 C61)

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

95

Study design details

Setting

This observational, retrospective, secondary data collection study will take place in Germany, within oncological and urological practices as well as in hospitals with urological/oncological departments that have a focus on systemic treatment for prostate cancer. Up to n = 30 study sites are planned to be included.

Patients aged 18 and older with a confirmed diagnosis of mCRPC whose treatment with talazoparib and enzalutamide was already initiated according to routine clinical practice and for whom informed consent is obtained, will be included in the study. EHR data will be extracted retrospectively at multiple data collection points, at baseline and roughly 3, 6, 12 and 24 months after index date, or until loss to follow up, death, or study termination, whichever occurs the earliest.

Comparators

Not Applicable

Outcomes

Primary Outcome

1. Progression-free survival of talazoparib + enzalutamide as landmark PFS rates

Secondary outcomes

2. Overall survival rates from start of talazoparib + enzalutamide, expressed at pre-defined timepoints
3. Describe pre-treatments given prior to the initiation of talazoparib and enzalutamide, as well as the time from pretreatment start and end to talazoparib + enzalutamide initiation
4. Time from assessment of castration resistance to initiation of talazoparib + enzalutamide
5. Best responses (PSA and/or radiological) to talazoparib + enzalutamide
6. Duration of response (PSA and/or radiological) to talazoparib + enzalutamide
7. Time-to-radiological- and/or -PSA-progression to talazoparib + enzalutamide
8. Time-to-next-therapy from start of talazoparib + enzalutamide
9. Frequency and type of dose modifications and discontinuations during therapy with talazoparib + enzalutamide
10. Reasons for modifications and discontinuations of talazoparib + enzalutamide
11. Treatment continuation after modifications and discontinuations during therapy with talazoparib + enzalutamide

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Data analysis plan

All analyses in this study are descriptive in nature. The effectiveness analysis set will include all enrolled participants who received at least one dose of talazoparib and enzalutamide.

Descriptive statistics will be presented to characterize patients in terms of demographic and clinical characteristics during the baseline period closest to the index date. Means with standard deviations, medians with interquartile will be provided for continuous variables. Numbers and percentages will be provided for dichotomous variables or categorical variables.
Patient characteristics captured during baseline and at timepoints following initiation of talazoparib + enzalutamide will be summarized using descriptive statistics (frequencies and percentages for categorial variables and mean (STD) and/or median (IQR) for continuous variables). Additionally, treatment patterns during follow up period will be described using the previously described summary statistics.
Time-to-event outcomes on basis of real-world data (rwPFS, rwOS, rwTTNT) will be summarized using the Kaplan-Meier method and estimated survival curves will be displayed graphically when appropriate. Graphs will describe the number of patients at risk over time. The median, quartiles, and probabilities of an event at particular points in time will be estimated by the Kaplan-Meier method. The 95% CIs for medians and quartiles are based on the Brookmeyer-Crowley method (Brookmeyer/Crowley 1982). CIs for the estimated probability of event at a particular time point will be generated using the log(-log) method with back transformation to a CI on the untransformed scale. Summaries of the number and percentages of patients with an event will also be provided on summary tables and figures.
Real-world response rate (rwRR) will be summarized using frequencies and percentages.
Differences in effectiveness outcome measures by pre-treatment status will also be assessed and summarized.

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

Electronic Heath Records (EHR)

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

No