An International, Multicenter, Prospective Non-Interventional Study of Real-World Treatment Outcomes in Patients with Metastatic Castrate Resistant Prostate Cancer (mCRPC) treated with Talazoparib and Enzalutamide (TALENZA)

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Last updated: 26/09/2024

Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/106720

EU PAS number

EUPAS106719

Study ID

106720

DARWIN EU® study

No

Study countries

- ☐ Canada
- ☐ Germany
- ☐ United States

Study description

This prospective, longitudinal non-interventional cohort study will evaluate the safety and effectiveness of talazoparib and enzalutatmide in patients ages 18 years and older who are treated for mCRPC with a follow-up period of ≤ 3 years. Approximately 150 patients will be recruited from primary care centers, oncology clinics, and academic centers from the US, Germany, and Canada with the potential to include additional countries from the IDM region. Study enrollment will begin once the combination of talazoparib and enzalutamide is approved by local Health Authorities in the respective study countries. The study will be open for enrollment for a period of 2 years after the first patient has been enrolled. Follow-up for overall survival beyond the prespecified study monitoring period may be taken into consideration on an individual basis. Each patient’s treatment will be consistent with routine practice, corresponding with the recommendations in the local Health Authority approved product label and at the discretion of the treating physician. Tumor or germline genotyping to identify alterations in HRR genes is not a required study procedure, however screening may be conducted as part of clinical care and will be captured for this study. Patients aged 18 and older with a confirmed diagnosis of mCRPC who are initiating treatment with talazoparib and enzalutamide according to routine clinical practice will be followed for up to 3 years, or until loss to follow up, death, or study termination, whichever occurs the earliest. Follow-up eCRFs will be completed when a patient returns for clinic visits per routine clinical practice

with data collection permissible at the time of enrollment into the study (baseline) and during months 1, 3, 6, 12, 18, 24, 30, and 36. Reporting of adverse events will begin after informed consent is collected and will continue through 28 days after the last dose of talazoparib and enzalutamide.

Study status

Planned

Research institutions and networks

Institutions

Pfizer

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Syneos Health

United Kingdom

First published: 23/04/2015

Last updated: 06/03/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Multiple centres: 70 centres involved in the study

Contact details

Study institution contact

NA NA

Study contact

PfizerMediaRelations@pfizer.com

Primary lead investigator

Shilpa Viswanathan

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 22/09/2023

Study start date

Planned: 31/12/2023

Data analysis start date

Planned: 30/04/2029

Date of interim report, if expected

Planned: 01/04/2026

Date of final study report

Planned: 31/07/2029

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Main study objective:

To characterize the effectiveness and safety profile of talezoparib and enzalutamide To describe supportive care measures, healthcare utilization, and physician management in relation to safety outcomes To evaluate quality-of-life (QoL) To capture the next anti-cancer treatment after discontinuation of talazoparib and enzalutamide

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

TALZENNA

XTANDI

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

ENZALUTAMIDE

TALAZOPARIB

Anatomical Therapeutic Chemical (ATC) code

(L01XK04) talazoparib

talazoparib

(L02BB04) enzalutamide

enzalutamide

Medical condition to be studied

Hormone-refractory prostate cancer

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

150

Study design details

Outcomes

Outcomes of interest: Effectiveness: real-world progression free survival (rwPFS), second real-world progression-free survival (rwPFS-2), real-world overall survival (rwOS), PSA response, PSA doubling time, real-world objective response rate (rwRR), and real-world time to next treatment (rwTTNT) Safety: safety events of interest Healthcare resource use

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Data analysis plan

The characteristics captured during baseline assessment and follow up will be summarized using descriptive statistics. To evaluate the safety of talazoparib and enzalutamide, AEs and SAEs will be characterized by type, grade, timing, and seriousness. Cumulative incidence will be calculated as appropriate and will be further described in the SAP. For the effectiveness outcomes of interest, rwPFS2, rwPFS, and rwOS (time to event outcomes) will be evaluated using Kaplan-Meier (KM) methods. KM curves will be illustrated and the median survival and corresponding 95% confidence interval (95% CI) will be computed. Subgroup analyses may be conducted by HRRm status, prior treatment lines

(NHTs, taxane, etc.), age, race/ethnicity, year of enrollment, enrollment country, and other key subgroups pending sufficient sample size.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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