Real-World Characteristics and Treatment Patterns of Patients Treated with Talazoparib + Enzalutamide for Metastatic Castration- Resistant Prostate Cancer in the US Community Oncology Setting

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Study Planned

Administrative details

EU PAS number

EUPAS1000000931

Study ID

1000000931

DARWIN EU® study

No

Study countries

United States

Study status

Planned

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Suvina Amin

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 09/08/2024

Actual: 09/08/2024

Study start date

Planned: 30/04/2025

Date of final study report

Planned: 31/12/2026

Study protocol

C3441070 Protocol v2.0 24Jul2026_Redacted2.pdf (4.81 MB)

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 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:

Retrospective observational cohort study of EHR data

Main study objective:

Primary objectives:

1. To describe patient demographics and clinical characteristics.

2. To describe the following HRRm testing patterns:

a) The count and proportion of patients with documentation of HRRm testing overall and by timing of the first HRRm test relative to metastatic diagnosis and initiation of talazoparib + enzalutamide (i.e., prior to metastatic diagnosis, between metastatic diagnosis and initiation of talazoparib + enzalutamide)

b) The count and proportion of patients undergoing subsequent HRRm testing prior to the end of the study observation period overall and by timing of HRRm test (sample size permitting)

c) Time to the first documented HRRm testingfrom metastatic diagnosis and from initiation of talazoparib + enzalutamide

d) The distribution of HRRm test results among patients who received HRRm testing, including the count and proportion of patients with BRCA mutation(s),non-BRCA mutationsonly, or no mutations

e) The distribution of testing modality and assay type for the first documented HRRm test among patients who received HRRm testing

3. To describe treatment patterns in the metastatic setting, including:

a) Line of therapy (LOT) of initiation of talazoparib + enzalutamide (as defined in Section 9.3.1)

b) Distribution of treatment regimens received prior to initiation of talazoparib + enzalutamide, including regimens received in the mCSPC and mCRPC settings by LOT (if applicable)

c) Distribution of regimens received following initiation of talazoparib + enzalutamide through the end of the follow-up period (as defined in Section 9.1)

d) Starting dose and dose modifications of talazoparib + enzalutamide

e) Reasons for discontinuation of talazoparib + enzalutamide

Secondary objectives:

1. To describe real-world clinical outcomes from initiation of talazoparib + enzalutamide, including:
a) Real-world time to treatment discontinuation (rwTTD)
b) Real-world time to next treatment (rwTTNT)
c) Real-world progression-free survival (rwPFS)
d) Overall survival (OS)

Exploratory Objectives:
1. To describe the availability and distribution of prostate-specific antigen (PSA) and hemoglobin (Hgb) results after initiation 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

Population studied

Short description of the study population

Patients with mCRPC who initiated talazoparib + enzalutamide within the US Oncology Network ("The Network") or Non-Network practices.

Study design details

Setting

The US Oncology Network includes over 2,500 affiliated physicians operating in over 600 sites of care across states. Approximately 1.4 million US cancer patients are treated annually in The US Oncology Network. Non-Network practices are independent community-based oncology clinics that have a partnership with Ontada. Approximately 50 non-Network clinics have adopted the iKnowMed EHR and participate in real-world research activities with Ontada.

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

clinical data from the EHR system of The Network and non-Network practices

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