Treatment and Clinical Characteristics in Patients with Metastatic Castration-Resistant Prostate Cancer (mCRPC) using Talazoparib and Enzalutamide (tala+enza) Combination Therapy

First published: 01/08/2025

Last updated: 23/10/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000580

Study ID

1000000580

DARWIN EU® study

No

Study countries

United States

Study description

This non-interventional study will be conducted using secondary data collection with human review of unstructured data (clinical notes) from the Mass General Brigham (MGB) Research Patient Data Registry (RPDR) to describe the patient demographic, clinical (including HRRm status), treatment (including dose management, treatment persistence, and reasons for treatment discontinuation), and AEs characteristics in patients with mCRPC treated under real-world routine clinical care with tala+enza.

Study status

Ongoing

Research institutions and networks

Institutions

Pfizer

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Institution

Contact details

Study institution contact

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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: 01/11/2024

Actual: 01/11/2024

Study start date

Planned: 01/08/2025

Actual: 12/08/2025

Date of final study report

Planned: 31/12/2025

Study protocol

C3441073 - Tala Enza in mCRPC MGB_Protocol 20250723_Redacted.pdf (580.03 KB)

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:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Drug utilisation

Data collection methods:

Secondary use of data

Study design:

Adult, male PC patients with prescription(s) for tala+enza combination treatment on or after June 20, 2023 will be identified and followed until the end of follow-up, which is the earliest of date of death or the end of data availability.

Main study objective:

Longitudinal data from the MGB RPDR will be used to address the study objectives. The MGB RPDR is drawn from the EPIC EHR system of teaching hospitals affiliated with Harvard Medical School.
For more details, please refer to the protocol.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

ENZALUTAMIDE

TALAZOPARIB

Anatomical Therapeutic Chemical (ATC) code

(L02BB04) enzalutamide

enzalutamide

(L01XK04) talazoparib

talazoparib

Medical condition to be studied

Prostate cancer

Additional medical condition(s)

Metastatic Castration-Resistant Prostate Cancer

Population studied

Short description of the study population

Adult, male PC patients with prescription(s) for tala+enza combination treatment on or after June 20,
2023 will be identified and followed until the end of follow-up, which is the earliest of date of death or the end of data availability. The source population comprises diverse real-world patients who have received care within the MGB healthcare system, as captured in the RPDR database.

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.

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