RENAISSANCE - A multi-centre, non-interventional study of RElugolix as aNdrogen-deprivAtion therapy In patientS with advanced hormone-Sensitive prostate cANCEr

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Study Planned

Administrative details

EU PAS number

EUPAS1000000077

Study ID

1000000077

DARWIN EU® study

No

Study countries

- ☐ France
- ☐ Germany

- [ ] Italy
- [ ] Romania
- [ ] Spain
- [ ] United Kingdom

Study status

Planned

Research institutions and networks

Institutions

Accord Healthcare Limited

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Maximilan Burger

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/01/2024

Study start date
Planned: 01/05/2024

Date of final study report
Planned: 01/08/2026

Sources of funding

- Pharmaceutical company and other private sector

Study protocol

Relugolix NIS protocol 19022024 VF.pdf(481.84 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:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Primary data collection

Study design:

The goal of this study is to generate real word evidence from Europe about the population, effectiveness, and persistence of relugolix treatment in patients with advanced hormone-sensitive prostate cancer and their clinical course during treatment.

Main study objective:

To describe the effectiveness of relugolix in patients with prostate cancer in a real-life setting.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

ORGOVYX

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

RELUGOLIX

Anatomical Therapeutic Chemical (ATC) code

(L02BX04) relugolix

relugolix

Medical condition to be studied

Prostate cancer

Population studied

Age groups

Adult and elderly population (≥18 years)

Estimated number of subjects

300

Study design details

Setting

This European, multicentric, prospective cohort study (i.e. non-interventional) will be conducted in patients with advanced hormone-sensitive prostate cancer who are initiating treatment with relugolix with a planned duration of treatment of at least twelve months.

Outcomes

- Demographics (country, age, ethnicity)
- Baseline clinical characteristics (ECOG PS, baseline disease stage, location of metastases, baseline PSA level / testosterone, prior prostatectomy / radiotherapy / other local intervention, prior ADT, most recent ADT, concomitant medications for PCa, CV comorbidities/risks)
- Medical history of prostate cancer (date of diagnosis, cTNM at diagnosis, Gleason, PSA, disease stage)
- Relugolix data (date of initiation, reason, posology, interruption with the duration and the reason, date of discontinuation and reason)
- Disease evolution during the follow-up (disease state, TNM, PSA, testosterone, interventions)
- Concomitant medications for prostate cancer (name of the drug, date of initiation/discontinuation, posology, reason)
- Safety (all AE, date, causality, severity)

Data analysis plan

The primary goal of this study is to establish a database of clinical data from patients with prostate cancer treated with relugolix in a real-world practice setting that will characterize treatment patterns for prostate cancer and associated effectiveness and treatment persistence.

As such, no formal hypotheses will be tested in this study.

Data management

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