Darolutamide Observational Study in non-metastatic castration-resistant prostate cancer patients (DAROL)

First published: 28/02/2020

Last updated: 29/03/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS31734

Study ID

49948

DARWIN EU® study

No

Study countries

- ☐ Australia
- ☐ Austria
- ☐ Belgium
- ☐ Brazil

- [ ] Canada
- [ ] China
- [ ] Colombia
- [ ] Denmark
- [ ] Finland
- [ ] France
- [ ] Greece
- [ ] India
- [ ] Ireland
- [ ] Italy
- [ ] Japan
- [ ] Luxembourg
- [ ] Mexico
- [ ] Netherlands
- [ ] Norway
- [ ] Russian Federation
- [ ] Slovakia
- [ ] Spain
- [ ] Sweden
- [ ] Türkiye
- [ ] United Kingdom
- [ ] United States

Study description

The purpose of this study is to find out in the real-world setting, if darolutamide is safe and effective for patients diagnosed with prostate cancer that has not spread to other parts of the body. When a patient is enrolled to the study, his/her physician would have already made the decision to treat patient with darolutamide per local standard practice.

Study status

Ongoing

Research institutions and networks

Institutions

Bayer AG

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Bayer Clinical Trials BAYER AG clinical-trials-contact@bayer.com

Study contact

clinical-trials-contact@bayer.com

Primary lead investigator

Bayer Clinical Trials BAYER AG

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 23/07/2019

Study start date
Planned: 30/01/2020

Actual: 30/01/2020

Date of final study report
Planned: 01/08/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bayer AG

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:

Safety study (incl. comparative)

Main study objective:

To describe the safety of darolutamide in patients with nmCRPC, including the incidence of TEAEs in the real-world setting.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

DAROLUTAMIDE

Medical condition to be studied

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

800

Study design details

Outcomes

Occurrence of treatment-emergent adverse events (TEAEs) Reasonable causal relationship between darolutamide and an adverse event (AE) Action taken related to darolutamide treatment, Subject's demographics and characteristics, Dosage and dose modification, Initiation and termination dates, Reasons for ending treatment and/or observation/follow-up and discontinuations or changes of treatments, Metastasis-Free Survival, Time to Symptomatic Skeletal Event, Time to Prostate-Specific Antigen progression, Survival rate, Imaging exams, Prior and post darolutamide treatment

Data analysis plan

Statistical analyses will be of an exploratory and descriptive nature. The study is not aimed to test predefined hypotheses. All variables will be analyzed descriptively with appropriate statistical methods: categorical variables by frequency tables (absolute and relative frequencies) and continuous variables by sample statistics (i.e. mean, standard deviation, minimum, median, quartiles, and maximum). Continuous variables will be described by absolute value and as change from baseline per analysis time point, if applicable. Patients who took at least one dose of darolutamide will be included in the safety analysis set (SAF). Patients who took at least one dose of darolutamide, did not violate a major inclusion/exclusion criterion, and had at least one post-

baseline assessment after receiving darolutamide will be included in the full analysis set (FAS). Safety data will be analyzed on the SAF, effectiveness data on the FAS.

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