Radium-223 alpha Emitter Agent in non-intervention Safety Study in mCRPC popUlation for long-teRm Evaluation (REASSURE)

First published: 06/08/2014

Last updated: 28/03/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS7187

Study ID

33628

DARWIN EU® study

No

Study countries

- ☐ Argentina
- ☐ Austria
- ☐ Belgium

- [ ] Canada
- [ ] Colombia
- [ ] Czechia
- [ ] Denmark
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Israel
- [ ] Italy
- [ ] Luxembourg
- [ ] Mexico
- [ ] Netherlands
- [ ] Portugal
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom
- [ ] United States

Study description

Observational study in the routine clinical practice setting to evaluate the short and long term safety profile of Radium-223 in metastatic castration resistant prostate cancer patients and to evaluate the risk of developing second primary cancers.

Study status

Ongoing

Research institutions and networks

Institutions

Bayer AG

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Last updated: 01/02/2024

Institution

Contact details

Study institution contact

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

Study contact

clinical-trials-contact@bayer.com

Primary lead investigator

Bayer Clinical Trials Contact Bayer AG

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 05/05/2014

Study start date

Planned: 31/08/2014

Actual: 20/08/2014

Date of final study report
Planned: 30/06/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bayer AG

Study protocol

16913_ REASSURE_Study Protocol.pdf(1.45 MB)

16913_Study Protocol_V5.0_2018-08-20_Redacted.pdf(6.57 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Other study registration identification numbers and links

CT.gov number: NCT02141438

Methodological aspects

Study type

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Main study objective:

To assess the incidence of all second primary malignancies in mCRPC patients treated with Radium-223, incidence of treatment-emergent SAEs, drug-related treatment emergent AEs, drug-related SAEs up to 7 years after last administration, and bone marrow suppression.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Non-randomised observational trial

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(V10XX03) radium (223Ra) dichloride

radium (223Ra) dichloride

Medical condition to be studied

Prostate cancer metastatic

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

1334

Study design details

Outcomes

-Incidence of developing second primary malignancies-Incidence of treatment-emergent SAEs -Incidence of drug-related treatment-emergent adverse events-Incidence of drug-related SAEs-Bone marrow suppression, -Overall survival-The worst pain score and pain interference score over time as determined by patient responses on the "Brief pain inventory short form" (BPI-SF) questionnaire-Incidence of bone fractures-The number of bone associated events

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Data analysis plan

Demographic data, baseline cancer characteristics, concomitant diseases, concomitant medication, BPI-SF of the included patients will be described with summary statistics. Development of second primary malignancy will be summarized using the incidence proportion and in-addition, the exposure-adjusted incidence rate (EAIR). The corresponding exact 95% confidence intervals will be given.Descriptive summaries of Kaplan-Meier (KM) estimates and KM curves will be presented for overall survival. Adverse events will be

summarized using MedDRA and the NCI-CTCAE coding system. The incidence proportion and EAIR will be estimated along with the corresponding exact 95% confidence interval.For the comparison with external reference group, incidence of second primanry malignacies in mCRPC patients treated with radium-223 from the REASSURE-study will be compared with corresponding information on patients with mCRPC indetified in the external secondary data source(s).

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 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