A Multicenter, Single-arm, Open-label, Post-marketing Safety Study to Evaluate the Risk of Seizure Among Subjects with Metastatic Castration-Resistant Prostate Cancer (mCRPC) Treated with Enzalutamide Who Are at Potential Increased Risk of Seizure

First published: 31/03/2014

Last updated: 31/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS5552

Study ID

32806

DARWIN EU® study

No

Study countries

- [ ] Argentina
- [ ] Australia
- [ ] Belgium
- [ ] Brazil
- [ ] Canada
- [ ] Chile
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Hong Kong
- [ ] Hungary
- [ ] Israel
- [ ] Italy
- [ ] Korea, Republic of
- [ ] New Zealand
- [ ] Singapore
- [ ] Spain
- [ ] Sweden
- [ ] Taiwan
- [ ] United Kingdom
- [ ] United States

Study status

Finalised

Research institutions and networks

Institutions

Astellas Pharma Global Development, Inc.

Multiple centres: 100 centres are involved in the study

Contact details

Study institution contact

Sr. Medical Director astellas.registration@astellas.com

Study contact

astellas.registration@astellas.com

Primary lead investigator

Sr. Medical Director

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/01/2013

Actual: 15/01/2013

Study start date

Planned: 20/10/2013

Actual: 23/09/2013

Data analysis start date
Planned: 11/01/2019

Actual: 12/01/2019

Date of final study report
Planned: 15/08/2019

Actual: 24/07/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Astellas Pharma Global Development, Inc.

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)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Clinical trial

Main study objective:

To evaluate the incidence of seizures and monitor the safety of enzalutamide treatment in subjects with metastatic castration-resistant prostate cancer known to have risk factor(s) for seizure.

Study Design

Clinical trial regulatory scope

Post-authorisation interventional clinical trial

Clinical trial phase

Therapeutic use (Phase IV)

Clinical trial randomisation

Non-randomised clinical trial

Clinical trial types

Single-arm trial

Study drug and medical condition

Medicinal product name

XTANDI

Medical condition to be studied

Metastases to prostate

Population studied

Short description of the study population

Metastatic Castration-Resistant Prostate Cancer (mCRPC) Treated with Enzalutamide Who Are at Potential Increased Risk of Seizure.

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)

Special population of interest

Other

Special population of interest, other

Prostate Cancer patients

Estimated number of subjects

400

Study design details

Outcomes

The proportion of evaluable subjects with at least one confirmed seizure as adjudicated by the Independent Adjudication Committee (IAC) during the 4-month treatment duration.

Data analysis plan

All data will be summarized with descriptive statistics (number of subjects, mean, standard deviation, minimum, median and maximum) for continuous endpoints, and frequency and percentage for categorical endpoints.

Documents

Study results

9785-cl-0403-eos-clrrs-02-disc01-en-final-02.pdf (129.32 KB)

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

Unknown