A Multicenter, Single-arm, Open-label, Postmarketing 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

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## 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

#### Name of medicine

**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)

### 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