# Clinical experience with cabazitaxel in patients with metastatic castrate resistant prostate cancer (ECLIPSE) (ELIPSE)

First published: 11/07/2017

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## Administrative details

EU PAS number	
EUPAS19826	
Study ID	
19827	
DARWIN EU® study	
-	
No	
Study countries	
United Kingdom	

**Study description** 

A multi-centre, observational, retrospective research study of patients with metastatic castrate resistant prostate cancer (mCRPC) who have received cabazitaxel in England. The primary objective is to describe the anti-cancer treatment pathways for patients who have received cabazitaxel following prior docetaxel treatment

#### **Study status**

Finalised

## Research institutions and networks

## **Institutions**

## Sanofi

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Institution

Multiple centres: 5 centres are involved in the study

## Contact details

**Study institution contact** 

# Medical Information Sanofi ukmedicalinformation@sanofi.com

Study contact

uk-medicalinformation@sanofi.com

## **Primary lead investigator**

Medical Information Sanofi

**Primary lead investigator** 

# Study timelines

Date when funding contract was signed

Actual: 25/03/2015

Study start date

Actual: 27/03/2015

#### Date of final study report

Actual: 07/11/2016

# Sources of funding

• Pharmaceutical company and other private sector

## More details on funding

Sanofi

# 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: Disease /health condition Human medicinal product Other
Study topic, other: Disease/Epidemiology study Study type:
Non-interventional study
Scope of the study: Disease epidemiology
Data collection methods: Secondary use of data

#### Main study objective:

Primary objective: To describe the anti-cancer treatment pathways for patients who have received cabazitaxel following prior docetaxel treatmentSecondary objectives:To describe the clinical outcomes of patientsTo describe the characteristics of patientsTo describe side effects associated with cabazitaxel use

# Study Design

#### Non-interventional study design

Other

#### Non-interventional study design, other

Observational retrospective study

# Study drug and medical condition

#### Additional medical condition(s)

Metastatic castrate resistant prostate cancer

# Population studied

#### Short description of the study population

Male patients diagnosed with metastatic castrate resistant prostate cancer (mCRPC) and had received cabazitaxel following failure of previous docetaxel treatment.

#### 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

Metastatic castrate resistant prostate cancer patients

#### **Estimated number of subjects**

150

# Study design details

#### **Data analysis plan**

Analyses are descriptive in nature. Nominal variables are described with frequencies and percentages, while ordinal variables are presented as medians and interquartile ranges (IQR). Time-to-event variables (progression-free survival PFS and overall survival OS) were analysed by the Kaplan-Meier method with data presented as survival plots and summarised as median, standard error (SE) and 95% confidence intervals 95% CI, within the follow up period available for each patient (i.e. patients still living at the date of data collection werecensored at the date of data collection for analysis of OS and patients still alive and not recorded as progressing at the time of data collection were censored on that date for analysis of PFS).

## **Documents**

#### **Study results**

SR Synopsis v1.0 07Nov2016-anonymised scan.pdf (2.75 MB)

# 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)**

Disease registry

# 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