A Post-Authorization Safety Study (PASS) to characterize the risk of secondary primary malignancy including MDS/AML among metastatic prostate cancer patients exposed to AKEEGA (niraparib/abiraterone acetate fixed-dose combination tablet) plus Prednisone/Prednisolone

First published: 24/02/2025

Last updated: 24/02/2025

Study Planned

Administrative details

EU PAS number

EUPAS1000000323

Study ID

1000000323

DARWIN EU® study

No

Study countries

Sweden

Study description

The primary objective is to estimate the incidence of myelodysplastic syndrome / acute myeloid leukemia and other second primary malignancies among patients exposed to AKEEGA and other BRCA1/2 mutated patients exposed to AAP or other neoadjuvant hormonal therapies (NHTs) indicated for metastatic castrate resistant prostate cancer (mCRPC).

Study status

Planned

Research institutions and networks

Institutions

Johnson & Johnson

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Institution

Contact details

Study institution contact

Dina Gifkins DGifkins@its.jnj.com

Study contact

DGifkins@its.jnj.com

Primary lead investigator

Dina Gifkins

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 17/07/2024

Actual: 17/07/2024

Study start date

Planned: 24/04/2025

Date of final study report

Planned: 31/12/2029

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Johnson and Johnson

Study protocol

niraparib-abiraterone-acetate niraparib-abiraterone-acetate (0015) - 1.8.2 PASS Protocol - Akeega - Clean.pdf(394.09 KB)

Regulatory

Was the study required by a regulatory body?

No

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:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Study drug and medical condition

Name of medicine

AKEEGA

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

NIRAPARIB

ABIRATERONE ACETATE

Anatomical Therapeutic Chemical (ATC) code

(L01XK52) niraparib and abiraterone

niraparib and abiraterone

Medical condition to be studied

Prostate cancer metastatic

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 source(s), other

Swedish Medical Registries, Optum Clinformatics DOD database

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes