Post-authorization safety study to evaluate the risks of myelodysplastic syndrome/acute myeloid leukemia and second primary malignancies in adult patients with platinum-sensitive, relapsed, high-grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer receiving maintenance treatment with ZEJULA® (niraparib) (213705 - Zejula PASS 3000-04-001)

First published: 07/06/2019

Last updated: 28/08/2025

Study Finalised

Administrative details

EU PAS number

EUPAS29407

Study ID

44185

DARWIN EU® study

No

Study countries

Germany

Italy

Netherlands

Spain

Study description

The post-authorization safety study is intended to determine the risk to develop myelodysplastic syndrome (MDS)/acute myeloid leukemia (AML) and secondary primary malignancy (SPM) in patients administered niraparib in the routine clinical setting to treat patients suffering from ovarian cancer.

Study status

Finalised

Research institutions and networks

Institutions

Universitäts-Frauenklinik Tübingen Calwerstraße

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Department für Frauengesundheit

Contact details

Study institution contact

GSK Clinical Disclosure Advisor Pharma.CDR@gsk.com

Study contact

Pharma.CDR@gsk.com

Primary lead investigator

GSK Clinical Disclosure Advisor

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/07/2019

Actual: 07/01/2019

Study start date

Planned: 06/11/2019

Actual: 06/11/2019

Date of final study report

Planned: 13/12/2024

Actual: 04/12/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GSK

Study protocol

Zejula PASS 3000-04-001 Protocol Version 5 Clean_02May19 Signed (005)_AMV.pdf (848.12 KB)

Protocol version 9 Anonymised 24 Aug 2025.pdf (2.26 MB)

Protocol_Amendment_Anonymized.pdf (569.13 KB)

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:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Primary data collection

Main study objective:

The objective of this PASS is to determine the risk of developing MDS/AML and SPMs in patients administered niraparib in the routine clinical setting.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

This post-authorization safety study (PASS) will be conducted as a prospective, non-interventional, single-arm study. It will also utilize a retrospective control arm as an exploratory/descriptive comparison with the results collected prospectively.

Study drug and medical condition

Medicinal product name

ZEJULA

Medicinal product name, other

Niraparib

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

NIRAPARIB

Anatomical Therapeutic Chemical (ATC) code

(L01XK02) niraparib

niraparib

Medical condition to be studied

Ovarian cancer

Population studied

Age groups

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

Estimated number of subjects

800

Study design details

Outcomes

Primary Objective: To estimate the incidence rate of MDS/AML among a cohort of adult patients with platinum-sensitive, relapsed, high-grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer treated with niraparib who are in a complete or partial response to platinum-based chemotherapy.
Secondary Objective: To estimate the incidence rate of SPMs in the same cohort.

Data analysis plan

The analysis population for all analyses is the safety population: all patients who receive any amount of niraparib (at least 1 dose). Analyses will be performed using SAS statistical software and include summary statistics (number and percentage for categorical variables and the number of patients, mean, standard deviation, median, minimum, and maximum for continuous variables).
Analyses will be descriptive, no hypothesis will be tested. Distributions of patient and tumor characteristics will be summarized. Incidence rates of MDS/AML and other SPM and their respective 95% CIs per 100 person-time units will be estimated.
The incidence of MDS/AML and SPM will be summarized across various potential risk factors for MDS/AML and SPM, such as: age, gender, chemo- and radiotherapy received, platelet transfusions, renal and/or hepatic insufficiency, CBC abnormalities, family history of MDS/AML, presence of autoimmune disorders, use of alcohol and/or tobacco and use of other PARP inhibitors.

Documents

Study report

Clinical Study Report Anonymised 28 Aug 2025.pdf (4.6 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)

Administrative healthcare records (e.g., claims)

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