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





# Administrative details

### **EU PAS number**

**EUPAS29407** 

### **Study ID**

44185

DARWIN EU® study	
No	
Charles accombates	
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

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# 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)</li>
    - 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**

# 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

# Unknown Check completeness Unknown

## **Check stability**

**Check conformance** 

Unknown

# **Check logical consistency**

Unknown

# Data characterisation

### **Data characterisation conducted**

No