Post-Marketing Observational Prospective Study to Assess Real World Outcomes and the Risk of Myelodysplastic syndromes (MDS)/acute myeloid leukaemia (AML) in Platinum Sensitive Relapsed breast cancer susceptibility gene (BRCA) Mutated Ovarian Cancer Patients Treated with Lynparza (olaparib); the LOCALISE Study

First published: 30/06/2016

Last updated: 02/07/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/18336

EU PAS number

EUPAS13757

Study ID

18336

DARWIN EU® study

No

Study countries

- [ ] Belgium
- [ ] Denmark
- [ ] Germany
- [ ] Italy
- [ ] Korea, Republic of
- [ ] Netherlands
- [ ] Poland
- [ ] Spain
- [ ] Sweden

Study description

This study is designed to collect real world outcomes in patients treated with Lynparza, will be conducted to comply with Post Authorisation Measures (PAM) in the EU and is part of additional Pharmacovigilance activities in the RMP. This non- interventional, prospective post-marketing study of Lynparza will be conducted among patients aged 18 and older with germline and/or somatic breast cancer susceptibility gene (BRCA) mutated (BRCAm) platinum sensitive relapsed high grade serous epithelial ovarian cancer, who are in response to the most recent platinum-based chemotherapy and who are on or initiating Lynparza maintenance treatment. The study will follow a group of individuals who have ovarian cancer and who share important disease factors, to collect information on outcomes and the risk of developing MDS/AML in real world, routine clinical practice. The medicines administered to the patients over the

course of the study will be selected by the patients' own physician in agreement with the patients and will be in line with the physician's standard practice, these treatments will include Lynparza. The prescription of Lynparza will be clearly separated from the decision to include the patient in the study and this decision has to be taken prior to informed consent form (ICF) signing. Following receipt of the final outcome of the PRACs assessment of the LOCALISE protocol on 01/12/16, the PRAC concluded that this PASS study was not feasible. The commitment related to MDS/AML remains in the EU, but instead of a PASS this will now be dealt with by providing them with a summary of data emerging from our ongoing clinical trial program. As a consequence, the LOCALISE PASS will no longer be conducted. Data Collection never started, but as for trial report, date of study closure has been used for actual milestone. There will be no study report.

Study status

Finalised

Research institutions and networks

Institutions

AstraZeneca

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Multiple centres: 78 centers are involved in the study

Contact details

Study institution contact

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Study contact

ClinicalTrialTransparency@astrazeneca.com

Primary lead investigator

Tapashi Dalvi

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 18/09/2016

Actual: 18/09/2015

Study start date

Planned: 17/03/2017

Actual: 01/12/2016

Data analysis start date

Planned: 06/02/2023

Date of final study report
Planned: 23/04/2023

Actual: 01/12/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AstraZeneca

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)

Other study registration identification numbers and links

D0816R00008

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

Other

If ‘other’, further details on the scope of the study

Evaluate the risk of developing MDS/AML among BRCAm platinum sensitive relapsed high grade serous epithelial ovarian cancer patients, who responded to the most recent platinum-based chemotherapy, treated with Lynparza in a real world setting.

Data collection methods:

Primary data collection

Main study objective:

The primary objective of this study is to evaluate the risk of developing MDS/AML among BRCAm platinum sensitive relapsed high grade serous epithelial ovarian cancer patients, who are in response to the most recent platinum-based chemotherapy, treated with Lynparza in real world conditions of clinical practice.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

This is an observational (non-interventional), multicentre, international, prospective cohort study of Lynparza maintenance monotherapy (prescribed in line with the EU-approved indication or local product information).

Study drug and medical condition

Name of medicine

LYNPARZA

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

OLAPARIB

Anatomical Therapeutic Chemical (ATC) code

(L01XX46) olaparib

olaparib

Medical condition to be studied

Acute myeloid leukaemia

Myelodysplastic syndrome

Population studied

Short description of the study population

Patients aged 18 and older with germline and/or somatic breast cancer susceptibility gene (BRCA) mutated (BRCAm) platinum sensitive relapsed high grade serous epithelial ovarian cancer, who were in response to the most recent platinum-based chemotherapy and who are on or initiating Lynparza maintenance 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

Ovarian Cancer Patients

Estimated number of subjects

765

Study design details

Outcomes

The primary outcome measure is the incidence rate of MDS and/or incidence rate of AML

Data analysis plan

The full analysis set (FAS) will consist of all enrolled patients without a history of MDS/AML prior to Lynparza exposure and who received at least one dose of Lynparza treatment. The FAS will be used for all analyses, although patients with a history of MDS/AML are eligible for the study, they will not be included in the FAS. Data from these patients will be listed or summarised as appropriate depending on the number of patients, and will be reported separately. Patient baseline and disease characteristics will be described using summary statistics.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

All data will be entered by site staff directly into an electronic data capture (EDC) system for review, real-time screening, and query by the designated contract research organisation (CRO) Data Management personnel.

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