A national, multi-centre, longitudinal observational study evaluating the efficacy and safety under real-life conditions of use of TALZENNA® (talazoparib) in patients with somatic or germline BRCA mutated HER2 negative, locally advanced or metastatic breast cancer (Vital Study)

First published: 17/09/2019

Last updated: 20/03/2024

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/33781

EU PAS number

EUPAS30803

Study ID

33781

DARWIN EU® study

No

Study countries

☐ France

Study description

According to estimates, locally advanced or metastatic HER2- breast cancer with the germline mutation of the gene for predisposition to breast cancer (BRCA) affected 1,160 female patients in France in 2018 and therefore is considered as a rare disorder. The benefit of treatment with talazoparib in locally advanced or metastatic breast cancer with the gBRCA mutation has been demonstrated in the phase 3 pivotal study (EMBRACA). Results obtained in this phase 3 study have also been confirmed by those obtained in the phase 2 study, ABRAZO, C3441008) and in the phase 1 study, PRP-001 (C3441007). ViTAL Study is a multi-centre, ambispective, observational study. Patients will be treated in both cohorts according to the indication of the MA or of the cohort ATU. The objective of this study is to evaluate the efficacy and safety under real-life conditions of use of talazoparib in patients treated for locally advanced or metastatic HER2- breast cancer with the BRCA mutation.

Study status

Ongoing

Research institutions and networks

Institutions

Pfizer

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Jean-Michel Vauthier

Multiple centres: 54 centres are involved in the study

Contact details

Study institution contact

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Primary lead investigator

Julien LAURENCIN

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 02/09/2019

Study start date
Planned: 08/01/2020

Actual: 18/12/2019

Data analysis start date
Planned: 31/10/2024

Date of final study report
Planned: 31/05/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

PFIZER

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 type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

To evaluate the efficacy of treatment with talazoparib in patients treated for locally advanced or metastatic HER2- breast cancer with the BRCA mutation.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

TALZENNA

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

TALAZOPARIB

Population studied

Short description of the study population

Cohort 1 : “Patient treated in the setting of a cohort ATU" ; N = 75 Cohort 2 : "Patient treated in the setting of the MA" ; N = 75

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)

Estimated number of subjects

150

Study design details

Outcomes

Efficacy of treatment evaluated by time to treatment discontinuation (TTD), all causes combined, defined as time between first and last dose of talazoparib or of death, Talazoparib Safety under real-life conditions of use/Time to treatment discontinuation of subsequent treatment/Overall survival/Best response to treatment with talazoparib/Time to treatment discontinuation of subsequent treatment/Duration of control of CNS metastases/Time before locoregional treatment in the central nervous system/Patient satisfaction concerning talazoparib treatment/Treatment

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Data analysis plan

Analyses of demographic data will be performed in the eligible populations evaluable overall and for each cohort. No inference between groups will be presented at inclusion. If an imbalance is observed, a possible adjustment will

be discussed. Analyses of efficacy will be performed in the evaluable population and the principal analysis in the 2 populations. Analyses of safety will be performed in the safety population.

Data management

Data sources

Data source(s), other

Pfizer Data Sources France

Data sources (types)

Administrative healthcare records (e.g., claims)

Electronic healthcare records (EHR)

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