Survey among healthcare professionals treating patients with metastatic breast cancer in selected European countries to evaluate their knowledge on management of hyperglycemia when using alpelisib

First published: 20/07/2021

Last updated: 28/01/2025

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/46588

EU PAS number

EUPAS42022

Study ID

46588

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Croatia
- [ ] Finland
- [ ] Italy
- [ ] Luxembourg
- [ ] Netherlands
- [ ] Norway
- [ ] Poland
- [ ] Slovenia
- [ ] Spain
- [ ] Sweden

Study description

In the EU/EEA Piqray (alpelisib) is indicated in combination with fulvestrant for postmenopausal women and men, with HR-positive HER2-negative, locally advanced or metastatic breast cancer (MBC) with PIK3CA mutation after disease progression, following endocrine monotherapy. Hyperglycemia is an expected effect of PI3K inhibition. To minimize the risk of hyperglycemia, Piqray was approved with a requirement for additional risk minimization measure using an educational material for oncologists/healthcare professionals (HCPs) prescribing Piqray in the EU/EEA, containing guidance for the management of hyperglycemia. The Piqray European Risk Management Plan (RMP) requires Novartis to conduct a Post-authorisation Safety Study (PASS) to assess the effectiveness of the educational material. This study is designed and conducted in accordance with Good Pharmacovigilance Practices Modules VIII and XVI for Category 3 PASS. This is a multinational, non-interventional, cross-sectional survey among HCPs based in the EU/EEA who prescribe Piqray. It will assess HCPs’ knowledge of the management of hyperglycemia in patients treated with Piqray, with a minimum of 100 completed surveys. A sample of HCPs who

may/do prescribe Piqray and care for patients with locally advanced or MBC will be included. Recruitment will start a minimum of 6 months following reimbursement and availability on the market of Piqray in each participating country. A web-based survey will be used in all countries. Data collected will include receipt and reading of the educational material, and knowledge of key messages included in the material. The survey is anticipated to be open for 3 months in each country. Follow-up reminders will be sent to non-respondents to support achieving the target sample size & reduce the impact of selection bias.

Study status

Ongoing

Research institutions and networks

Institutions

Novartis Pharmaceuticals

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Institution

Contact details

Study institution contact

Novartis Clinical Disclosure Officer

Study contact

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Primary lead investigator

Novartis Clinical Disclosure Officer

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 07/04/2021

Study start date

Planned: 28/02/2022

Actual: 28/02/2022

Data analysis start date

Planned: 30/12/2024

Actual: 05/06/2024

Date of final study report

Planned: 31/05/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novartis Pharma AG

Study protocol

byl719c2005--protocol_12-_Redacted.pdf(1.76 MB)

byl719c2005-01--protocol amendment_Redacted.pdf(2.14 MB)

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

BYL719C2005

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Other

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

Assess the effectiveness of HCP educational materials

Data collection methods:

Primary data collection

Main study objective:

Assess HCPs’ knowledge and understanding of the key information included in the Piqray Prescriber’s/HCP Guide for hyperglycemia, including -Risk of hyperglycemia and its potential risk factors -Signs and symptoms of hyperglycemia -Recommendations for monitoring for hyperglycemia prior to and during treatment with Piqray -Recommendations for managing hyperglycemia during treatment with Piqray.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Name of medicine

PIQRAY

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

ALPELISIB

Anatomical Therapeutic Chemical (ATC) code

(L01XE) Protein kinase inhibitors

Protein kinase inhibitors

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

103

Study design details

Outcomes

A composite based on the percentages of HCPs with correct responses to questions in the composite regarding the information below. -Risk of hyperglycemia and its potential risk factors -Signs and symptoms of hyperglycemia -Recommendations for monitoring hyperglycemia prior to and during treatment with Piqray -Recommendations for managing hyperglycemia during treatment with Piqray, - Assess HCPs' reported levels of receipt, and reading, of the Piqray Prescriber's/HCP Guide for hyperglycemia - Assess HCPs' knowledge levels for each survey question regarding knowledge of, and management of, hyperglycemia - Assess the primary source from which HCPs

learned about the messages included in the Piqray Prescriber's/HCP Guide for hyperglycemia

Data analysis plan

Survey details (e.g. number of invited HCPs, number and percentage of responding HCPs, number and percentage of eligible vs. ineligible HCPs, and number and percentage of HCPs with partially vs. fully completed surveys) and analysis sets will be described overall and by country Respondent characteristics/covariates will be summarized overall and by country. Frequencies, percentages, and corresponding 95% 2-sided CI will be used to summarize primary and secondary endpoints overall and by country. Subgroup analyses of primary endpoints may be analyzed by specialty and experience with Piqray. For the primary endpoint, the point estimate of the weighted average composite percentage of HCPs who provide correct responses to key questions will be estimated and assessed against the 70% threshold. Where subgroup analyses have small sample sizes the results should be handled with caution. Although a 70% threshold is considered success, CI for small subgroups will be wide reflecting imprecision.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Survey among healthcare providers

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