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

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# Administrative details

EU PAS number	
EUPAS42022	
Charles ID	
Study ID	
46588	
DARWIN FILE study	
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) required Novartis to conduct a Post-authorisation Safety Study (PASS) to assess the effectiveness of the educational material. This study was designed and conducted in accordance with Good Pharmacovigilance Practices Modules VIII and XVI for Category 3 PASS.

This was a multinational, non-interventional, cross-sectional survey among HCPs based in the EU/EEA who prescribe Piqray.

The primary objective of the survey was to assess the knowledge of HCPs who prescribe Piqray, specifically regarding their understanding and management of hyperglycemia in patients who are being treated with Piqray.

As per RMP requirement, the survey endeavored to collect a minimum of 100 completed surveys. HCPs were recruited from a targeted population of those who prescribe Piqray and were included in the distribution lists for the Piqray Prescriber's/HCP Guide for hyperglycemia.

Recruitment took place after at least 6 months following reimbursement and launch of Pigray in each participating country.

A web-based survey was used in all countries.

Data collected included receipt and reading of the educational material, and knowledge of key messages included in the material.

Follow-up reminders were sent to non-respondents to support achieving the target sample size and reducing the impact of selection bias.

## **Study status**

Finalised

# Research institutions and networks

## Institutions

# **Novartis Pharmaceuticals**

First published: 01/02/2024

**Last updated:** 01/02/2024

Institution

# Contact details

Study institution contact

# Novartis Clinical Disclosure Officer trialandresults.registries@novartis.com

Study contact

trialandresults.registries@novartis.com

## **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

Actual: 25/04/2025

# 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

NCT05073120

ClinicalTrials.gov registration form for BYL719C2005

# Methodological aspects

Study type

Study type list

#### **Study topic:**

Disease /health condition

#### 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 Pigray.

# 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**

(L01EM03) alpelisib alpelisib

# 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 Pigray;
- Recommendations for managing hyperglycemia during treatment with Pigray;
- 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 Pigray 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 were described overall and by country Respondent characteristics/covariates were summarized overall and by country. Frequencies, percentages, and corresponding 95% 2-sided CI were used to summarize primary and secondary endpoints overall and by country. For the primary endpoint, the point estimate of the weighted average composite percentage of HCPs who provide correct responses to key questions was estimated and assessed against the 70% threshold.

#### **Summary results**

In this study, success criteria on the primary endpoint is defined as a weighted composite knowledge level of at least 70% across key questions.

This endpoint was designed to assess overall knowledge retention and

comprehension among Health Care Professionals.

Overall, a composite score of 81.3% (95% CI: 79.1-83.4) was achieved by Health Care Professionals, thereby meeting the primary objective.

## **Documents**

#### **Study report**

CBYL719C2005\_Non-Interventional Study Final Report\_V1.0\_25Apr2025\_23 May 2025 Redacted.pdf (9.86 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)

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