Adequate effectiveness of ribociclib plus letrozole or fulvestrant in patients with advanced or metastatic hormone receptor-positive, human epidermal growth factor receptor 2-negative breast cancer treated in routine Bulgarian clinical practice

First published: 25/03/2024

Last updated: 25/03/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000083

EU PAS number

EUPAS1000000083

Study ID

1000000083

DARWIN EU® study

No

Study countries

Bulgaria

Study description

A Real-World Evidence comparison of effectiveness and outcomes of Breast Cancer Targeted Therapy with Randomized Controlled Trials (RCTs) Using Danny Platform.

Study status

Finalised

Research institutions and networks

Institutions

Sqilline Health

Bulgaria

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Non-Pharmaceutical company

The Bulgarian National Council on Prices and Reimbursement of Medicinal Products (NCPRMP)

Contact details

Study institution contact

Sqilline Health

Study contact

info@sqilline.com

Primary lead investigator

Manoela Manova

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 18/01/2023

Actual: 18/01/2023

Study start date

Planned: 01/01/2018

Actual: 01/01/2018

Date of final study report

Planned: 31/12/2022

Actual: 14/04/2023

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Main study objective:

The objective of this study was to perform a comprehensive analysis of real-world data (RWD) from the Bulgarian population.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(L01EF02) ribociclib

ribociclib

(L02BA03) fulvestrant

fulvestrant

(L02BG04) letrozole

letrozole

Additional medical condition(s)

Advanced or metastatic hormone receptor-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer

Population studied

Age groups

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

812

Study design details

Outcomes

Clinical benefit rate (CBR, defined as complete remission [CR] or partial remission [PR] or stable disease [SD]), progression-free survival (PFS) and overall survival (OS).

Documents

Study publications

Manova M, Arabadjiev J, Mangaldzhiev R, Dudov A, Penchev D, Hemetsberger M, Sha...

Data management

Data sources

Data source(s)

Danny Platform

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes