

# 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:** 01/08/2025

Study

Finalised

## Administrative details

### EU PAS number

EUPAS1000000083

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### Study ID

1000000083

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### DARWIN EU® study

No

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### Study countries

 Bulgaria

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### Study description

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

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### 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 info@sqilline.com

Study contact

[info@sqilline.com](mailto: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

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### **Study start date**

Planned: 01/01/2018

Actual: 01/01/2018

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### **Date of final study report**

Planned: 31/12/2022

Actual: 14/04/2023

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## Regulatory

### **Was the study required by a regulatory body?**

Yes

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

Not applicable

## Other study registration identification numbers and links

[Adequate effectiveness of ribociclib plus letrozole or fulvestrant in patients ...](#)

## Methodological aspects

### Study type

### Study type list

#### **Study topic:**

Human medicinal product

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#### **Study type:**

Non-interventional study

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#### **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

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### **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 ( $\geq$  65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)
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### **Estimated number of subjects**

## 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

[Adequate effectiveness of ribociclib plus letrozole or fulvestrant in patients ...](#)

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## 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 source(s)

Danny Platform

## Use of a Common Data Model (CDM)

## **CDM mapping**

No

## Data quality specifications

### **Check conformance**

Yes

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### **Check completeness**

Yes

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### **Check stability**

Yes

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### **Check logical consistency**

Yes

## Data characterisation

### **Data characterisation conducted**

Yes