# A phase IV multicentre, open-label, non-interventional study of postmenopausal women with oestrogen receptor positive locally advanced or metastatic breast cancer treated with Afinitor® (everolimus RAD001) in combination with exemestane, after progression following therapy with a non-steroidal aromatase inhibitor (BOUDICA)

**First published:** 26/03/2015

**Last updated:** 14/03/2024

Study Finalised

## Administrative details

**EU PAS number**

EUPAS9076

**Study ID**

37830

**DARWIN EU® study**

No

**Study countries**

☐ United Kingdom

**Study description**

In July 2012, Afinitor in combination with exemestane was approved for the treatment of postmenopausal women with ER+, HER2- ABC after progression on a non-steroidal aromatase inhibitor and has become an option in United Kingdom (UK) clinical practice. UK audit data and anecdotal evidence to date has suggested a higher incidence of adverse events (AEs) than expected from the reported safety profile in the BOLERO-2 trial. The primary objective of this observational study is to describe, in patients commencing treatment with Afinitor in combination with exemestane two specific toxicities, namely stomatitis and non- infectious pneumonitis (NIP) in terms of: • incidence, severity, length of time to onset, duration and clinical course, • specific management (prophylaxis and intervention), • any potential predisposing factors

**Study status**

Finalised

# Research institutions and networks

## Institutions

### Novartis Pharmaceuticals

**First published:** 01/02/2024

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

Institution

Multiple centres: 25 centres are involved in the study

## Contact details

**Study institution contact**

Novartis Clinical Disclosure Officer

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Study contact

trialandresults.registries@novartis.com

**Primary lead investigator**

Novartis Clinical Disclosure Officer

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 01/05/2014

Actual: 01/05/2014

**Study start date**
Planned: 01/04/2015

Actual: 14/04/2015

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**Data analysis start date**
Planned: 01/12/2015

Actual: 01/08/2016

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**Date of final study report**
Planned: 01/03/2017

Actual: 01/08/2017

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Novartis Pharmaceuticals

## Study protocol

crad001jgb14--protocol-v4.0-12Oct2015_Redacted.pdf (963.2 KB)

## Regulatory

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

No

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

Non-EU RMP only

## Other study registration identification numbers and links

CRAD001JGB14

# Methodological aspects

## Study type

## Study type list

**Study topic:**

Disease /health condition

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Drug utilisation

Effectiveness study (incl. comparative)

**Data collection methods:**

Combined primary data collection and secondary use of data

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**Main study objective:**

The primary objective of this study is to describe two specific toxicities, stomatitis and NIP, in patients treated with Afinitor in combination with exemestane for ABC after progression on a NSAI.

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Observational Study

## Study drug and medical condition

**Medicinal product name**

AFINITOR

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**Medicinal product name, other**

exemestane

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**Medical condition to be studied**

Breast neoplasm

## Population studied

**Short description of the study population**

The target population of this study was postmenopausal female patients ≥ 18 years of age with ER+ locally advanced or metastatic BC for whom a decision had been taken to initiate treatment with Afinitor® in combination with exemestane. There were no restrictions regarding the last anticancer treatment prior to enrolment. Treatment was not administered for the purpose of inclusion in the NIS, but was given exclusively for the purpose of medical and therapeutic need. Only patients meeting all of the inclusion criteria were invited to enter this study.

Inclusion criteria

Patients eligible for inclusion in this study had to fulfill all of the following criteria:

• Postmenopausal women with ER+ locally advanced or metastatic BC.

• Patients ≥ 18 years of age.

• Prior decision to initiate Afinitor® plus exemestane.

• Provided written and signed informed consent to participate in the study

Exclusion criteria

There were no exclusion criteria except for the contraindications listed in the SmPC. Participating patients were not allowed to take part in any clinical study whilst on Afinitor® plus exemestane, as that would not constitute routine medical practice and would, therefore, counter to the aims of a NIS. On progression, patients could be enrolled onto further clinical studies, which was captured in the electronic case report form (eCRF) until the end of the study.

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**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)

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**Special population of interest**

Other

**Special population of interest, other**

Breast cancer

**Estimated number of subjects**

250

## Study design details

**Outcomes**

The descriptions will comprise incidence, severity, length of time to onset, duration, clinical course, specific management (prophylaxis and intervention) and will look to identify any potential predisposing factors on the likelihood of development. Determine the dosing, schedule and duration of treatment with Afinitor and exemestane, PFS, PRO with EQ-5D and SWB questionnaires

**Data analysis plan**

All analyses will be performed by Novartis or a contracted designee.Descriptive statistics include n, mean, standard deviation, median and ranges for continuous variables and frequencies and percentages for categorical variables and will be provided unless otherwise specified

## Documents

**Study results**

rad001jgb14--clinical-study-report_Redacted_02 Sep 2019.pdf (1.17 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**

Prospective patient-based data collection, Patient medical records

## 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