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

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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

Data analysis start date
Planned: 01/12/2015

Actual: 01/08/2016

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

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

Study type:

Non-interventional study

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

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

Non-interventional study design, other

Observational Study

Study drug and medical condition

Name of medicine

AFINITOR

Name of medicine, other

exemestane

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.

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)

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

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