Observational prospective study in post-menopausal women with advanced HR+/HER2- breast cancer treated with a combination of Afinitor® + exemestane to describe the management of two Adverse Events, non-infectious lung disease and stomatitis (TANGO)

First published: 02/09/2014

Last updated: 14/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS7325

Study ID

37868

DARWIN EU® study

No

Study countries

France

Study description

This observational study aims to describe two specific AEs, non infectious lung disease and stomatitis, and their management in women with ER+/HER2- advanced breast cancer treated with Afinitor® + exemestane.Primary objective: To describe the patterns of management for stomatitis and non-infectious lung disease (therapeutic classes, specific management)

Study status

Finalised

Research institutions and networks

Institutions

Novartis Pharmaceuticals

First published: 01/02/2024

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Institution

Multiple centres: 150 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: 08/08/2013

Actual: 08/08/2013

Study start date

Planned: 15/11/2014

Actual: 07/11/2014

Data analysis start date

Planned: 15/11/2015

Actual: 28/04/2017

Date of final study report

Planned: 30/11/2017

Actual: 21/03/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novartis Pharmaceuticals

Study protocol

RAD001JFR38_TANGO_Protocol_V4_Amendement -2015 07 21_Redacted.pdf
(244.93 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

CRAD001JFR38

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

To describe the patterns of management for stomatitis and non-infectious lung disease (therapeutic classes, specific management)

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Observational prospective study

Study drug and medical condition

Medicinal product name

AFINITOR

Medical condition to be studied

Breast cancer

Population studied

Short description of the study population

Post-menopausal women (≥ 18-year-old) with metastatic or locally advanced HR+/HER2- breast cancer, for whom the physician decided to initiate Afinitor® + exemestane treatment under their EMA labels.

Inclusion criteria

Patients were consecutively included in each centre if the answer to all of the following statements was ‘yes’:

1. Post-menopausal women (≥ 18-year-old) with advanced HR+/HER2- breast cancer.
2. Patients for whom it was decided to initiate Afinitor® + exemestane treatment under their EMA labels.
3. Patients informed and having provided their consent to participate in the study.

Exclusion criteria

Patients with any of the following criteria were not included:

1. Patients previously or currently treated with a mTOR inhibitor.
2. Patients having a contra-indication to Afinitor® treatment as specified in the SmPC.
3. Patients already participating in a clinical study at inclusion.

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 patients

Estimated number of subjects

639

Study design details

Outcomes

The primary objective assessment of this observational study is to describe the management of two specific AEs, stomatitis and non-infectious lung disease (prescribed treatments: therapeutic class, specific actions taken), for post-menopausal women with advanced ER+ / HER2- breast cancer. Characteristics of stomatitis and non-infectious lung diseasePrevious treatments administered for metastatic disease:Adjuvant hormonal therapy : type, treatment duration, time to recurrence.Afinitor® + exemestane:Overall duration of Afinitor® from first dose until discontinuation or end-of-study.Sequential therapies prescribed after stop of Afinitor® and/or exemestane

Data analysis plan

The statistical analysis plan will be written by the CRO in charge of the study and will be validated by Novartis Pharma S.A.S. prior to performing the

analysis.Quantitative variables will be presented in terms of mean, standard deviation, median and extreme values, and in terms of absolute frequency and percentage by modality for qualitative variables. 95% confidence intervals will be presented.All patients included in the study will be analyzed. The reference population for the analysis will be the patients included having available monitoring data relating to Afinitor® + exemestane treatment (monitoring visit, AE / SAE data or end-of-study form). Analyses will be performed using SAS® software version 9.2 or higher.

Documents

Study results

RAD001JFR38_TANGO_CSR_Final_authors_masked_21MAR2018.pdf (826.06 KB)

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)

Electronic healthcare records (EHR)

Other

Data sources (types), other

Prospective patient-based data collection

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