# 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

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

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

Trialandresults.registries@Novartis.com

**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

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**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

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**Study type:**

Non-interventional study

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**Scope of the study:**

Safety study (incl. comparative)

**Data collection methods:**

Primary data collection

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**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

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**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