



# Study of Efficacy and Safety of LEE011 in Men and Postmenopausal Women With Advanced Breast Cancer ( MONALEESA 3)

20/08/2025 08:57:20

## Main Information

### Primary registry identifying number

LBCTR2019080232

### Protocol number

CLEE011F2301

### MOH registration number

6427/ص

### Study registered at the country of origin

Yes

### Study registered at the country of origin: Specify

### Type of registration

Retrospective

### Type of registration: Justify

LCTR was recently initiated, original file was previously submitted by Paper

### Date of registration in national regulatory agency

15/07/2015

### Primary sponsor

Novartis Pharma Services Inc.

### Primary sponsor: Country of origin

Novartis Pharmaceuticals

### Date of registration in primary registry

04/01/2022

### Date of registration in national regulatory agency

15/07/2015

### Public title

Study of Efficacy and Safety of LEE011 in Men and Postmenopausal Women With Advanced Breast Cancer ( MONALEESA 3)

### Acronym

### Scientific title

A Randomized Double-blind, Placebo-controlled Study of Ribociclib in Combination With Fulvestrant for the Treatment of Men and Postmenopausal Women With Hormone Receptor Positive, HER2-negative, Advanced Breast Cancer Who Have Received no or Only One Line of Prior Endocrine Treatment

### Acronym

### Brief summary of the study: English

This is a multi-center, randomized double-blind, placebo controlled study of ribociclib in combination with fulvestrant for the treatment of postmenopausal women and men with hormone receptor positive, Her2 negative, advanced breast cancer who have received no or only one line of endocrine therapy for advanced breast cancer.

### Brief summary of the study: Arabic

دراسة عشوائية مزدوجة التعمية ومرتكزة على المقارنة بدواء وهمي حول دواء ريبوسيكليب بالتزامن مع فولفستران لتعلاج الرجال والنساء بعد الذين لم يتلقوا أي علاج سابق للغدد الصماء أو تلقوا 2 انقطاع الطمث المصابين بسرطان الثدي المتقدم الإيجابي مستقبلات الهرمون وسليبي الهير نوعاً واحداً منه فقط

### Health conditions/problem studied: Specify

advanced breast cancer

### Interventions: Specify

•Drug: Ribociclib





Ribociclib 600mg daily oral (days 1 to 21 in a 28-day Cycle)

Other Name: LEE011

•Drug: fulvestrant

Fulvestrant 500mg i.m. injections every 28 days (Cycle n Day 1) with 1 additional dose on Day 15 of Cycle 1

Other Name: Faslodex

•Drug: Ribociclib placebo

Ribociclib placebo 600mg daily oral (days 1 to 21 in a 28-day Cycle)

Other Name: LEE011 placebo

## Key inclusion and exclusion criteria: Inclusion criteria

Inclusion Criteria:

- 1.Patient is an adult male/female  $\geq 18$  years old at the time of informed consent and has signed informed consent before any trial related activities and according to local guidelines. Female patients must be postmenopausal.
- 2.Patient has a histologically and/or cytologically confirmed diagnosis of estrogen-receptor positive and/or progesterone receptor positive breast cancer by local laboratory and has HER2-negative breast cancer.
- 3.Patient must have either measurable disease by RECIST 1.1 or at least one predominantly lytic bone lesion.
- 4.Patient has advanced (loco regionally recurrent not amenable to curative therapy, e.g. surgery and/or radiotherapy, or metastatic) breast cancer.

Patients may be:

- newly diagnosed advanced/metastatic breast cancer, treatment naïve
- relapsed with documented evidence of relapse more than 12 months from completion of (neo)adjuvant endocrine therapy with no treatment for advanced/metastatic disease
- relapsed with documented evidence of relapse on or within 12 months from completion of (neo)adjuvant endocrine therapy with no treatment for advanced/metastatic disease
- relapsed with documented evidence of relapse more than 12 months from completion of adjuvant endocrine therapy and then subsequently progressed with documented evidence of progression after one line of endocrine therapy (with either an antiestrogen or an aromatase inhibitor) for advanced/metastatic disease
- newly diagnosed advanced/metastatic breast cancer at diagnosis that progressed with documented evidence of progression after one line of endocrine therapy (with either an antiestrogen or an aromatase inhibitor)

5.Patient has an Eastern Cooperative Oncology Group (ECOG) performance status 0 or 1

6.Patient has adequate bone marrow and organ function

## Key inclusion and exclusion criteria: Gender

Both

## Key inclusion and exclusion criteria: Specify gender

## Key inclusion and exclusion criteria: Age minimum

18

## Key inclusion and exclusion criteria: Age maximum

99

## Key inclusion and exclusion criteria: Exclusion criteria

Exclusion Criteria:

- 1.Patient with symptomatic visceral disease or any disease burden that makes the patient ineligible for endocrine therapy per the investigator's best judgment.
- 2.Patient has received prior treatment with chemotherapy (except for neoadjuvant/ adjuvant chemotherapy), fulvestrant or any CDK4/6 inhibitor.
- 3.Patient with inflammatory breast cancer at screening .
- 4.Patient with CNS involvement unless they are at least 4 weeks from prior therapy completion to starting the study treatment and have stable CNS tumor at the time of screening and not receiving steroids and/or enzyme inducing anti-epileptic medications for brain metastases
- 5.Clinically significant, uncontrolled heart disease and/or cardiac repolarization abnormality
- 6.Patient is currently receiving any of the following substances and cannot be discontinued 7 days prior to start the treatment:
  - Known strong inducers or inhibitors of CYP3A4/5,
  - That have a known risk to prolong the QT interval or induce Torsades de Pointes.
  - Those have a narrow therapeutic window and are predominantly metabolized through CYP3A4/5.
  - Herbal preparations/medications, dietary supplements.

## Type of study

Interventional

## Type of intervention

Pharmaceutical

## Type of intervention: Specify type

N/A

## Trial scope

Therapy

## Study design: Allocation

Randomized controlled trial

## Study design: Control

Placebo

## Study design: Purpose

Treatment

## Study design: Assignment

Parallel

## IMP has market authorization

Yes, Lebanon and Worldwide

## Name of IMP

Ribociclib ( Kisqali)

## Type of IMP

Others

## Pharmaceutical class

Orally bioavailable, highly selective small molecule inhibitor of cyclin-dependent kinases 4 and 6 (CDK4/6).

## Therapeutic indication

Men and Pre/Postmenopausal Women With Hormone Receptor-positive (HR+) HER2-negative (HER2 -) Advanced Breast Cancer

## Therapeutic benefit

increase OS & PFS

## Study model

N/A

## Study model: Specify model

N/A

## Time perspective

N/A

## Time perspective: Specify perspective

N/A

## Target follow-up duration

## Number of groups/cohorts

## Biospecimen retention

## Trial scope: Specify scope

N/A

## Study design: Masking

Blinded (masking used)

## Study phase

3

## Study design: Specify purpose

N/A

## Study design: Specify assignment

N/A

## IMP has market authorization: Specify

Worldwide ; Lebanon MOH approval: Postmenopausal

## Year of authorization

2017

## Month of authorization

8

## Study model: Explain model

N/A

## Time perspective: Explain time perspective

N/A

## Target follow-up duration: Unit

## Biospecimen description



Samples with DNA\*\*

Q2 lab is the lab used in this study, ambient lab samples shipped to central lab, Blood and urine samples . Samples for circulating tumor DNA (ctDNA) is also required

**Target sample size**

6

**Actual enrollment target size**

6

**Date of first enrollment: Type**

Actual

**Date of first enrollment: Date**

22/12/2015

**Date of study closure: Type**

Actual

**Date of study closure: Date**

23/10/2022

**Recruitment status**

Complete

**Recruitment status: Specify**

**Date of completion**

06/05/2016

**IPD sharing statement plan**

No

**IPD sharing statement description**

Undecided ; Novartis is committed to sharing with qualified external researchers, access to patient-level data and supporting clinical documents from eligible studies. These requests are reviewed and approved by an independent expert panel on the basis of scientific merit. All data provided is anonymized to respect the privacy of patients who have participated in the trial in line with applicable laws and regulations.  
This trial data is currently available according to the process described on [www.clinicalstudydatarequest.com](http://www.clinicalstudydatarequest.com).

**Additional data URL**

<https://clinicaltrials.gov/ct2/show/record/NCT02422615?term=breast+cancer+lebanon&draw=10>

**Admin comments**

**Trial status**

Approved

## Secondary Identifying Numbers

| Full name of issuing authority | Secondary identifying number |
|--------------------------------|------------------------------|
| Clinicaltrials.gov             | NCT02422615                  |

## Sources of Monetary or Material Support

| Name                          |
|-------------------------------|
| Novartis Pharma Services Inc. |



## Secondary Sponsors

Name

NA

## Contact for Public/Scientific Queries

| Contact type | Contact full name | Address    | Country | Telephone              | Email                         | Affiliation                                  |
|--------------|-------------------|------------|---------|------------------------|-------------------------------|--|
| Public       | Nagi El Saghir    | Beirut     | Lebanon | 961 1 350000 ext 7489  | ns23@aub.edu.lb               | American University of Beirut Medical Center |
| Scientific   | Hind Khairallah   | Sin El Fil | Lebanon | +961 1 512002 Ext. 271 | Hind.Khairallah@fattal.com.lb | Khalil Fattal et Fils s.a.l.                 |
| Public       | Marwan Ghosn      | Beirut     | Lebanon | 00961 1 613395         | marwanghosnmd@yahoo.com       | Hotel Dieu De France                         |

## Centers/Hospitals Involved in the Study

| Center/Hospital name                         | Name of principles investigator | Principles investigator speciality | Ethical approval |
|--|---------------------------------|------------------------------------|------------------|
| Hotel Dieu De France                         | Marwan Ghosn                    | Hematology Oncology                | Approved         |
| American University of Beirut Medical Center | Nagi El Saghir                  | Hematology Oncology                | Approved         |

## Ethics Review

| Ethics approval obtained                     | Approval date | Contact name | Contact email   | Contact phone               |
|--|---------------|--------------|-----------------|-----------------------------|
| American University of Beirut Medical Center | 14/09/2015    | Fuad Ziyadeh | fz05@aub.edu.lb | +961 (0) 1 350 000 ext:5445 |
| Hotel Dieu de France                         | 17/06/2015    | Sami Richa   | cue@usj.edu.lb  | 961421229                   |



| Countries of Recruitment |  |
|--------------------------|--|
| Name                     |  |
| Lebanon                  |  |
| Argentina                |  |
| Austria                  |  |
| Belgium                  |  |
| Bulgaria                 |  |
| Canada                   |  |
| Colombia                 |  |
| Czech Republic           |  |
| France                   |  |
| Denmark                  |  |
| Germany                  |  |
| Hungary                  |  |
| Italy                    |  |
| Jordan                   |  |
| Mexico                   |  |
| Switzerland              |  |
| United Kingdom           |  |
| United States of America |  |

| Health Conditions or Problems Studied |                             |                        |
|---------------------------------------|-----------------------------|------------------------|
| Condition                             | Code                        | Keyword                |
| Advanced Breast Cancer                | Breast, unspecified (C50.9) | Advanced Breast Cancer |



## Interventions

| Intervention   | Description  | Keyword                  |
|--|--|--------------------------|
| ICF, medical history, demography, radiology, vital signs, IMP administration | ICF, medical history, demography, radiology, vital signs, IMP administration | ICF, Lab, IMP, radiology |

## Primary Outcomes

| Name  | Time Points | Measure   |
|---|-------------|-----------|
| Progression Free Survival (PFS) Per Investigator Assessment | 26 months   | 26 months |

## Key Secondary Outcomes

| Name   | Time Points | Measure   |
|--|-------------|-----------|
| Overall Survival (OS)  | 58 months   | 58 months |
| •Progression Free Survival (PFS) Per Blinded Independent Review Committee (BICR) | 26 months   | 26 months |
| •Overall Response Rate (ORR)   | 26 months   | 26 months |
| •Safety and Tolerability of LEE011   | 26 months   | 26 months |



## Trial Results

Summary results

Study results globally

Date of posting of results summaries

Date of first journal publication of results

Results URL link

Baseline characteristics

Participant flow

Adverse events

Outcome measures

URL to protocol files