



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

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## 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

14/10/2020

### 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

**Trial scope: Specify scope**

N/A

**Study design: Allocation**

Randomized controlled trial

**Study design: Masking**

Blinded (masking used)

**Study design: Control**

Placebo

**Study phase**

3

**Study design: Purpose**

Treatment

**Study design: Specify purpose**

N/A

**Study design: Assignment**

Parallel

**Study design: Specify assignment**

N/A

**IMP has market authorization**

Yes, Lebanon and Worldwide

**IMP has market authorization: Specify**

Worldwide ; Lebanon MOH approval: Postmenopausal

**Name of IMP**

Ribociclib ( Kisqali)

**Year of authorization**

2017

**Month of authorization**

8

**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: Explain model**

N/A

**Study model: Specify model**

N/A

**Time perspective**

N/A

**Time perspective: Explain time perspective**

N/A

**Time perspective: Specify perspective**

N/A

**Target follow-up duration****Target follow-up duration: Unit****Number of groups/cohorts****Biospecimen retention****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**

23/02/2021

**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	Khailil 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	Nancy Alam	nancy.alam@usj.edu.lb	+961 (0) 1 421000 ext 2335



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**