



A phase III randomized , double blind, placebo controlled study of LEE011 or placebo in combination with tamoxifen and goserelin or a non-steroidal aromatase inhibitor (NSAI) and goserelin for the treatment of premenopausal women with hormone receptor positive, HER 2 negative, advanced breast cancer. ( MONALEESA 7)

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## Main Information

**Primary registry identifying number**

LBCTR2019020194

**Protocol number**

CLEE011E2301

**MOH registration number**

9878/ص-أ

**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**

10/11/2014

**Primary sponsor**

Novartis Pharma Services Inc.

**Primary sponsor: Country of origin**

Novartis Pharmaceuticals

**Date of registration in primary registry**

20/01/2020

**Date of registration in national regulatory agency**

10/11/2014

**Public title**

A phase III randomized , double blind, placebo controlled study of LEE011 or placebo in combination with tamoxifen and goserelin or a non-steroidal aromatase inhibitor (NSAI) and goserelin for the treatment of premenopausal women with hormone receptor positive, HER 2 negative, advanced breast cancer. ( MONALEESA 7)

**Acronym**

MONALEESA 7

**Scientific title**

A phase III randomized , double blind, placebo controlled study of LEE011 or placebo in combination with tamoxifen and goserelin or a non-steroidal aromatase inhibitor (NSAI) and goserelin for the treatment of premenopausal women with hormone receptor positive, HER 2 negative, advanced breast cancer.

**Acronym****Brief summary of the study: English**

This is a multi-center, randomized, double-blinded, placebo controlled trial in pre-menopausal women with advanced breast cancer.

The purpose of this study is to assess the efficacy of LEE011, as measured by progression free survival (PFS), in premenopausal women with HR positive, HER2 negative advanced breast cancer



## Brief summary of the study: Arabic

أو الدواء الوهمي بالتزامن مع التاموكسيفين LEE011 دراسة عشوائية مزدوجة التعمية ومضبوطة بدواء وهمي في المرحلة الثالثة حول دواء الغوزيريلين أو مثبّط أروماتيز غير ستيرويدي والغوزيريلين لعلاج النساء قبل انقطاع الطمث المصابات بسرطان الثدي المتقدم الإيجابي HER2 مستقبلات الهرمون وسليبي الهير

## Health conditions/problem studied: Specify

Premenopausal Women With Hormone Receptor Positive, HER2-negative Advanced Breast Cancer

## Interventions: Specify

•Drug: LEE011  
LEE011 600 mg daily oral

•Drug: Tamoxifen  
tamoxifen 20 mg daily oral

•Drug: Letrozole  
letrozole 2.5 mg daily oral

•Drug: Anastrozole  
anastrozole 1 mg daily oral

•Drug: Goserelin  
Goserelin 3.6 mg subcutaneous injection

•Drug: LEE011 Placebo  
LEE011 placebo 600 mg daily oral

## Key inclusion and exclusion criteria: Inclusion criteria

Inclusion Criteria:

- Patient has advanced (locoregionally recurrent or metastatic) breast cancer not amenable to curative therapy
- Patient is premenopausal or perimenopausal at the time of study entry
- Patients who received (neo) adjuvant therapy for breast cancer are eligible
- Patient has a histologically and/or cytologically confirmed diagnosis of estrogen-receptor positive and/or progesterone receptor positive breast cancer
- Patient has HER2-negative breast cancer
- Patient must have either measurable disease or If no measurable disease is present, then at least one predominantly lytic bone lesion
- Patient has an Eastern Cooperative Oncology Group (ECOG) performance status 0 or 1
- Patient has adequate bone marrow and organ function

## Key inclusion and exclusion criteria: Gender

Female

## Key inclusion and exclusion criteria: Specify gender

## Key inclusion and exclusion criteria: Age minimum

18

## Key inclusion and exclusion criteria: Age maximum

59

## Key inclusion and exclusion criteria: Exclusion criteria

Exclusion Criteria:

- Patient who has received a prior CDK4/6 inhibitor
- Patient is postmenopausal
- Patients who currently have inflammatory breast cancer at screening.
- Patients who received any prior hormonal anti-cancer therapy for advanced breast cancer, except for  $\leq 14$  days of tamoxifen or NSAID  $\pm$  goserelin for advanced breast cancer prior to randomization.
- Patient has a concurrent malignancy or malignancy within 3 years of randomization, with the exception of adequately treated basal cell skin carcinoma, squamous cell skin carcinoma, non-melanomatous skin cancer or curatively resected cervical cancer.
- Patient with CNS metastases.
- Patient has active cardiac disease or a history of cardiac dysfunction
- Patient is currently using other antineoplastic agents
- Patient is pregnant or nursing or physiologically capable of becoming pregnant and not using highly effective contraception

Other protocol-defined Inclusion/Exclusion may apply.

## 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

**Name of IMP**

LEE011 ( Kiqsali)

**Year of authorization**

2017

**Month of authorization**

7

**Type of IMP**

Others

**Pharmaceutical class**

inhibitor of CDK4/6

**Therapeutic indication**

Hormone Receptor positive, HER 2 negative breast cancer. LEE011 is an effective anti-cancer agent in a variety of pRb-positive human neoplasms, especially in those that contain activated CDK4/6-pRb pathway.

**Therapeutic benefit**

Progression free survival

**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\*\*

Samples are being sent to Q2 solutions central laboratory , this include as well safety labs for Hematology , biochemistry, urinalysis , in addition to circulating tumor DNA samples

**Target sample size**

28

**Actual enrollment target size**

28

**Date of first enrollment: Type**

Actual

**Date of first enrollment: Date**

18/11/2014

**Date of study closure: Type**

Actual

**Date of study closure: Date**

26/02/2021

**Recruitment status**

Complete

**Recruitment status: Specify**

**Date of completion**

12/01/2016

**IPD sharing statement plan**

No

**IPD sharing statement description**

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 review 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 availability is according to the criteria and process described on [www.clinicalstudydatarequest.com](http://www.clinicalstudydatarequest.com)

**Additional data URL**

<https://clinicaltrials.gov/ct2/show/record/NCT02278120?term=CLEE011E2301&rank=1>

**Admin comments**

**Trial status**

Approved

## Secondary Identifying Numbers

Full name of issuing authority	Secondary identifying number
Clinical Trials.gov	NCT02278120

## 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	Fadi Farhat	Saida	Lebanon	+9613753155	drfadi.trials@gmail.com	Hammoud Hospital
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## Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
Hammoud Hospital University Medical Center	Fadi Farhat	Hematology Oncology	Approved
American University of Beirut Medical Center	Nagi El Saghir	Hematology Oncology	Approved
Hotel Dieu De France	Marwan Ghosn	Hematology Oncology	Approved
Bellevue Medical Center	Dany Abi Gerges	Hematology Oncology	Approved
Saint Georges Hospital UNiversity Medical Center	Joseph Makdessi	Hematology Oncology	Approved
Ain Wazein Medical Village	Jawad Makarem	Hematology Oncology	Approved



## Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
American University of Beirut Medical Center	26/02/2015	Fuad Ziyadeh	fz05@aub.edu.lb	+961 (0) 1 350 000 ext:5445
Hotel Dieu de France	05/11/2014	Nancy Alam	nancy.alam@usj.edu.lb	+961 (0) 1 421000 ext 2335
Saint George Hospital University Medical Center	29/01/2015	Michel Daher	mndaher@stgeorgehospital.org	+961 (0)1 441 733
Bellevue Medical Center	28/10/2014	Ghassan Maalouf	gmaalouf@bmc.com.lb	+961 (0) 1 682666 ext 7600
Ain w Zein Medical Village	29/05/2015	Khaled Abdel Baki	Khaled.abdelbaki@awmedicalvillage.org	+961 (0) 5 509 001 ext 2000
Hammoud Hospital University Medical Center	21/10/2014	Ahmad Zaatari	zaatari@hammoudhospital.com	+961 (0) 7 723111 ext 1160



Countries of Recruitment	
Name	
Lebanon	
Australia	
Belgium	
Brazil	
Bulgaria	
Canada	
Colombia	
France	
Germany	
Greece	
Hungary	
Italy	
India	
Malaysia	
Mexico	
Poland	
Portugal	
Saudi Arabia	
Spain	
Switzerland	
Turkey	
United Arab Emirates	
United States of America	



## Health Conditions or Problems Studied

Condition	Code	Keyword
breast cancer	Breast, unspecified (C50.9)	Premenopausal advanced breast cancer

## Interventions

Intervention	Description	Keyword
Informed consent, questionnaires, Lab tests, drug administration, radiology	Informed consent / patient history / drug administration / Lab tests	ICF, IMP, Lab tests and ECG , diary completion

## Primary Outcomes

Name	Time Points	Measure
Progression Free Survival	25 months	25 months

## Key Secondary Outcomes

Name	Time Points	Measure
Overall survival	69 Months	up to 69 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**