# A phase III randomized , double blind, placebo controlled study of LEE011or 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)

**11/04/2025 06:51:07**

## Main Information

**Primary registry identifying number**
LBCTR2019020194

**Protocol number**
CLEE011E2301

**MOH registration number**
9878/ص-A

**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**
29/09/2023

**Date of registration in national regulatory agency**
10/11/2014

**Public title**
A phase III randomized , double blind, placebo controlled study of LEE011or 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 LEE011or 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**

دراسة عشوائية مزدوجة التعمية ومضبّطة بدواء وهميّ في المرحلة الثالثة حول دواء LEE011 أو الدواء الوهمي بالتزامن مع التاموكسيفن والغوزيريلين أو متبّط أروماتيز غير ستيرويدي والغوزيريلين لعلاج النساء قبل انقطاع الطمث المصابات بسرطان الثدي المتقدّم الإيجابيّ مستقبلات الهرمون وسلبيّ الهير 2 HER2

**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 ≤ 14 days of tamoxifen or NSAI ± 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 ( Kisqali)

**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**

24/03/2015

**Date of study closure: Type**

Actual

**Date of study closure: Date**

24/08/2023

**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

**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 |
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| Public | Jawad Makarem | Al Chouf | Lebanon | +9613484 288 | jawad.makarem@awmedicalvillage.org | Ain Wazein Medical Village |

## 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 | Sami Richa | cue@usj.edu.lb | 961421229 |
| 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 5006 |
| Ain w Zein Medical Village | 29/05/2015 | Hayat Kamaleddine | irb@awmedicalvillage.org | +961 (0) 5 509 001 ext 2014 |
| 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) | Premenaupausal 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**