



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)

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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

14/10/2020

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

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 HER2² مستقبلات الهرمون وسلبّي 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 ≤ 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

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

LEE011 (Kisqali)

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: 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

Year of authorization

2017

Month of authorization

7

Study model: Explain model

N/A

Time perspective: Explain time perspective

N/A

Target follow-up duration: Unit
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

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 | +9613484288 | 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 | 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 |
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| 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