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)

04/07/2025 09:47:23

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
04/01/2021

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

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
Public	Fadi Farhat	Saida	Lebanon	+9613753 155	drfadi.trials@gmail.com	Hammoud Hospital
Scientific	Hind Khairallah	Sin el fil	Lebanon	+961 1512002 #271	Hind.Khairallah@fattal.com.lb	Khalil Fattal et Fils s.a.l.
Public	Nagi El Saghir	Beirut	Lebanon	+9611350000 #7977	ns23@aub.edu.lb	American University Of Beirut Medical Center
Public	Marwan Ghosn	Beirut	Lebanon	00961 1613395	marwanghosnmd@yahoo.com	Hotel Dieu De France
Public	Dany Abi Gerges	Beirut	Lebanon	+9613341 960	abgerges@idm.net.lb	Bellevue Medical Center
Public	Joseph Makdessi	Ashrafieh	Lebanon	+9613585 999	josejoce@yahoo.fr	Saint Georges Hospital University Medical Center
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