Study of Efficacy and Safety of LEE011 in Postmenopausal Women With Advanced Breast Cancer.(MONALEESA-2)

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Main Information

Primary registry identifying number
LBCTR2019050229

Protocol number
CLEE011A2301

MOH registration number
9695/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
05/11/2014

Primary sponsor
Novartis Pharma Services Inc.

Primary sponsor: Country of origin
Novartis Pharmaceuticals

Date of registration in primary registry
11/11/2021

Date of registration in national regulatory agency
05/11/2014

Public title
Study of Efficacy and Safety of LEE011 in Postmenopausal Women With Advanced Breast Cancer.(MONALEESA-2)

Acronym

Scientific title
A Randomized Double-blind, Placebo-controlled Study of LEE011 in Combination With Letrozole for the Treatment of Postmenopausal Women With Hormone Receptor Positive, HER2 Negative, Advanced Breast Cancer Who Received no Prior Therapy for Advanced Disease

Acronym

Brief summary of the study: English
This is a multi-center, randomized, double-blinded, placebo controlled trial. , The primary purpose of this study was to assess the efficacy of LEE011, as measured by progression free survival (PFS), in postmenopausal women with HR positive, HER2 negative advanced breast cancer who received no prior treatment for advanced disease.

Brief summary of the study: Arabic
دراسة عشوائية مزدوجة التعمية ومضبّطة بدواء وهميّ حول سلامة استخدام الدواء LEE011 مع ليتروزول Letrozole وفعاليته في معالجة النساء بعد انقطاع الطمث المصابات بسرطان ثدي متقدّم إيجابيّ مستقبلات الهرمون وسلبيّ الهير2 في المرضى واللواتي لم يتلقّين علاجاً سابقاً مراحله المتقدّمة

Health conditions/problem studied: Specify
Advanced Breast Cancer

Interventions: Specify
•Drug: LEE011
Ribociclib was administered orally at a dose of 600 mg once daily (three 200 mg capsules).

•Drug: Letrozole

Letrozole 2.5 mg tablets taken orally.

•Drug: LEE011 Placebo
Matching ribociclib placebo was the control drug and was administered orally once daily.

Key inclusion and exclusion criteria: Inclusion criteria

1.Women with advanced (locoregionally recurrent or metastatic) breast cancer not amenable to curative therapy.

2.Patient is postmenopausal. Postmenopausal status is defined either by:
◦Prior bilateral oophorectomy
◦Age ≥60
◦Age <60 and amenorrhea for 12 or more months (in the absence of chemotherapy, tamoxifen, toremifen, or ovarian suppression) and FSH and estradiol in the postmenopausal range per local normal range Note: For women with therapy-induced amenorrhea, serial measurements of FSH and/or estradiol are needed to ensure postmenopausal status. Ovarian radiation or treatment with a luteinizing hormone-releasing hormone agonist (LH-RHa) (goserelin acetate or leuprolide acetate) is not permitted for induction of ovarian suppression in this trial.

3.No prior systemic anti-cancer therapy for advanced disease.
4.Patient has a histologically and/or cytologically confirmed diagnosis of estrogen-receptor positive and/or progesterone receptor positive breast cancer by local laboratory.
5.Patient has HER2-negative breast cancer defined as a negative in situ hybridization test or an IHC status of 0, 1+ or 2+. If IHC is 2+, a negative in situ hybridization (FISH, CISH, or SISH) test is required by local laboratory testing.

6.Patient must have either:

• Measurable disease, i.e., at least one measurable lesion as per RECIST 1.1 criteria (Tumor lesions previously irradiated or subjected to other locoregional therapy will only be considered measurable if disease progression at the treated site after completion of therapy is clearly documented).

OR

• If no measurable disease is present, then at least one predominantly lytic bone lesion must be present (Patients with no measurable disease and only one predominantly lytic bone lesion that has been previously irradiated are eligible if there is documented evidence of disease progression of the bone lesion after irradiation).

7.Patient has an Eastern Cooperative Oncology Group (ECOG) performance status 0 or 1

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

99

Key inclusion and exclusion criteria: Exclusion criteria

1.Patient who received any CDK4/6 inhibitor.

2.Patient who received any prior systemic anti-cancer therapy (including hormonal therapy and chemotherapy) for advanced breast cancer

Note:
◦Patients who received (neo) adjuvant therapy for breast cancer are eligible. If the prior neo (adjuvant) therapy included letrozole or anastrozole the disease free interval must be greater than 12 months from the completion of treatment until randomization.
◦Patients who received ≤ 14 days of letrozole or anastrozole for advanced disease prior to randomization are eligible.
◦Any prior (neo) adjuvant anti-cancer therapy must be stopped at least 5 half-lives or 7 days, whichever is longer, before randomization

3.Patient is concurrently using other anti-cancer therapy.
4.Patient has a concurrent malignancy or malignancy within 3 years of randomization, with the exception of adequately treated, basal or squamous cell carcinoma, non-melanomatous skin cancer or curatively resected cervical cancer.

5.Patient has active cardiac disease or a history of cardiac dysfunction including any of the following:
◦History of angina pectoris, symptomatic pericarditis, or myocardial infarction within 12 months prior to study entry
◦History of documented congestive heart failure (New York Heart Association functional classification III-IV)
◦Documented cardiomyopathy
◦Patient has a Left Ventricular Ejection Fraction (LVEF) < 50% as determined by Multiple Gated acquisition (MUGA) scan or echocardiogram (ECHO)
◦History of any cardiac arrhythmias, e.g., ventricular, supraventricular, nodal arrhythmias, or conduction abnormality in the previous 12 months.
◦On screening, any of the following cardiac parameters:

bradycardia (heart rate < 50 at rest), tachycardia (heart rate > 90 at rest), PR interval > 220 msec, QRS interval >109 msec, or QTcF >450 msec.

•Systolic blood pressure >160 or <90 mmHg

6. Patient is currently receiving any of the following medications and cannot be discontinued 7 days prior start if the treatment:

•That are known strong inducers or inhibitors of CYP3A4.
•That have a known risk to prolong the QT interval or induce Torsades de Pointes.
•That have a narrow therapeutic window and are predominantly metabolized through CYP3A4.
•Herbal preparations/medications

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

Lebanon and Worldwide

Name of IMP	Year of authorization	Month of authorization
Ribociclib	2017	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

postmenopausal women with hormone receptor positive, HER2-negative, advanced breast cancer who received no prior therapy for advanced disease.

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

Time perspective: Specify perspective

N/A

N/A

Target follow-up duration

Target follow-up duration: Unit

Number of groups/cohorts

Biospecimen retention

Samples with DNA**

Biospecimen description

Samples with circulating tumor DNA will be done, in addition to safety Labs (CBC, chemistry) sent to central lab : Covance located in Switzerland.

Target sample size

15

Actual enrollment target size

15

Date of first enrollment: Type

Actual

Date of first enrollment: Date

29/04/2014

Date of study closure: Type

Actual

Date of study closure: Date

20/12/2021

Recruitment status

Complete

Recruitment status: Specify

Date of completion

12/02/2015

IPD sharing statement plan

Yes

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 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.

URL: http://www.clinicalstudydatarequest.com

Additional data URL

https://clinicaltrials.gov/ct2/show/record/NCT01958021?id=CLEE011A2301&rank=1

Admin comments

Trial status

Approved

Secondary Identifying Numbers

Full name of issuing authority	Secondary identifying number
Clinicaltrials.gov	NCT01958021

Sources of Monetary or Material Support

Name
Novartis Pharma Services Inc.

Secondary Sponsors

No Sponsors

Contact for Public/Scientific Queries

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Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
Hotel Dieu De France	Dr Joseph Kattan	Hematology Oncology	Approved
Hammoud Hospital University Medical Center	Dr Fadi Farhat	Hematology Oncology	Approved
Bellevue Medical Center	Dr Fadi El Karak	Hematology Oncology	Approved
American University of Beirut Medical Center	Dr Ziad Salem	Hematology Oncology	Approved

Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
American University of Beirut Medical Center	05/09/2014	Fuad Ziyadeh	fz05@aub.edu.lb	+961 (0) 1 350 000 ext:5445
Hotel Dieu de France	20/09/2013	Sami Richa	cue@usj.edu.lb	961421229
Bellevue Medical Center	20/02/2014	Ghassan Maalouf	gmaalouf@bmc.com.lb	+961 (0) 1 682666 ext 5006
Hammoud Hospital University Medical Center	30/10/2013	Ahmad Zaatari	zaatari@hammoudhospital.com	+961 (0) 7 723111 ext 1160

Countries of Recruitment

Name
Lebanon
Argentina
Australia
Austria
Belgium
Brazil
Canada
Denmark
Finland
France
Germany
Hungary
Ireland
Italy
Netherlands
Norway
Singapore
Spain
Sweden
Turkey
United Kingdom
United States of America

Health Conditions or Problems Studied

Condition	Code	Keyword
Advanced Breast Cancer	Malignant neoplasm of breast (C50)	ABC

Interventions

Intervention	Description	Keyword
Physical Exam, Vital signs, ECG, Echocardiography, Urinalysis, Serum/ urine pregnancy test, lab test, completion of QoL questionnaires	Physical Exam, Vital signs, ECG, Echocardiography, Urinalysis, Serum/ urine pregnancy test, lab test, completion of QoL questionnaires	ICF, Lab, IMP, radiology

Primary Outcomes

Name	Time Points	Measure
Progression Free Survival	20 months	PFS up to approximately 20 months

Key Secondary Outcomes

Name	Time Points	Measure
•Overall Response Rate (ORR)	20 months	20 months
Overall survival	65 months	65 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