COMPLEEMENT-1: An Open-label, Multicenter, Phase IIIb Study to Assess the Safety and Efficacy of Ribociclib (LEE011) in Combination With Letrozole for the Treatment of Men and Pre/Postmenopausal Women With Hormone Receptor-positive (HR+) HER2-negative (HER2-) Advanced Breast Cancer (aBC) With no Prior Hormonal Therapy for Advanced Disease

05/04/2025 02:18:07

Main Information

Primary registry identifying number
LBCTR2019010184

Protocol number
CLEE011A2404

MOH registration number
20521/2017

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 already initiated, original file was previously submitted by Paper

Date of registration in national regulatory agency
01/06/2017

Primary sponsor
Novartis Pharma Services Inc.

Primary sponsor: Country of origin
Novartis Pharmaceuticals

Date of registration in primary registry
18/10/2022

Date of registration in national regulatory agency
01/06/2017

Public title
COMPLEEMENT-1: An Open-label, Multicenter, Phase IIIb Study to Assess the Safety and Efficacy of Ribociclib (LEE011) in Combination With Letrozole for the Treatment of Men and Pre/Postmenopausal Women With Hormone Receptor-positive (HR+) HER2-negative (HER2-) Advanced Breast Cancer (aBC) With no Prior Hormonal Therapy for Advanced Disease

Acronym
COMPLEEMENT 1

Scientific title
COMPLEEMENT-1: An Open-label, Multicenter, Phase IIIb Study to Assess the Safety and Efficacy of Ribociclib (LEE011) in Combination With Letrozole for the Treatment of Men and Pre/Postmenopausal Women With Hormone Receptor-positive (HR+) HER2-negative (HER2-) Advanced Breast Cancer (aBC) With no Prior Hormonal Therapy for Advanced Disease

Acronym

Brief summary of the study: English
The purpose of this Phase IIIb study is to collect additional safety and efficacy data for the combination of ribociclib + letrozole in men and pre/postmenopausal women with HR+HER2- advanced breast cancer.

Brief summary of the study: Arabic

بالاشتراك مع ليتروزول لعلاج (LEE011) دراسة مفتوحة اللصاقة، متعددة المراكز في المرحلة الثالثة ب لتقييم سلامة وفعاليّة ريبوسيكليب
الذين (HER2-) 2وسلبيّ الهير (HR+) الرجال والنساء قبل/بعد انقطاع الطمث المصابين بسرطان الثدي المتقدّم الإيجابيّ مستقبلات الهرمون
لم يتلقوا أي علاج هرمونيّ سابق للمرض المتقدّم

Health conditions/problem studied: Specify

Advanced Breast Cancer

Interventions: Specify

•Drug: Ribociclib
•Drug: Letrozole
•Drug: Goserelin

Key inclusion and exclusion criteria: Inclusion criteria

•Male or female advanced (locoregionally recurrent or metastatic) breast cancer not amenable to curative therapy.

•In the case of women, both pre/perimenopausal and postmenopausal patients 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 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

•Patient has an Eastern Cooperative Oncology Group (ECOG) performance status ≤2

•Patient has adequate bone marrow and organ function as defined by ALL of the following laboratory values (as assessed by local laboratory):
◦Absolute neutrophil count ≥ 1.5 × 10^9/L
◦Platelets ≥ 100 × 10^9/L
◦Hemoglobin ≥ 9.0 g/dL
◦Potassium, sodium, calcium corrected for serum albumin and magnesium within normal limits or corrected to within normal limits with supplements before first dose of the study medication
◦INR ≤1.5
◦Serum creatinine <1.5 mg/dl or creatinine clearance≥50 mL/min
◦In absence of liver metastases, alanine aminotransferase (ALT) and aspartate aminotransferase (AST) should be below 2.5 × ULN. If the patient has liver metastases, ALT and AST should be < 5 × ULN.
◦Total serum bilirubin < ULN; or total bilirubin ≤ 3.0 × ULN with direct bilirubin within normal range in patients with well-documented Gilbert's Syndrome

•Patient must have a 12-lead ECG with ALL of the following parameters at screening:
◦QTcF interval at screening <450 msec (using Fridericia's correction)
◦Resting heart rate ≥ 50 bpm

Key inclusion and exclusion criteria: Gender

Both

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

•Patient who received any CDK4/6 inhibitor
•Patient who received any prior systemic hormonal therapy for advanced breast cancer; no more than one prior regimen of chemotherapy for the treatment of metastatic disease is permitted

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

N/A: Single arm study

Study design: Masking

Open (masking not used)

Study design: Control

Study phase

N/A

3

Study design: Purpose

Treatment

Study design: Specify purpose

N/A

Study design: Assignment

Single

Study design: Specify assignment

N/A

IMP has market authorization

Yes, Lebanon and Worldwide

IMP has market authorization: Specify

USA, EU & other countries

Name of IMP

Ribociclib (Kisqali)

Year of authorization

2017

Month of authorization

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

Men and Pre/Postmenopausal Women With Hormone Receptor-positive (HR+) HER2-negative (HER2 -) Advanced Breast Cancer

Therapeutic benefit

increase Overall survival and 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

None retained

Biospecimen description

Local lab is being used, no samples will be shipped outside Lebanon, Lab samples are mainly CBC, Chemistry to follow up on patient safety

Target sample size

20

Actual enrollment target size

17

Date of first enrollment: Type

Actual

Date of first enrollment: Date

10/08/2018

Date of study closure: Type

Actual

Date of study closure: Date

01/06/2022

Recruitment status

Complete

Recruitment status: Specify

Date of completion

12/01/2018

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 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.

Additional data URL

https://clinicaltrials.gov/ct2/show/record/NCT02941926?recrs=d&rslt=Without&type=Intr&cond=Advanced+Breast+Cancer&titles=compleement&spons=novartis&phase=2&rank=1

Admin comments

Trial status

Approved

Secondary Identifying Numbers

Full name of issuing authority	Secondary identifying number
Clinical Trials.Gov	NCT02941926

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	+961 3 753 155	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	Dr Fadi Farhat	Hematology Oncology	Approved
Hotel Dieu De France	Dr Georges Chahine	Hematology Oncology	Approved
Bellevue Medical Center	Dr Fadi El Karak	Hematology Oncology	Approved

Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Hotel Dieu de France	02/05/2017	Sami Richa	cue@usj.edu.lb	961421229
Bellevue Medical Center	21/08/2017	Ghassan Maalouf	Gmaalouf@bmc.com.lb	961 (0) 1 682666 ext 5006
Hammoud Hospital University Medical Center	02/05/2017	Ahmad Zaatari	zaatari@hammoudhospital.com	961 (0) 7 723111 ext 1160

Countries of Recruitment

Name
Lebanon
Argentina
Austria
Belgium
Bulgaria
Canada
Jordan
Oman
Saudi Arabia
Spain
United Kingdom
United States of America

Health Conditions or Problems Studied

Condition	Code	Keyword
Advanced Breast Cancer	Breast, unspecified (C50.9)	Breast Cancer

Interventions

Intervention	Description	Keyword
> Hematology tests: WBC, ANC, lymphocyte, hemoglobin, platelets (as clinically indicated), Chemistry tests: Alkaline phosphatase, ALT (SGPT), AST (SGOT), calcium corrected for serum albumin, creatinine or creatinine clearance, potassium, sodium, magnesium,direct bilirubin, total bilirubin (as clinically indicated), ECG	Lab tests , ECG , Radiology assessment	Lab tests , Radiology , ECG

Primary Outcomes

Name	Time Points	Measure
The number of participants with adverse events as a measure of safety and tolerability	PFS	Progression free survival

Key Secondary Outcomes

Name	Time Points	Measure
Time-to-Progression (TTP), Overall response rate (ORR), , Clinical Benefit Rate (CBR)	PFS	Progression free survival

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