



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 06:19:24

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

17/12/2019

Date of registration in national regulatory agency

01/06/2017

Public title

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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 لينتروزول لعلاج (LEE011) دراسة مفتوحة اللصاق، متعددة المراكز في المرحلة الثالثة ب تقييم سلامة وفعالية ريبوسيكليب
الذين (HER2-) 2وسلبي الهير (HR+) الرجال والنساء قبل/بعد انقطاع الطمث المصابين بسرطان الثدي المتقدم الإيجابي مستقبلات الهرمون
لم يتلقوا أي علاج هرموني سابق للمرض المتقدم

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 $\geq 1.5 \times 10^9/L$
 - Platelets $\geq 100 \times 10^9/L$
 - 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 $2.5 \times ULN$. If the patient has liver metastases, ALT and AST should be $< 5 \times ULN$.
 - Total serum bilirubin $< ULN$; or total bilirubin $\leq 3.0 \times ULN$ 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

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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 31/12/2020 |
| 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=complement&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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| Public | Fadi El Karak | Mansourieh | Lebanon | +961 3 061 621 | felkarak@yahoo.com | Bellevue Medical Center |
| Public | Georges Chahine | Beirut | Lebanon | +9613 647778 | Chahine_georges@hotmail.com | Hotel Dieu De France |

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 | Georges Chahine | Chahine_georges@hotmail.com | 009613 647778 |
| Bellevue Medical Center | 21/08/2017 | Fadi El Karak | felkarak@yahoo.com | 00961 3 061 621 |
| Hammoud Hospital University Medical Center | 02/05/2017 | Fadi Farhat | drfadi.trials@gmail.com | 00961 3 753 155 |



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